BROOKE ARMY MEDICAL CENTER
PROTOCOL FOR CLINICAL INVESTIGATION -- HUMAN

1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel:

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Other Study Staff (engaged in research and/or authorized to obtain informed consent from subject). To be named and approved by the IRB.

3.0 Location(s): Carl R. Darnall Army Medical Center (CRDAMC), Ft Hood, Texas.

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OEF). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?
2. Are there differences in outcomes between individual and group CPT-C treatment?
3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature:

Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the
Cognitive Processing Therapy for Combat-Related PTSD

therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a supportive group intervention typically used within the Department of Veteran’s Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods:

The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly
assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups, ensuring that there is a minimum of three women in each group treatment in order to reduce the discomfort for female participants who may have experienced a sexual trauma. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: Session 1: The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. Session 2: In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the
relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants' trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on a weekly basis (i.e., PTSD CheckList – Military, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

**Therapists & Evaluators.** Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

**Training of Therapists.** Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Videotapes of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

**Supervision of Therapists.** Videotapes of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.
Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be videotaped for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Videotapes will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters who will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList – Military, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.
4.7 Source of Research Material:

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<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>Defense &amp; Veterans Brain Injury Center TBI Screen</td>
<td>No</td>
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<td>Automated Neuropsychological Assessment Metrics (ANAM®)</td>
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<td>Deployment Risk and Resilience Inventory (DRRI)</td>
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<td>Combat Experience Sub-Scale</td>
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<td>Deployment Risk and Resilience Inventory (DRRI)</td>
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<td>Aftermath-of-Battle Sub-Scale</td>
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<td>PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>SF-12 (Functional Impact)</td>
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<td>Brief Conflict Tactics Scale</td>
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<td>State-Trait Anger Expression Inventory (STAXI)</td>
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<td>Beck Depression Inventory (BDI)</td>
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<td>Beck Scale for Suicidal Ideation (SSI) Screen</td>
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<td>National Center for PTSD Trait Resilience Scale</td>
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<td>Peri-Traumatic &amp; Post-Traumatic Emotions Scale</td>
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<td>Interpersonal Support Evaluation List (ISEL)</td>
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<td>Trauma-Related Guilt Inventory (TRGI)</td>
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<td>Walter Reed Army Institute of Research (WRAIR) Military Vertical &amp; Horizontal Cohesion Scales</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration.

Defense & Veterans Brain Injury Center TBI Screen: All participants will complete the DVBIC TBI screening tool, a three question screening measure developed by the Defense and Veterans Brain Injury Center (Vanderplaeg, Collins, Sigford, Date, Schwab & Warden, 2006). We anticipate approximately 25% of participants will have mild TBI (Seel, Wright, Wallace, Newman & Dennis, 2007).

Automated Neuropsychological Assessment Metrics (ANAM®): Those participants screening positive for a traumatic brain injury (TBI) will be asked to complete an additional measure, the ANAM. The ANAM is a computer-based tool comprised of a series of neuropsychological tests designed to detect deficits in cognitive functioning. Examples of individual tests incorporated within the ANAM include math, running memory, and logical
reasoning. Administration of the ANAM will take an additional 20 minutes.

**Deployment Risk and Resilience Inventory (DRRI) Combat Experience and Aftermath of Battle Sub-Scales**: Eligibility screening will be conducted using two subscales from the *Deployment Risk and Resilience Inventory* (DRRI; King, King, Vogt, Knight & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has very good internal consistency ($\alpha = .85$ to $.89$) and construct validity. It has been revised and tested with OEF/OIF returnees (Vogt, et al., in press). High intensity/magnitude stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. At the bottom of the Combat Experiences DRRI subscale, the following question will be asked to ascertain the presence of a Criterion-A event: “*What experience above was the worst event for you (what is the # above: ___)? Either at the time that this event occurred or after the immediate danger or threat had passed, did you experience intense fear, helplessness, or horror? Circle one: YES NO.*” If no Criterion-A event is endorsed on either of these scales, the service member will not be eligible for a clinical trial. Low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale.

**PTSD Symptom Scale, Interview Version (PSS-I)**: The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site.

**PTSD CheckList (PCL-M)**: We will use the *PTSD Checklist* (PCL; Weathers, Litz, Herman, Huska, & Keane, 1993), a 17 item self-report measure that evaluates the severity of PTSD symptoms in the past month as a result of the stressful life events checked off by participant on the LEC. The PCL has been found to have excellent psychometric properties (Blanchard, Jones-Alexander, Buckley & Forneris 1996). We will use the PTSD caseness definition used by Hoge, Castro, Messer, McGurk, Cotting, & Koffman (2004) to generate base rate estimates.

**SF-12**: Because a level of PTSD symptoms is an occupational hazard among service members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. Limitations in role functioning will be assessed using the SF-12v2, an abbreviated version of the *Medical Outcomes Study Short Form Survey* (SF-36; Ware, Kosinsky, & Keller, 1994). The SF-12 is recommended for use in larger samples when monitoring overall physical and mental health outcomes (Ware, Kosinski, & Keller, 1996).

**Brief Conflict Tactics Scale (aggressive behaviors)**: We will use a modified version of the *Conflict Tactics Scale* (CTS; Straus, 1979) to assess aggressive behaviors. The CTS has been used widely as a measure of interpersonal violence in military personnel (e.g. McCarroll, Ursano, Liu, Thayer, Newby, Norwood & Fullerton, 2000). It has high internal consistency (Straus, et al., 1979).

**State-Trait Anger Expression Inventory**: We will also use an abbreviated version of the *State-Trait Anger Expression Inventory* (STAXI; Spielberger, 1988), a 44-item scale that evaluates dimensions of anger. Specifically, participants will be asked to respond to the 10 items related to the State-Anger (S-Anger) subscale on a four-point scale that assesses the intensity of anger felt at a particular moment in time. Internal consistency of the subscale was found to be strong ($\alpha = .90$), as was its convergent validity with measures of hostility and other
personality scales.

**Beck Depression Inventory:** The Beck Depression Inventory or the (BDI) consists of 21 items that assess depressive symptoms. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

**Beck Scale for Suicidal Ideation:** The self-report version of the Scale for Suicide Ideation (SSI; Beck, Kovacs & Weissman, 1979) will be used to evaluate the current intensity of the patient’s specific attitudes, behaviors, and plans to commit suicide. The correlations between the self-reported and clinically rated versions for both inpatients and outpatients were > .90, which suggests strong concurrent validity. The Cronbach coefficient alpha for the paper-and-pencil was .93 and indicated high internal consistency (Beck, Brown & Steer, 1997).

**Beck Anxiety Inventory:** We will use the Beck Anxiety Inventory (BAI) to assess anxiety. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a 4-point scale, with anchors *Not At All* to *Severely*. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

**Alcohol Use Disorders Identification Test (AUDIT):** We will use the Alcohol Use Disorders Identification Test (AUDIT; Babor et al., 2001). This is a 10-item screening measure with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those diagnosed as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .65-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993).

**National Center for PTSD Trait Resilience Scale (The Response to Stressful Experiences Scale):** This is a 22-item questionnaire that asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 4 (“Exactly like me”) and 0 (“Not at all like me”). The scale has excellent reliability.

**Life Events Checklist:** The Life Events Checklist (LEC) includes a list of 17 different potentially traumatic life events that are commonly associated with PTSD symptoms, and is designed to assess previous exposure to trauma/traumatic events. Individuals are asked to respond whether an event happened to them personally, they witnessed, or they learned about happening to someone close to them. The LEC has been shown to have good temporal stability, convergent validity with other measures such as the TLEQ and to be significantly correlated with psychological distress and PTSD symptoms among combat veterans (Gray, Litz, Hsu, & Lombardo, 2004). We have added a two-item screen to the LEC. The VA uses this screen with everyone who seeks services at the VA. The two items ask about military sexual trauma.

**PERI Life Events Scale (Brief):** The original PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 100-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. The abbreviated version we will be using, consists of only 11 of the items from the original scale. Items were chosen based on their relevance to military members.

**Peri-traumatic and Posttraumatic Emotions Scale:** The Peri-traumatic and Posttraumatic
Emotions Scale was derived from a structured trauma interview yielding descriptive characteristics about the participant and traumatic event (Resick, et al., 1988). This measure assesses emotions experienced during the traumatic event, as well as emotions currently experienced with regard to the past trauma. Participants indicate to what extent they felt each of 20 emotions during the traumatic event on a scale from 0 (none of the time) to 4 (all of the time). Participants also rate the extent to which they currently feel the 20 emotions when reminded of the traumatic event. This scale has been shown to have high internal consistency in previous research (α = .81-.85; Resick, 1991, 1994). Participants will complete both the Peritraumatic and Posttraumatic Emotions scales during the initial assessment; at the follow up assessments, they will complete only the Posttraumatic Emotions scale.

Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: appraisal, belonging, and tangible. Responses are given on a 4-point scale with anchors, 1 (Definitely false) to 4 (Definitely true).

Trauma Related Guilt Inventory (TRGI) (brief): The original measure (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996) is a 32-item questionnaire that includes three scales (the Global Guilt Scale, the Distress Scale and the Guilt Cognitions Scale) and three subscales (the Hindsight/Bias/Responsibility Subscale, the Wrongdoing Subscale and the Lack of Justification Subscale). An abbreviated version will be used in the current study, consisting of the 16-items necessary to calculate the three subscale scores. Each subscale has been shown to have acceptable levels of internal consistency, test-rest reliability, convergent and divergent validity (Kubany et al., 1996).

Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members' psychological health and wellness. The scales have excellent reliability and validity (e.g., Podsakoff & MacKenzie, 1994). We will generate a subscale score for vertical and horizontal cohesion as well as a total cohesion score.

Posttraumatic Cognitions Inventory (PTCI): The PTCI (Foa, Elhers, Clark, Tolin, & Orsillo, 1999) is a 33-item scale comprised of three subscales that have been shown a high degree of intercorrelation (rs = .57–.75) and internal consistency (Negative Cognitions About the Self, α = .97; Negative Cognitions About the World, α = .88; Self-Blame, α = .86). Test–retest reliability for a 1-week interval ranged from .75 to .89 and for a 3-week interval ranged from .80 to .86 for the three subscales. The PTCI has also been shown to be able to differentiate individuals with and without PTSD (sensitivity = .78, specificity = .93).

Credibility/ Expectancy Questionnaire (CEQ): The CEQ (Devilly & Borkovec, 2000) is a 4-item measure that is designed to assess between group differences in treatment expectancy and rationale credibility and whether these variables predict treatment response. Each item is
based on a 9-point scale (1= not at all, 9= extremely). The measure has demonstrated high internal consistency and good test-retest reliability (Devilly & Borkovec, 2000).

Cognitive Emotion Regulation Questionnaire (CERQ-short): The CERQ-short (Garnefski & Kraaij, 2006) is an 18-item self-report questionnaire designed to measure the cognitive components of emotion regulation. Items are measured on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always). This abbreviated measure retains the original nine subscales of the original CERQ (Garnefski, Kraaij, & Spinhoven, 2001), including Self-blame, Other-blame, Rumination, Catastrophizing, Putting into perspective, Refocusing, Positive reappraisal, Acceptance, and Planning. The subscales have been shown to have good factorial validity, discriminative properties, construct validity, and internal consistency (α=.62-.85; Garnefski & Kraaij, 2006).

Patient Health Questionnaire-15: The Patient Health Questionnaire-15 (PHQ-15; Kroenke, Spitzer, & Williams, 2002) is a brief, self-administered questionnaire that assesses somatic symptom severity. Participants rate the severity of 15 somatic symptoms as 0 (not bothered at all), 1 (bothered a little) or 2 (bothered a lot). The scale has strong psychometric properties in terms of internal reliability, convergent validity, and discriminant validity (Kroenke, et al., 2002), and has been used in recent research using an active duty military sample (Hoge, et al., 2008).

Health Care Utilization (HCU): The Health Care Utilization is a 14-item questionnaire that was originally developed for Patricia A. Resick’s grant 2-R01-MH51509 titled “Cognitive Processes in PTSD: Treatment II” funded by the National Institute of Health in 2000. The questionnaire was formatted based on the 1999 Behavioral Risk Factor Surveillance System. The measure includes questions regarding mental health services, current psychiatric medication, past psychiatric medication, hospitalization, and outpatient medical services. The questions will be asked about the previous six months at the pretreatment, six month, and 12 month assessments.

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- be over the age of 18
- speak and read English
- be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- current suicide or homicide risk meriting crisis intervention
active psychosis
- moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the videotape and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 500 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment:

Potential participants will be recruited through flyers posted on base and in the local community (see Appendix E) as well as through provider referrals from the Resilience and Restoration Center Triage section that the On-Site PI, LTC Lester, supervises. Also, Research Staff ask to present the research opportunities to the Family Readiness Groups (FRGs) and provide the same flyers for Service Members to call for screening.

Callers responding to the flyers will be handled using a standard telephone script (see Appendix F). Those who appear eligible and are interested in possibly enrolling in a STRONG STAR study will be scheduled for consent and an in-person screening. Service Members referred from Triage will be pre-screened using the same standard telephone script. While screeners will be meeting and speaking with the Service Member, no personal health information (PHI) will be collected or recorded. Those who appear eligible and are interested in possibly enrolling in a STRONG STAR study will either be seen immediately for consent or be scheduled for consent.

Following consent and Screening Assessment those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16-18 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

In order to assure that more than two women are in a group (although there could be cohorts in which there are no women), when one woman is consented and determined to meet study criteria she will not be randomized until a total of three women are consented and determined to meet study criteria. These women will then be randomized together into the same treatment option. Women who have to wait more than 6 weeks for three women to be identified will be given the option of continuing to wait for additional women to be recruited into the study or being treated off-study through the normal Resilience and Restoration Center procedures.
5.2 **Benefits:** Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 **Risks:** Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 **Safeguards for Protecting Subjects:**

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix G).

Data will be coded using an assigned number. Data collected during treatment will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and videotapes will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix H)

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix I.)

5.5 **Risk:Benefit Assessment:** The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 **Alternatives:** Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 **Data Analysis:**

**Hypothesis Tests.** The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect
to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (>.5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for at an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only three data points to reflect the interview measures that will be collected at pre, post, and follow-up. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 3-times-repeated measures, and 202 subjects in per treatment arm, we have a power of 80% to detect an effect size of 0.3. Therefore, a sample of 404 should be sufficient to test the hypotheses.
8.0 Duration of Study: estimated to be 5 years

9.0 Funding: $33,065,523 from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U.S. Army, as represented by CIRO.

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


Schnurr, P.P., Friedman, M.J., Foy, D.W., Shea, M.T., Hsieh, F.Y., Lavori, P.W., Glynn, S.M.,

**Measurements References**


Cognitive Processing Therapy for Combat-Related PTSD


12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)

B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)

C – Homework Compliance Forms

D – Summary of the Assessments and Timing of Administration

E – Study Flyer

F – STRONG STAR Pre-Screening Interview

G – Managing Suicidal Behaviors

H – STRONG STAR Database Policies & Procedures

I – Data Safety Monitoring Plan (DSMP)
17.0 Signature Section:

On-Site Principal Investigator
I am aware that I am not authorized to accept any funds or other form of compensation for conducting research. All subjects will be treated in compliance with all applicable organizational, service, DoD and Federal regulations, and all applicable IRS and HHS guidelines.

[Signature]
KATHLEEN S. LESTER
LTC, MS
Chief, Research and Evaluation Center
Carl R. Darnall Army Medical Center
Fort Hood, TX

Date 10/19/02

PI's Service Chief
I have considered this protocol and am able to approve Carl R. Darnall Army Medical Center (CRDAMC) personnel and resource support. I understand that I will be in frequent contact for correction of deficiencies should the Principal Investigator fail to meet the stipulated study requirements as outlined in the protocol.

[Signature]
AMIR PHILLIPS, MD
LTC, MC
Chief, Behavioral Health Division
Carl R. Darnall Army Medical Center
Fort Hood, TX

Date 10/19/02

Command Support
I have considered this protocol and am able to approve Carl R. Darnall Army Medical Center (CRDAMC) personnel and resource support.

[Signature]
WILMA LARSON, MD
COL, MC
Deputy Chief of Clinical Services
Carl R. Darnall Army Medical Center
Fort Hood, TX

Date 10/19/02
Overall Study Principal Investigator
All subjects will be treated in compliance with all applicable organizational, service, DoD and Federal regulations, and all applicable FDA and HHS guidelines.

Patricia A. Resick, Ph.D.
Director, Women's Health Sciences Division National Center for PTSD
VA Boston Healthcare System and
Professor, Departments of Psychiatry and Psychology
Boston University

Date 10/10/03
CPT for Combat-Related PTSD

Consortium Director Signature
I have read the above protocol and agree with its content. All subjects will be treated in compliance with all applicable organizational, service, DoD and Federal regulations, and all applicable FDA and HHS guidelines.

[Signature]

Alan L. Peterson, Ph.D., ABPP, Col(Sel) (Ret)
Professor, Behavioral Wellness Center for Clinical Trials
School of Medicine, Department of Psychiatry
University of Texas Health Science Center San Antonio

Date 10/10/08

Consortium Biostatistics Core Director Signature
I have read the above protocol and agree with its content. All subjects will be treated in compliance with all applicable organizational, service, DoD and Federal regulations, and all applicable FDA and HHS guidelines.

[Signature]

Jim Mintz, Ph.D.
Professor, Psychiatry and Epidemiology/Biostatistics
University of Texas Health Science Center San Antonio

Date 10/10/08
BROOKE ARMY MEDICAL CENTER
PROTOCOL FOR CLINICAL INVESTIGATION -- HUMAN

1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel:

On-Site Principal Investigator (PI): Kathleen Lester, LTC, MS, Chief, Psychology Warrior Transition Brigade, Carl R. Darnall Army Medical Center, 36000 Darnall Loop, Fort Hood, TX, 76544, Kathleen.Lester@amedd.army.mil, (254) 553-4268 or (254) 462-8252.

Overall Principal Investigator (PI): Patricia Resick, PhD, Boston University, National Center for PTSD and VA Boston Healthcare System, 150 South Huntington Avenue (116B-3) Boston, MA 02130, Patricia.Resick@va.gov, (857) 364-4129.

Consultant: Paula Schnurr, PhD, National Center for PTSD (116D), VA Medical Center, 215 N. Main Street, White River Junction, VT 05009, Paula.Schnurr@dartmouth.edu, (802) 296-5132.

South Texas Research Organizational Network Guiding Studies on Trauma and Resilience (STRONG STAR) Consortium Director: Alan L. Peterson, Ph.D., ABPP, Professor, Behavioral Wellness Center for Clinical Trials, Department of Psychiatry-Mail Code 7792, University of Texas Health Science Center at San Antonio (UTHSCSA), 7703 Floyd Curl Drive, San Antonio, TX 78229-3900, petersona3@uthscsa.edu, (210) 562-5407.

Project Coordinator. Jennifer L. Schuster, Ph.D., Women’s Health Sciences Division, National Center for PTSD, VA Boston Healthcare System, 150 South Huntington Avenue (116B-3), Boston, MA 02130, Jennifer.Schuster@va.gov, (857) 364-5444

Other Study Staff (engaged in research and/or authorized to obtain informed consent from subject).

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Kelly Leaming, BA, Research Assistant, Department of Psychiatry-Mail Code 7747, University of Texas Health Science Center at San Antonio (UTHSCSA), 7703 Floyd Curl Drive, San Antonio, TX 78229-3900, with duty at Carl R. Darnall Army Medical Center, 36000 Darnall Loop, Fort Hood, TX, 76544, leaming@uthscsa.edu
4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OEF). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?
2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g., gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature:

Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral
Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a supportive group intervention typically used within the Department of Veteran’s Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).
4.6 Research Design and Methods:

The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups, ensuring that there is a minimum of three women in each group treatment in order to reduce the discomfort for female participants who may have experienced a sexual trauma. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets.
based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: Session 1: The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. Session 2: In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework.

Session 3-4: Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. Session 5-6: In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions.

Session 7-12: In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on a weekly basis (i.e., PTSD CheckList – Military, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of
therapy the received to the evaluators at the post-treatment assessments.

**Training of Therapists.** Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Videotapes of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

**Supervision of Therapists.** Videotapes of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

**Treatment Adherence & Competence.** The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be videotaped for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Videotapes will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters who will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and determination of inter-rater reliabilities (kappas).

**Assessments.** The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.
In addition to these assessments, three measures (i.e., PTSD CheckList – Military, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

4.7 Source of Research Material:

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<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>Defense &amp; Veterans Brain Injury Center TBI Screen</td>
<td>No</td>
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<tr>
<td>Automated Neuropsychological Assessment Metrics (ANAM®)</td>
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<td>Deployment Risk and Resilience Inventory (DRRI) Combat Experience Sub-Scale</td>
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<td>Deployment Risk and Resilience Inventory (DRRI) Aftermath-of-Battle Sub-Scale</td>
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<td>Deployment Risk and Resilience Inventory (DRRI) Deployment Environment Sub-Scale</td>
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<td>PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>PTSD CheckList (PCL-M)</td>
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<td>SF-12 (Functional Impact)</td>
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<td>Brief Conflict Tactics Scale</td>
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<td>State-Trait Anger Expression Inventory (STAXI)</td>
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<td>Beck Depression Inventory (BDI)</td>
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<td>Beck Scale for Suicidal Ideation (SSI) Screen</td>
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<td>Beck Anxiety Inventory (BAI)</td>
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<td>Alcohol Use Disorders Identification Test (AUDIT)</td>
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<td>National Center for PTSD Trait Resilience Scale</td>
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<td>Life Event Checklist (LEC)</td>
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<td>PERI Life Events Checklist</td>
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<td>Peri-Traumatic &amp; Post-Traumatic Emotions Scale</td>
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<td>Demographics &amp; Military Service Characteristics</td>
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<td>Interpersonal Support Evaluation List (ISEL)</td>
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<td>Trauma-Related Guilt Inventory (TRGI)</td>
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<td>Walter Reed Army Institute of Research (WRAIR) Military Vertical &amp;</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration.

Defense & Veterans Brain Injury Center TBI Screen: All participants will complete the DVBIC TBI screening tool, a three question screening measure developed by the Defense and Veterans Brain Injury Center (Vanderploeg, Collins, Sigford, Date, Schwab & Warden, 2006). We anticipate approximately 25% of participants will have mild TBI (Seel, Wright, Wallace, Newman & Dennis, 2007).

Automated Neuropsychological Assessment Metrics (ANAM®): Those participants screening positive for a traumatic brain injury (TBI) will be asked to complete an additional measure, the ANAM. The ANAM is a computer-based tool comprised of a series of neuropsychological tests designed to detect deficits in cognitive functioning. Examples of individual tests incorporated within the ANAM include math, running memory, and logical reasoning. Administration of the ANAM will take an additional 20 minutes.

Deployment Risk and Resilience Inventory (DRRI) Combat Experience and Aftermath of Battle Sub-Scales: Eligibility screening will be conducted using two subscales from the Deployment Risk and Resilience Inventory (DRRI; King, King, Vogt, Knight & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has very good internal consistency (α = .85 to .89) and construct validity. It has been revised and tested with OEF/OIF returnees (Vogt, et al., in press). High intensity / magnitude stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. At the bottom of the Combat Experiences DRRI subscale, the following question will be asked to ascertain the presence of a Criterion-A event: “What experience above was the worst event for you (what is the # above: ____)? Either at the time that this event occurred or after the immediate danger or threat had passed, did you experience intense fear, helplessness, or horror? Circle one: YES  NO.” If no Criterion-A event is endorsed on either of these scales, the service member will not be eligible for a clinical trial. Low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale.

PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site.

PTSD CheckList (PCL-M): We will use the PTSD Checklist (PCL; Weathers, Litz, Herman, Huska, & Keane, 1993), a 17 item self-report measure that evaluates the severity of
PTSD symptoms in the past month as a result of the stressful life events checked off by participant on the LEC. The PCL has been found to have excellent psychometric properties (Blanchard, Jones-Alexander, Buckley & Forneris 1996). We will use the PTSD caseness definition used by Hoge, Castro, Messer, McGurk, Cotting, & Koffman (2004) to generate base rate estimates.

**SF-12**: Because a level of PTSD symptoms is an occupational hazard among service members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. Limitations in role functioning will be assessed using the SF-12v2, an abbreviated version of the *Medical Outcomes Study Short Form Survey* (SF-36; Ware, Kosinsky, & Keller, 1994). The SF-12 is recommended for use in larger samples when monitoring overall physical and mental health outcomes (Ware, Kosinski, & Keller, 1996).

**Brief Conflict Tactics Scale (aggressive behaviors)**: We will use a modified version of the *Conflict Tactics Scale* (CTS; Straus, 1979) to assess aggressive behaviors. The CTS has been used widely as a measure of interpersonal violence in military personnel (e.g. McCarroll, Ursano, Liu, Thayer, Newby, Norwood & Fullerton, 2000). It has high internal consistency (Straus, et al., 1979).

**State-Trait Anger Expression Inventory**: We will also use an abbreviated version of the *State-Trait Anger Expression Inventory* (STAXI; Spielberger, 1988), a 44-item scale that evaluates dimensions of anger. Specifically, participants will be asked to respond to the 10 items related to the State-Anger (S-Anger) subscale on a four-point scale that assesses the intensity of anger felt at a particular moment in time. Internal consistency of the subscale was found to be strong (α = .90), as was its convergent validity with measures of hostility and other personality scales.

**Beck Depression Inventory**: The *Beck Depression Inventory* or the (BDI) consists of 21 items that assess depressive symptoms. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

**Beck Scale for Suicidal Ideation**: The self-report version of the Scale for Suicide Ideation (SSI; Beck, Kovacs & Weissman, 1979) will be used to evaluate the current intensity of the patient’s specific attitudes, behaviors, and plans to commit suicide. The correlations between the self-reported and clinically rated versions for both inpatients and outpatients were > .90, which suggests strong concurrent validity. The Cronbach coefficient alpha for the paper-and-pencil was .93 and indicated high internal consistency (Beck, Brown & Steer, 1997).

**Beck Anxiety Inventory**: We will use the *Beck Anxiety Inventory* (BAI) to assess anxiety. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a 4-point scale, with anchors *Not At All* to *Severely*. The BAI has been shown to have high internal consistency (α = .92) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

**Alcohol Use Disorders Identification Test (AUDIT)**: We will use the *Alcohol Use Disorders Identification Test* (AUDIT; Babor et al., 2001). This is a 10-item screening measure with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those diagnosed as using alcohol in a harmful manner, 92% had scores of 8 or more, though...
determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency (\( \alpha = .65-.93 \)) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993).

National Center for PTSD Trait Resilience Scale (The Response to Stressful Experiences Scale): This is a 22-item questionnaire that asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 4 (“Exactly like me”) and 0 (“Not at all like me”). The scale has excellent reliability.

Life Events Checklist: The Life Events Checklist (LEC) includes a list of 17 different potentially traumatic life events that are commonly associated with PTSD symptoms, and is designed to assess previous exposure to trauma/traumatic events. Individuals are asked to respond whether an event happened to them personally, they witnessed, or they learned about happening to someone close to them. The LEC has been shown to have good temporal stability, convergent validity with other measures such as the TLEQ and to be significantly correlated with psychological distress and PTSD symptoms among combat veterans (Gray, Litz, Hsu, & Lombardo, 2004). We have added a two-item screen to the LEC. The VA uses this screen with everyone who seeks services at the VA. The two items ask about military sexual trauma.

PERI Life Events Scale (Brief): The original PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 100-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. The abbreviated version we will be using, consists of only 11 of the items from the original scale. Items were chosen based on their relevance to military members.

Peri-traumatic and Posttraumatic Emotions Scale: The Peri-traumatic and Posttraumatic Emotions Scale was derived from a structured trauma interview yielding descriptive characteristics about the participant and traumatic event (Resick, et al., 1988). This measure assesses emotions experienced during the traumatic event, as well as emotions currently experienced with regard to the past trauma. Participants indicate to what extent they felt each of 20 emotions during the traumatic event on a scale from 0 (none of the time) to 4 (all of the time). Participants also rate the extent to which they currently feel the 20 emotions when reminded of the traumatic event. This scale has been shown to have high internal consistency in previous research (\( \alpha = .81-.85 \); Resick, 1991, 1994). Participants will complete both the Peri-traumatic and Posttraumatic Emotions scales during the initial assessment; at the follow up assessments, they will complete only the Posttraumatic Emotions scale.

Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: appraisal, belonging, and tangible. Responses are given on a 4-point scale with anchors, 1 (Definitely false) to 4 (Definitely true).
Trauma Related Guilt Inventory (TRGI) (brief): The original measure (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996) is a 32-item questionnaire that includes three scales (the Global Guilt Scale, the Distress Scale and the Guilt Cognitions Scale) and three subscales (the Hindsight/Bias/Responsibility Subscale, the Wrongdoing Subscale and the Lack of Justification Subscale). An abbreviated version will be used in the current study, consisting of the 16-items necessary to calculate the three subscale scores. Each subscale has been shown to have acceptable levels of internal consistency, test-rest reliability, convergent and divergent validity (Kubany et al., 1996).

Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. The scales have excellent reliability and validity (e.g., Podsakoff & MacKenzie, 1994). We will generate a subscale score for vertical and horizontal cohesion as well as a total cohesion score.

Posttraumatic Cognitions Inventory (PTCI): The PTCI (Foa, Elhers, Clark, Tolin, & Orsillo, 1999) is a 33-item scale comprised of three subscales that have been shown a high degree of intercorrelation ($r_s = .57-.75$) and internal consistency (Negative Cognitions About the Self, $\alpha = .97$; Negative Cognitions About the World, $\alpha = .88$; Self-Blame, $\alpha = .86$). Test–retest reliability for a 1-week interval ranged from .75 to .89 and for a 3-week interval ranged from .80 to .86 for the three subscales. The PTCI has also been shown to be able to differentiate individuals with and without PTSD (sensitivity = .78, specificity = .93).

Credibility/ Expectancy Questionnaire (CEQ): The CEQ (Devilly & Borkovec, 2000) is a 4-item measure that is designed to assess between group differences in treatment expectancy and rationale credibility and whether these variables predict treatment response. Each item is based on a 9-point scale (1= not at all, 9= extremely). The measure has demonstrated high internal consistency and good test-retest reliability (Devilly & Borkovec, 2000).

Cognitive Emotion Regulation Questionnaire (CERQ-short): The CERQ-short (Garnefski & Kraaij, 2006) is an 18-item self-report questionnaire designed to measure the cognitive components of emotion regulation. Items are measured on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always). This abbreviated measure retains the original nine subscales of the original CERQ (Garnefski, Kraij, & Spinhoven, 2001), including Self-blame, Other-blame, Rumination, Catastrophizing, Putting into perspective, Refocusing, Positive reappraisal, Acceptance, and Planning. The subscales have been shown to have good factorial validity, discriminative properties, construct validity, and internal consistency ($\alpha = .62-.85$; Garnefski & Kraij, 2006).

Patient Health Questionnaire-15: The Patient Health Questionnaire-15 (PHQ-15; Kroenke, Spitzer, & Williams, 2002) is a brief, self-administered questionnaire that assesses somatic symptom severity. Participants rate the severity of 15 somatic symptoms as 0 (not bothered at all), 1 (bothered a little) or 2 (bothered a lot). The scale has strong psychometric properties in terms of internal reliability, convergent validity, and discriminant validity (Kroenke, et al., 2002), and has been used in recent research using an active duty military sample (Hoge, et al., 2008).
Health Interview (Pre- & Post-Treatment): The Health Interview (Pre- & Post-Treatment) is a 14-item questionnaire that was originally developed for Patricia A. Resick’s grant 2-R01-MH51509 titled “Cognitive Processes in PTSD: Treatment II” funded by the National Institute of Health in 2000. The questionnaire was formatted based on the 1999 Behavioral Risk Factor Surveillance System. The measure includes questions regarding mental health services, current psychiatric medication, past psychiatric medication, hospitalization, and outpatient medical services. The questions will be asked about the previous six months at the pretreatment, six month, and 12 month assessments.

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF military personnel or OIF/OEF veterans seeking treatment for PTSD
- diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.
- be over the age of 18
- speak and read English
- be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- current suicide or homicide risk meriting crisis intervention
- active psychosis
- moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the videotape and determine, through consensus judgment, if the case should be excluded from analysis.
4.10 **Number of Subjects**: 500 from CRDAMC

5.0 **Human Subject Protection**

5.1 **Recruitment:**

Potential participants will be recruited through provider referrals from the Resilience and Restoration (R&R) Center Triage Section. A study coordinator will be available to talk with interested individuals in person, and immediately walk them to the STRONG STAR research offices. Potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant.

Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16 -18 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

In order to assure that more than two women are in a group (although there could be cohorts in which there are no women), when one woman is consented and determined to meet study criteria she will not be randomized until a total of three women are consented and determined to meet study criteria. These women will then be randomized together into the same treatment option. Women who have to wait more than 6 weeks for three women to be identified will be given the option of continuing to wait for additional women to be recruited into the study or being treated off-study through the normal Resilience and Restoration Center procedures.

5.2 **Benefits**: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 **Risks**: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C,
there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix G).

Data will be coded using an assigned number. Data collected during treatment will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and videotapes will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix H)

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix I.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random
regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for at an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only three data points to reflect the interview measures that will be collected at pre, post, and follow-up. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 3-times-repeated measures, and 202 subjects in per treatment arm, we have a power of 80% to detect an effect size of 0.3. Therefore, a sample of 404 should be sufficient to test the hypotheses.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: $33,065,523 from the U. S. Army Medical Research and Materiel Command
Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


Measurements References


Stress, 6, 459-473.


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**Version (01-27-10)**

**BAMC IRB Approval Date: 2/1/10**

**UTHSCSA IRB Approval Date: 3/19/10**
12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)

B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)

C – Homework Compliance Forms

D – Summary of the Assessments and Timing of Administration

E – Managing Suicidal Behaviors

F – STRONG STAR Database Policies & Procedures

G – Data Safety Monitoring Plan (DSMP)
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel:

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3.0 Location(s):
- Carl R. Darnall Army Medical Center (CRDAMC) – performance site
- Boston University & VA Boston Healthcare System – Overall Study PI & research staff affiliation
- University of Texas Health Science Center at San Antonio (UTHSCSA) – research staff affiliation

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OEF). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on
treatment outcome?

4.3 Significance: Recent studies of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.
Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a supportive group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups, ensuring that there is a minimum of three women in each group treatment in order to reduce the discomfort for female participants who may have experienced a sexual trauma. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes.
Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: Session 1: The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. Session 2: In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. Session 3-4: Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are
given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

**Therapists & Evaluators.** Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

**Training of Therapists.** Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

**Supervision of Therapists.** Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

**Treatment Adherence & Competence.** The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of
therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

4.7 Source of Research Material:
### Source of Research Material

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<th>Source of Research Material</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
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<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. SF-12 (Functional Impact)</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>17. Peri-Traumatic &amp; Post-Traumatic Emotions Questionnaire</td>
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<td>19. Interpersonal Support Evaluation List (ISEL)</td>
<td>No</td>
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<tr>
<td>20. Trauma-Related Guilt Inventory (TRGI)</td>
<td>No</td>
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<tr>
<td>21. Walter Reed Army Institute of Research (WRAIR) Military Vertical &amp; Horizontal Cohesion Scales</td>
<td>No</td>
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<tr>
<td>22. Post-Traumatic Cognitions Inventory (PTCI)</td>
<td>No</td>
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<td>23. Credibility / Expectancy Questionnaire (CEQ)</td>
<td>No</td>
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<td>24. Cognitive Emotions Regulation Questionnaire (CERQ)</td>
<td>No</td>
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<td>25. Patient Health Questionnaire (PHQ)-15</td>
<td>No</td>
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<td>26. Homework Compliance</td>
<td>No</td>
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<tr>
<td>27. Health Interview (Pre- &amp; Post-Treatment)</td>
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#### 4.8 Instrumentation:

See Appendix D for a summary of the assessments and timing of administration.

1. **Head Injury Assessment**: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen...
were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury: the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): Those participants screening positive on the 3-Question DVBIC Screening Tool (see description above) will be asked to complete an additional measure, the ANAM to provide additional descriptive information of cognitive function. The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition,
low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency ($\alpha = .85$ to .89) and construct validity (Vogt et al., 2008).

4. **PTSD Symptom Scale, Interview Version (PSS-I)**: The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSS symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. **Columbia-Suicide Severity Rating Scale (C-SSRS)**: The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. **PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V)**: The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to
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put the findings of the study in the context of the most current criteria of PTSD.

7. SF-12: Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. Health status will be assessed using the Medical Outcomes Study (MOS) 12-Item Short-Form Health Survey (SF-12; Quality Metric, Lincoln, RI; Ware, Kosinski & Keller, 1996). The MOS Health Surveys are self-administered questionnaires designed as a generic indicator of health status for use in clinical practice and research, health policy evaluations, and general population surveys (Padilla, Frank-Stromborg, & Koreshaw, 2004). Using the SF-12, participants respond to 12 items designed to measure physical functioning, role limitations due to physical health problems, bodily pain, social functioning, general mental health, role limitations due to emotional problems, vitality, and general health perceptions. All health measures are scored on scales of 0 to 100, with higher scores indicating better health. The median alpha internal reliability coefficients for the eight scales of the Short Forms reported in more than 25 studies exceeded 0.70 (Padilla, Frank-Stromborg, & Koreshaw, 2004). The Short Forms have been normed in the general United States population as well as for patients with depressive disorders (Ware & Sherbourne, 1992). The SF-12 is recommended for use in larger samples when monitoring overall physical and mental health outcomes (Ware, Kosinski, & Keller, 1996).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i.e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal
depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), postraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD
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(Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffen, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffen, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffen, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoferman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & Mackenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elbers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed
as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.

24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptable high (a = 0.67 to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).
25. **Patient Health Questionnaire-15**: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. **Homework Compliance**: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. **Health Interview (Pre- & Post-Treatment)**: The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

4.9 **Inclusion / Exclusion Criteria**: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

**Inclusion Criteria**:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF military personnel or OIF/OEF veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.
- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

**Exclusion Criteria**:
- Currently undergoing a Medical Evaluation Board (MEB).
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)
We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 500 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment: Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

Participants will first be recruited as cohorts of 16-24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

In order to assure that more than two women are in a group (although there could be cohorts in which there are no women), when one woman is consented and determined to meet study criteria she will not be randomized until a total of three women are consented and determined to meet study criteria. These women will then be randomized together into the same treatment option. Women who have to wait more than 6 weeks for three women to be identified will be
given the option of continuing to wait for additional women to be recruited into the study or being treated off-study through the normal Resilience and Restoration Center procedures.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.
6.0 Data Analysis:

**Hypothesis Tests.** The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this
situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


**Measurement References**


Cognitive Processing Therapy for Combat-Related PTSD

(3rd ed) (pp. 128-149). Sudbury, MA: Jones and Bartlett.


Cognitive Processing Therapy for Combat-Related PTSD


12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
BROOKE ARMY MEDICAL CENTER  
PROTOCOL FOR CLINICAL INVESTIGATION -- HUMAN

1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OEF). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.
The public policy implications of the results of this trial are significant. If both group and individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a supportive group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to
control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups, ensuring that there is a minimum of three women in each group treatment in order to reduce the discomfort for female participants who may have experienced a sexual trauma. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: **Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. **Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas--safety, trust, control, esteem, and intimacy--are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

**Assessments.** The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

**Timeline** The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

**4.7 Source of Research Material:**

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<thead>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>16. PERI Life Events Scale</td>
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**4.8 Instrumentation:** See Appendix D for a summary of the assessments and timing of administration.

1. **Head Injury Assessment:** Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. **Automated Neuropsychological Assessment Metrics (ANAM®):** Those participants screening positive on the 3-Question DVBIC Screening Tool (see description above) will be asked to complete an additional measure, the ANAM to provide additional descriptive information of cognitive function. The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time.
Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency (α = .85 to .89) and construct validity (Vogt et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to
affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. SF-12: Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. Health status will be assessed using the Medical Outcomes Study (MOS) 12-Item Short-Form Health Survey (SF-12; Quality Metric, Lincoln, RI; Ware, Kosinski & Keller, 1996). The MOS Health Surveys are self-administered questionnaires designed as a generic indicator of health status for use in clinical practice and research, health policy evaluations, and general population surveys (Padilla, Frank-Stromborg, & Koresawa, 2004). Using the SF-12, participants respond to 12 items designed to measure physical functioning, role limitations due to physical health problems, bodily pain, social functioning, general mental health, role limitations due to emotional problems, vitality, and general health perceptions. All health measures are scored on scales of 0 to 100, with higher scores indicating better health. The median alpha internal reliability coefficients for the eight scales of the Short Forms reported in more than 25 studies exceeded 0.70 (Padilla, Frank-Stromborg, & Koresawa, 2004). The Short Forms have been normed in the general United States population as well as for patients with depressive disorders (Ware & Sherbourne, 1992). The SF-12 is recommended for use in larger samples when monitoring overall physical and mental health outcomes (Ware, Kosinski, & Keller, 1996).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus &
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Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i.e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of
anxiety. The BAI has been shown to have high internal consistency (α = .92) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency (α = .80-.93) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10
items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffen, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffen, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffen, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i. e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i. e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the
testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23,
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(Excerpt from the document)

24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty-six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high (α = 0.67 to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability (α = .80) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychotropic medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.
4.9 **Inclusion / Exclusion Criteria:** The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

**Inclusion Criteria:**
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF military personnel or OIF/OEF veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.
- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

**Exclusion Criteria:**
- Currently undergoing a Medical Evaluation Board (MEB).
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 **Number of Subjects:** 500 from CRDAMC

5.0 **Human Subject Protection**

5.1 **Recruitment:** Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will
include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16 -24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

In order to assure that more than two women are in a group (although there could be cohorts in which there are no women), when one woman is consented and determined to meet study criteria she will not be randomized until a total of three women are consented and determined to meet study criteria. These women will then be randomized together into the same treatment option. Women who have to wait more than 6 weeks for three women to be identified will be given the option of continuing to wait for additional women to be recruited into the study or being treated off-study through the normal Resilience and Restoration Center procedures.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:
During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF). All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of
PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes,
we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


posttraumatic stress disorder: Results from a Department of Veterans Affairs cooperative study. *Archives of General Psychiatry*, 60, 481-489.

**Measurement References**


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316.


12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a
cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and
there were no differences between treatments. In a study of individual PCT compared to PE
(Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six
month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT.
Given that CPT can be administered as either a group or individual treatment, it is important to
determine whether the two are equivalent or whether one type of format is sufficiently superior
to warrant recommendation either for or against group administration. To address this question,
this study was designed to compare group and individual CPT for the treatment of PTSD in
military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version
of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be
tested, as a recent clinical trial designed to dismantle the components of CPT found that a
cognitive-only version was equally effective to the full version of CPT and perhaps more efficient
(Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical
trial designed with two primary objectives. One objective is to compare the effectiveness of
group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-
Centered Therapy (PCT) modality. The other research objective is to compare the
effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer
the first research question, the first 96 participants will be randomly assigned to group CPT-C or
PCT groups (48 per group). After these initial participants have been randomized, the
remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per
group), in order to answer the second and third research questions. We will include both
genders in groups. Women consenting to the study will be asked about participating in a group
with men because they may feel uncomfortable especially those who may have experienced a
sexual trauma. If a woman does not want to participate in a group with men, she will be referred
to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual
CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C
and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for
exact therapy time would be an option, it would be an unfair disadvantage for group treatment
with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of
sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al.
(2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See
Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing
Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for
focusing on current issues rather than the traumatic events themselves. The first two sessions
will provide psychoeducation about PTSD symptoms and the problem areas often associated
with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between
sessions, participants will be asked to monitor their problem-solving attempts and outcomes as
well as to keep a mood diary and list of current issues to be addressed in the next group. At the
beginning of each group meeting there will be a check-in for each participant to discuss briefly
the events and problems of the prior week and any issues they may want to discuss. Therapists
and clients will develop an agenda based on emerging themes. Education regarding PTSD and
depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: Session 1: The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. Session 2: In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. Session 3-4: Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. Session 5-6: In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. Session 7-12: In sessions 7-12, over-generalized beliefs in five areas--safety, trust, control, esteem, and intimacy--are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
<td>No</td>
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<tr>
<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
<td>No</td>
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<tr>
<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
<td>No</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
<td>No</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
<td>No</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
<td>No</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
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<td>12. Beck Anxiety Inventory (BAI)</td>
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<td>13. Alcohol Use Disorders Identification Test (AUDIT)</td>
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<td>14. Response to Stressful Experiences Scale (RSES)</td>
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<td>15. Life Event Checklist (LEC)</td>
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### 4.8 Instrumentation:

**4.8.1 Head Injury Assessment:** Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

**4.8.2 Automated Neuropsychological Assessment Metrics (ANAM®):** Those participants screening positive on the 3-Question DVBIC Screening Tool (see description above) will be asked to complete an additional measure, the ANAM to provide additional descriptive information of cognitive function. The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time.

<table>
<thead>
<tr>
<th>Instrumentation</th>
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<tr>
<td>16. PERI Life Events Scale</td>
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<tr>
<td>17. Peri-Traumatic &amp; Post-Traumatic Emotions Questionnaire</td>
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<td>18. Demographics &amp; Military Service Characteristics</td>
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<td>19. Interpersonal Support Evaluation List (ISEL)</td>
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<td>20. Trauma-Related Guilt Inventory (TRGI)</td>
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<td>21. Walter Reed Army Institute of Research (WRAIR)</td>
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<tr>
<td>Military Vertical &amp; Horizontal Cohesion Scales</td>
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<td>22. Post-Traumatic Cognitions Inventory (PTCI)</td>
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<td>23. Credibility / Expectancy Questionnaire (CEQ)</td>
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<td>24. Cognitive Emotions Regulation Questionnaire (CERQ)</td>
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<td>25. Patient Health Questionnaire (PHQ)-15</td>
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<td>26. Homework Compliance</td>
<td>No</td>
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<tr>
<td>27. Health Interview (Pre- &amp; Post-Treatment)</td>
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</table>
Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency ($\alpha = .85$ to $.89$) and construct validity (Vogt et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to
affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .88 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/ vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the...
general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglass, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i.e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTSS2) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based
on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency (\(\alpha = .92\)) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency (\(\alpha = .80-.93\)) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa =
0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Merzelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.
20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three
subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.

24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaj, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high (α = 0.67 to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Ruminating, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaj, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal
reliability (α = .80) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.
- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.
4.10 Number of Subjects: 500 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment: Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16 -24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of
5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimaging related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study databases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)
5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up
analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


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Cognitive Processing Therapy for Combat-Related PTSD


12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
Cognitive Processing Therapy for Combat-Related PTSD

individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, "The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect" (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a
cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and
there were no differences between treatments. In a study of individual PCT compared to PE
(Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six
month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT.
Given that CPT can be administered as either a group or individual treatment, it is important to
determine whether the two are equivalent or whether one type of format is sufficiently superior
to warrant recommendation either for or against group administration. To address this question,
this study was designed to compare group and individual CPT for the treatment of PTSD in
military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version
of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be
tested, as a recent clinical trial designed to dismantle the components of CPT found that a
cognitive-only version was equally effective to the full version of CPT and perhaps more efficient
(Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical
trial designed with two primary objectives. One objective is to compare the effectiveness of
group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-
Centered Therapy (PCT) modality. The other research objective is to compare the
effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer
the first research question, the first 96 participants will be randomly assigned to group CPT-C or
PCT groups (48 per group). After these initial participants have been randomized, the
remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per
group), in order to answer the second and third research questions. We will include both
genders in groups. Women consenting to the study will be asked about participating in a group
with men because they may feel uncomfortable especially those who may have experienced a
sexual trauma. If a woman does not want to participate in a group with men, she will be referred
to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual
CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C
and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for
exact therapy time would be an option, it would be an unfair disadvantage for group treatment
with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of
sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al.
(2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See
Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing
Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for
focusing on current issues rather than the traumatic events themselves. The first two sessions
will provide psychoeducation about PTSD symptoms and the problem areas often associated
with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between
sessions, participants will be asked to monitor their problem-solving attempts and outcomes as
well as to keep a mood diary and list of current issues to be addressed in the next group. At the
beginning of each group meeting there will be a check-in for each participant to discuss briefly
the events and problems of the prior week and any issues they may want to discuss. Therapists
and clients will develop an agenda based on emerging themes. Education regarding PTSD and
depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C:  
- **Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened.  
- **Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework.  
- **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma.  
- **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions.  
- **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

**Therapists & Evaluators.** Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

**Training of Therapists.** Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

**Supervision of Therapists.** Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

**Treatment Adherence & Competence.** The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

**Assessments.** The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

**Timeline** The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

**Incentives for Completing Assessments:** Choice of a nominal incentive; such as a coin, coffee mug, T-shirt, or ball cap; costing less than $25 per participant will be offered to Service Members participants completing follow-up assessments.

### 4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
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<tr>
<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration.

1. **Head Injury Assessment:** Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. **Automated Neuropsychological Assessment Metrics (ANAM®):** Those participants screening positive on the 3-Question DVBIC Screening Tool (see description above) will be asked to complete an additional measure, the ANAM to provide additional descriptive information of cognitive function. The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive...
functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM 
battery is a collection of tests that assess different basic functions or domains of cognition to include 
reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory 
(code substitution), working memory (mathematical processing), and spatial memory (matching). The test 
assesses both speed and accuracy. "Throughput" is the number of correct items within a certain time. 
Norms for military Service Members and college studies, both male and female ranging in age from 18 to 
51 have been established. Test print-outs compare scores for the individual being tested to a preselected 
normative group. The ANAM has compared favorably to a variety of traditional neuropsychological 
measures including the math, running memory, code substitution delayed memory, logical reasoning, the 
Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, 
Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, 
and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been 
used to screen for impairment in various clinical populations including patients with multiple sclerosis, 
systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and 
aquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled 
in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants 
marginal impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their 
throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 
2007). When the marginally and mildly impaired individuals were grouped together, the ANAM 
differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 
25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM 
scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, 
Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side 
effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, 
mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that 
is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is 
administering the ANAM to provide additional descriptive data about the cognitive functioning of study 
participants based upon the recommendations of civilian and military experts in TBI and the STRONG 
STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the 
USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health 
Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and 
Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be 
assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was 
developed and tested in three separate national samples of veterans of the first Gulf War. It has been 
revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures 
will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to 
these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher 
scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In 
addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment 
subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) 
to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are 
indicative of a more difficult living and working environment. All three subscales have very good internal 
consistency (α = .85 to .89) and construct validity (Vogt et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview 
that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 
1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician 
Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). 
Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores 
are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and 
arousal. The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater 
reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each 
study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent 
Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the
index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1- 5); Avoidance/ Emotional Numbing symptoms (items 6- 12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women's Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is
comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i.e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh,
The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory (BAI): The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency (α = .92) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency (α = .80-.93) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned
about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about.

In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kayser, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kayser, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kayser, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their
relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a
university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.

24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERO-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about
both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability (α = .80) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.
- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In
less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

**4.10 Number of Subjects:** 1,000 from CRDAMC

**5.0 Human Subject Protection**

**5.1 Recruitment:** Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16-24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

**5.2 Benefits:** Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

**5.3 Risks:** Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C,
there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant's willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.
A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (>0.5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if
there is less than a .3 effect size difference between individual and group treatment, then the
differences are not large enough to warrant individual treatment on average, and group
treatment would be considered a more efficient modality. However, if there is a larger than .3
effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up
analyses on predictors of treatment outcome would then be valuable to determine who might
especially need individual therapy. Although we will have more than nine assessments with the
self-report scales that should allow .9 power and the ability to detect even smaller effect sizes,
we conducted a power analysis with only four data points to reflect the interview measures that
will be collected at pre, post, and the 6- and 12-month follow-up periods. Comparing individual
and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a
uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely
coded GROUP with N=8. The total numbers of subjects are the same between the two
conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this
situation. After 200 replications, we found that intraclass correlation of this magnitude made
minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-
times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to
detect an effect size of 0.3. To account for potential attrition over this year-long study, we will
oversample, requesting permission to recruit 404 participants until 110 participants have
completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical
Research and Materiel Command Congressionally Directed Medical Research Program
(CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the
University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be
accomplished through a Cooperative Research and Development Agreement (CRADA)
between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory
Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:

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study of cognitive processing therapy for the treatment of chronic posttraumatic stress disorder in


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Cognitive Processing Therapy for Combat-Related PTSD


Measurement References


Cognitive Processing Therapy for Combat-Related PTSD


**12.0 Support Services Required (Impact Statement/Letter of Support):**  none

**13.0 Use of Investigation Drugs:**  not applicable

**14.0 Use of Investigational Devices:**  not applicable

**15.0 Appendices:**
A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder that impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups. Women consenting to the study will be asked about participating in a group with men because they may feel uncomfortable especially those who may have experienced a sexual trauma. If a woman does not want to participate in a group with men, she will be referred to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: Session 1: The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. Session 2: In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. Session 3-4: Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. Session 5-6: In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. Session 7-12: In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

Incentives for Completing Assessments: Choice of a nominal incentive; such as a coin, coffee mug, T-shirt, or ball cap; costing less than $25 per participant will be offered to Service Members participants completing follow-up assessments.

### 4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tr>
<td>1. Head Injury Assessment</td>
<td>No</td>
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<tr>
<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
<td>No</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
<td>No</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
<td>No</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
<td>No</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
<td>No</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
<td>No</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
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12. Beck Anxiety Inventory (BAI) No
13. Alcohol Use Disorders Identification Test (AUDIT) No
14. Response to Stressful Experiences Scale (RSES) No
15. Life Event Checklist (LEC) No
16. PERI Life Events Scale No
17. Peri-Traumatic & Post-Traumatic Emotions Questionnaire No
18. Demographics & Military Service Characteristics No
19. Interpersonal Support Evaluation List (ISEL) No
20. Trauma-Related Guilt Inventory (TRGI) No
21. Walter Reed Army Institute of Research (WRAIR) Military Vertical & Horizontal Cohesion Scales No
22. Post-Traumatic Cognitions Inventory (PTCI) No
23. Credibility / Expectancy Questionnaire (CEQ) No
24. Cognitive Emotions Regulation Questionnaire (CERQ) No
25. Patient Health Questionnaire (PHQ)-15 No
26. Homework Compliance No
27. Health Interview (Pre- & Post-Treatment) No
28. Mini International Neuropsychiatric Interview (MINI), Modules C (Mania) & (Psychosis) No

**4.8 Instrumentation:** See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

1. Head Injury Assessment: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head
injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): Those participants screening positive on the 3-Question DVBIC Screening Tool (see description above) will be asked to complete an additional measure, the ANAM to provide additional descriptive information of cognitive function. The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency (α = .85 to .89) and construct validity (Vogt et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum,
The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpsiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two
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point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i.e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).
10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency (α = .92) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency (α = .80-.93) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), post-traumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor
model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. **Life Events Checklist:** The LEC includes a list of 16 different potentially traumatic life events that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. **PERI Life Events Scale (Brief):** The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. **Peri-traumatic and Posttraumatic Emotions Scale:** The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.
18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Merrielstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed
to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foia, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foia and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foia and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foia, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.

24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual's style of responding to stressful events. Thirty six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner's office practice
in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to $0.81$). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraajj, 2006).

25. **Patient Health Questionnaire-15**: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. **Homework Compliance**: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. **Health Interview (Pre- & Post-Treatment)**: The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. **Mini-International Neuropsychiatric Interview (MINI)**. The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

4.9 **Inclusion / Exclusion Criteria**: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

**Inclusion Criteria:**
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.
- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be
required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

**Exclusion Criteria:**
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

**4.10 Number of Subjects:** 1,000 from CRDAMC

**5.0 Human Subject Protection**

**5.1 Recruitment:** Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16 -24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously.
The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study.
However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data
set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:

Cognitive Processing Therapy for Combat-Related PTSD


Measurement References


12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups. Women consenting to the study will be asked about participating in a group with men because they may feel uncomfortable especially those who may have experienced a sexual trauma. If a woman does not want to participate in a group with men, she will be referred to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: 

**Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. 

**Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. 

**Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. 

**Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. 

**Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

**Therapists & Evaluators.** Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

**Training of Therapists.** Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

**Supervision of Therapists.** Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

**Treatment Adherence & Competence.** The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and...
determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment if someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

Incentives for Completing Assessments: Choice of a nominal incentive; such as a coin, coffee mug, T-shirt, or ball cap; costing less than $25 per participant will be offered to Service Members participants completing follow-up assessments.

4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
<td>No</td>
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<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
<td>No</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
<td>No</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
<td>No</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
<td>No</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<tr>
<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
<td>No</td>
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12. Beck Anxiety Inventory (BAI)  No  
13. Alcohol Use Disorders Identification Test (AUDIT)  No  
14. Response to Stressful Experiences Scale (RSES)  No  
15. Life Event Checklist (LEC)  No  
16. PERI Life Events Scale  No  
17. Peri-Traumatic & Post-Traumatic Emotions Questionnaire  No  
18. Demographics & Military Service Characteristics  No  
19. Interpersonal Support Evaluation List (ISEL)  No  
20. Trauma-Related Guilt Inventory (TRGI)  No  
21. Walter Reed Army Institute of Research (WRAIR) Military Vertical & Horizontal Cohesion Scales  No  
22. Post-Traumatic Cognitions Inventory (PTCI)  No  
23. Credibility / Expectancy Questionnaire (CEQ)  No  
24. Cognitive Emotions Regulation Questionnaire (CERQ)  No  
25. Patient Health Questionnaire (PHQ)-15  No  
26. Homework Compliance  No  
27. Health Interview (Pre- & Post-Treatment)  No  
28. Mini International Neuropsychiatric Interview (MINI), Modules C (Mania) & (Psychosis)  No  
29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire  No

4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBNet 364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBNet 364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member’s spouse required to complete the packet.

1. Head Injury Assessment: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins,
Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): Those participants screening positive on the 3-Question DVBIC Screening Tool (see description above) will be asked to complete an additional measure, the ANAM to provide additional descriptive information of cognitive function. The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been
revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency ($\alpha = .85$ to .89) and construct validity (Vogt, et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three
avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al. 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i.e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminant validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to
9. **State-Trait Anger Expression Inventory (STAXI):** The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. **Beck Depression Inventory II (BDI-II):** The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. **Beck Scale for Suicidal Ideation (BSSI):** The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. **Beck Anxiety Inventory:** The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. **Alcohol Use Disorders Identification Test (AUDIT) – Interview Version:** The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

14. **Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale):** The RSES is a 22-item questionnaire developed by a team of experts at the
National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick,
Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i. e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i. e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList — Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994).
Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.

24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess
cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty six (36)-
items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point determination. In a follow-up study, Wolfe et. al. further modified the criteria to facilitate its use as a simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011). The intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an examiner. The modification replaced a physician-judged scale of somatic symptom severity with four questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3
minutes to complete the questionnaire.

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.
- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment: Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will
include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16-24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).
Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk: Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:
Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-
times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


Measurement References


Cognitive Processing Therapy for Combat-Related PTSD


Cognitive Processing Therapy for Combat-Related PTSD


Litz, B. T., Gray, M. J., Bryant, R., & Adler, A. B. (2002). Early intervention for trauma: Current status and


Cognitive Processing Therapy for Combat-Related PTSD


12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)

B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on
Cognitive Processing Therapy for Combat-Related PTSD

disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups. Women consenting to the study will be asked about participating in a group with men because they may feel uncomfortable especially those who may have experienced a sexual trauma. If a woman does not want to participate in a group with men, she will be referred to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: **Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. **Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 12-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

Incentives for Completing Assessments: Choice of a nominal incentive; such as a coin, coffee mug, T-shirt, or ball cap; costing less than $25 per participant will be offered to Service Members participants completing follow-up assessments.

4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
<td>No</td>
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<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
<td>No</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
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<td>12. Beck Anxiety Inventory (BAI)</td>
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<td>13. Alcohol Use Disorders Identification Test (AUDIT)</td>
<td>No</td>
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<td>14. Response to Stressful Experiences Scale (RSES)</td>
<td>No</td>
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<td>15. Life Event Checklist (LEC)</td>
<td>No</td>
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<td>16. PERI Life Events Scale</td>
<td>No</td>
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<td>17. Peri-Traumatic &amp; Post-Traumatic Emotions Questionnaire</td>
<td>No</td>
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<td>18. Demographics &amp; Military Service Characteristics</td>
<td>No</td>
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<td>19. Interpersonal Support Evaluation List (ISEL)</td>
<td>No</td>
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<td>20. Trauma-Related Guilt Inventory (TRGI)</td>
<td>No</td>
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<td>21. Walter Reed Army Institute of Research (WRAIR) Military Vertical &amp; Horizontal Cohesion Scales</td>
<td>No</td>
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<td>22. Post-Traumatic Cognitions Inventory (PTCI)</td>
<td>No</td>
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<td>23. Credibility / Expectancy Questionnaire (CEQ)</td>
<td>No</td>
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<td>24. Cognitive Emotions Regulation Questionnaire (CERQ)</td>
<td>No</td>
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<td>25. Patient Health Questionnaire (PHQ)-15</td>
<td>No</td>
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<td>26. Homework Compliance</td>
<td>No</td>
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<td>27. Health Interview (Pre- &amp; Post-Treatment)</td>
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<td>28. Mini International Neuropsychiatric Interview (MINI), Modules C (Mania) &amp; (Psychosis)</td>
<td>No</td>
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<td>29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire</td>
<td>No</td>
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<td>30. Frequency of Nightmares Questionnaire</td>
<td>No</td>
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<td>31. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen</td>
<td>No</td>
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<td>32. Epworth Sleepiness Scale (ESS)</td>
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<td>33. Insomnia Severity Index (ISI)</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBNet 364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBNet 364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member's spouse required to complete the packet.

1. Head Injury Assessment: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the
Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): Those participants screening positive on the 3-Question DVBIC Screening Tool (see description above) will be asked to complete an additional measure, the ANAM to provide additional descriptive information of cognitive function. The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. "Throughput" is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency ($\alpha = .85$ to .89) and construct validity (Vogt et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD.
PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/ vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i. e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use
coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al., 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. **State-Trait Anger Expression Inventory (STAXI)**: The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. **Beck Depression Inventory II (BDI-II)**: The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. **Beck Scale for Suicidal Ideation (BSSI)**: The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. **Beck Anxiety Inventory**: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. **Alcohol Use Disorders Identification Test (AUDIT) – Interview Version**: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993).
Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

**14. Response to Stressful Experiences Scale (RSES)** (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

**15. Life Events Checklist:** The LEC includes a list of 16 different potentially traumatic life events that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

**16. PERI Life Events Scale (Brief):** The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

**17. Peri-traumatic and Posttraumatic Emotions Scale:** The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand...
why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Merrellstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These
cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The
combined responses are used to generate a score for credibility and another score for expectancy.

24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point
determination. In a follow-up study, Wolfe et al. further modified the criteria to facilitate its use as a simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011). The intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an examiner. The modification replaced a physician-judged scale of somatic symptom severity with four questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3 minutes to complete the questionnaire.

It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be administered to determine the effect of treatment for PTSD on sleep.

30. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare disturbance were selected from The Trauma-Related Nightmare Survey (TRNS; Davis, Wright, & Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period for frequency of nightmares (r = .64), and disturbance of nightmares (r = .63). Convergent validity was also found with daily behavioral records of nights with nightmares (r = .82) and the Modified PTSD Symptom Scale – Self-Report (MPSS-SR; Resick, Falsetti, Resnick, & Kilpatrick, 1991) nightmare frequency (r = .64) and disturbance (r = .45). The item assessing nights with nightmares was selected as it is thought to be a more clinical significant measure of the impact of nightmares than the total number of nightmares experienced.

31. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated in 211 pre-operative surgical patients. Using the answering of 2 or more questions "yes," the sensitivity of the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of polysomnography depending upon the AHI cut-off used. Individuals answering "yes" to 2 or more of the questions will be advised that they may be at risk for having sleep apnea and advised that they may want to speak with their primary care provider to consider referral for an overnight sleep evaluation at the CRDAMC Sleep Clinic.

32. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in various situations, will be used to assess daytime function. The ESS has good internal consistency (α = .73 - .88) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness (Chervin, Aldrich, Pickett & Guilleminault, 1997).

33. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4 (very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the Pittsburgh Sleep Quality Index (r = 0.67), the Dysfunctional Beliefs and Attitudes about Sleep (r = 0.55), and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale
Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.

- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment: Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the
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consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16-24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store
specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention
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to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory
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Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


Measurement References


initial validation of the Response to Stressful Experiences Scale (RSES). Unpublished manuscript, Naval Health Research Center, San Diego, CA.


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12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:
A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
BROOKE ARMY MEDICAL CENTER
PROTOCOL FOR CLINICAL INVESTIGATION -- HUMAN

1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups. Women consenting to the study will be asked about participating in a group with men because they may feel uncomfortable especially those who may have experienced a sexual trauma. If a woman does not want to participate in a group with men, she will be referred to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others' traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: Session 1: The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. Session 2: In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. Session 3-4: Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. Session 5-6: In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. Session 7-12: In sessions 7-12, over-generalized beliefs in five areas--safety, trust, control, esteem, and intimacy--are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 9-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 9-12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

Incentives for Completing Assessments: Choice of a nominal incentive; such as a coin, coffee mug, T-shirt, or ball cap; costing less than $25 per participant will be offered to Service Members participants completing follow-up assessments.

4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
<td>Yes</td>
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<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
<td>No</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
<td>No</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
<td>No</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
<td>No</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
<td>No</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
<td>No</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
<td>No</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
<td>No</td>
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<tr>
<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
<td>No</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 9-12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBN364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBN364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member’s spouse required to complete the packet.

1. Head Injury Assessment: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIIC) 3-I Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer,
Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency ($\alpha = .85$ to .89) and construct validity (Vogt, et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1- 5); Avoidance/ Emotional Numbing symptoms (items 6- 12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women's Study PTSD Module (NWS-PTSD; Keen,
Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i.e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate
validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al., 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Rigg, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on
14. **Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale):** The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. **Life Events Checklist:** The LEC includes a list of 16 different potentially traumatic life events that that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder Checklist – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder Checklist – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. **PERI Life Events Scale (Brief):** The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. **Peri-traumatic and Posttraumatic Emotions Scale:** The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered
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(P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders
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(Vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Cronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test–retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.
24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty-six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraalj, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point determination. In a follow-up study, Wolfe et. al. further modified the criteria to facilitate its use as a
simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011). The intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an examiner. The modification replaced a physician-judged scale of somatic symptom severity with four questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3 minutes to complete the questionnaire.

It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be administered to determine the effect of treatment for PTSD on sleep.

30. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare disturbance were selected from The Trauma-Related Nightmare Survey (TRNS; Davis, Wright, & Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period for frequency of nightmares ($r = .64$), and disturbance of nightmares ($r = .63$). Convergent validity was also found with daily behavioral records of nights with nightmares ($r = .82$) and the Modified PTSD Symptom Scale – Self-Report (MPSS-SR; Resick, Falsetti, Resnick, & Kilpatrick, 1991) nightmare frequency ($r = .64$) and disturbance ($r = .45$). The item assessing nights with nightmares was selected as it is thought to be a more clinical significant measure of the impact of nightmares than the total number of nightmares experienced.

31. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated in 211 pre-operative surgical patients. Using the answering of 2 or more questions “yes,” the sensitivity of the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of polysomnography depending upon the AHI cut-off used. Individuals answering “yes” to 2 or more of the questions will be advised that they may be at risk for having sleep apnea and advised that they may want to speak with their primary care provider to consider referral for an overnight sleep evaluation at the CRDAMC Sleep Clinic.

32. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in various situations, will be used to assess daytime function. The ESS has good internal consistency ($\alpha = .73 - .88$) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness (Chervin, Aldrich, Pickett & Guilleminault, 1997).

33. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4 (very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the Pittsburgh Sleep Quality Index ($r = 0.67$), the Dysfunctional Beliefs and Attitudes about Sleep ($r = 0.55$), and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).

34. Beliefs in a Just World (BJW) Scale. The BJW is a 16-item self-report measure that assesses the belief in a just world for self and others. Just world beliefs are the idea that everything happens for a reason and people get what they deserve in life. This may be protective for some people because it gives them the illusion that they have control over the world and what they experience. However, for trauma survivors, it can lead to feelings of self blame. For example, if people get what they deserve in life, then what did I do to deserve to be raped. This can lead to both behavioral and characterological self blame. Belief in a just world is related to psychological well-being. The BJW Scale has strong psychometric properties (Lipkus, et al., 1996). Factor analysis using promax rotation revealed 2 intercorrelator factors with eigenvalues greater than one. Items had moderate to high loadings on each factor. The BJW scale for self demonstrated good internal consistency (\( \alpha = .84 \)) in 2 studies. The BJW scale for others also demonstrated good internal consistency (\( \alpha = .84 \) in one study and \( \alpha = .83 \) in another). Homogeneity of the BJW scales was assessed using principal component analysis with oblique rotation. The scale for self had a single factor which accounted for 62% of the variance and the scale for others also had single factor which accounted for 64% of the variance. Additionally, the BJW Scale significantly correlated with
existing measures of just world beliefs. Service Members with PTSD have been noted to endorse just world beliefs during therapy such as “It's not fair that this trauma happened,” or “People with young children are not supposed to die.” Potentially treatment for PTSD modifies these beliefs.

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard
  OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale
  (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high
  magnitude operational experience that occurred during a military deployment in support of
  OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion
  A event.
- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be
  required to meet psychotropic medication stabilization criteria for the periods preceding and
  overlapping with the diagnostic assessment and treatment. This criterion is established in
  order to minimize the likelihood that significant outcome effects may be attributed to
  changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the
  baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment: Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment
materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16 -24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium.
Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEF/OIF/OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study databases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.
6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (>.5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 9-12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this
situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


**Measurement References**


of the International Society for Traumatic Stress Studies, San Antonio, TX.


12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?
2. Are there differences in outcomes between individual and group CPT-C treatment?
3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a
cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and
there were no differences between treatments. In a study of individual PCT compared to PE
(Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six
month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT.
Given that CPT can be administered as either a group or individual treatment, it is important to
determine whether the two are equivalent or whether one type of format is sufficiently superior
to warrant recommendation either for or against group administration. To address this question,
this study was designed to compare group and individual CPT for the treatment of PTSD in
military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version
of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be
tested, as a recent clinical trial designed to dismantle the components of CPT found that a
cognitive-only version was equally effective to the full version of CPT and perhaps more efficient
(Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical
trial designed with two primary objectives. One objective is to compare the effectiveness of
group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-
Centered Therapy (PCT) modality. The other research objective is to compare the
effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer
the first research question, the first 96 participants will be randomly assigned to group CPT-C or
PCT groups (48 per group). After these initial participants have been randomized, the
remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per
group), in order to answer the second and third research questions. We will include both
genders in groups. Women consenting to the study will be asked about participating in a group
with men because they may feel uncomfortable especially those who may have experienced a
sexual trauma. If a woman does not want to participate in a group with men, she will be referred
to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual
CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C
and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for
exact therapy time would be an option, it would be an unfair disadvantage for group treatment
with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of
sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al.
(2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See
Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing
Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for
focusing on current issues rather than the traumatic events themselves. The first two sessions
will provide psychoeducation about PTSD symptoms and the problem areas often associated
with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between
sessions, participants will be asked to monitor their problem-solving attempts and outcomes as
well as to keep a mood diary and list of current issues to be addressed in the next group. At the
beginning of each group meeting there will be a check-in for each participant to discuss briefly
the events and problems of the prior week and any issues they may want to discuss. Therapists
and clients will develop an agenda based on emerging themes. Education regarding PTSD and
depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: 

**Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. 

**Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. 

**Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. 

**Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. 

**Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas--safety, trust, control, esteem, and intimacy--are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

**Assessments.** The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 9-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 9-12-month follow-up.

**Timeline** The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

### 4.7 Source of Research Material:

<table>
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<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
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<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
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<td>12. Beck Anxiety Inventory (BAI)</td>
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<td>13. Alcohol Use Disorders Identification Test (AUDIT)</td>
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<td>14. Response to Stressful Experiences Scale (RSES)</td>
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### 4.8 Instrumentation:

See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 9-12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBNet 364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBNet 364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member’s spouse required to complete the packet.

#### 1. Head Injury Assessment

Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the
Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and
Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency ($\alpha = .85$ to $.89$) and construct validity (Vogt, et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to
determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/ vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i. e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation.
and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al., 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.
14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the
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Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennen, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army
Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=382) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test–retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.
24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual's style of responding to stressful events. Thirty-six (36) items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner's office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point determination. In a follow-up study, Wolfe et. al. further modified the criteria to facilitate its use as a simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011).
intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an examiner. The modification replaced a physician-judged scale of somatic symptom severity with four questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3 minutes to complete the questionnaire.

It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be administered to determine the effect of treatment for PTSD on sleep.

While many clinicians use the 24-question Pittsburg Sleep Quality Index (PSQI; Buysse et al., 1989) to assess for “disordered” sleep, the PSQI has not been validated to provide specific diagnostic data for nightmares, apnea, daytime sleepiness, or insomnia. Instead of using the PSQI, five sleep assessments (totaling 24 questions) will be administered to assess typical sleep durations and patterns on weekends and weekdays as well as to assess for specific sleep difficulties (i.e., nightmares, apnea, daytime sleepiness, and insomnia) often found in patients with PTSD and other behavioral health issues using established diagnostic criteria.

30. Self-Assessment of Sleep Questionnaire. The Self-Assessment of Sleep questionnaire was developed by a board-certified sleep specialist and one of the STRONG STAR investigators, Daniel Taylor PhD, to be a brief assessment of self-reported sleep quantity and sleep quality. Five items assess estimated total sleep times during the week and during weekends, self-reported hours of sleep needed to feel rested, overall sleep quality, and duration of current sleep pattern. Although there are no established psychometrics for this measure, combined with the other four measures of sleep the battery will provide the information needed to comprehensively assess sleep in study participants.

31. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare disturbance were selected from The Trauma-Related Nightmare Survey (TRNS; Davis, Wright, & Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period for frequency of nightmares (r = .64), and disturbance of nightmares (r = .63). Convergent validity was also found with daily behavioral records of nights with nightmares (r = .82) and the Modified PTSD Symptom Scale – Self-Report (MPSS-SR; Resick, Falsetti, Resnick, & Kilpatrick, 1991) nightmare frequency (r = .64) and disturbance (r = .45). The item assessing nights with nightmares was selected as it is thought to be a more clinical significant measure of the impact of nightmares than the total number of nightmares experienced.

32. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated in 211 pre-operative surgical patients. Using the answering of 2 or more questions “yes,” the sensitivity of the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of polysomnography depending upon the AHI cut-off used. Individuals answering “yes” to 2 or more of the questions will be advised that they may be at risk for having sleep apnea and advised that they may want to speak with their primary care provider to consider referral for an overnight sleep evaluation at the CRDAMC Sleep Clinic.

33. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in various situations, will be used to assess daytime function. The ESS has good internal consistency (α = .73 - .88) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness (Chervin, Aldrich, Pickett & Guilleminault, 1997).

34. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4 (very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the Pittsburgh Sleep Quality Index (r = 0.67), the Dysfunctional Beliefs and Attitudes about Sleep (r = 0.55), and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).
35. Beliefs in a Just World (BJW) Scale. The BJW is a 16-item self-report measure that assesses the belief in a just world for self and others. Just world beliefs are the idea that everything happens for a reason and people get what they deserve in life. This may be protective for some people because it gives them the illusion that they have control over the world and what they experience. However, for trauma survivors, it can lead to feelings of self blame. For example, if people get what they deserve in life, then what did I do to deserve to be raped. This can lead to both behavioral and characterological self blame. Belief in a just world is related to psychological well-being. The BJW Scale has strong psychometric properties (Lipkus, et al., 1996). Factor analysis using promax rotation revealed 2 intercorrelator factors with eigenvalues greater than one. Items had moderate to high loadings on each factor. The BJW scale for self demonstrated good internal consistency ($\alpha$=.84) in 2 studies. The BJW scale for others also demonstrated good internal consistency ($\alpha$=.84 in one study and $\alpha$=.83 in another). Homogeneity of the BJW scales was assessed using principal component analysis with oblique rotation. The scale for self had a single factor which accounted for 62% of the variance and the scale for others also had single factor which accounted for 64% of the variance. Additionally, the BJW Scale significantly correlated with existing measures of just world beliefs. Service Members with PTSD have been noted to endorse just world beliefs during therapy such as “It's not fair that this trauma happened,” or “People with young children are not supposed to die.” Potentially treatment for PTSD modifies these beliefs.

36. Patient Reported Outcomes Measurement Information System (PROMIS) Sexual Functioning Inventory: The PROMIS questionnaires are a system of reliable measures of patient–reported health status for physical, mental, and social well–being developed with funding under the National Institutes of Health (NIH) Roadmap for Medical Research Initiative to re-engineer the clinical research enterprise (http://www.nihroadmap.nih.gov). PROMIS measures can be across a wide variety of chronic diseases and conditions and in the general population (Cella et al, 2010). One of the PROMIS instruments is a Sexual Functioning Inventory (Jeffery et al, 2009). The PROMIS Sexual Function Inventory provides scores on seven different sub-domains of sexual function: interest in sexual activity, vaginal discomfort (women only), lubrication (women only), erectile function (men only), orgasm, and global satisfaction with sex life. Each question asks respondents to report on their experiences over the past 30 days. With the exception of the orgasm sub-domain, all sub-domain scores are expressed as T scores (mean = 50, standard deviation = 10). While the Inventory is intended for broad use, almost all of the development work was with patients with cancer. Research is ongoing to expand development beyond cancer. In testing with 819 individuals (388 males, 430 females, 1 person did not specify sex), correlations between the PROMIS Sexual Functioning Inventory and corresponding sub-domains of two well-established measures, the Female Sexual Function Index (FSFI) and the International Index of Erectile Function (IIEF), ranged between .48 and .92. The sub-domains of the Inventory discriminate between people who had and had not asked a provider about sexual problems. Test-retest correlations over one month are >.65 for all sub-domains (Sexual Function and Satisfaction Measures User Manual, 2012).

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of
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OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.

- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:

- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment: Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into
the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact
the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the
study.

Participants will first be recruited as cohorts of 16 -24 eligible participants for randomization into
one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously.
The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either
group. Once data have been collected on at least 48 participants in each condition to answer
the first research question, participants will be randomized into either group CPT-C or individual
CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD
symptoms over the course of therapy. In addition, the knowledge gained from this study will
serve to inform the most effective early interventions for the prevention and treatment of
combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include
becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the
discussion of traumatic events, including increased risk for suicide. However, in past research
conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C,
there have been no serious adverse events or related difficulties with emotionally upset
participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of
confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and
techniques used to manage distressing emotions both within the group and outside the group
setting by the study therapist. Distress experienced by participants is expected to be
temporary. Any indication that the participant is considering suicide will be handled using
processes developed by military and civilian Consultants for the STRONG STAR Consortium
studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered
into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will
be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA)
STRONG STAR offices by a STRONG STAR staff member who will place it into the locked
cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the
National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for
receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research
Team will be trained and monitored about how to handle and protect both medical and research
records. Furthermore, the Research Team strictly controls access to study data. (See
Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and
BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store
specimens and data for future use. The STRONG STAR Repository will create a large
comprehensive database of information, biological specimens and neuroimages related to the
identification, assessment, and treatment of PTSD in our active duty and retired veterans of
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OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally.
Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (>.5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 9-12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 5 years

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable
11.0 Bibliography:


Measurement References


Assessments, 8, 423-444.


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12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a
cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and
there were no differences between treatments. In a study of individual PCT compared to PE
(Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six
month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT.
Given that CPT can be administered as either a group or individual treatment, it is important to
determine whether the two are equivalent or whether one type of format is sufficiently superior
to warrant recommendation either for or against group administration. To address this question,
this study was designed to compare group and individual CPT for the treatment of PTSD in
military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version
of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be
tested, as a recent clinical trial designed to dismantle the components of CPT found that a
cognitive-only version was equally effective to the full version of CPT and perhaps more efficient
(Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical
trial designed with two primary objectives. One objective is to compare the effectiveness of
group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-
Centered Therapy (PCT) modality. The other research objective is to compare the
effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer
the first research question, the first 96 participants will be randomly assigned to group CPT-C or
PCT groups (48 per group). After these initial participants have been randomized, the
remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per
group), in order to answer the second and third research questions. We will include both
genders in groups. Women consenting to the study will be asked about participating in a group
with men because they may feel uncomfortable especially those who may have experienced a
sexual trauma. If a woman does not want to participate in a group with men, she will be referred
to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual
CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C
and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for
exact therapy time would be an option, it would be an unfair disadvantage for group treatment
with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of
sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al.
(2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See
Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing
Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for
focusing on current issues rather than the traumatic events themselves. The first two sessions
will provide psychoeducation about PTSD symptoms and the problem areas often associated
with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between
sessions, participants will be asked to monitor their problem-solving attempts and outcomes as
well as to keep a mood diary and list of current issues to be addressed in the next group. At the
beginning of each group meeting there will be a check-in for each participant to discuss briefly
the events and problems of the prior week and any issues they may want to discuss. Therapists
and clients will develop an agenda based on emerging themes. Education regarding PTSD and
depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: **Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. **Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas--safety, trust, control, esteem, and intimacy--are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
Cognitive Processing Therapy for Combat-Related PTSD

a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive
Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four
questionnaires will be completed at the beginning of one of the weekly sessions, while the
remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out
the treatment protocols and study evaluations. At least two therapists will co-lead both types of
treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal
caseload of individual participants receiving individual CPT-C therapy. Because both therapists
are providing both treatments, this will reduce the risk of having the competence of the therapist
over-ride any differences between conditions. The evaluators will be independent of the
therapists and will be blind as to condition. Participants will be asked not to reveal the type of
therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following
established procedures used in other studies (e. g., Schnurr et al., 2007). Training workshops
will be conducted in San Antonio or at another military base or VA if the timing for training
coincides with an official training workshop. Therapists will be a credentialed provider at the
facility. Each therapist will treat training patients under supervision prior to treating consented
study participants. Video recordings of treatment sessions (using the standard consent for
electronic recordings of patients) will be reviewed by designated CPT supervisors, and all
therapists will be required to meet therapy certification requirements prior to seeing consented
study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT
supervisor, who will then provide the therapist with individual feedback on each training case.
All therapists will participate in a weekly CPT therapist supervision teleconference with Dr.
Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely
monitored to ensure that the therapy conditions are distinct and true to the protocols. The
therapists will be trained early in the project by Dr. Resick to conduct each of the three types of
therapy. They will also be instructed on the data they will need to collect within their roles (e.g.,
self-report measures before and during treatment, homework compliance) and any required
paperwork for the patients. The therapists will be provided manuals and will have taped
examples of the therapy to study. They will be required to treat pilot cases prior to starting the
main data collection under close supervision to ensure that they are administering the therapies
competently. During the data collection phase, therapists will continue to receive weekly
supervision on their cases by project staff and will have local back-up as well as case
consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and
competence will be determined by independent raters who are not otherwise involved in the
project. The raters will have served on prior CPT studies as adherence and competence raters.
In order to ensure that the CPT treatment is administered in accordance with the manual for
both groups, all sessions in the study will be video recorded for supervision purposes and for
possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500
participants. Video recordings will then be sent using an express service (e. g., UPS, FedEx, or
DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR
database. The raters will determine adherence to the CPT-C and PCT therapies and
competence in delivering the therapies. We will randomly select 5% (300) for viewing and
Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 9-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 9-12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
<td>No</td>
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<tr>
<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
<td>No</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
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<td>12. Beck Anxiety Inventory (BAI)</td>
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<td>13. Alcohol Use Disorders Identification Test (AUDIT)</td>
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<td>14. Response to Stressful Experiences Scale (RSES)</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 9-12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBNet 364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBNet 364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member’s spouse required to complete the packet.

**1. Head Injury Assessment:** Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the

<table>
<thead>
<tr>
<th>Questionnaire/Scale</th>
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<tr>
<td>Life Event Checklist (LEC)</td>
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<td>PERI Life Events Scale</td>
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<td>Peri-Traumatic &amp; Post-Traumatic Emotions Questionnaire</td>
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<td>Demographics &amp; Military Service Characteristics</td>
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<td>Interpersonal Support Evaluation List (ISEL)</td>
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<td>Trauma-Related Guilt Inventory (TRGI)</td>
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<td>Walter Reed Army Institute of Research (WRAIR) Military Vertical &amp; Horizontal Cohesion Scales</td>
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<td>Post-Traumatic Cognitions Inventory (PTCI)</td>
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<td>Credibility / Expectancy Questionnaire (CEQ)</td>
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<td>Cognitive Emotions Regulation Questionnaire (CERQ)</td>
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<td>Patient Health Questionnaire (PHQ)-15</td>
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<td>Homework Compliance</td>
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<td>Health Interview (Pre- &amp; Post-Treatment)</td>
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<td>Mini International Neuropsychiatric Interview (MINI), Modules C (Mania) &amp; (Psychosis)</td>
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<tr>
<td>American College of Rheumatology (ACR) Fibromyalgia Questionnaire</td>
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<td>Self-Assessment of Sleep Questionnaire</td>
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<td>Frequency of Nightmares Questionnaire</td>
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<td>Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen</td>
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<td>Epworth Sleepiness Scale (ESS)</td>
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<td>Insomnia Severity Index (ISI)</td>
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<td>Beliefs in a Just World (BJW) Scale</td>
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<tr>
<td>PROMIS Sexual Function Profile</td>
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Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.
Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency (α = .85 to .89) and construct validity (Vogt, et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guidelines for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to
determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service
Members injured in Iraq or Afghanistan (Grieger et al., 2006; Hoge et al., 2004, 2008; Smith et al., 2008)
subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three
avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher
during the past month, and if they received a total severity score of 50 or higher. At baseline and again
following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as
well as the PCL-S so that when the results of this study are published the Research Team will be able to
put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an
occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to
functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was
adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from
physical to psychological health status. It includes two modifications. The first modification is an increase
in the number of response choices for the role physical (RP) and role emotional (RE) items from a two
point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of
the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to
assess health change, one focusing on physical health and one on emotional problems, in contrast to the
one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The
VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA)
with close to 2 million questionnaires administered nationally in six national surveys since 1996. The
changes to the survey have increased the overall precision of the instrument and the discriminant validity
of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is
comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems,
body pain, general health perceptions, energy/ vitality, social functioning, role limitations due to
emotional problems, and mental health. Also, there are two summary scales: a physical component
summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each
summary is expressed as a T score, which facilitates comparisons between the VA patients and the
general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the
eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was
developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven
of the eight scales and provides 90% of the reliable variance in the two component summary measures
using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996
National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very
closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS
and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was
designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979)
and over time has become the most widely used instrument to assess intimate partner violence (Straus &
Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39
questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or
marital couples, i. e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual
Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales
(CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test
administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the
Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening
the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances
as well as the family as these subscales represent the content areas of most interest and are most
relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-
educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby,
Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument
demonstrated construct and discriminate validity in that men were shown to be more likely to use
coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate
validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation
and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al., 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.
14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (= endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the...
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Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRAIR). Vertical and Horizontal Cohesion Scales: These scales are the gold standard method of evaluating attitudes about support from leaders and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army Institute of Research (WRAIR).
Institute of Research (WRARI) and they are used extensively in research on service members' psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

### 22. Posttraumatic Cognitions Inventory (PTCI)

The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

### 23. Credibility/ Expectancy Questionnaire (CEQ)

The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test–retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1 = not at all, 9 = extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.
24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual's style of responding to stressful events. Thirty-six (36)-items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always).

Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Gamefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner's office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high (α = 0.67 to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 ("not bothered at all") to 2 ("bothered a lot"). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability (α = .80) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The health interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point determination. In a follow-up study, Wolfe et. al. further modified the criteria to facilitate its use as a simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011). The
The intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an examiner. The modification replaced a physician-judged scale of somatic symptom severity with four questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3 minutes to complete the questionnaire.

It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be administered to determine the effect of treatment for PTSD on sleep.

While many clinicians use the 24-question Pittsburg Sleep Quality Index (PSQI; Buysse et al., 1989) to assess for “disordered” sleep, the PSQI has not been validated to provide specific diagnostic data for nightmares, apnea, daytime sleepiness, or insomnia. Instead of using the PSQI, five sleep assessments (totaling 24 questions) will be administered to assess typical sleep durations and patterns on weekends and weekdays as well as to assess for specific sleep difficulties (i.e., nightmares, apnea, daytime sleepiness, and insomnia) often found in patients with PTSD and other behavioral health issues using established diagnostic criteria.

30. Self-Assessment of Sleep Questionnaire. The Self-Assessment of Sleep questionnaire was developed by a board-certified sleep specialist and one of the STRONG STAR investigators, Daniel Taylor PhD, to be a brief assessment of self-reported sleep quantity and sleep quality. Five items assess estimated total sleep times during the week and during weekends, self-reported hours of sleep needed to feel rested, overall sleep quality, and duration of current sleep pattern. Although there are no established psychometrics for this measure, combined with the other four measures of sleep the battery will provide the information needed to comprehensively assess sleep in study participants.

31. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare disturbance were selected from The Trauma-Related Nightmare Survey (TRNS; Davis, Wright, & Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period for frequency of nightmares (r = .64), and disturbance of nightmares (r = .63). Convergent validity was also found with daily behavioral records of nights with nightmares (r = .82) and the Modified PTSD Symptom Scale – Self-Report (MPSS-SR; Resick, Falsetti, Resnick, & Kilpatrick, 1991) nightmare frequency (r = .64) and disturbance (r = .45). The item assessing nights with nightmares was selected as it is thought to be a more clinical significant measure of the impact of nightmares than the total number of nightmares experienced.

32. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated in 211 pre-operative surgical patients. Using the answering of 2 or more questions “yes,” the sensitivity of the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of polysomnography depending upon the AHI cut-off used. Individuals answering “yes” to 2 or more of the questions will be advised that they may be at risk for having sleep apnea and advised that they may want to speak with their primary care provider to consider referral for an overnight sleep evaluation at the CRDAMC Sleep Clinic.

33. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in various situations, will be used to assess daytime function. The ESS has good internal consistency (α = .73 - .88) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness (Chervin, Aldrich, Pickett & Guilleminault, 1997).

34. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4 (very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the Pittsburgh Sleep Quality Index (r = 0.67), the Dysfunctional Beliefs and Attitudes about Sleep (r = 0.55), and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).
Beliefs in a Just World (BJW) Scale. The BJW is a 16-item self-report measure that assesses the belief in a just world for self and others. Just world beliefs are the idea that everything happens for a reason and people get what they deserve in life. This may be protective for some people because it gives them the illusion that they have control over the world and what they experience. However, for trauma survivors, it can lead to feelings of self blame. For example, if people get what they deserve in life, then what did I do to deserve to be raped. This can lead to both behavioral and characterological self blame. Belief in a just world is related to psychological well-being. The BJW Scale has strong psychometric properties (Lipkus, et al., 1996). Factor analysis using promax rotation revealed 2 intercorrelator factors with eigenvalues greater than one. Items had moderate to high loadings on each factor. The BJW scale for self demonstrated good internal consistency (α=.84 in one study and α=.83 in another). Homogeneity of the BJW scales was assessed using principal component analysis with oblique rotation. The scale for self had a single factor which accounted for 62% of the variance and the scale for others also had single factor which accounted for 64% of the variance. Additionally, the BJW Scale significantly correlated with existing measures of just world beliefs. Service Members with PTSD have been noted to endorse just world beliefs during therapy such as “It's not fair that this trauma happened,” or “People with young children are not supposed to die.” Potentially treatment for PTSD modifies these beliefs.

36. Patient Reported Outcomes Measurement Information System (PROMIS) Sexual Functioning Inventory: The PROMIS questionnaires are a system of reliable measures of patient–reported health status for physical, mental, and social well-being developed with funding under the National Institutes of Health (NIH) Roadmap for Medical Research Initiative to re-engineer the clinical research enterprise (http://www.nihroadmap.nih.gov). PROMIS measures can be across a wide variety of chronic diseases and conditions and in the general population (Cella et al, 2010). One of the PROMIS Instruments is a Sexual Functioning Inventory (Jeffery et al, 2009). The PROMIS Sexual Function Inventory provides scores on seven different sub-domains of sexual function: interest in sexual activity, vaginal discomfort (women only), lubrication (women only), erectile function (men only), orgasm, and global satisfaction with sex life. Each question asks respondents to report on their experiences over the past 30 days. With the exception of the orgasm sub-domain, all sub-domain scores are expressed as T scores (mean = 50, standard deviation = 10). While the Inventory is intended for broad use, almost all of the development work was with patients with cancer. Research is ongoing to expand development beyond cancer. In testing with 819 individuals (388 males, 430 females, 1 person did not specify sex), correlations between the PROMIS Sexual Functioning Inventory and corresponding sub-domains of two well-established measures, the Female Sexual Function Index (FSFI) and the International Index of Erectile Function (IIEF), ranged between .48 and .92. The sub-domains of the Inventory discriminate between people who had and had not asked a provider about sexual problems. Test-retest correlations over one month are >.65 for all sub-domains (Sexual Function and Satisfaction Measures User Manual, 2012).

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:

- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of
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OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.

- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:

- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment: Potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into
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Participants will first be recruited as cohorts of 16-24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of
OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study databases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally.
Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (>0.5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 9-12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 Duration of Study: estimated to be 8 years, ending by December 31, 2016.

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable
11.0 Bibliography:


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12.0 Support Services Required (Impact Statement/Letter of Support): none
13.0 Use of Investigation Drugs: not applicable
14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a
cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and
there were no differences between treatments. In a study of individual PCT compared to PE
(Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six
month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT.
Given that CPT can be administered as either a group or individual treatment, it is important to
determine whether the two are equivalent or whether one type of format is sufficiently superior
to warrant recommendation either for or against group administration. To address this question,
this study was designed to compare group and individual CPT for the treatment of PTSD in
military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version
of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be
tested, as a recent clinical trial designed to dismantle the components of CPT found that a
cognitive-only version was equally effective to the full version of CPT and perhaps more efficient
(Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical
trial designed with two primary objectives. One objective is to compare the effectiveness of
group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-
Centered Therapy (PCT) modality. The other research objective is to compare the
effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer
the first research question, the first 96 participants will be randomly assigned to group CPT-C or
PCT groups (48 per group). After these initial participants have been randomized, the
remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per
group), in order to answer the second and third research questions. We will include both
genders in groups. Women consenting to the study will be asked about participating in a group
with men because they may feel uncomfortable especially those who may have experienced a
sexual trauma. If a woman does not want to participate in a group with men, she will be referred
to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual
CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C
and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for
exact therapy time would be an option, it would be an unfair disadvantage for group treatment
with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of
sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al.
(2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See
Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing
Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for
focusing on current issues rather than the traumatic events themselves. The first two sessions
will provide psychoeducation about PTSD symptoms and the problem areas often associated
with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between
sessions, participants will be asked to monitor their problem-solving attempts and outcomes as
well as to keep a mood diary and list of current issues to be addressed in the next group. At the
beginning of each group meeting there will be a check-in for each participant to discuss briefly
the events and problems of the prior week and any issues they may want to discuss. Therapists
and clients will develop an agenda based on emerging themes. Education regarding PTSD and
depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: **Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. **Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
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determination of inter-rater reliabilities (kappas).

**Assessments.** The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 9-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 9-12-month follow-up.

**Timeline** The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

### 4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
<td>No</td>
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<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
<td>No</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
<td>No</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
<td>No</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
<td>No</td>
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<td>12. Beck Anxiety Inventory (BAI)</td>
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<td>13. Alcohol Use Disorders Identification Test (AUDIT)</td>
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<td>14. Response to Stressful Experiences Scale (RSES)</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 9-12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBNet 364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBNet 364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member’s spouse required to complete the packet.

1. Head Injury Assessment: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the
Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and
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Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency (α = .85 to .89) and construct validity (Vogt, et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to
determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point Likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i. e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation
and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al., 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.
14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kayser, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the
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interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium’s data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, & Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women’s program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army
Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test-retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.
24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Gamefksi, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual’s style of responding to stressful events. Thirty-six (36) items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraajj, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point determination. In a follow-up study, Wolfe et. al. further modified the criteria to facilitate its use as a simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011).
intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an
examiner. The modification replaced a physician-judged scale of somatic symptom severity with four
questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3
minutes to complete the questionnaire.

It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive
behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be
administered to determine the effect of treatment for PTSD on sleep.

While many clinicians use the 24-question Pittsburg Sleep Quality Index (PSQI; Buysse et al., 1989) to
assess for “disordered” sleep, the PSQI has not been validated to provide specific diagnostic data for
nightmares, apnea, daytime sleepiness, or insomnia. Instead of using the PSQI, five sleep assessments
totaling 24 questions will be administered to assess typical sleep durations and patterns on weekends
and weekdays as well as to assess for specific sleep difficulties (i.e., nightmares, apnea, daytime
sleepiness, and insomnia) often found in patients with PTSD and other behavioral health issues using
established diagnostic criteria.

30. Self-Assessment of Sleep Questionnaire. The Self-Assessment of Sleep questionnaire was
developed by a board-certified sleep specialist and one of the STRONG STAR investigators, Daniel
Taylor PhD, to be a brief assessment of self-reported sleep quantity and sleep quality. Five items assess
estimated total sleep times during the week and during weekends, self-reported hours of sleep needed to
feel rested, overall sleep quality, and duration of current sleep pattern. Although there are no established
psychometrics for this measure, combined with the other four measures of sleep the battery will provide
the information needed to comprehensively assess sleep in study participants.

31. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare
disturbance were selected from The Trauma-Related Nightmare Survey (TRNS; Davis, Wright, &
Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period
for frequency of nightmares (r = .64), and disturbance of nightmares (r = .63). Convergent validity was
also found with daily behavioral records of nights with nightmares (r = .82) and the Modified PTSD
Symptom Scale – Self-Report (MPSS-SR; Resick, Falsett, Resnick, & Kilpatrick, 1991) nightmare
frequency (r = .64) and disturbance (r = .45). The item assessing nights with nightmares was selected as
it is thought to be a more clinical significant measure of the impact of nightmares than the total number of
nightmares experienced.

32. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To
better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be
administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated
in 211 pre-operative surgical patients. Using the answering of 2 or more questions “yes,” the sensitivity of
the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of
polysomnography depending upon the AHI cut-off used. Individuals answering “yes” to 2 or more of the
questions will be advised that they may be at risk for having sleep apnea and advised that they may want
to speak with their primary care provider to consider referral for an overnight sleep evaluation at the
CRDAMC Sleep Clinic.

33. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in
various situations, will be used to assess daytime function. The ESS has good internal consistency (α =
.73 - .88) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness
(Chervin, Aldrich, Pickett & Guilleminault, 1997).

34. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses
perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4
(very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal
consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the
Pittsburgh Sleep Quality Index (r = 0.67), the Dysfunctional Beliefs and Attitudes about Sleep (r = 0.55),
and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).
35. Beliefs in a Just World (BJW) Scale. The BJW is a 16-item self-report measure that assesses the belief in a just world for self and others. Just world beliefs are the idea that everything happens for a reason and people get what they deserve in life. This may be protective for some people because it gives them the illusion that they have control over the world and what they experience. However, for trauma survivors, it can lead to feelings of self blame. For example, if people get what they deserve in life, then what did I do to deserve to be raped. This can lead to both behavioral and characterological self blame. Belief in a just world is related to psychological well-being. The BJW Scale has strong psychometric properties (Lipkus, et al., 1996). Factor analysis using promax rotation revealed 2 intercorrelator factors with eigenvalues greater than one. Items had moderate to high loadings on each factor. The BJW scale for self demonstrated good internal consistency (α=.84) in 2 studies. The BJW scale for others also demonstrated good internal consistency (α=.84 in one study and α=.83 in another). Homogeneity of the BJW scales was assessed using principal component analysis with oblique rotation. The scale for self had a single factor which accounted for 62% of the variance and the scale for others also had single factor which accounted for 64% of the variance. Additionally, the BJW Scale significantly correlated with existing measures of just world beliefs. Service Members with PTSD have been noted to endorse just world beliefs during therapy such as “It's not fair that this trauma happened,” or “People with young children are not supposed to die.” Potentially treatment for PTSD modifies these beliefs.

36. Patient Reported Outcomes Measurement Information System (PROMIS) Sexual Functioning Inventory: The PROMIS questionnaires are a system of reliable measures of patient–reported health status for physical, mental, and social well-being developed with funding under the National Institutes of Health (NIH) Roadmap for Medical Research Initiative to re-engineer the clinical research enterprise (http://www.nihroadmap.nih.gov). PROMIS measures can be across a wide variety of chronic diseases and conditions and in the general population (Cella et al, 2010). One of the PROMIS Instruments is a Sexual Functioning Inventory (Jeffery et al, 2009). The PROMIS Sexual Function Inventory provides scores on seven different sub-domains of sexual function: interest in sexual activity, vaginal discomfort (women only), lubrication (women only), erectile function (men only), orgasm, and global satisfaction with sex life. Each question asks respondents to report on their experiences over the past 30 days. With the exception of the orgasm sub-domain, all sub-domain scores are expressed as T scores (mean = 50, standard deviation = 10). While the Inventory is intended for broad use, almost all of the development work was with patients with cancer. Research is ongoing to expand development beyond cancer. In testing with 819 individuals (388 males, 430 females, 1 person did not specify sex), correlations between the PROMIS Sexual Functioning Inventory and corresponding sub-domains of two well-established measures, the Female Sexual Function Index (FSFI) and the International Index of Erectile Function (IIEF), ranged between .48 and .92. The sub-domains of the Inventory discriminate between people who had and had not asked a provider about sexual problems. Test-retest correlations over one month are >.65 for all sub-domains (Sexual Function and Satisfaction Measures User Manual, 2012).

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of
OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.

- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment:
Service Members who screen out from other BAMC IRB-approved STRONG STAR protocols including C.2009.021 / IRBNet 363398 (Prolonged Exposure for PTSD in OIF/OEF Personnel: Massed vs. Spaced Trials), C.2011.120 / IRBNet 364801 (Comparing Internet and In-Person Brief Cognitive Behavioral Therapy of Insomnia), C.2011.004d / IRBNet 363539 (Genetic and Environmental Predictors of Combat-Related PTSD), and C.2011.120 / IRBNet 368445 (The Role of Exercise in the Treatment of PTSD Symptoms) will be offered the opportunity to be screened for participation in this study at the conclusion of their study visit for the previously-referenced protocol. If interested, a member of the research team will review eligibility with these potential participants (e.g., pre-screen) and either obtain informed consent at that time, if authorized, or schedule another visit at a later date.

Additionally, potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment...
and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16-24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked
cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEF/OIF ODN. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant's willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study databases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects.
Cognitive Processing Therapy for Combat-Related PTSD

(therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 9-12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.
8.0 Duration of Study: estimated to be 8 years, ending by December 31, 2016.

9.0 Funding: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 Staff Monitor (for resident and fellow projects): not applicable

11.0 Bibliography:


**Measurement References**


Cognitive Processing Therapy for Combat-Related PTSD


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12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – Managing Suicidal Behaviors (updated)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots
1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder that impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group
treatment would be a much more efficient and cost-effective therapy modality in most cases.
On the other hand, if individual therapy is found to be superior, the DoD and VA will have
justification for the investment of greater resources into individual therapy in order to provide the
most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA
is in the development and validation of effective treatments for combat-related PTSD and
related psychosocial health problems in military personnel. This research gap is highlighted in
three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the
Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA
Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF
veterans suggest that between 5 and 17% of U.S. military personnel returning from
deployments have symptoms of PTSD, and as many as 25% report some psychological
problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also
highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in
veterans, and it concluded that well-designed research is needed to answer the key questions
regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-
based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session
manualized program that focuses on challenging beliefs and assumptions related to the trauma,
one’self, and the world. CPT was first developed as a group treatment (Resick & Schnicke,
1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-
validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it
was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials
using CPT followed suit testing the therapy either as an individual treatment (Monson et al.,
2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies
have shown that individual CPT is an effective treatment for symptoms of PTSD. However,
CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without
Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for
the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If
effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group
treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee
judged the overall body of evidence regarding group therapy formats to be low quality to inform
a conclusion regarding efficacy because of the lack of well-designed studies comparing group
and individual formats and including appropriate controls. The Committee is uncertain about the
presence of an effect, and believes that future well-designed studies will have an important
impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is
important to establish the effectiveness of CPT administered in a group format compared to
other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within
the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans
with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may
be related to past traumatic events, but does not address specific memories or cognitions about
the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003)
to control for nonspecific benefits that are common to most types of psychotherapy. With this
comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups. Women consenting to the study will be asked about participating in a group with men because they may feel uncomfortable especially those who may have experienced a sexual trauma. If a woman does not want to participate in a group with men, she will be referred to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but
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no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others' traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: **Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. **Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas—safety, trust, control, esteem, and intimacy—are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

**Assessments.** The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 9-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 9-12-month follow-up.

**Timeline** The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

### 4.7 Source of Research Material:

<table>
<thead>
<tr>
<th>Source of Research Material</th>
<th>Standard Care</th>
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<tbody>
<tr>
<td>1. Head Injury Assessment</td>
<td>No</td>
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<tr>
<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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<td>6. PTSD CheckList – Stressor Specific (PCL-S) &amp; PTSD CheckList – Version for proposed DSM-V (PCL-V)</td>
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<td>7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)</td>
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<td>8. Revised Conflict Tactics Scale (CTS2)</td>
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<td>9. State-Trait Anger Expression Inventory (STAXI)</td>
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<td>10. Beck Depression Inventory-II (BDI-II)</td>
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<td>11. Beck Scale for Suicidal Ideation (SSI) Screen</td>
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<td>12. Beck Anxiety Inventory (BAI)</td>
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<td>13. Alcohol Use Disorders Identification Test (AUDIT)</td>
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<td>14. Response to Stressful Experiences Scale (RSES)</td>
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15. Life Event Checklist (LEC)  No
16. PERI Life Events Scale  No
17. Peri-Traumatic & Post-Traumatic Emotions Questionnaire  No
18. Demographics & Military Service Characteristics  No
19. Interpersonal Support Evaluation List (ISEL)  No
20. Trauma-Related Guilt Inventory (TRGI)  No
21. Walter Reed Army Institute of Research (WRAIR) Military Vertical & Horizontal Cohesion Scales  No
22. Post-Traumatic Cognitions Inventory (PTCI)  No
23. Credibility / Expectancy Questionnaire (CEQ)  No
24. Cognitive Emotions Regulation Questionnaire (CERQ)  No
25. Patient Health Questionnaire (PHQ)-15  No
26. Homework Compliance  No
27. Health Interview (Pre- & Post-Treatment)  No
28. Mini International Neuropsychiatric Interview (MINI), Modules C (Mania) & (Psychosis)  No
29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire  No
30. Self-Assessment of Sleep Questionnaire  No
31. Frequency of Nightmares Questionnaire  No
32. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen  No
33. Epworth Sleepiness Scale (ESS)  No
34. Insomnia Severity Index (ISI)  No
35. Beliefs in a Just World (BJW) Scale  No
36. PROMIS Sexual Function Profile  No

4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 9-12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBNet 364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBNet 364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member’s spouse required to complete the packet.

1. Head Injury Assessment: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the...
Cognitive Processing Therapy for Combat-Related PTSD

The Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and
Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency (α = .85 to .89) and construct validity (Vogt et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .88 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to
determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or married couples, i. e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation
and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al., 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha = .80-.93$) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.
14. **Response to Stressful Experiences Scale (RSES)** (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. **Life Events Checklist**: The LEC includes a list of 16 different potentially traumatic life events that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder Checklist – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder Checklist – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. **PERI Life Events Scale (Brief)**: The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. **Peri-traumatic and Posttraumatic Emotions Scale**: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the...
interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium's data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographics and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women's program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army
Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test–retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.
24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual's style of responding to stressful events. Thirty six (36)- items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner's office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Ruminating, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 ("not bothered at all") to 2 ("bothered a lot"). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability (($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview.

28. Mini-International Neuropsychiatric Interview (MINI): The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point determination. In a follow-up study, Wolfe et. al. further modified the criteria to facilitate its use as a simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011).
intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an examiner. The modification replaced a physician-judged scale of somatic symptom severity with four questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3 minutes to complete the questionnaire.

It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be administered to determine the effect of treatment for PTSD on sleep.

While many clinicians use the 24-question Pittsburg Sleep Quality Index (PSQI; Buysse et al., 1989) to assess for “disordered” sleep, the PSQI has not been validated to provide specific diagnostic data for nightmares, apnea, daytime sleepiness, or insomnia. Instead of using the PSQI, five sleep assessments (totaling 24 questions) will be administered to assess typical sleep durations and patterns on weekends and weekdays as well as to assess for specific sleep difficulties (i.e., nightmares, apnea, daytime sleepiness, and insomnia) often found in patients with PTSD and other behavioral health issues using established diagnostic criteria.

30. Self-Assessment of Sleep Questionnaire. The Self-Assessment of Sleep questionnaire was developed by a board-certified sleep specialist and one of the STRONG STAR investigators, Daniel Taylor PhD, to be a brief assessment of self-reported sleep quantity and sleep quality. Five items assess estimated total sleep times during the week and during weekends, self-reported hours of sleep needed to feel rested, overall sleep quality, and duration of current sleep pattern. Although there are no established psychometrics for this measure, combined with the other four measures of sleep the battery will provide the information needed to comprehensively assess sleep in study participants.

31. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare disturbance were selected from The Trauma-Related Nightmare Survey (TRNS; Davis, Wright, & Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period for frequency of nightmares (r = .64), and disturbance of nightmares (r = .63). Convergent validity was also found with daily behavioral records of nights with nightmares (r = .82) and the Modified PTSD Symptom Scale – Self-Report (MPSS-SR; Resick, Falsetti, Resnick, & Kilpatrick, 1991) nightmare frequency (r = .64) and disturbance (r = .45). The item assessing nights with nightmares was selected as it is thought to be a more clinical significant measure of the impact of nightmares than the total number of nightmares experienced.

32. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated in 211 pre-operative surgical patients. Using the answering of 2 or more questions “yes,” the sensitivity of the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of polysomnography depending upon the AHI cut-off used. Individuals answering “yes” to 2 or more of the questions will be advised that they may be at risk for having sleep apnea and advised that they may want to speak with their primary care provider to consider referral for an overnight sleep evaluation at the CRDAMC Sleep Clinic.

33. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in various situations, will be used to assess daytime function. The ESS has good internal consistency (α = .73 - .88) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness (Chervin, Aldrich, Pickett & Guilleminault, 1997).

34. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4 (very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the Pittsburgh Sleep Quality Index (r = 0.67), the Dysfunctional Beliefs and Attitudes about Sleep (r = 0.55), and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).
35. Beliefs in a Just World (BJW) Scale. The BJW is a 16-item self-report measure that assesses the belief in a just world for self and others. Just world beliefs are the idea that everything happens for a reason and people get what they deserve in life. This may be protective for some people because it gives them the illusion that they have control over the world and what they experience. However, for trauma survivors, it can lead to feelings of self blame. For example, if people get what they deserve in life, then what did I do to deserve to be raped. This can lead to both behavioral and characterological self blame. Belief in a just world is related to psychological well-being. The BJW Scale has strong psychometric properties (Lipkus, et al., 1996). Factor analysis using promax rotation revealed 2 intercorrelator factors with eigenvalues greater than one. Items had moderate to high loadings on each factor. The BJW scale for self demonstrated good internal consistency (α=.84) in 2 studies. The BJW scale for others also demonstrated good internal consistency (α=.84 in one study and α=.83 in another). Homogeneity of the BJW scales was assessed using principal component analysis with oblique rotation. The scale for self had a single factor which accounted for 62% of the variance and the scale for others also had single factor which accounted for 64% of the variance. Additionally, the BJW Scale significantly correlated with existing measures of just world beliefs. Service Members with PTSD have been noted to endorse just world beliefs during therapy such as “It's not fair that this trauma happened,” or “People with young children are not supposed to die.” Potentially treatment for PTSD modifies these beliefs.

36. Patient Reported Outcomes Measurement Information System (PROMIS) Sexual Functioning Inventory: The PROMIS questionnaires are a system of reliable measures of patient–reported health status for physical, mental, and social well-being developed with funding under the National Institutes of Health (NIH) Roadmap for Medical Research Initiative to re-engineer the clinical research enterprise (http://www.nihroadmap.nih.gov). PROMIS measures can be across a wide variety of chronic diseases and conditions and in the general population (Cella et al, 2010). One of the PROMIS Instruments is a Sexual Functioning Inventory (Jeffery et al, 2009). The PROMIS Sexual Function Inventory provides scores on seven different sub-domains of sexual function: interest in sexual activity, vaginal discomfort (women only), lubrication (women only), erectile function (men only), orgasm, and global satisfaction with sex life. Each question asks respondents to report on their experiences over the past 30 days. With the exception of the orgasm sub-domain, all sub-domain scores are expressed as T scores (mean = 50, standard deviation = 10). While the Inventory is intended for broad use, almost all of the development work was with patients with cancer. Research is ongoing to expand development beyond cancer. In testing with 819 individuals (388 males, 430 females, 1 person did not specify sex), correlations between the PROMIS Sexual Functioning Inventory and corresponding sub-domains of two well-established measures, the Female Sexual Function Index (FSFI) and the International Index of Erectile Function (IIEF), ranged between .48 and .92. The sub-domains of the Inventory discriminate between people who had and had not asked a provider about sexual problems. Test-retest correlations over one month are >.65 for all sub-domains (Sexual Function and Satisfaction Measures User Manual, 2012).

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale (PSS-I)
- Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of
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OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.

- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment:
Service Members who screen out from other BAMC IRB-approved STRONG STAR protocols including C.2009.021 / IRBNet 363398 (Prolonged Exposure for PTSD in OIF/OEF Personnel: Massed vs. Spaced Trials), C.2011.120 / IRBNet 364801 (Comparing Internet and In-Person Brief Cognitive Behavioral Therapy of Insomnia), C.2011.004d / IRBNet 363539 (Genetic and Environmental Predictors of Combat-Related PTSD), and C.2011.120 / IRBNet 368445 (The Role of Exercise in the Treatment of PTSD Symptoms) will be offered the opportunity to be screened for participation in this study at the conclusion of their study visit for the previously-referenced protocol. If interested, a member of the research team will review eligibility with these potential participants (e.g., pre-screen) and either obtain informed consent at that time, if authorized, or schedule another visit at a later date.

Additionally, potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment...
and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16-24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked
cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEF OIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have either already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy, cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects
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(therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 9-12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.
8.0 **Duration of Study:** estimated to be 8 years, ending by December 31, 2016.

9.0 **Funding:** The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 **Staff Monitor (for resident and fellow projects):** not applicable

11.0 **Bibliography:**


**Measurement References**


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12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)
B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)
C – Homework Compliance Forms
D – Summary of the Assessments and Timing of Administration
E – STRONG STAR SOP for Suicide Risk Assessment & Management (dated 12-12-13)
F – STRONG STAR Database Policies & Procedures
G – Data Safety Monitoring Plan (DSMP) (updated)
H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots

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1.0 Title: Cognitive Processing Therapy for Combat-Related PTSD

2.0 Study Personnel: See P01-Core Application-HSR-Part A

Medical Monitor: See P01-Core Application-HSR-Part A

3.0 Location(s): See P01-Core Application-HSR-Part A

4.0 Research Plan

4.1 Purpose: The first purpose of this study is to compare group-administered Cognitive Processing Therapy (CPT) to Present Centered Therapy (PCT) in order to determine whether the results of CPT exceed those of receiving a therapy that focuses on current problems rather than past trauma and other nonspecific therapy effects in a group format. A second purpose is to conduct a randomized controlled trial (RCT) to compare group and individual Cognitive Processing Therapy (CPT) for the treatment of post-traumatic stress disorder (PTSD) in military personnel who have deployed in support of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND). In this study, Cognitive Processing Therapy, Cognitive-only version (CPT-C), which is CPT without the written account, will be tested.

4.2 Hypotheses/Research Questions:

1. Are there differences in outcomes between group CPT-C and PCT?

2. Are there differences in outcomes between individual and group CPT-C treatment?

3. What is the effect of other variables (e.g. gender, traumatic brain injury, co-morbid symptoms, type of trauma, length of time since worst event, number of deployments, etc.) on treatment outcome?

4.3 Significance: Recent studies of OIF, OEF, and OND veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). Almost 2 million U.S. military personnel have deployed in support of OIF/OEF/OND. Estimates of the rate of PTSD in this population indicate that about 100,000-300,000 OIF/OEF/OND veterans are at significant risk for chronic PTSD.

PTSD can become a chronic disorder than impacts all areas of a person’s life including work, health, family and social life. The costs to the Department of Defense (DoD) and the Veterans Affairs (VA) as well as society at large are substantial. PTSD treatment programs are being developed throughout DoD and VA but because of the large number of service members returning from deployment with PTSD, it is often necessary to provide psychotherapy in groups. Cognitive processing therapy (CPT), an evidence-based treatment for PTSD, was originally developed as a group-based intervention. However, most of the research conducted on CPT focused on individually-applied treatment, and group-based CPT treatment has never been systematically compared to other forms of group treatment or to individual CPT treatment.

The public policy implications of the results of this trial are significant. If both group and
individual CPT treatment formats are equivalent or if group treatment is better, then group treatment would be a much more efficient and cost-effective therapy modality in most cases. On the other hand, if individual therapy is found to be superior, the DoD and VA will have justification for the investment of greater resources into individual therapy in order to provide the most effective treatment for PTSD to military personnel.

4.4 Military Relevance: One of the most significant research gaps of PTSD in the DoD and VA is in the development and validation of effective treatments for combat-related PTSD and related psychosocial health problems in military personnel. This research gap is highlighted in three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF veterans suggest that between 5 and 17% of U.S. military personnel returning from deployments have symptoms of PTSD, and as many as 25% report some psychological problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in veterans, and it concluded that well-designed research is needed to answer the key questions regarding the efficacy of treatment modalities in combat veterans.

4.5 Background / Review of Literature: Cognitive Processing Therapy (CPT) is an evidence-based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session manualized program that focuses on challenging beliefs and assumptions related to the trauma, oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke, 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials using CPT followed suit testing the therapy either as an individual treatment (Monson et al., 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies have shown that individual CPT is an effective treatment for symptoms of PTSD. However, CPT in a group-only format has never been studied with a randomized controlled trial.

Even without evidence from well-designed clinical trials, group therapy with and without Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, “The Committee judged the overall body of evidence regarding group therapy formats to be low quality to inform a conclusion regarding efficacy because of the lack of well-designed studies comparing group and individual formats and including appropriate controls. The Committee is uncertain about the presence of an effect, and believes that future well-designed studies will have an important impact on confidence in the effect and the size of the effect” (p. 4-32-33). Therefore, it is important to establish the effectiveness of CPT administered in a group format compared to other forms of group treatment for PTSD.

Present Centered Therapy (PCT) is a problem solving group intervention typically used within the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may be related to past traumatic events, but does not address specific memories or cognitions about the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003) to control for nonspecific benefits that are common to most types of psychotherapy. With this comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the
results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and there were no differences between treatments. In a study of individual PCT compared to PE (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six month follow-up.

Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT. Given that CPT can be administered as either a group or individual treatment, it is important to determine whether the two are equivalent or whether one type of format is sufficiently superior to warrant recommendation either for or against group administration. To address this question, this study was designed to compare group and individual CPT for the treatment of PTSD in military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be tested, as a recent clinical trial designed to dismantle the components of CPT found that a cognitive-only version was equally effective to the full version of CPT and perhaps more efficient (Resick et al., 2008).

4.6 Research Design and Methods: The proposed project is a longitudinal randomized clinical trial designed with two primary objectives. One objective is to compare the effectiveness of group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-Centered Therapy (PCT) modality. The other research objective is to compare the effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer the first research question, the first 96 participants will be randomly assigned to group CPT-C or PCT groups (48 per group). After these initial participants have been randomized, the remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per group), in order to answer the second and third research questions. We will include both genders in groups. Women consenting to the study will be asked about participating in a group with men because they may feel uncomfortable especially those who may have experienced a sexual trauma. If a woman does not want to participate in a group with men, she will be referred to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for exact therapy time would be an option, it would be an unfair disadvantage for group treatment with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of sessions rather than time.

Description of Treatment Protocols (Independent Variable).

Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al. (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for focusing on current issues rather than the traumatic events themselves. The first two sessions will provide psychoeducation about PTSD symptoms and the problem areas often associated with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between sessions, participants will be asked to monitor their problem-solving attempts and outcomes as well as to keep a mood diary and list of current issues to be addressed in the next group. At the beginning of each group meeting there will be a check-in for each participant to discuss briefly the events and problems of the prior week and any issues they may want to discuss. Therapists and clients will develop an agenda based on emerging themes. Education regarding PTSD and depression, support, and current-focused problem-solving can be included as interventions, but
no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of each group meeting, the participants will develop an action plan for problems discussed in the group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.

The most recent Cognitive Processing Therapy (CPT) manual (Resick et al., 2007), including CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT is a highly structured protocol in which clients learn the skills of recognizing and challenging dysfunctional cognitions, first about the worst traumatic event and then with regard to the meaning of the events for current beliefs about self and others. Recently, Resick and her colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-C), which is particularly helpful when providing CPT in a group format (Resick et al., 2008). In the group format of this treatment, participants will not share the details of their particular traumatic event with the group. Rather, the group will discuss themes that are common to a wide range of traumas, and individuals will complete homework activities and group worksheets based on their own traumas that will not be shared with the group. The purpose of this is to reduce the likelihood that group members will be triggered by accounts of others’ traumatic events.

In CPT, there are practice assignments, typically worksheets to complete each day, between sessions that are particular to the work of the session. The following sessions are included in CPT-C: **Session 1:** The initial session of CPT is psycho-educational; symptoms of PTSD are explained within a cognitive and information processing theory framework. At the conclusion of this session, patients are asked to write an impact statement about the meaning of the traumatic event as well as beliefs about why the event happened. **Session 2:** In session 2, the impact statement is read and discussed with a focus on identifying problematic beliefs and cognitions (“stuck points”). The therapist introduces the A-B-C worksheet with an explanation of the relationship between thoughts, feelings and behaviors. Patients are then taught to identify the connection between events, thoughts and feelings and asked to practice this skill for homework. **Session 3-4:** Sessions 3 and 4 include a review of the self-monitoring homework and a discussion of stuck points. Socratic questioning is used to identify issues of assimilation and self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are given the Challenging Questions worksheet, which challenges single beliefs related to the trauma. **Session 5-6:** In session 5, the Challenging Questions Worksheet is reviewed and the Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the identification of patterns of problematic thinking through both homework review and the introduction of the Challenging Beliefs Worksheet. Participants are asked to use the worksheets daily with everyday events and challenge trauma-related self-blame cognitions. **Session 7-12:** In sessions 7-12, over-generalized beliefs in five areas--safety, trust, control, esteem, and intimacy--are challenged as they relate to self and others. Treatment gains are consolidated in the final sessions.

All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week for six weeks following an initial meeting with one of the therapists in order for them to discuss the participants’ trauma history and PTSD symptoms and to pick an index event, the worst traumatic event, that will be the initial focus of therapy. Participants will receive their randomization information at this session and times and dates for therapy will be scheduled. All therapy conditions include out-of-session practice assignments. Prior to each session, participants will be asked to complete a form (see Appendix C) to measure the frequency with which they completed the practice assignments between sessions (a measure of therapy compliance). Participants will also be asked to complete the same four self-report measures on
a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four questionnaires will be completed at the beginning of one of the weekly sessions, while the remaining two will be completed at the start of the other weekly session.

Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out the treatment protocols and study evaluations. At least two therapists will co-lead both types of treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal caseload of individual participants receiving individual CPT-C therapy. Because both therapists are providing both treatments, this will reduce the risk of having the competence of the therapist over-ride any differences between conditions. The evaluators will be independent of the therapists and will be blind as to condition. Participants will be asked not to reveal the type of therapy the received to the evaluators at the post-treatment assessments.

Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following established procedures used in other studies (e.g., Schnurr et al., 2007). Training workshops will be conducted in San Antonio or at another military base or VA if the timing for training coincides with an official training workshop. Therapists will be a credentialed provider at the facility. Each therapist will treat training patients under supervision prior to treating consented study participants. Video recordings of treatment sessions (using the standard consent for electronic recordings of patients) will be reviewed by designated CPT supervisors, and all therapists will be required to meet therapy certification requirements prior to seeing consented study cases.

Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT supervisor, who will then provide the therapist with individual feedback on each training case. All therapists will participate in a weekly CPT therapist supervision teleconference with Dr. Resick to review all new and ongoing treatment cases.

Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely monitored to ensure that the therapy conditions are distinct and true to the protocols. The therapists will be trained early in the project by Dr. Resick to conduct each of the three types of therapy. They will also be instructed on the data they will need to collect within their roles (e.g., self-report measures before and during treatment, homework compliance) and any required paperwork for the patients. The therapists will be provided manuals and will have taped examples of the therapy to study. They will be required to treat pilot cases prior to starting the main data collection under close supervision to ensure that they are administering the therapies competently. During the data collection phase, therapists will continue to receive weekly supervision on their cases by project staff and will have local back-up as well as case consultation with the Overall Study PI on an ongoing basis as needed.

Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and competence will be determined by independent raters who are not otherwise involved in the project. The raters will have served on prior CPT studies as adherence and competence raters. In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, all sessions in the study will be video recorded for supervision purposes and for possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500 participants. Video recordings will then be sent using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR database. The raters will determine adherence to the CPT-C and PCT therapies and competence in delivering the therapies. We will randomly select 5% (300) for viewing and
determination of inter-rater reliabilities (kappas).

Assessments. The participants will be assessed 4 times during the course of the study with diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-months following treatment, and 9-months following treatment (or the equivalent time periods if they dropped out). The assessment measures will consist of a battery of measures that will be used in consortium studies, plus a number of study-specific measures examining cognitive and emotional processing of the traumatic event. Independent evaluators blind as to condition, will conduct the follow-up interviews using measures from the pre-treatment assessment.

In addition to these assessments, three measures (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, and the CERQ) will be administered weekly (i.e., six times) at the beginning of the treatment session. At each session as an indicator of therapy compliance, we will also track whether clients completed homework assignments. The Beck Scale for Suicide Ideation will also be administered every week as a safety measure per the Consortium policy. See Appendix D for a summary of the assessments and timing of administration.

Those who drop out of treatment will be asked to return for the post-treatment assessment two weeks after their projected end date and at the 6-month and 9-12-month follow-up.

Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of the assessment battery, IRB approval, training and piloting of therapists, and training of evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of therapists and evaluators will take place weekly throughout the data collection period. Adherence/competence ratings and interviewer reliability ratings will be collected throughout the project. Data cleaning, entry and scoring will take place throughout the project. The major data analyses will be conducted at the end of the data collection for the group CPT-C and PCT comparison and again in the final 6 months, as will manuscript preparation and the final report.

4.7 Source of Research Material:

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<th>Source of Research Material</th>
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<td>1. Head Injury Assessment</td>
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<td>2. Automated Neuropsychological Assessment Metrics (ANAM®)</td>
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<td>3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, &amp; Deployment Environment Sub-Scales</td>
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<td>4. PTSD Symptom Scale – Interview (PSS-I)</td>
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<td>5. Columbia-Suicide Severity Rating Scale (C-SSRS)</td>
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4.8 Instrumentation: See Appendix D for a summary of the assessments and timing of administration. For participants who have left military service $25 compensation will be offered for completion of the 6- and 9-12-month follow-up assessments (for a total of $50). Payment will only be offered to participants who have left military service to be in compliance with the recently published Department of Defense Instruction (DoDI) 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated 20 October 2011.

One questionnaire, the American College of Rheumatology (ACR) Fibromyalgia Questionnaire, is being included in the questionnaire packet in support of another BAMC IRB-approved protocol, Prevalence of Fibromyalgia (FM) in Posttraumatic Stress Disorder (PTSD) (C.2011.145d, IRBNet 364862). Additionally, participants will be given the option of taking a questionnaire packet home to their spouse offering the spouse participation in C.2011.145d, IRBNet 364862. This packet includes a demographics form for spouses and the ACR Fibromyalgia Questionnaire. As described in the informed consent document for the treatment study, Service Members are not required to take the packet home; neither is the Service Member’s spouse required to complete the packet.

1. Head Injury Assessment: Traumatic brain injury (TBI), in particular mild TBI is very difficult to assess and diagnose with an administered questionnaire or automated testing. Yet, it is imperative that some assessment for TBI be made to more fully assess TBI in the presence of PTSD and more fully evaluate response to PTSD treatment. In consultation with civilian and military experts in TBI, STRONG STAR is administering a modified version of the Defense and Veterans Brain Injury Center (DVBI) 3-Item Screening Tool (Schwab, Baker, Ivins, Sluss-Tiller, Lux & Warden, 2006; Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006) to all participants. This instrument, initially called the
Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a Masters’ level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins, Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was modified for this study to capture the number of injuries, and to answer question 2 based on the worst injury; the original form does not recognize the possibility of multiple head injuries during deployment. Participants who are positive using this screen will then be further tested using the Automated Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head injuries prior to deployment, an additional four questions have been added to solicit information about each head injury sustained outside of deployment.

2. Automated Neuropsychological Assessment Metrics (ANAM®): The ANAM is a computerized battery of neuropsychological tests originally developed within the Department of Defense in the early 1990s to provide a standardized and valid method of testing to detect deficits in cognitive functioning in various clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of tests that assess different basic functions or domains of cognition to include reaction time, processing speed (procedural reaction time), learning (code substitution), delayed memory (code substitution), working memory (mathematical processing), and spatial memory (matching). The test assesses both speed and accuracy. “Throughput” is the number of correct items within a certain time. Norms for military Service Members and college studies, both male and female ranging in age from 18 to 51 have been established. Test print-outs compare scores for the individual being tested to a preselected normative group. The ANAM has compared favorably to a variety of traditional neuropsychological measures including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been used to screen for impairment in various clinical populations including patients with multiple sclerosis, systemic lupus erythematosus, Parkinson’s disease, Alzheimer’s dementia, migraine headache, and acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer, Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine, mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is administering the ANAM to provide additional descriptive data about the cognitive functioning of study participants based upon the recommendations of civilian and military experts in TBI and the STRONG STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.

3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and
Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be assessed using scales from the DRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRI was developed and tested in three separate national samples of veterans of the first Gulf War. It has been revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures will be assessed using the DRRI Combat Experiences and Aftermath of Battle subscales. Responses to these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In addition, low-intensity deployment stress will be assessed with the DRRI Deployment Environment subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time) to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are indicative of a more difficult living and working environment. All three subscales have very good internal consistency (α = .85 to .89) and construct validity (Vogt et al., 2008).

4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000). Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and arousal. The scale has excellent internal consistency (α = .91), test-retest reliability (.80), and inter-rater reliability (kappa = .91). This measure will be administered by a blinded Independent Evaluator at each study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not specifically reference the index event are: loss of interest in free time activities, feelings of detachment, impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep, irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle. This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to better understand the study outcomes.

5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation. The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. Distinctions will be made between multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a multiple attempter if they answered 2 or more attempts.

6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD symptoms in the past month as a result of the stressful life events identified by either the participant, or by the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales: Re-experiencing symptoms (items 1-5); Avoidance/ Emotional Numbing symptoms (items 6-12); and Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21 studies testing 9,628 subjects, almost one-third of which (n=2,767) were military Veterans, reported overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen, Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to
determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008) subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher during the past month, and if they received a total severity score of 50 or higher. At baseline and again following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as well as the PCL-S so that when the results of this study are published the Research Team will be able to put the findings of the study in the context of the most current criteria of PTSD.

7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. It includes two modifications. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Also, there are two summary scales: a physical component summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each summary is expressed as a T score, which facilitates comparisons between the VA patients and the general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven of the eight scales and provides 90% of the reliable variance in the two component summary measures using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979) and over time has become the most widely used instrument to assess intimate partner violence (Straus & Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or marital couples, i. e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances as well as the family as these subscales represent the content areas of most interest and are most relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby, Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument demonstrated construct and discriminate validity in that men were shown to be more likely to use coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation
and injury, were shown to not be correlated. Various versions of the CTS have been used in other studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, & Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to assess.

9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that evaluates dimensions of anger, to assess participants’ feelings of anger at a given moment. Only the 10 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging from 1 (“not at all”) to 4 (“very much so”). Scores on all 10 items are summed to assess the overall intensity of anger felt at a particular moment in time. We are only interested in the state items because they are the most likely to change with treatment. Internal consistency of the subscale was found to be strong (average \( \alpha = .90 \)), as was its convergent validity with measures of hostility and other personality scales (Spielberger, 1988).

10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and somatic symptoms related to depression and depressive disorders. Each item is composed of four statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28), or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+ positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3 categories. There will be no “low” category for multiple attempters. In a sample of 330 psychiatric inpatients, the BSSI was found to have a Cronbach’s alpha coefficient of .95, indicating high internal consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent validity.

12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a four-point scale ranging from 0 (“not at all”) to 3 (“severely”). Scores on all items are summed to obtain a general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of anxiety. The BAI has been shown to have high internal consistency (\( \alpha = .92 \)) and test-retest reliability. It has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck, Epstein, Brown & Steer, 1988).

13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001) will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be administered through an interview, with the interviewer reading each question to the participant as written. The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the clinician, depending upon the population being studied. The AUDIT has good internal consistency (\( \alpha = .80-93 \)) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993). Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.
14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson, et al., 2008). It asks participants to assess how well each statement describes them, both during and after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The instrument correlated negatively with psychological symptom distress as assessed with the Patient Health Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality, self-efficacy, and restoration.

15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three totals will be generated: number of events experienced, number of events witnessed, and number of events learned about. In a group of 108 undergraduate psychology students the instrument demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as well as sexual assault.

16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, & Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful events a person has experienced in the previous six months. In order to minimize time burden, the 10 items most relevant to the military population to which the measure will be administered were selected by military subject matter experts. In some cases, the military experts combined items to adequately cover all of the major content areas of the original measure with the fewest number of items. This measure is intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just because someone has one stressful event does not necessarily make it more likely that s/he would have another stressful event). The intent is to capture the most common, yet most stressful life events, which could affect treatment outcome.

17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick, Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand why some people developed psychological problems after being raped while some people recovered (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the
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interview and asked questions about peri-traumatic emotions the interview has been further refined. Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2) Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). Responses indicative of a Freeze Response were associated with greater PTSD and depressive symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 = “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the Consortium's data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ during treatment for PTSD to assess when change in emotions occurs.

18. Demographic and Military Service Characteristics Form: The Demographics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures multiple dimensions of perceived social support. This measure has been shown to have good internal consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11), Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social support.

20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996). Often survivors of trauma experience guilt related to the trauma about things they did or did not do or feelings they had or did not have. A combat veteran may experience guilt about having provided first aid to some of his or her wounded colleagues but not others even though it was not possible to care for everyone. Or, an individual may experience survivor’s guilt not understanding why he lived while others died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI is scored into three scales (i.e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt Cognitions Scale) and 3 subscales (i.e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using almost 600 individuals including 357 university students, 163 women receiving counseling services in a battered women's program, and 74 Vietnam veterans. Internal consistency was high across all the testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the Posttraumatic CheckList – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 (p<.05). In a sample of 32 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7, 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These cohesion scales are the gold standard method of evaluating attitudes about support from leaders (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army
Institute of Research (WRARI) and they are used extensively in research on service members’ psychological health and wellness. Horizontal cohesion will be measured using a revised three-item cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994). Items assess the degree to which unit members are cooperative, can depend on one another, and stand up for one another. The wording was revised to match the military description of work group (i.e., unit). Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and whether they had a consistent response options set, were not redundant, and related to Company-level ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion score will be calculated.

22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.

23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Devilly & Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick, personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23, 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the therapy works (credibility) as well as whether the person affectively believes that the therapy will work for them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ was able to differentiate between two treatment rationales in one study, one with and one without an encompassing theory while maintaining equivalence between three rationales in another study. Responses to four questions are scored using a 9-point Likert scale (1 = not at all, 9 = extremely). Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The combined responses are used to generate a score for credibility and another score for expectancy.
24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess cognitive coping strategies people tend to use, or what someone thinks, after having experienced threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess cognitive strategies that characterize the individual's style of responding to stressful events. Thirty six (36) items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4) Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective, and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always). Individual subscale scores are obtained by summing up the scores belonging to the particular subscale. The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner’s office practice in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high (α = 0.67 to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were comparable to reported results with the original CERQ in that the Rumination, Self-Blame and Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure asks patients to report symptom severity on a scale ranging from 0 (“not bothered at all”) to 2 (“bothered a lot”). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal reliability (α = .80) and good convergent validity with scales such as the SF-12 and other measures of symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty; Kroenke, Spitzer, & Williams, 2002).

26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored through a self-report worksheet administered prior to each session.

27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services, utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of increased relevance to active-duty service personnel. After treatment, we also ask about changes in military status and important life events since the last interview. This data will be verified by a review of the medical record that will include medical diagnoses, healthcare utilization (e.g., inpatient hospitalizations), prescribed medications, and the review and recording of any polysomnography (PSG) or sleep studies done as part of clinical care.

28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment on this study.

29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to
the old criteria which required a tender point examination, this simpler clinical case definition correctly classified 88% of old-criteria patients, and obviates the need for physician examination and tender point determination. In a follow-up study, Wolfe et. al further modified the criteria to facilitate its use as a simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011). The intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an examiner. The modification replaced a physician-judged scale of somatic symptom severity with four questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3 minutes to complete the questionnaire.

It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be administered to determine the effect of treatment for PTSD on sleep.

While many clinicians use the 24-question Pittsburg Sleep Quality Index (PSQI; Buysse et al., 1989) to assess for “disordered” sleep, the PSQI has not been validated to provide specific diagnostic data for nightmares, apnea, daytime sleepiness, or insomnia. Instead of using the PSQI, five sleep assessments (totaling 24 questions) will be administered to assess typical sleep durations and patterns on weekends and weekdays as well as to assess for specific sleep difficulties (i.e., nightmares, apnea, daytime sleepiness, and insomnia) often found in patients with PTSD and other behavioral health issues using established diagnostic criteria.

30. Self-Assessment of Sleep Questionnaire. The Self-Assessment of Sleep questionnaire was developed by a board-certified sleep specialist and one of the STRONG STAR investigators, Daniel Taylor PhD, to be a brief assessment of self-reported sleep quantity and sleep quality. Five items assess estimated total sleep times during the week and during weekends, self-reported hours of sleep needed to feel rested, overall sleep quality, and duration of current sleep pattern. Although there are no established psychometrics for this measure, combined with the other four measures of sleep the battery will provide the information needed to comprehensively assess sleep in study participants.

31. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare disturbance were selected from The Trauma-Related Nightmare Survey (TRNS; Davis, Wright, & Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period for frequency of nightmares (r = .64), and disturbance of nightmares (r = .63). Convergent validity was also found with daily behavioral records of nights with nightmares (r = .82) and the Modified PTSD Symptom Scale – Self-Report (MPSS-SR; Resick, Falsetti, Resnick, & Kilpatrick, 1991) nightmare frequency (r = .64) and disturbance (r = .45). The item assessing nights with nightmares was selected as it is thought to be a more clinical significant measure of the impact of nightmares than the total number of nightmares experienced.

32. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated in 211 pre-operative surgical patients. Using the answering of 2 or more questions ”yes,” the sensitivity of the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of polysomnography depending upon the AHI cut-off used. Individuals answering ”yes” to 2 or more of the questions will be advised that they may be at risk for having sleep apnea and advised that they may want to speak with their primary care provider to consider referral for an overnight sleep evaluation at the CRDAMC Sleep Clinic.

33. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in various situations, will be used to assess daytime function. The ESS has good internal consistency (α = .73 - .88) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness (Chervin, Aldrich, Pickett & Guilleminault, 1997).

34. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4
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(very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the Pittsburgh Sleep Quality Index ($r = 0.67$), the Dysfunctional Beliefs and Attitudes about Sleep ($r = 0.55$), and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).

35. Beliefs in a Just World (BJW) Scale. The BJW is a 16-item self-report measure that assesses the belief in a just world for self and others. Just world beliefs are the idea that everything happens for a reason and people get what they deserve in life. This may be protective for some people because it gives them the illusion that they have control over the world and what they experience. However, for trauma survivors, it can lead to feelings of self blame. For example, if people get what they deserve in life, then what did I do to deserve to be raped. This can lead to both behavioral and characterological self blame. Belief in a just world is related to psychological well-being. The BJW Scale has strong psychometric properties (Lipkus, et al., 1996). Factor analysis using promax rotation revealed 2 intercorrelator factors with eigenvalues greater than one. Items had moderate to high loadings on each factor. The BJW scale for self demonstrated good internal consistency (α=.84) in 2 studies. The BJW scale for others also demonstrated good internal consistency (α=.84 in one study and α=.83 in another). Homogeneity of the BJW scales was assessed using principal component analysis with oblique rotation. The scale for self had a single factor which accounted for 62% of the variance and the scale for others also had single factor which accounted for 64% of the variance. Additionally, the BJW Scale significantly correlated with existing measures of just world beliefs. Service Members with PTSD have been noted to endorse just world beliefs during therapy such as “It's not fair that this trauma happened,” or “People with young children are not supposed to die.” Potentially treatment for PTSD modifies these beliefs.

36. Patient Reported Outcomes Measurement Information System (PROMIS) Sexual Functioning Inventory: The PROMIS questionnaires are a system of reliable measures of patient–reported health status for physical, mental, and social well–being developed with funding under the National Institutes of Health (NIH) Roadmap for Medical Research Initiative to re-engineer the clinical research enterprise (http://www.nihroadmap.nih.gov). PROMIS measures can be across a wide variety of chronic diseases and conditions and in the general population (Cella et al, 2010). One of the PROMIS instruments is a Sexual Functioning Inventory (Jeffery et al, 2009). The PROMIS Sexual Function Inventory provides scores on seven different sub-domains of sexual function: interest in sexual activity, vaginal discomfort (women only), lubrication (women only), erectile function (men only), orgasm, and global satisfaction with sex life. Each question asks respondents to report on their experiences over the past 30 days. With the exception of the orgasm sub-domain, all sub-domain scores are expressed as T scores (mean = 50, standard deviation = 10). While the Inventory is intended for broad use, almost all of the development work was with patients with cancer. Research is ongoing to expand development beyond cancer. In testing with 819 individuals (388 males, 430 females, 1 person did not specify sex), correlations between the PROMIS Sexual Functioning Inventory and corresponding sub-domains of two well-established measures, the Female Sexual Function Index (FSFI) and the International Index of Erectile Function (IIEF), ranged between .48 and .92. The sub-domains of the Inventory discriminate between people who had and had not asked a provider about sexual problems. Test-retest correlations over one month are >.65 for all sub-domains (Sexual Function and Satisfaction Measures User Manual, 2012).

4.9 Inclusion / Exclusion Criteria: The inclusion and exclusion criteria are consistent with research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson, et al., 2006). The target population will be over the age 18 and there is no upper limit as long as they are active military. Because the study sample will be comprised of active duty military personnel, it is anticipated that they will be of sufficient physical health to maintain their active duty status.

Inclusion Criteria:
- Adult male and female active duty, activated Reservist, or activated National Guard OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale
Person has experienced a Criterion A event that is a specific combat-related event or high magnitude operational experience that occurred during a military deployment in support of OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion A event.

- Be over the age of 18
- Speak and read English
- Be stable on any psychotropic medications they may be taking. (Participants will be required to meet psychotropic medication stabilization criteria for the periods preceding and overlapping with the diagnostic assessment and treatment. This criterion is established in order to minimize the likelihood that significant outcome effects may be attributed to changes in psychotropic medications rather than to the treatment protocol.)

Exclusion Criteria:
- Current suicide or homicide risk meriting crisis intervention
- Active psychosis
- Moderate to severe brain damage (as determined by the inability to comprehend the baseline screening questionnaires)

We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater reliability team to determine the validity of an assessment. If a participant is clearly unable to comprehend or conform to the study procedures, the evaluator will terminate the protocol. In less obvious cases where there are concerns about the validity of an assessment but the participant completes the protocol nonetheless, the inter-rater reliability team will review the video recording and determine, through consensus judgment, if the case should be excluded from analysis.

4.10 Number of Subjects: 1,000 from CRDAMC

5.0 Human Subject Protection

5.1 Recruitment:
Service Members who screen out from other BAMC IRB-approved STRONG STAR protocols including C.2009.021 / IRBNet 363398 (Prolonged Exposure for PTSD in OIF/OEF Personnel: Massed vs. Spaced Trials), C.2011.120 / IRBNet 364801 (Comparing Internet and In-Person Brief Cognitive Behavioral Therapy of Insomnia), C.2011.004d / IRBNet 363539 (Genetic and Environmental Predictors of Combat-Related PTSD), and C.2011.120 / IRBNet 368445 (The Role of Exercise in the Treatment of PTSD Symptoms) will be offered the opportunity to be screened for participation in this study at the conclusion of their study visit for the previously-referenced protocol. If interested, a member of the research team will review eligibility with these potential participants (e.g., pre-screen) and either obtain informed consent at that time, if authorized, or schedule another visit at a later date.

Additionally, potential participants may be identified through referrals from various health care providers at CRDAMC clinics. Providers may forward contact information of interested individuals directly to STRONG STAR. Or, potential participants may self-refer in response to recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment materials will be distributed to various health care providers and will be posted in locations in CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants
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may also self refer in response to recruitment information on the STRONG STAR website (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment and eligibility requirements with the interested person. If the person believes they may qualify for the study, an appointment will be made for consent and screening. During this appointment, potential participants will have the study explained to them in a safe and private location. The potential participant will be given a copy of the informed consent document (ICD) to read. After the subject has read the ICD they will be given the opportunity to take the consent home to discuss the research with family and friends. The Research Team will be available to answer any questions about the research. Once the potential participant has reached a decision, the advising staff member will go over the risks and benefits of the study and ensure the subject understands the research. The advising staff member will have the Service Member sign the consent form. A copy of the signed ICD will be given to the subject. The advising staff member will document the informed consent process in the medical record of the participant. Following the consent process, those who meet the inclusion criteria for the study will be randomized into the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the study.

Participants will first be recruited as cohorts of 16 -24 eligible participants for randomization into one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously. The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either group. Once data have been collected on at least 48 participants in each condition to answer the first research question, participants will be randomized into either group CPT-C or individual CPT-C for the remainder of the study.

5.2 Benefits: Potential benefits of participation in this study may include a reduction in PTSD symptoms over the course of therapy. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of combat-related PTSD in active-duty military personnel.

5.3 Risks: Potential risks or discomfort that may arise from participation in this study include becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events, including increased risk for suicide. However, in past research conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C, there have been no serious adverse events or related difficulties with emotionally upset participants due to the treatments.

With the handling of medical and research records, there is always the possibility of a breach of confidentiality.

5.4 Safeguards for Protecting Subjects:

During the early sessions of treatment, participants will be provided immediate coping tools and techniques used to manage distressing emotions both within the group and outside the group setting by the study therapist. Distress experienced by participants is expected to be temporary. Any indication that the participant is considering suicide will be handled using processes developed by military and civilian Consultants for the STRONG STAR Consortium studies (see Appendix E).

Data will be coded using an assigned number. Data collected during treatment will be entered
into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the National Center for PTSD using an express service (e.g., UPS, FedEx, or DHL) and tracked for receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. (See Appendix F)

A STRONG STAR Repository has been approved by both the UTHSCSA (HSC20100475H) and BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository will create a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of PTSD in our active duty and retired veterans of OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and/or supported by the projects of the STRONG STAR Consortium. These study databases will be established and maintained by the Biostatistics and Data Management Core of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Biostatistics and Data Management Core. Data, biological specimens and images will constitute the STRONG STAR PTSD Repository. Participation in the repository will be completely voluntary and entirely optional which means that a potential participant’s willingness to participate in the repository has no influence upon their eligibility to participate in the primary STRONG STAR study they have already enrolled in or are considering enrolling in. At the conclusion of this study, participants who signed the consent to have their specimens and data placed in the STRONG STAR Repository will be maintained under the IRB-approved Repository protocol. Biological specimens and information from study participants who declined participation in the STRONG STAR Repository will be permanently de-identified (i.e., all PHI will be deleted from the study data bases) and the de-identified blood and information placed in the STRONG STAR Repository for future use.

A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the appropriate clinical safety monitoring of study subjects participating in this study. (See Appendix G.)

5.5 Risk:Benefit Assessment: The risks of the project are minimal, and participants may expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of PTSD.

5.6 Alternatives: Alternative mental health treatment is available at the Resilience and Restoration Center at Carl R. Darnell Army Medical Center including various forms of psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.

6.0 Data Analysis:

Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy,
cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect to be larger comparing CPT-C to a treatment that controls for non-specific effects (therapist/other group member contact) and an effort to work on problems but not traumatic events. The primary analyses will be through mixed effects regression analyses, including all available data regardless of how many sessions the participants attended (intention-to-treat). The advantage of this type of analysis is that missing data are replaced, it accounts for correlated repeated measures for each participant, and individual variability in change. Random regression can also account for variable measurement intervals. This will be important in the proposed trial because there will be variability in the timing of assessments, especially when participants miss group sessions or cannot come in at exact intervals. The analyses to compare group and individual CPT-C (aim 2) will also use mixed effects random regression with intention to treat samples.

The third aim is to examine the effect of other variables on treatment outcome more generally. Because we have a large sample size, we can collapse across groups and use the results, such as reduction in symptoms, as the outcome variable. There are many interesting questions that can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event, number of deployments etc. Specifying all possible analyses and secondary questions are beyond the scope of this short description. However, given the sample size and repeated assessments, we should be able to conduct many interesting post-hoc studies with this rich data set as well as to collapse data sets across the other STRONG STAR consortium studies.

Data analysis will be performed by the data analysis core staff of the STRONG STAR consortium.

7.0 Sample Size Estimation & Power Analysis

With a medium effect size (> .5) between the Cognitive Processing Therapy, cognitive-only version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group should be sufficient to examine the two types of groups and answer the first research question.

The aim of the comparison of group versus individual CPT-C was powered for equivalence analysis, meaning that we will power our study sufficiently to test for no meaningful differences between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if there is less than a .3 effect size difference between individual and group treatment, then the differences are not large enough to warrant individual treatment on average, and group treatment would be considered a more efficient modality. However, if there is a larger than .3 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up analyses on predictors of treatment outcome would then be valuable to determine who might especially need individual therapy. Although we will have more than nine assessments with the self-report scales that should allow .9 power and the ability to detect even smaller effect sizes, we conducted a power analysis with only four data points to reflect the interview measures that will be collected at pre, post, and the 6- and 9-12-month follow-up periods. Comparing individual and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely coded GROUP with N=8. The total numbers of subjects are the same between the two conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this situation. After 200 replications, we found that intraclass correlation of this magnitude made minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to
detect an effect size of 0.3. To account for potential attrition over this year-long study, we will oversample, requesting permission to recruit 404 participants until 110 participants have completed each of the treatment arms.

8.0 **Duration of Study**: estimated to be 8 years, ending by December 31, 2016.

9.0 **Funding**: The funding for this project is through a grant from the U. S. Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) Psychological Health (PH) & Traumatic Brain Injury (TBI) Program with a grant to the University of Texas Health Sciences San Antonio (UTHSCSA). Funding for this research will be accomplished through a Cooperative Research and Development Agreement (CRADA) between UTHSCSA and the U. S. Army represented by the Clinical Investigation Regulatory Office (CIRO).

10.0 **Staff Monitor (for resident and fellow projects)**: not applicable

11.0 **Bibliography**:


**Measurement References**


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12.0 Support Services Required (Impact Statement/Letter of Support): none

13.0 Use of Investigation Drugs: not applicable

14.0 Use of Investigational Devices: not applicable

15.0 Appendices:

A – Present-Centered Therapy (PCT) Manual (Schnurr et al., 2007) (one copy provided on disk to the IRB Protocol office)

B – Cognitive Processing Therapy (CPT) Manual (Resick et al., 2007) (one copy provided on disk to the IRB Protocol office)

C – Homework Compliance Forms

D – Summary of the Assessments and Timing of Administration

E – STRONG STAR SOP for Suicide Risk Assessment & Management (dated 12-12-13)

F – STRONG STAR Database Policies & Procedures

G – Data Safety Monitoring Plan (DSMP) (updated)

H - Recruitment Flyer/Pamphlet and STRONG STAR Web Screen Shots