

**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 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 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 they 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:

Source of Research Material	Standard Care
Defense & Veterans Brain Injury Center TBI Screen	No
Automated Neuropsychological Assessment Metrics (ANAM®)	No
Deployment Risk and Resilience Inventory (DRRI) Combat Experience Sub-Scale	No
Deployment Risk and Resilience Inventory (DRRI) Aftermath-of-Battle Sub-Scale	No
Deployment Risk and Resilience Inventory (DRRI) Deployment Environment Sub-Scale	No
PTSD Symptom Scale – Interview (PSS-I)	No
PTSD CheckList (PCL-M)	No
SF-12 (Functional Impact)	No
Brief Conflict Tactics Scale	No
State-Trait Anger Expression Inventory (STAXI)	No
Beck Depression Inventory (BDI)	No
Beck Scale for Suicidal Ideation (SSI) Screen	No
Beck Anxiety Inventory (BAI)	No
Alcohol Use Disorders Identification Test (AUDIT)	No
National Center for PTSD Trait Resilience Scale	No
Life Event Checklist (LEC)	No
PERI Life Events Checklist	No
Peri-Traumatic & Post-Traumatic Emotions Scale	No
Demographics & Military Service Characteristics	No
Interpersonal Support Evaluation List (ISEL)	No
Trauma-Related Guilt Inventory (TRGI)	No
Walter Reed Army Institute of Research (WRAIR) Military Vertical & Horizontal Cohesion Scales	No
Post-Traumatic Cognitions Inventory (PTCI)	No
Credibility / Expectancy Questionnaire (CEQ)	No
Cognitive Emotions Regulation Questionnaire (CERQ)	No
Patient Health Questionnaire (PHQ)-15	No
Homework Compliance	No
Health Care Utilization Follow-Up Questionnaire	No

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 ($\alpha = .85$ 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 ($\alpha = .81-.85$; 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-retest 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 (Deville & 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 (Deville & 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 ($\alpha = .62-.85$; 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

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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 – 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

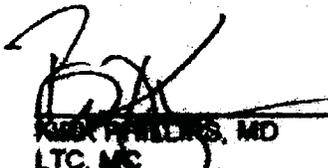
I am aware that I am not authorized to accept any funds or other form of compensation for conducting research. All subjects will be treated in compliance with all applicable organizational, service, DoD and Federal regulations, and all applicable HHS and HRIS guidelines.


KATHLEEN S. LESTER
LTC, MS
Chief, ~~Responsible for the~~ ^{Psychiatry} ~~Responsible Center~~ ^{WTR}
Carl R. Darnall Army Medical Center
Fort Hood, TX

Date 10/19/08

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 the point of contact for correction of deficiencies should the Principal Investigator fail to meet the agreed upon study requirements as outlined in the protocol.


KIRK PHILLIPS, MD
LTC, MC
Chief, Behavioral Health Division
Carl R. Darnall Army Medical Center
Fort Hood, TX

Date 10/19/08

Command Support

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


WILMA LARSON, MD
COL, MC
Deputy Chief of Clinical Services
Carl R. Darnall Army Medical Center
Fort Hood, TX
For Acting
Michael P. Wynn
LTC, MC
Chief, Department of Family & Community Medicine

Date 10/19/08

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

10/10/08

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.

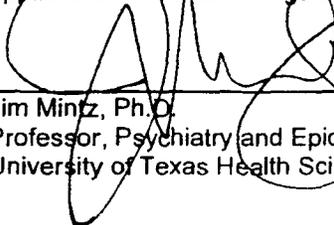


Date 10/10/08

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

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.



Date 10/10/08

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

**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.

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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.

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

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Version (01-27-10)

BAMC IRB Approval Date: 2/1/10
UTHSCSA IRB Approval Date: 3/19/10

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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?
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Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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).

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10
UTHSCSA IRB Approval Date: 3/19/10

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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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.

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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:

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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

Horizontal Cohesion Scales	
Post-Traumatic Cognitions Inventory (PTCI)	No
Credibility / Expectancy Questionnaire (CEQ)	No
Cognitive Emotions Regulation Questionnaire (CERQ)	No
Patient Health Questionnaire (PHQ)-15	No
Homework Compliance	No
Health Interview (Pre- & Post-Treatment)	No

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 ($\alpha = .85$ 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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10
UTHSCSA IRB Approval Date: 3/19/10

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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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).

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10
UTHSCSA IRB Approval Date: 3/19/10

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-retest 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, Ehlers, 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 (Devilley & 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 (Devilley & 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 ($\alpha = .62-.85$; 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 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.

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10
UTHSCSA IRB Approval Date: 3/19/10

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,

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10
UTHSCSA IRB Approval Date: 3/19/10

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

Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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

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Version (01-27-10)

BAMC IRB Approval Date: 2/1/10

UTHSCSA IRB Approval Date: 3/19/10

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Version (01-27-10)

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UTHSCSA IRB Approval Date: 3/19/10

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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

F – STRONG STAR Database Policies & Procedures

G – Data Safety Monitoring Plan (DSMP)

**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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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 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 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 they 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	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD CheckList – Stressor Specific (PCL-S) & PTSD CheckList – Version for proposed DSM-V (PCL-V)	No
7. SF-12 (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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

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 DRR1 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. 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 & 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, 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, Ehlers, 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 discriminant 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.

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 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

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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 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 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 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 they 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	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. SF-12 (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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

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 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. 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 &

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, 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, Ehlers, 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 discriminant 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 (Deville & 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.

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

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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 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 they 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	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD CheckList – Stressor Specific (PCL-S) & PTSD CheckList – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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

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/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 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 & Marhofer-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 & Marhofer-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, Ehlers, 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 PTCL demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCL 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 PTCL was able to differentiate individuals with and without PTSD demonstrating discriminant 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 (Devilley & 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.

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

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

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No

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

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/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 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, Ehlers, 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 discriminant 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 (Deville & 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.

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 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 (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

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No

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 DVVIC 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 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, Ehlers, 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 discriminant 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 (Deville & 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.

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

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No

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 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, Ehlers, 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 discriminant 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 (Deville & 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

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No

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
30. Frequency of Nightmares Questionnaire	No
31. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen	No
32. Epworth Sleepiness Scale (ESS)	No
33. Insomnia Severity Index (ISI)	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 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 & Marhofer-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, Ehlers, 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 discriminant 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 ($\alpha = .73 - .88$) 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).

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 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 (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

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No

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
30. Frequency of Nightmares Questionnaire	No
31. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen	No
32. Epworth Sleepiness Scale (ESS)	No
33. Insomnia Severity Index (ISI)	No
34. Beliefs in a Just World (BJW) Scale	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 Veterans 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 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, & 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 & Marhofer-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, Ehlers, 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 discriminant 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 (Deville & 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 ($\alpha = .73 - .88$) 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

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 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

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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
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

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 DRRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRRI 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 DRRRI 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 DRRRI 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 health 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 & Marhofer-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 discriminant 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 (Deville & 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.

While many clinicians use the 24-question Pittsburgh 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 ($\alpha = .73 - .88$) 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

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 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

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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 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

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

57
58 **4.4 Military Relevance:** One of the most significant research gaps of PTSD in the DoD and VA
59 is in the development and validation of effective treatments for combat-related PTSD and
60 related psychosocial health problems in military personnel. This research gap is highlighted in
61 three recent reports: the Institute of Medicine report on the treatment of PTSD (IOM, 2007); the
62 Report of the DoD Task Force on Mental Health (DoD TFMH, 2007); and the Joint DoD/VA
63 Conference on Post-Deployment Mental Health (2005). Recent studies of OIF and OEF
64 veterans suggest that between 5 and 17% of U.S. military personnel returning from
65 deployments have symptoms of PTSD, and as many as 25% report some psychological
66 problem (Hoge et al., 2004, 2006, 2007; Milliken et al., 2007). The IOM report (2007) also
67 highlighted the scant evidence exploring the unique aspects of treating combat-related PTSD in
68 veterans, and it concluded that well-designed research is needed to answer the key questions
69 regarding the efficacy of treatment modalities in combat veterans.

70
71 **4.5 Background / Review of Literature:** Cognitive Processing Therapy (CPT) is an evidence-
72 based form of Cognitive Behavioral Therapy (CBT) used to treat PTSD. CPT is a 12-session
73 manualized program that focuses on challenging beliefs and assumptions related to the trauma,
74 oneself, and the world. CPT was first developed as a group treatment (Resick & Schnicke,
75 1992, 1993). However, on a large randomized controlled trial that compared CPT with a well-
76 validated form of exposure treatment for PTSD, Prolonged Exposure (PE; Resick et al., 2002), it
77 was necessary to test CPT as an individual therapy to compare it to PE. Later clinical trials
78 using CPT followed suit testing the therapy either as an individual treatment (Monson et al.,
79 2006) or as a combined individual and group therapy (Chard, 2005). Results of these studies
80 have shown that individual CPT is an effective treatment for symptoms of PTSD. However,
81 CPT in a group-only format has never been studied with a randomized controlled trial.

82
83 Even without evidence from well-designed clinical trials, group therapy with and without
84 Cognitive Processing Therapy (CPT) is currently being used in both military and VA settings for
85 the treatment of PTSD. In FY 2007, over 1,200 VA and DoD clinicians were trained in CPT. If
86 effective, group CPT is an efficient way to treat PTSD. However, it is unknown whether group
87 treatment is effective. The 2007 Institute of Medicine (IOM) Report stated, "The Committee
88 judged the overall body of evidence regarding group therapy formats to be low quality to inform
89 a conclusion regarding efficacy because of the lack of well-designed studies comparing group
90 and individual formats and including appropriate controls. The Committee is uncertain about the
91 presence of an effect, and believes that future well-designed studies will have an important
92 impact on confidence in the effect and the size of the effect" (p. 4-32-33). Therefore, it is
93 important to establish the effectiveness of CPT administered in a group format compared to
94 other forms of group treatment for PTSD.

95
96 Present Centered Therapy (PCT) is a problem solving group intervention typically used within
97 the Department of Veterans Affairs (VA) healthcare systems to address problems of veterans
98 with PTSD (Rosen, et al., 2004). PCT focuses on problem-solving current difficulties that may
99 be related to past traumatic events, but does not address specific memories or cognitions about
100 the trauma. This type of treatment has been used in previous studies (i.e., Schnurr, et al., 2003)
101 to control for nonspecific benefits that are common to most types of psychotherapy. With this
102 comparison group, it is possible to determine if the effects of CPT-C group treatment exceed the

103 results of group PCT for treatment of PTSD. In the Schnurr et al. study of group PCT and a
104 cognitive behavioral treatment (not CPT), both types of therapy resulted in improvements and
105 there were no differences between treatments. In a study of individual PCT compared to PE
106 (Schnurr et al. 2007), both groups improved but PE showed greater improvement until the six
107 month follow-up.

108
109 Group Cognitive Processing Therapy (CPT) has not been directly compared to individual CPT.
110 Given that CPT can be administered as either a group or individual treatment, it is important to
111 determine whether the two are equivalent or whether one type of format is sufficiently superior
112 to warrant recommendation either for or against group administration. To address this question,
113 this study was designed to compare group and individual CPT for the treatment of PTSD in
114 military personnel who have deployed in support of OIF/OEF/OND. The cognitive-only version
115 of Cognitive Processing Therapy (CPT-C) that omits the writing component of therapy will be
116 tested, as a recent clinical trial designed to dismantle the components of CPT found that a
117 cognitive-only version was equally effective to the full version of CPT and perhaps more efficient
118 (Resick et al., 2008).

119
120 **4.6 Research Design and Methods:** The proposed project is a longitudinal randomized clinical
121 trial designed with two primary objectives. One objective is to compare the effectiveness of
122 group Cognitive Processing Therapy, Cognitive-only version (CPT-C) to a group Present-
123 Centered Therapy (PCT) modality. The other research objective is to compare the
124 effectiveness of CPT-C delivered as a group therapy versus as an individual therapy. To answer
125 the first research question, the first 96 participants will be randomly assigned to group CPT-C or
126 PCT groups (48 per group). After these initial participants have been randomized, the
127 remaining 404 participants will be randomly assigned to group or individual CPT-C (202 per
128 group), in order to answer the second and third research questions. We will include both
129 genders in groups. Women consenting to the study will be asked about participating in a group
130 with men because they may feel uncomfortable especially those who may have experienced a
131 sexual trauma. If a woman does not want to participate in a group with men, she will be referred
132 to another STRONG STAR PTSD treatment study or for other clinical treatment. Individual
133 CPT-C will be conducted twice weekly for 6-weeks for 1 hour each session, while group CPT-C
134 and PCT will be conducted twice weekly for 6-weeks for 90 minutes. Although matching for
135 exact therapy time would be an option, it would be an unfair disadvantage for group treatment
136 with eight clients to meet for only 1 hour. Therefore, matching will be based on the number of
137 sessions rather than time.

138
139 Description of Treatment Protocols (Independent Variable).

140
141 Present Centered Therapy (PCT) groups will use a manual developed for the Schnurr et al.
142 (2003) VA cooperative study to compare trauma-focused group therapy with PCT. (See
143 Appendix A.) A similar format was also used in a subsequent VA cooperative study comparing
144 Prolonged Exposure and PCT (Schnurr et al., 2007). Participants will be given a rationale for
145 focusing on current issues rather than the traumatic events themselves. The first two sessions
146 will provide psychoeducation about PTSD symptoms and the problem areas often associated
147 with PTSD. Subsequent sessions will focus on problem-solving present difficulties. Between
148 sessions, participants will be asked to monitor their problem-solving attempts and outcomes as
149 well as to keep a mood diary and list of current issues to be addressed in the next group. At the
150 beginning of each group meeting there will be a check-in for each participant to discuss briefly
151 the events and problems of the prior week and any issues they may want to discuss. Therapists
152 and clients will develop an agenda based on emerging themes. Education regarding PTSD and
153 depression, support, and current-focused problem-solving can be included as interventions, but

154 no cognitive therapy or exposure-based treatments for PTSD will be incorporated. By the end of
155 each group meeting, the participants will develop an action plan for problems discussed in the
156 group. Any participants who still have PTSD at the end of treatment will be offered CPT-C.
157

158 The most recent Cognitive Processing Therapy (CPT) manual (Resick *et al.*, 2007), including
159 CPT-C, was produced by the VA in April, 2007 for a national VA/DoD training initiative. (See
160 Appendix B) We have recently completed a group treatment manual for VA/DoD as well. CPT
161 is a highly structured protocol in which clients learn the skills of recognizing and challenging
162 dysfunctional cognitions, first about the worst traumatic event and then with regard to the
163 meaning of the events for current beliefs about self and others. Recently, Resick and her
164 colleagues demonstrated the effectiveness of CPT without the written exposure account (CPT-
165 C), which is particularly helpful when providing CPT in a group format (Resick *et al.*, 2008). In
166 the group format of this treatment, participants will not share the details of their particular
167 traumatic event with the group. Rather, the group will discuss themes that are common to a
168 wide range of traumas, and individuals will complete homework activities and group worksheets
169 based on their own traumas that will not be shared with the group. The purpose of this is to
170 reduce the likelihood that group members will be triggered by accounts of others' traumatic
171 events.
172

173 In CPT, there are practice assignments, typically worksheets to complete each day, between
174 sessions that are particular to the work of the session. The following sessions are included in
175 CPT-C: Session 1: The initial session of CPT is psycho-educational; symptoms of PTSD are
176 explained within a cognitive and information processing theory framework. At the conclusion of
177 this session, patients are asked to write an impact statement about the meaning of the traumatic
178 event as well as beliefs about why the event happened. Session 2: In session 2, the impact
179 statement is read and discussed with a focus on identifying problematic beliefs and cognitions
180 ("stuck points"). The therapist introduces the A-B-C worksheet with an explanation of the
181 relationship between thoughts, feelings and behaviors. Patients are then taught to identify the
182 connection between events, thoughts and feelings and asked to practice this skill for homework.
183 Session 3-4: Sessions 3 and 4 include a review of the self-monitoring homework and a
184 discussion of stuck points. Socratic questioning is used to identify issues of assimilation and
185 self-blame. Participants are then re-assigned an A-B-C worksheet. In Session 4, participants are
186 given the Challenging Questions worksheet, which challenges single beliefs related to the
187 trauma. Session 5-6: In session 5, the Challenging Questions Worksheet is reviewed and the
188 Patterns of Problematic Thinking Worksheet is introduced. Session 6 focuses on the
189 identification of patterns of problematic thinking through both homework review and the
190 introduction of the Challenging Beliefs Worksheet. Participants are asked to use the
191 worksheets daily with everyday events and challenge trauma-related self-blame cognitions.
192 Session 7-12: In sessions 7-12, over-generalized beliefs in five areas--safety, trust, control,
193 esteem, and intimacy--are challenged as they relate to self and others. Treatment gains are
194 consolidated in the final sessions.
195

196 All therapy, whether individual or group CPT-C or group PCT, will be conducted twice a week
197 for six weeks following an initial meeting with one of the therapists in order for them to discuss
198 the participants' trauma history and PTSD symptoms and to pick an index event, the worst
199 traumatic event, that will be the initial focus of therapy. Participants will receive their
200 randomization information at this session and times and dates for therapy will be scheduled. All
201 therapy conditions include out-of-session practice assignments. Prior to each session,
202 participants will be asked to complete a form (see Appendix C) to measure the frequency with
203 which they completed the practice assignments between sessions (a measure of therapy
204 compliance). Participants will also be asked to complete the same four self-report measures on

205 a weekly basis (i.e., PTSD CheckList –Stressor Specific, Beck Depression Inventory, Cognitive
206 Emotion Regulation Questionnaire, and the Beck Scale for Suicide Ideation). Two of the four
207 questionnaires will be completed at the beginning of one of the weekly sessions, while the
208 remaining two will be completed at the start of the other weekly session.

209
210 Therapists & Evaluators. Therapists and Evaluators hired specifically for this study will carry out
211 the treatment protocols and study evaluations. At least two therapists will co-lead both types of
212 treatment groups (i.e., CPT-C and PCT). Additionally, both therapists will carry an equal
213 caseload of individual participants receiving individual CPT-C therapy. Because both therapists
214 are providing both treatments, this will reduce the risk of having the competence of the therapist
215 over-ride any differences between conditions. The evaluators will be independent of the
216 therapists and will be blind as to condition. Participants will be asked not to reveal the type of
217 therapy the received to the evaluators at the post-treatment assessments.

218
219 Training of Therapists. Therapists will be trained by Dr. Resick and her training staff following
220 established procedures used in other studies (e. g., Schnurr et al., 2007). Training workshops
221 will be conducted in San Antonio or at another military base or VA if the timing for training
222 coincides with an official training workshop. Therapists will be a credentialed provider at the
223 facility. Each therapist will treat training patients under supervision prior to treating consented
224 study participants. Video recordings of treatment sessions (using the standard consent for
225 electronic recordings of patients) will be reviewed by designated CPT supervisors, and all
226 therapists will be required to meet therapy certification requirements prior to seeing consented
227 study cases.

228
229 Supervision of Therapists. Video recordings of training cases will be reviewed by the CPT
230 supervisor, who will then provide the therapist with individual feedback on each training case.
231 All therapists will participate in a weekly CPT therapist supervision teleconference with Dr.
232 Resick to review all new and ongoing treatment cases.

233
234 Treatment Adherence & Competence. The fidelity to the treatment conditions will be closely
235 monitored to ensure that the therapy conditions are distinct and true to the protocols. The
236 therapists will be trained early in the project by Dr. Resick to conduct each of the three types of
237 therapy. They will also be instructed on the data they will need to collect within their roles (e.g.,
238 self-report measures before and during treatment, homework compliance) and any required
239 paperwork for the patients. The therapists will be provided manuals and will have taped
240 examples of the therapy to study. They will be required to treat pilot cases prior to starting the
241 main data collection under close supervision to ensure that they are administering the therapies
242 competently. During the data collection phase, therapists will continue to receive weekly
243 supervision on their cases by project staff and will have local back-up as well as case
244 consultation with the Overall Study PI on an ongoing basis as needed.

245
246 Aside from weekly supervision to assure ongoing treatment fidelity, treatment adherence and
247 competence will be determined by independent raters who are not otherwise involved in the
248 project. The raters will have served on prior CPT studies as adherence and competence raters.
249 In order to ensure that the CPT treatment is administered in accordance with the manual for
250 both groups, all sessions in the study will be video recorded for supervision purposes and for
251 possible selection for fidelity rating. There are potentially 6,000 sessions available from the 500
252 participants. Video recordings will then be sent using an express service (e. g., UPS, FedEx, or
253 DHL) and tracked for receipt to the raters, or will be uploaded to a secure STRONG STAR
254 database. The raters will determine adherence to the CPT-C and PCT therapies and
255 competence in delivering the therapies. We will randomly select 5% (300) for viewing and

256 determination of inter-rater reliabilities (kappas).

257

258 Assessments. The participants will be assessed 4 times during the course of the study with
 259 diagnostic and other symptoms measures: prior to treatment, 2-weeks following treatment (or at
 260 2 months after the pretreatment assessment when someone stops treatment prematurely), 6-
 261 months following treatment, and 9-months following treatment (or the equivalent time periods if
 262 they dropped out). The assessment measures will consist of a battery of measures that will be
 263 used in consortium studies, plus a number of study-specific measures examining cognitive and
 264 emotional processing of the traumatic event. Independent evaluators blind as to condition, will
 265 conduct the follow-up interviews using measures from the pre-treatment assessment.

266

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

273

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

276

277 Timeline The first 6 months of the project will be start up, including hiring of staff, finalization of
 278 the assessment battery, IRB approval, training and piloting of therapists, and training of
 279 evaluators. The next 4 years will be data collection (assessments and therapy). Supervision of
 280 therapists and evaluators will take place weekly throughout the data collection period.

281 Adherence/competence ratings and interviewer reliability ratings will be collected throughout
 282 the project. Data cleaning, entry and scoring will take place throughout the project. The major
 283 data analyses will be conducted at the end of the data collection for the group CPT-C and PCT
 284 comparison and again in the final 6 months, as will manuscript preparation and the final report.

285

286

287 **4.7 Source of Research Material:**

288

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD CheckList – Stressor Specific (PCL-S) & PTSD CheckList – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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
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

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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

315 Brief Traumatic Brain Injury Screen (BTBIS), was tested with 596 Soldiers returning from duty in Iraq
316 and/or Afghanistan and responses compared with a Quarterly Survey administered to assess ballistic
317 helmets, a Computerized Traumatic Brain Injury (TBI) Questionnaire, responses to the Neurobehavioral
318 Symptom Inventory (that includes criteria for postconcussional syndrome or PCS) and an interview by a
319 Masters' level psychologist or staff member trained and supervised by the psychologist (Schwab, Ivins,
320 Cramer, Johnson, Sluss-Tiller, Kiley, Lux & Warden, 2006). The interview was used as the gold standard
321 for the diagnosis of TBI in this sample. Testing indicated that the 3-Questions DVBIC Screening Tool has
322 good concurrent validity in that it identified more self-reported TBIs than either the Quarterly Survey or the
323 Computerized TBI Questionnaire. Furthermore, participants who reported TBI on the 3-Question Screen
324 were more likely to report three or more post-concussive symptoms on the Neurobehavioral Symptom
325 Inventory than those who denied TBI. As recommended by the DVBIC, for the STRONG STAR studies
326 the 3-Question Screen is positive when the participant endorses an injury (question 1) and altered
327 consciousness (question 2, items A-E) for the worst head injury sustained while deployed. The form was
328 modified for this study to capture the number of injuries, and to answer question 2 based on the worst
329 injury; the original form does not recognize the possibility of multiple head injuries during deployment.
330 Participants who are positive using this screen will then be further tested using the Automated
331 Neuropsychological Assessment Metrics (ANAM). As the 3-Question Screen does not query head
332 injuries prior to deployment, an additional four questions have been added to solicit information about
333 each head injury sustained outside of deployment.
334

335 2. Automated Neuropsychological Assessment Metrics (ANAM®): The ANAM is a computerized battery
336 of neuropsychological tests originally developed within the Department of Defense in the early 1990s to
337 provide a standardized and valid method of testing to detect deficits in cognitive functioning in various
338 clinical and military settings (Reeves, Winter, Bleiberg & Kane, 2007). The ANAM battery is a collection of
339 tests that assess different basic functions or domains of cognition to include reaction time, processing
340 speed (procedural reaction time), learning (code substitution), delayed memory (code substitution),
341 working memory (mathematical processing), and spatial memory (matching). The test assesses both
342 speed and accuracy. "Throughput" is the number of correct items within a certain time. Norms for military
343 Service Members and college studies, both male and female ranging in age from 18 to 51 have been
344 established. Test print-outs compare scores for the individual being tested to a preselected normative
345 group. The ANAM has compared favorably to a variety of traditional neuropsychological measures
346 including the math, running memory, code substitution delayed memory, logical reasoning, the Wechsler
347 Adult Intelligence Scale (WAIS-III) Digits Backward and Digit Symbol, Trail Making Tests A&B, Paced
348 Auditory Serial Addition Test (PASAT), the Controlled Oral Word Association Test, Animal Naming, and
349 the Rivermead Behavioral memory Test Short (Cernich, Wilken & Kane, 2007). The ANAM has been
350 used to screen for impairment in various clinical populations including patients with multiple sclerosis,
351 systemic lupus erythematosus, Parkinson's disease, Alzheimer's dementia, migraine headache, and
352 acquired brain injury (Kane, Roebuck-Spencer, Short, Kabat & Wilken, 2007). In 22 individuals enrolled
353 in a traumatic brain injury rehabilitation program, the ANAM was able to differentiate between participants
354 marginally impaired, mildly impaired, and moderately impaired with 91% accuracy based upon their
355 throughput scores (Levinson & Reeves, 1997 as cited in Kane, Roebuck-Spencer, Short, Kabat & Wilken,
356 2007). When the marginally and mildly impaired individuals were grouped together, the ANAM
357 differentiated between these individuals and those moderately impaired with 100% accuracy. Testing in
358 25 individuals with migraine headaches demonstrated that the ANAM is sensitive to change with ANAM
359 scores declining following migraine onset and improving following migraine treatment (Roebuck-Spencer,
360 Sun, Cernich, Farmer & Bleiberg, 2007). Furthermore, the ANAM was able to discern differences in side
361 effect profiles of various medications including antihistamines, desloratadine, transdermal nicotine,
362 mianserin (Wilken, Sullivan, Lewandowski & Kane, 2007). While there is not a specific ANAM score that
363 is indicative of no, mild, moderate, or severe traumatic brain injury, the STRONG STAR Consortium is
364 administering the ANAM to provide additional descriptive data about the cognitive functioning of study
365 participants based upon the recommendations of civilian and military experts in TBI and the STRONG
366 STAR Consortium External Advisory Board and consistent with the assessment of TBI being used for the
367 USAMRMC Congressionally Directed Medical Research Program (CDMRP) Psychological Health
368 Research Program Multidisciplinary Research Consortium for TBI, Mission Connect.
369

370 3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath of Battle, and

371 Deployment Environment Sub-Scales: High- and low-intensity deployment stress exposure will be
 372 assessed using scales from the DRRRI (King, King, Vogt, Knight, & Samper, 2006). The DRRRI was
 373 developed and tested in three separate national samples of veterans of the first Gulf War. It has been
 374 revised and tested with OEF/OIF/OND returnees (Vogt et al., 2008). High intensity stressor exposures
 375 will be assessed using the DRRRI Combat Experiences and Aftermath of Battle subscales. Responses to
 376 these scales are on a 5-point Likert scale. The total score is the sum of the item scores, where higher
 377 scores signify greater exposure to combat or exposure to the consequences of combat, respectively. In
 378 addition, low-intensity deployment stress will be assessed with the DRRRI Deployment Environment
 379 subscale. Responses to this scale are on a 5-point Likert scale with anchors 1 (almost none of the time)
 380 to 5 (almost all of the time). The total score equals the sum of the item scores, where higher scores are
 381 indicative of a more difficult living and working environment. All three subscales have very good internal
 382 consistency ($\alpha = .85$ to $.89$) and construct validity (Vogt, et al., 2008).
 383

384 4. PTSD Symptom Scale, Interview Version (PSS-I): The PSS-I is a 20-minute, 17-item clinical interview
 385 that evaluates DSM-IV PTSD symptoms on a frequency/severity scale (Foa, Riggs, Dancu, & Rothbaum,
 386 1993). The PSS-I is comparable to the gold standard employed in studies of veterans (the Clinician
 387 Administered PTSD Scale; CAPS) yet takes considerably less time to administer (Foa & Tolin, 2000).
 388 Each symptom is rated on a 4-point scale ranging from 0 (not at all) to 3 (very much). Subscale scores
 389 are calculated by summing items in each of the PTSD symptom clusters: re-experiencing, avoidance, and
 390 arousal. The scale has excellent internal consistency ($\alpha = .91$), test-retest reliability (.80), and inter-rater
 391 reliability ($\kappa = .91$). This measure will be administered by a blinded Independent Evaluator at each
 392 study site. At the end of the PSS-I, there are nine items from the CAPS that ask the Independent
 393 Evaluator to judge the extent to which various PTSD symptoms that do not specifically reference the
 394 index event are related to the index event (1=definite, 2=probable, 3=unlikely). The items that do not
 395 specifically reference the index event are: loss of interest in free time activities, feelings of detachment,
 396 impairment in the range of emotions, change in future plans or hopes, difficulty in falling or staying asleep,
 397 irritability or outbursts of anger, difficulty concentrating, over alertness, jumpiness and ease of startle.
 398 This assessment of “relatedness” was added to assist the adjudication of caseness decisions but not to
 399 affect either the integrity or validity of the PSS-I instrument. The data will be used in data analysis to
 400 better understand the study outcomes.
 401

402 5. Columbia-Suicide Severity Rating Scale (C-SSRS): The Columbia-Suicide Severity Rating Scale (C-
 403 SSRS; Posner, Oquendo, Gould, Stanley & Davies, 2007) will be used to assess past suicide ideation.
 404 The C-SSRS will be administered by an Independent Evaluator, who will instruct the participants to
 405 answer the questions based on their entire lifetime of experience. Distinctions will be made between
 406 multiple and non-multiple attempters. In the Suicidal Behavior section of the C-SSRS, the participant will
 407 be considered a non-multiple attempter if they answered 0 or 1 for total number of attempts, and a
 408 multiple attempter if they answered 2 or more attempts.
 409

410 6. PTSD CheckList – Stressor Specific Version (PCL-S) & PTSD CheckList – DSM-V (PCL-V): The PCL-
 411 S is a 17 item self-report measure based upon the PTSD Checklist – Military (PCL-M; Weathers, Litz,
 412 Herman, Huska, & Keane, 1993) that evaluates how much participants have been bothered by PTSD
 413 symptoms in the past month as a result of the stressful life events identified by either the participant, or by
 414 the Independent Evaluator following administration of the PSS-I. Each item of the PCL-S is scored on a
 415 five-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The measure is divided into 3 subscales:
 416 Re-experiencing symptoms (items 1- 5); Avoidance/ Emotional Numbing symptoms (items 6- 12); and
 417 Hyper-arousal symptoms (items 12-17). This is the instrument recommended to assess post-traumatic
 418 stress in military members by the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice
 419 Guideline for the Management of Post-Traumatic Stress (Veterans Affairs Office of Performance and
 420 Quality & U. S. Army Medical Command Quality Management Directorate, 2004). A recent review of 21
 421 studies testing 9,628 subjects, almost one-third of which ($n=2,767$) were military Veterans, reported
 422 overall internal consistency alpha coefficients between .85 and .96, test-retest reliability between .96 (at 2
 423 to 3 days) and .68 (at 12 to 14 days), and convergent validity with the Clinician-Administered PTSD Scale
 424 (CAPS), Center for Epidemiological Studies – Depression (CESD), Mississippi Scale for Combat-Related
 425 PTSD, Impact of Event Scale (IES), and the National Women’s Study PTSD Module (NWS-PTSD; Keen,
 426 Kutter, Niles & Krinsley, 2008). The 21 studies reviewed used PCL scores between 30 and 50 to

427 determine a diagnosis of PTSD. In the most recent studies using the PCL to assess PTSD in Service
428 Members injured in Iraq or Afghanistan (Grieger et al, 2006; Hoge et al, 2004, 2008; Smith et al, 2008)
429 subjects were categorized as positive for PTSD if they reported at least one intrusion symptom, three
430 avoidance symptoms, and two hyperarousal symptoms, each present at the level of moderate or higher
431 during the past month, and if they received a total severity score of 50 or higher. At baseline and again
432 following treatment, the PCL-V based upon the proposed DSM-V criteria for PTSD will be administered as
433 well as the PCL-S so that when the results of this study are published the Research Team will be able to
434 put the findings of the study in the context of the most current criteria of PTSD.

435
436 7. Veterans Rand 12-Item Health Survey (VR-12): Because a certain level of PTSD symptoms is an
437 occupational hazard among Service Members redeployed for combat, it is critical to pay close attention to
438 functional capacities as an important index of intervention efficacy. The Veterans SF-36 (VR-36) was
439 adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from
440 physical to psychological health status. It includes two modifications. The first modification is an increase
441 in the number of response choices for the role physical (RP) and role emotional (RE) items from a two
442 point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of
443 the time, yes, most of the time, yes, all of the time). The second modification is the use of two items to
444 assess health change, one focusing on physical health and one on emotional problems, in contrast to the
445 one general health change item in the RAND SF-36 (Kazis, Lee et al., 2004; Kazis, Miller, Clark et al 2004). The
446 VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA)
447 with close to 2 million questionnaires administered nationally in six national surveys since 1996. The
448 changes to the survey have increased the overall precision of the instrument and the discriminant validity
449 of the physical and mental component summary scales (Kazis, Nethercot, et al 2006). The VR-36 is
450 comprised of 37 items and eight scales: physical functioning, role limitations due to physical problems,
451 bodily pain, general health perceptions, energy/ vitality, social functioning, role limitations due to
452 emotional problems, and mental health. Also, there are two summary scales: a physical component
453 summary (PCS) and mental component summary (MCS). Higher scores indicate better health. Each
454 summary is expressed as a T score, which facilitates comparisons between the VA patients and the
455 general U.S. population. The PCS and MCS scores provide at least 90% of the reliable variance in the
456 eight SF-36 concepts (Kazis & Wilson, 1998; Kazis, Wilson, et al., 1999). The Veterans SF-12 was
457 developed from the Veterans SF-36 and adapted from the MOS SF-36. It includes fewer items for seven
458 of the eight scales and provides 90% of the reliable variance in the two component summary measures
459 using the Veterans SF-36. Using independent results from the Veterans Health Study and the 1996
460 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 corresponded very
461 closely with the results for the Veterans SF-36 (average differences of 0.06 points between them for PCS
462 and 0.31 points for MCS; Kazis et al., 1996; Kazis & Wilson, 1998).

463
464
465 8. Revised Conflict Tactics Scale Psychological Aggression & Physical Assault Sub-Scales: The CTS was
466 designed to assess the use of reasoning, verbal aggression, and violence within the family (Straus, 1979)
467 and over time has become the most widely used instrument to assess intimate partner violence (Straus &
468 Douglas, 2004; Straus, Hamby, Boney-McCoy & Sugarman, 1996). The CTS (revised; CTS2) poses 39
469 questions to assess five tactics used when there is conflict in the relationships of dating, cohabitating, or
470 marital couples, i. e., Physical Assault, Psychological Aggression, Negotiation, Injury, and Sexual
471 Coercion (Straus, Hamby, Boney-McCoy & Sugarman, 1996). In 2004 a revised Conflict Tactics Scales
472 (CTS2S) was developed shortening the instrument from 78 questions to 20 reducing the test
473 administration time to three minutes (Straus & Douglas, 2004). For the STRONG STAR studies, only the
474 Physical Assault and Psychological Aggression subscales (20 items) of the CTS2 will be used broadening
475 the assessment of conflict to query interpersonal conflict among friends, colleagues, and acquaintances
476 as well as the family as these subscales represent the content areas of most interest and are most
477 relevant to the targeted populations. Testing in a sample of 317 undergraduate students from well-
478 educated parents, the CTS2 demonstrated alpha reliabilities ranging from 0.79 to 0.95 (Straus, Hamby,
479 Boney-McCoy & Sugarman, 1996). Furthermore, Straus et al (1996) felt that the instrument
480 demonstrated construct and discriminate validity in that men were shown to be more likely to use
481 coercion to obtain sex and more likely to have serious injury result from physical assault. Discriminate
482 validity was demonstrated in that two of the subscales, negotiation and sexual coercion and negotiation

483 and injury, were shown to not be correlated. Various versions of the CTS have been used in other
 484 studies of military personnel (Adler et al, 2008; McCarroll et al., 2000; Taft, Street, Marshall, Dowdall, &
 485 Riggs, 2007), but to assess conflict in the family and not wider affiliations as STRONG STAR intends to
 486 assess.

487
 488 9. State-Trait Anger Expression Inventory (STAXI): The STAXI (Spielberger, 1988), a 44-item scale that
 489 evaluates dimensions of anger, to assess participants' feelings of anger at a given moment. Only the 10
 490 items related to the State-Anger (S-Anger) subscale will be used. Items in this subscale ask participants
 491 to indicate how much they are experiencing certain feelings and desires on a four-point scale ranging
 492 from 1 ("not at all") to 4 ("very much so"). Scores on all 10 items are summed to assess the overall
 493 intensity of anger felt at a particular moment in time. We are only interested in the state items because
 494 they are the most likely to change with treatment. Internal consistency of the subscale was found to be
 495 strong (average $\alpha = .90$), as was its convergent validity with measures of hostility and other personality
 496 scales (Spielberger, 1988).

497
 498 10. Beck Depression Inventory II (BDI-II): The BDI-II is one of the most widely used instruments for
 499 measuring the severity of depressive symptoms. It consists of 21 items that assess both affective and
 500 somatic symptoms related to depression and depressive disorders. Each item is composed of four
 501 statements that reflect symptom severity. The statements are scaled from 0 (no disturbance) to 3 (maximal
 502 disturbance). Scores on all items are summed to obtain a total severity score. Scores reflect minimal
 503 depressive symptoms (0-13), mild depressive symptoms (14-19), moderate depressive symptoms (20-28),
 504 or major depressive symptoms (29-63; Beck, Steer & Brown, 1996). The BDI has internal consistency of
 505 .91, and correlates strongly with other measures of depression (Beck, Ward, Mendelson, Mock, & Erbaugh,
 506 1961). The BDI has internal consistency of .91, and correlates strongly with other measures of depression
 507 (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

508
 509 11. Beck Scale for Suicidal Ideation (BSSI): The BSSI (Beck & Steer 1991) will be used to assess current
 510 suicide ideation. The BSSI will be self-report. Instructions will instruct the participants to respond based
 511 on the past week. Current intent will be calculated using questions 11-19 on the BSSI. A person with 0
 512 positives will be considered to have low intent, 1-3 positives will be considered moderate intent, and 3+
 513 positives will be considered severe intent. Non-multiple attempters will be placed in one of these 3
 514 categories. There will be no "low" category for multiple attempters. In a sample of 330 psychiatric
 515 inpatients, the BSSI was found to have a Cronbach's alpha coefficient of .95, indicating high internal
 516 consistency (Steer, Rissmiller, Ranieri, & Beck, 1993). The BSSI was also found to correlate with severity
 517 of anxiety, depression, and the BDI suicidal ideation item in this sample, suggesting strong concurrent
 518 validity.

519
 520 12. Beck Anxiety Inventory: The BAI will be used to assess anxiety symptomology. This is a 21-item
 521 measure that asks participants to rate the severity of their symptoms of anxiety within the past week on a
 522 four-point scale ranging from 0 ("not at all") to 3 ("severely"). Scores on all items are summed to obtain a
 523 general severity of anxiety score, indicating the presence of physical and/or psychological symptoms of
 524 anxiety. The BAI has been shown to have high internal consistency ($\alpha = .92$) and test-retest reliability. It
 525 has also been shown to reliably discriminate between anxious and non-anxious diagnostic groups (Beck,
 526 Epstein, Brown & Steer, 1988).

527
 528 13. Alcohol Use Disorders Identification Test (AUDIT) – Interview Version: The AUDIT (Babor et al., 2001)
 529 will be used to identify people with hazardous or harmful patterns of alcohol consumption. It will be
 530 administered through an interview, with the interviewer reading each question to the participant as written.
 531 The AUDIT is a 10-item screening measure, developed by the World Health Organization (WHO), with
 532 three subscales (alcohol consumption, drinking behavior, and alcohol-related problems) that are scored
 533 on a 4-point scale for a highest possible total score of 40. Among those identified as using alcohol in a
 534 harmful manner, 92% had scores of 8 or more, though determining a cutoff score should be left up to the
 535 clinician, depending upon the population being studied. The AUDIT has good internal consistency ($\alpha =$
 536 .80-.93) as well as sensitivity and specificity (Saunders, Aasland, Babor, De La Fuente & Grant, 1993).
 537 Alcohol dependence will be determined by the following cut-off criteria: a combined score of 4 or more on
 538 questions 4-6 (i.e. the alcohol dependence questions) and total scores of 20 and above.

539
 540 14. Response to Stressful Experiences Scale (RSES) (previously known as the National Center for PTSD
 541 Trait Resilience Scale): The RSES is a 22-item questionnaire developed by a team of experts at the
 542 National Center for PTSD to assess trait-related cognitive, emotional, and behavioral resilience (Johnson,
 543 et al., 2008). It asks participants to assess how well each statement describes them, both during and
 544 after stressful events in their lives. Responses are given on a 5-point scale, with anchors 0 (not at all like
 545 me) to 4 (exactly like me). Psychometric testing in 1,014 active duty, reserve and veteran groups showed
 546 that the instrument has sound internal consistency (coefficient alpha 0.91 to 0.93) as well as good test-
 547 retest reliability over 7-days (reliability correlation = 0.87). The instrument correlated positively with
 548 another measure of resilience, the Connor-Davidson Resilience Scale (coefficient alpha 0.61 to 0.81) as
 549 well as unit cohesion (coefficient = 0.38), and post-deployment support (coefficient 0.36 to 0.56). The
 550 instrument correlated negatively with psychological symptom distress as assessed with the Patient Health
 551 Questionnaire - 9 (coefficient = -0.51), posttraumatic stress as assessed with the PCL-M (coefficient -0.23
 552 to -0.39), and overall mental health as assessed with the Minnesota Multiphasic Personality Inventory-2
 553 Neuroticism (coefficient = -0.35) demonstrating concurrent validity. Factor analysis revealed a six-factor
 554 model of resilience including subscales for active coping, meaning-making, cognitive flexibility, spirituality,
 555 self-efficacy, and restoration.

556
 557 15. Life Events Checklist: The LEC includes a list of 16 different potentially traumatic life events that that
 558 are commonly associated with PTSD symptoms, and was designed to facilitate the diagnosis of PTSD
 559 (Gray, Litz, Hsu, & Lombardo, 2004). In this study, the LEC will also be used to identify the index event
 560 and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their
 561 experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned
 562 about it, 4 = not sure, and 5 = does not apply). However, for data entry purposes each nominal point will
 563 be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant). Three
 564 totals will be generated: number of events experienced, number of events witnessed, and number of
 565 events learned about. In a group of 108 undergraduate psychology students the instrument
 566 demonstrated good convergence with the Traumatic Life Events Questionnaire (TLEQ) (average kappa =
 567 0.55) and correlated with the Posttraumatic Stress Disorder CheckList – Civilian (PCL-C) (reliability
 568 coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7-days (all kappa
 569 statistics except one for “caused serious injury / death of another” >0.52). In 131 combat veterans the
 570 LEC was related in the predicted directions with other measures of psychopathology known to be
 571 associated with potentially traumatic life events as assessed with the Posttraumatic Stress Disorder
 572 CheckList – Military (PCL-M), Clinician Administered PTSD Scale (CAPS), and the Mississippi Scale for
 573 Combat-Related PTSD. The STRONG STAR Consortium has added the two-item screen for military
 574 sexual trauma to the LEC that is used in the VA to assess for uninvited and unwanted sexual attention as
 575 well as sexual assault.

576
 577 16. PERI Life Events Scale (Brief): The PERI Life Events Scale (Dohrenwend, Askenasy, Krasnoff, &
 578 Dohrenwend, 1978) is a 102-item measure, designed to assess the number and severity of stressful
 579 events a person has experienced in the previous six months. In order to minimize time burden, the 10
 580 items most relevant to the military population to which the measure will be administered were selected by
 581 military subject matter experts. In some cases, the military experts combined items to adequately cover
 582 all of the major content areas of the original measure with the fewest number of items. This measure is
 583 intended to be a checklist; therefore, it is not expected to have high internal consistency (i.e., just
 584 because someone has one stressful event does not necessarily make it more likely that s/he would have
 585 another stressful event). The intent is to capture the most common, yet most stressful life events, which
 586 could affect treatment outcome.

587
 588 17. Peri-traumatic and Posttraumatic Emotions Scale: The PTEQ is a self-report measure that has been
 589 adapted from various Trauma Interviews (Bernat, Ronfeldt, Calhoun & Arias, 1998; Kilpatrick, Resnick,
 590 Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick, Jordan, Girelli, Hutter & Marhofer-Dvorak,
 591 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). The PTEQ was developed by Dean Kilpatrick,
 592 Karen Calhoun and Patricia Resick from clinical interviews of rape victims in an attempt to understand
 593 why some people developed psychological problems after being raped while some people recovered
 594 (P.A. Resick, personal communication, February 15, 2010). Over time, as more research used the

595 interview and asked questions about peri-traumatic emotions the interview has been further refined.
 596 Published studies have slightly different items and different names for the PTEQ (Bernat, Ronfeldt,
 597 Calhoun & Arias, 1998; Kilpatrick, Resnick, Freedy, Pelcovitz, Resick, Roth & van der Kolk, 1998; Resick,
 598 Jordan, Girelli, Hutter & Marhoefer-Dvorak, 1988; Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008). In one
 599 study of 296 individuals (145 rape victims and 151 assault victims), the responses to a 29-item PTEQ
 600 were subjected to exploratory factor analysis revealing four factors: 1) Negative Affect (other than fear), 2)
 601 Fear, 3) Active Responding, and 4) Freeze Responses (Rizvi, Kaysen, Gutner, Griffin, & Resick, 2008).
 602 Responses indicative of a Freeze Response were associated with greater PTSD and depressive
 603 symptomatology while Fighting was associated with lower symptomatology. The questionnaire in its
 604 current form asks respondents to identify how much they felt to a series of 20 emotions (ranging from 0 =
 605 “not at all” to 4 = “all of the time”) during the time of their traumatic experience and how much they
 606 currently feel to the same 20 emotions. This 40-item version of the instrument will be used for the
 607 STRONG STAR studies; however a factor analysis and psychometric testing will be done as part of the
 608 Consortium's data analysis. One of the innovations of the STRONG STAR studies is to use the PTEQ
 609 during treatment for PTSD to assess when change in emotions occurs.

610
 611 18. Demographics and Military Service Characteristics Form: The Demographics Form measures
 612 standard demographics (race, gender, age) and military service information (e.g., rank).

613
 614 19. Interpersonal Support Evaluation List (ISEL): The ISEL (Cohen & Hoberman, 1983) measures
 615 multiple dimensions of perceived social support. This measure has been shown to have good internal
 616 consistency with alpha levels ranging in the general population from 0.88 to 0.90 (Cohen, Mermelstein,
 617 Kamarck, & Hoberman, 1985). The short form is a 12-item measure that asks participants about their
 618 relationships with other people in their lives. It covers three subscales: Appraisal (items 2, 3, 6, and 11),
 619 Belonging (items 1, 5, 7, and 9), and Tangible (items 3, 8, 10, and 12). Responses are given on a 4-point
 620 scale with anchors, 1 (definitely false) to 4 (definitely true). Scoring involves summing all items with the
 621 following items reverse coded: 1, 2, 7, 8, 11, and 12. Higher scores indicate more perceived social
 622 support.

623
 624 20. Trauma Related Guilt Inventory (TRGI): The TRGI was developed to assess guilt feelings and
 625 attitudes about a specific traumatic event (Kubany, Haynes, Abueg, Manke, Brennan, Stahura, 1996).
 626 Often survivors of trauma experience guilt related to the trauma about things they did or did not do or
 627 feelings they had or did not have. A combat veteran may experience guilt about having provided first aid
 628 to some of his or her wounded colleagues but not others even though it was not possible to care for
 629 everyone. Or, an individual may experience survivor's guilt not understanding why he lived while others
 630 died. These feelings of guilt can be important in evaluating the various treatments for PTSD. The TRGI
 631 is scored into three scales (i. e., 4-item Global Guilt Scale, 6-item Distress Scale, and a 22-item Guilt
 632 Cognitions Scale) and 3 subscales (i. e., the Hindsight-Bias / Responsibility Subscale, the Wrongdoing
 633 Subscale, and the Lack of Justification Subscale). Psychometric testing has been conducted using
 634 almost 600 individuals including 357 university students, 163 women receiving counseling services in a
 635 battered women's program, and 74 Vietnam veterans. Internal consistency was high across all the
 636 testing samples. In the sample of Vietnam veterans the alpha coefficient ranged from 0.66 to 0.94. In the
 637 Vietnam veterans, the scores on the various scales and subscales were significantly correlated with the
 638 Posttraumatic Checklist – Military (PCL-M), the Mississippi Scale for Combat-Related Posttraumatic
 639 Stress Disorder, the Zung Self-Rating Depression Scale, the Guilt Inventory, and the Social Avoidance
 640 and Distress Scale with reliability coefficients ranging from 0.36 to 0.77 ($p < .05$). In a sample of 32
 641 university students, the test-retest correlations after two days ranged from 0.74 to 0.83. An abbreviated
 642 16-item version of the TRGI will be used in the STRONG STAR studies allowing only for the calculation of
 643 the three subscale scores. The Hindsight-Bias / Responsibility Subscale score = (sum of scores on Items
 644 1, 5, 9, 14, 19, 23, and 26) divided by 7. The Wrongdoing Subscale score = (sum of scores on Items 3, 7,
 645 11, 16, and 21) divided by 5. And, the Lack of Justification Subscale score = [sum of scores on Items 4
 646 (R), 8 (R), 12 (R), and 17 (R)] divided by 4.

647
 648 21. Walter Reed Army Institute of Research (WRAIR) Vertical and Horizontal Cohesion Scales: These
 649 cohesion scales are the gold standard method of evaluating attitudes about support from leaders
 650 (vertical) and peers (horizontal). They were developed by a team of researchers at the Walter Reed Army

651 Institute of Research (WRARI) and they are used extensively in research on service members'
 652 psychological health and wellness. Horizontal cohesion will be measured using a revised three-item
 653 cohesion scale. This scale has a Chronbach Alpha from .86 to .88 (Podsakoff & MacKenzie, 1994).
 654 Items assess the degree to which unit members are cooperative, can depend on one another, and stand
 655 up for one another. The wording was revised to match the military description of work group (i.e., unit).
 656 Agreement is rated on a 5-point scale (1 = strongly disagree to 5 = strongly agree). The vertical cohesion
 657 subscale was derived from the Unit Manning Research (see Vaitkus, 1994 for a complete overview) and
 658 consists of 12 items on a 5-point scale (1 = never to 5 = always). Items for the vertical cohesion scale
 659 were selected based on inter-item correlations greater than .50 as reported by Vaitkus (1994), and
 660 whether they had a consistent response options set, were not redundant, and related to Company-level
 661 ratings. Individuals will answer the questionnaire for the unit they are currently assigned to, rather than
 662 assigned to previously. Subscale scores for vertical and horizontal cohesion as well as a total cohesion
 663 score will be calculated.

664
 665 22. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed
 666 to determine how an individual views the trauma and its sequelae in an attempt to understand both how
 667 PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional
 668 processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of
 669 disruptions in the normal processes of recovery when an individual has excessively rigid concepts about
 670 self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed
 671 as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative
 672 Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was
 673 tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a
 674 university community. Approximately 65% (n=392) of individuals reported having experienced a trauma
 675 in which their own life or that of another person was perceived to be in danger and their response at the
 676 time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162)
 677 denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms
 678 of at least moderate severity while the remaining 185 reported a low symptom severity. The three
 679 subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to
 680 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World
 681 Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the
 682 appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and
 683 without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test-retest
 684 reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week
 685 interval ranged from 0.80 to 0.86.

686
 687 23. Credibility/ Expectancy Questionnaire (CEQ): The CEQ is a 6-item measure that was designed to
 688 assess treatment expectancy and rationale credibility for use in clinical outcomes studies (Deville &
 689 Borkovec, 2000). It has been expanded from a 5-item measure designed primarily to assess credibility
 690 (Borkovec & Nau, 1972), 4-items of which have been used by both Foa and Resick (P.A. Resick,
 691 personal communication, February 22, 2010; E.A. Hembree, personal communication, February 23,
 692 2010; E. B. Foa, personal communication, February 25, 2010) with the name Expectancy of Therapeutic
 693 Outcomes (ETO). The 6-item CEQ assesses both whether the person cognitively understands how the
 694 therapy works (credibility) as well as whether the person affectively believes that the therapy will work for
 695 them personally (expectancy). The 6-item CEQ has been tested in 217 individuals including 68 male
 696 Vietnam veterans and 58 female spouses, 69 individuals diagnosed with general anxiety disorder who
 697 had received treatment, and 22 individuals who had received either Cognitive Based Therapy (CBT) or
 698 Eye Movement Desensitization and Reprocessing (EMDR) for the treatment of PTSD. The scale
 699 demonstrated high internal consistency (alpha coefficients ranged from 0.84 to 0.85). Test-retest
 700 reliability over a one-week period was found to be 0.82 for expectancy and 0.75 for credibility. The CEQ
 701 was able to differentiate between two treatment rationales in one study, one with and one without an
 702 encompassing theory while maintaining equivalence between three rationales in another study.
 703 Responses to four questions are scored using a 9-point Likert scale (1= not at all, 9= extremely).
 704 Responses to two of the questions are scored using an 11-point Likert Scale (0% to 100%). The
 705 combined responses are used to generate a score for credibility and another score for expectancy.
 706

707 24. Cognitive Emotion Regulation Questionnaire (CERQ) – Short: The CERQ was designed to assess
 708 cognitive coping strategies people tend to use, or what someone thinks, after having experienced
 709 threatening or stressful events (Garnefski, Kraaij, & Spinhoven, 2001). The CERQ can be used to assess
 710 cognitive strategies that characterize the individual's style of responding to stressful events. Thirty six (36)-
 711 items are scored to produce nine subscales including: 1) Self-Blame, 2) Blaming Others, 3) Rumination, 4)
 712 Catastrophizing, 5) Positive Refocusing, 6) Planning, 7) Positive Reappraisal, 8) Putting into Perspective,
 713 and 9) Acceptance. The answer categories for each item range from 1 (almost never) to 5 (almost always).
 714 Individual subscale scores are obtained by summing up the scores belonging to the particular subscale.
 715 The higher the subscale score, the more a specific cognitive strategy is used. Psychometric testing of the
 716 36-item CERQ was conducted using a group of 547 secondary school students aged 12 to 16 attending a
 717 state school in the Netherlands. Internal consistency of the subscales ranged from 0.71 to 0.92. The CERQ
 718 was positively correlated with both depression and anxiety as assessed with the subscales of the Symptom
 719 Check List-90. Test-retest reliability for each of the subscales at five months ranged from 0.41 to 0.59. The
 720 CERQ-short form (Garnefski & Kraaij, 2006) is an 18-item questionnaire that produces the same 9
 721 subscales as the 36-item questionnaire. A study of 611 adults from a general practitioner's office practice
 722 in the Netherlands indicated that the internal consistency of the 2-item subscales remained acceptably high
 723 ($\alpha = 0.67$ to 0.81). In support of the validity of the CERQ-short, correlations with outcome measures were
 724 comparable to reported results with the original CERQ in that the Rumination, Self-Blame and
 725 Catastrophizing subscales were related to more depression and anxiety symptoms, while the Positive
 726 Reappraisal subscale was related to fewer symptoms (Garnefski & Kraaij, 2006).

727
 728 25. Patient Health Questionnaire-15: The original PHQ (Spitzer, Kroenke, & Williams, 1999) was derived
 729 from the PRIME-MD and consisted of a three-page, self-administered questionnaire that asked about
 730 both somatic and psychological symptoms. The PHQ-15 (Kroenke, Spitzer, & Williams, 2002) is an
 731 abbreviated version of the original PHQ that asks about somatic symptoms and symptom clusters that
 732 account for more than 90% of physical complaints reported in an outpatient setting. The 15-item measure
 733 asks patients to report symptom severity on a scale ranging from 0 ("not bothered at all") to 2 ("bothered a
 734 lot"). Research on the psychometric characteristics of the PHQ-15 has found it to have excellent internal
 735 reliability ($\alpha = .80$) and good convergent validity with scales such as the SF-12 and other measures of
 736 symptom severity and functionality (e.g., sick days, healthcare utilization and symptom-related difficulty;
 737 Kroenke, Spitzer, & Williams, 2002).

738
 739 26. Homework Compliance: Compliance completing homework for the CPT conditions will be monitored
 740 through a self-report worksheet administered prior to each session.

741
 742 27. Health Interview (Pre- & Post-Treatment): The Health Interview that will be administered as part of
 743 the STRONG STAR Consortium includes items regarding general health, hospitalizations, current and
 744 past psychiatric medications, thoughts about wanting to harm others, utilization of mental health services,
 745 utilization of outpatient medical services, and caffeine and tobacco use. It is also formatted to be of
 746 increased relevance to active-duty service personnel. After treatment, we also ask about changes in
 747 military status and important life events since the last interview.

748
 749 28. Mini-International Neuropsychiatric Interview (MINI). The MINI is a short, structured diagnostic
 750 interview that was originally developed in 1990 by psychiatrists and clinicians in the United States and
 751 Europe to diagnose DSM-IV and ICD-10 psychiatric disorders (Sheehan, et al., 1998). Modules C (for
 752 Mania) and K (for Psychosis) will be used to assess, in a standardized way, for any evidence or
 753 schizophrenia, bipolar disorder, or other psychotic disorder that would exclude participants from treatment
 754 on this study.

755
 756 29. American College of Rheumatology (ACR) Fibromyalgia Questionnaire (Wolfe et al, 2010). This is a
 757 landmark publication by top experts in the field of fibromyalgia diagnosis. The new criteria were validated
 758 in a multi-center study of 829 patients previously diagnosed with fibromyalgia and controls. Compared to
 759 the old criteria which required a tender point examination, this simpler clinical case definition correctly
 760 classified 88% of old-criteria patients, and obviates the need for physician examination and tender point
 761 determination. In a follow-up study, Wolfe et. al. further modified the criteria to facilitate its use as a
 762 simple questionnaire rather than requiring a history taken by medical personnel (Wolfe et al, 2011). The

763 intent of this latest tool is to allow its use in epidemiologic and clinical studies without requirement for an
 764 examiner. The modification replaced a physician-judged scale of somatic symptom severity with four
 765 questions, which resulted in loss of only 0.3% accuracy over the ACR 2010 criteria. It takes less than 3
 766 minutes to complete the questionnaire.

767
 768 It is not clear that trauma-related sleep disturbance is treated to the point of remission with cognitive
 769 behavioral therapy for PTSD such as PE. Therefore the following assessments of sleep will be
 770 administered to determine the effect of treatment for PTSD on sleep.

771
 772 While many clinicians use the 24-question Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) to
 773 assess for “disordered” sleep, the PSQI has not been validated to provide specific diagnostic data for
 774 nightmares, apnea, daytime sleepiness, or insomnia. Instead of using the PSQI, five sleep assessments
 775 (totaling 24 questions) will be administered to assess typical sleep durations and patterns on weekends
 776 and weekdays as well as to assess for specific sleep difficulties (i. e., nightmares, apnea, daytime
 777 sleepiness, and insomnia) often found in patients with PTSD and other behavioral health issues using
 778 established diagnostic criteria.

779
 780 30. Self-Assessment of Sleep Questionnaire. The Self -Assessment of Sleep questionnaire was
 781 developed by a board-certified sleep specialist and one of the STRONG STAR investigators, Daniel
 782 Taylor PhD, to be a brief assessment of self-reported sleep quantity and sleep quality. Five items assess
 783 estimated total sleep times during the week and during weekends, self-reported hours of sleep needed to
 784 feel rested, overall sleep quality, and duration of current sleep pattern. Although there are no established
 785 psychometrics for this measure, combined with the other four measures of sleep the battery will provide
 786 the information needed to comprehensively assess sleep in study participants.

787
 788 31. Frequency of Nightmares Questionnaire. The items assessing nightmare frequency and nightmare
 789 disturbance were selected from *The Trauma-Related Nightmare Survey* (TRNS; Davis, Wright, &
 790 Borntrager, 2001). Davis and Wright (2007) report adequate test-retest reliabilities over a 2-week period
 791 for frequency of nightmares ($r = .64$), and disturbance of nightmares ($r = .63$). Convergent validity was
 792 also found with daily behavioral records of nights with nightmares ($r = .82$) and the Modified PTSD
 793 Symptom Scale – Self-Report (MPSS-SR; Resick, Falsetti, Resnick, & Kilpatrick, 1991) nightmare
 794 frequency ($r = .64$) and disturbance ($r = .45$). The item assessing nights with nightmares was selected as
 795 it is thought to be a more clinical significant measure of the impact of nightmares than the total number of
 796 nightmares experienced.

797
 798 32. Snoring, Tired, Observed, Blood Pressure (STOP) Sleep Apnea Screen (Chung et al., 2008). To
 799 better understand sleep disturbance associated with PTSD and PTSD treatment, the STOP screen will be
 800 administered to screen for sleep apnea. The STOP is a four-item questionnaire developed and validated
 801 in 211 pre-operative surgical patients. Using the answering of 2 or more questions “yes,” the sensitivity of
 802 the STOP ranged from 66% to 80% as compared with the apnea-hypopnea index (AHI) of
 803 polysomnography depending upon the AHI cut-off used. Individuals answering “yes” to 2 or more of the
 804 questions will be advised that they may be at risk for having sleep apnea and advised that they may want
 805 to speak with their primary care provider to consider referral for an overnight sleep evaluation at the
 806 CRDAMC Sleep Clinic.

807
 808 33. Epworth Sleepiness Scale (ESS; Johns, 1994). The ESS, 8-items rating likelihood of dozing off in
 809 various situations, will be used to assess daytime function. The ESS has good internal consistency ($\alpha =$
 810 $.73 - .88$) and adequate test-retest reliability and correlates with objective measures of daytime sleepiness
 811 (Chervin, Aldrich, Pickett & Guilleminault, 1997).

812
 813 34. Insomnia Severity Index (ISS; Morin, 1993). The ISI is a 7-item self-report measure that assesses
 814 perceived severity of insomnia. Each item uses a 4-point Likert type scale from 0 (not at all satisfied) to 4
 815 (very much satisfied). The items sum to produce a total score (range 0 – 28). The ISI has an internal
 816 consistency alpha coefficient of 0.74, and has shown convergent validity with other measures such as the
 817 Pittsburgh Sleep Quality Index ($r = 0.67$), the Dysfunctional Beliefs and Attitudes about Sleep ($r = 0.55$),
 818 and sleep diaries (range from 0.32-0.91) (Bastien, Vallieres & Morin, 2001).

819
 820 35. Beliefs in a Just World (BJW) Scale. The BJW is a 16-item self-report measure that assesses the
 821 belief in a just world for self and others. Just world beliefs are the idea that everything happens for a
 822 reason and people get what they deserve in life. This may be protective for some people because it gives
 823 them the illusion that they have control over the world and what they experience. However, for trauma
 824 survivors, it can lead to feelings of self blame. For example, if people get what they deserve in life, then
 825 what did I do to deserve to be raped. This can lead to both behavioral and characterological self blame.
 826 Belief in a just world is related to psychological well-being. The BJW Scale has strong psychometric
 827 properties (Lipkus, et al., 1996). Factor analysis using promax rotation revealed 2 intercorrelator factors
 828 with eigenvalues greater than one. Items had moderate to high loadings on each factor. The BJW scale
 829 for self demonstrated good internal consistency ($\alpha=.84$) in 2 studies. The BJW scale for others also
 830 demonstrated good internal consistency ($\alpha=.84$ in one study and $\alpha=.83$ in another). Homogeneity of the
 831 BJW scales was assessed using principal component analysis with oblique rotation. The scale for self
 832 had a single factor which accounted for 62% of the variance and the scale for others also had single
 833 factor which accounted for 64% of the variance. Additionally, the BJW Scale significantly correlated with
 834 existing measures of just world beliefs. Service Members with PTSD have been noted to endorse just
 835 world beliefs during therapy such as “It’s not fair that this trauma happened,” or “People with young
 836 children are not supposed to die.” Potentially treatment for PTSD modifies these beliefs.

837
 838 36. Patient Reported Outcomes Measurement Information System (PROMIS) Sexual Functioning
 839 Inventory: The PROMIS questionnaires are a system of reliable measures of patient-reported health
 840 status for physical, mental, and social well-being developed with funding under the National Institutes of
 841 Health (NIH) Roadmap for Medical Research Initiative to re-engineer the clinical research enterprise
 842 (<http://www.nihroadmap.nih.gov>). PROMIS measures can be across a wide variety of chronic diseases
 843 and conditions and in the general population (Cella et al, 2010). One of the PROMIS instruments is a
 844 Sexual Functioning Inventory (Jeffery et al, 2009). The PROMIS Sexual Function Inventory provides
 845 scores on seven different sub-domains of sexual function: interest in sexual activity, vaginal discomfort
 846 (women only), lubrication (women only), erectile function (men only), orgasm, and global satisfaction with
 847 sex life. Each question asks respondents to report on their experiences over the past 30 days. With the
 848 exception of the orgasm sub-domain, all sub-domain scores are expressed as T scores (mean = 50,
 849 standard deviation = 10). While the Inventory is intended for broad use, almost all of the development
 850 work was with patients with cancer. Research is ongoing to expand development beyond cancer. In
 851 testing with 819 individuals (388 males, 430 females, 1 person did not specify sex), correlations between
 852 the PROMIS Sexual Functioning Inventory and corresponding sub-domains of two well-established
 853 measures, the Female Sexual Function Index (FSFI) and the International Index of Erectile Function
 854 (IIEF), ranged between .48 and .92. The sub-domains of the Inventory discriminate between people who
 855 had and had not asked a provider about sexual problems. Test-retest correlations over one month are
 856 $>.65$ for all sub-domains (Sexual Function and Satisfaction Measures User Manual, 2012).

857
 858 **4.9 Inclusion / Exclusion Criteria:** The inclusion and exclusion criteria are consistent with
 859 research using the CPT protocol with combat veterans with PTSD in VA settings (e.g., Monson,
 860 et al., 2006). The target population will be over the age 18 and there is no upper limit as long as
 861 they are active military. Because the study sample will be comprised of active duty military
 862 personnel, it is anticipated that they will be of sufficient physical health to maintain their active
 863 duty status.

864
 865 Inclusion Criteria:

- 866 • Adult male and female active duty, activated Reservist, or activated National Guard
- 867 OIF/OEF/OND military personnel or OIF/OEF/OND veterans seeking treatment for PTSD
- 868 • Diagnosis of PTSD determined by a clinician-administered Posttraumatic Stress Scale
- 869 (PSS-I)
- 870 • Person has experienced a Criterion A event that is a specific combat-related event or high
- 871 magnitude operational experience that occurred during a military deployment in support of

872 OIF/OEF/OND. The diagnosis of PTSD may be indexed to that event or to another Criterion
873 A event.

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

881
882 Exclusion Criteria:

- 883 • Current suicide or homicide risk meriting crisis intervention
- 884 • Active psychosis
- 885 • Moderate to severe brain damage (as determined by the inability to comprehend the
886 baseline screening questionnaires)

887
888 We propose to rely on the clinical judgment of the evaluator and the consensus of the inter-rater
889 reliability team to determine the validity of an assessment. If a participant is clearly unable to
890 comprehend or conform to the study procedures, the evaluator will terminate the protocol. In
891 less obvious cases where there are concerns about the validity of an assessment but the
892 participant completes the protocol nonetheless, the inter-rater reliability team will review the
893 video recording and determine, through consensus judgment, if the case should be excluded
894 from analysis.

895
896 **4.10 Number of Subjects:** 1,000 from CRDAMC

897
898 **5.0 Human Subject Protection**

899
900 **5.1 Recruitment:** Potential participants may be identified through referrals from various health
901 care providers at CRDAMC clinics. Providers may forward contact information of interested
902 individuals directly to STRONG STAR. Or, potential participants may self-refer in response to
903 recruitment flyers and pamphlets previously approved by the IRB (Appendix H). Recruitment
904 materials will be distributed to various health care providers and will be posted in locations in
905 CRDAMC and on Fort Hood frequented by Service Members. Primary locations on base will
906 include the R&R Center, fitness centers, chapels, barracks, and the PX. Potential participants
907 may also self refer in response to recruitment information on the STRONG STAR website
908 (Appendix H). Interested persons may call or walk in to the STRONG STAR offices. Research
909 staff will field incoming phone calls and walk-ins. Research staff will discuss the study treatment
910 and eligibility requirements with the interested person. If the person believes they may qualify
911 for the study, an appointment will be made for consent and screening. During this appointment,
912 potential participants will have the study explained to them in a safe and private location. The
913 potential participant will be given a copy of the informed consent document (ICD) to read. After
914 the subject has read the ICD they will be given the opportunity to take the consent home to
915 discuss the research with family and friends. The Research Team will be available to answer
916 any questions about the research. Once the potential participant has reached a decision, the
917 advising staff member will go over the risks and benefits of the study and ensure the subject
918 understands the research. The advising staff member will have the Service Member sign the
919 consent form. A copy of the signed ICD will be given to the subject. The advising staff member
920 will document the informed consent process in the medical record of the participant. Following
921 the consent process, those who meet the inclusion criteria for the study will be randomized into

922 the study. For Service Members not meeting study inclusion criteria, the Study Staff will contact
 923 the Resilience and Restoration Center staff to coordinate appropriate follow-up outside of the
 924 study.

925
 926 Participants will first be recruited as cohorts of 16 -24 eligible participants for randomization into
 927 one of two conditions (group CPT-C or group PCT). The two conditions will run simultaneously.
 928 The first 6 cohorts of 16-18 participants (96-108 individuals) will be randomized into either
 929 group. Once data have been collected on at least 48 participants in each condition to answer
 930 the first research question, participants will be randomized into either group CPT-C or individual
 931 CPT-C for the remainder of the study.

932
 933 **5.2 Benefits:** Potential benefits of participation in this study may include a reduction in PTSD
 934 symptoms over the course of therapy. In addition, the knowledge gained from this study will
 935 serve to inform the most effective early interventions for the prevention and treatment of
 936 combat-related PTSD in active-duty military personnel.

937
 938 **5.3 Risks:** Potential risks or discomfort that may arise from participation in this study include
 939 becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the
 940 discussion of traumatic events, including increased risk for suicide. However, in past research
 941 conducted by the overall study Principal Investigator, Patricia Resick, using CPT or CPT-C,
 942 there have been no serious adverse events or related difficulties with emotionally upset
 943 participants due to the treatments.

944
 945 With the handling of medical and research records, there is always the possibility of a breach of
 946 confidentiality.

947
 948 **5.4 Safeguards for Protecting Subjects:**

949
 950 During the early sessions of treatment, participants will be provided immediate coping tools and
 951 techniques used to manage distressing emotions both within the group and outside the group
 952 setting by the study therapist. Distress experienced by participants is expected to be
 953 temporary. Any indication that the participant is considering suicide will be handled using
 954 processes developed by military and civilian Consultants for the STRONG STAR Consortium
 955 studies (see Appendix E).

956
 957 Data will be coded using an assigned number. Data collected during treatment will be entered
 958 into a secure STRONG STAR database, and hardcopies will be placed into a lock box which will
 959 be transported by car to University of Texas Health Science Center San Antonio (UTHSCSA)
 960 STRONG STAR offices by a STRONG STAR staff member who will place it into the locked
 961 cabinets at the STRONG STAR offices. Audio and video recordings will be mailed to the
 962 National Center for PTSD using an express service (e. g., UPS, FedEx, or DHL) and tracked for
 963 receipt or will be uploaded to a secure STRONG STAR server. Every member of the Research
 964 Team will be trained and monitored about how to handle and protect both medical and research
 965 records. Furthermore, the Research Team strictly controls access to study data. (See
 966 Appendix F)

967
 968 A *STRONG STAR Repository* has been approved by both the UTHSCSA (HSC20100475H) and
 969 BAMC (C.2011.054d; IRBNet #363444) IRBs to enable the STRONG STAR Consortium to store
 970 specimens and data for future use. The STRONG STAR Repository will create a large
 971 comprehensive database of information, biological specimens and neuroimages related to the
 972 identification, assessment, and treatment of PTSD in our active duty and retired veterans of

973 OEFOIF OND. All information entered into the STRONG STAR Repository will be extracted
 974 from primary datasets collected as part of IRB-approved studies, including this study, being
 975 conducted and /or supported by the projects of the STRONG STAR Consortium. These study
 976 databases will be established and maintained by the Biostatistics and Data Management Core
 977 of the STRONG STAR Consortium, led by Dr. Jim Mintz. A unique, sequential alpha-numeric
 978 STRONG STAR ID will be assigned to each participant at the time of recruitment into this study.
 979 However, all repository data will be identified with a different code number that can be cross
 980 linked to the original study code only through records maintained by the STRONG STAR
 981 Biostatistics and Data Management Core. Data, biological specimens and images will constitute
 982 the STRONG STAR PTSD Repository. Participation in the repository will be completely
 983 voluntary and entirely optional which means that a potential participant's willingness to
 984 participate in the repository has no influence upon their eligibility to participate in the primary
 985 STRONG STAR study they have either already enrolled in or are considering enrolling in. At
 986 the conclusion of this study, participants who signed the consent to have their specimens and
 987 data placed in the STRONG STAR Repository will be maintained under the IRB-approved
 988 Repository protocol. Biological specimens and information from study participants who declined
 989 participation in the STRONG STAR Repository will be permanently de-identified (i. e., all PHI
 990 will be deleted from the study data bases) and the de-identified blood and information placed in
 991 the STRONG STAR Repository for future use.

992
 993 A Data Safety and Monitoring Plan (DSMP) has been developed in accordance with the
 994 National Institutes of Health (NIH) Office of Human Research Protection (OHRP) to assure the
 995 appropriate clinical safety monitoring of study subjects participating in this study. (See
 996 Appendix G.)
 997

998 **5.5 Risk:Benefit Assessment:** The risks of the project are minimal, and participants may
 999 expect to gain valuable knowledge and skills that may serve to reduce or eliminate symptoms of
 1000 PTSD.
 1001

1002 **5.6 Alternatives:** Alternative mental health treatment is available at the Resilience and
 1003 Restoration Center at Carl R. Darnell Army Medical Center including various forms of
 1004 psychotherapy, including Cognitive Processing Therapy (CPT), and drug treatments.
 1005

1006 **6.0 Data Analysis:**

1007
 1008 Hypothesis Tests. The first analysis will examine group Cognitive Processing Therapy,
 1009 cognitive-only version (CPT-C) compared to group Present Centered Therapy (PCT). Unlike the
 1010 smaller effect sizes that are hypothesized for individual and group CPT-C, we expect the effect
 1011 to be larger comparing CPT-C to a treatment that controls for non-specific effects
 1012 (therapist/other group member contact) and an effort to work on problems but not traumatic
 1013 events. The primary analyses will be through mixed effects regression analyses, including all
 1014 available data regardless of how many sessions the participants attended (intention-to-treat).
 1015 The advantage of this type of analysis is that missing data are replaced, it accounts for
 1016 correlated repeated measures for each participant, and individual variability in change. Random
 1017 regression can also account for variable measurement intervals. This will be important in the
 1018 proposed trial because there will be variability in the timing of assessments, especially when
 1019 participants miss group sessions or cannot come in at exact intervals. The analyses to compare
 1020 group and individual CPT-C (aim 2) will also use mixed effects random regression with intention
 1021 to treat samples.
 1022

1023 The third aim is to examine the effect of other variables on treatment outcome more generally.

1024 Because we have a large sample size, we can collapse across groups and use the results, such
1025 as reduction in symptoms, as the outcome variable. There are many interesting questions that
1026 can be examined, such as gender, TBI, co-morbid conditions, length of time since worst event,
1027 number of deployments etc. Specifying all possible analyses and secondary questions are
1028 beyond the scope of this short description. However, given the sample size and repeated
1029 assessments, we should be able to conduct many interesting post-hoc studies with this rich data
1030 set as well as to collapse data sets across the other STRONG STAR consortium studies.

1031
1032 Data analysis will be performed by the data analysis core staff of the STRONG STAR
1033 consortium.

1034 **7.0 Sample Size Estimation & Power Analysis**

1035
1036
1037 With a medium effect size ($>.5$) between the Cognitive Processing Therapy, cognitive-only
1038 version (CPT-C) and Present Centered Therapy (PCT) groups, a sample of 48 in each group
1039 should be sufficient to examine the two types of groups and answer the first research question.

1040
1041 The aim of the comparison of group versus individual CPT-C was powered for equivalence
1042 analysis, meaning that we will power our study sufficiently to test for no meaningful differences
1043 between group outcomes. We have set a cut-off for an effect size (ES) of 0.3 assuming that if
1044 there is less than a .3 effect size difference between individual and group treatment, then the
1045 differences are not large enough to warrant individual treatment on average, and group
1046 treatment would be considered a more efficient modality. However, if there is a larger than .3
1047 effect, this is sufficiently meaningful that individual therapy may be warranted. The follow-up
1048 analyses on predictors of treatment outcome would then be valuable to determine who might
1049 especially need individual therapy. Although we will have more than nine assessments with the
1050 self-report scales that should allow .9 power and the ability to detect even smaller effect sizes,
1051 we conducted a power analysis with only four data points to reflect the interview measures that
1052 will be collected at pre, post, and the 6- and 9-12-month follow-up periods. Comparing individual
1053 and group CPT-C is a two-armed randomized trial. In one condition (TX=0) every individual is a
1054 uniquely coded GROUP with N=1, and in the second condition (TX=1) groups of 8 form uniquely
1055 coded GROUP with N=8. The total numbers of subjects are the same between the two
1056 conditions. Based on previous studies, the intraclass correlations are 0.05 at most in this
1057 situation. After 200 replications, we found that intraclass correlation of this magnitude made
1058 minimal impact on the power of the study. In summary, with a two-tailed alpha at 0.05 and 4-
1059 times-repeated measures, and 110 subjects per treatment arm, we have a power of 80% to
1060 detect an effect size of 0.3. To account for potential attrition over this year-long study, we will
1061 oversample, requesting permission to recruit 404 participants until 110 participants have
1062 completed each of the treatment arms.

1063
1064 **8.0 Duration of Study:** estimated to be 8 years, ending by December 31, 2016.

1065
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1067 Research and Materiel Command Congressionally Directed Medical Research Program
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1072 Office (CIRO).

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1074 **10.0 Staff Monitor (for resident and fellow projects):** not applicable

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD CheckList – Stressor Specific (PCL-S) & PTSD CheckList – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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
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

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 ($\alpha = .85$ 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 health 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 & Marhofer-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 discriminant 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 (Deville & 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.

While many clinicians use the 24-question Pittsburgh 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 ($\alpha = .73 - .88$) 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

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 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 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

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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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD CheckList – Stressor Specific (PCL-S) & PTSD CheckList – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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
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

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 ($\alpha = .85$ 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 health 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 & Marhofer-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 discriminant 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 (Deville & 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.

While many clinicians use the 24-question Pittsburgh 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 ($\alpha = .73 - .88$) 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

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 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 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

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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

**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 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 they 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:

Source of Research Material	Standard Care
1. Head Injury Assessment	No
2. Automated Neuropsychological Assessment Metrics (ANAM®)	No
3. Deployment Risk and Resilience Inventory (DRRI) Combat Experience, Aftermath-of-Battle, & Deployment Environment Sub-Scales	No
4. PTSD Symptom Scale – Interview (PSS-I)	No
5. Columbia-Suicide Severity Rating Scale (C-SSRS)	No
6. PTSD Checklist – Stressor Specific (PCL-S) & PTSD Checklist – Version for proposed DSM-V (PCL-V)	No
7. Veterans Rand 12-Item Health Survey (VR-12) (Functional Impact)	No
8. Revised Conflict Tactics Scale (CTS2)	No
9. State-Trait Anger Expression Inventory (STAXI)	No
10. Beck Depression Inventory-II (BDI-II)	No
11. Beck Scale for Suicidal Ideation (SSI) Screen	No
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
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

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 ($\alpha = .85$ 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 health 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 & Marhofer-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 discriminant 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 (Deville & 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. 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 ($\alpha = .73 - .88$) 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 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 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 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

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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