Study Protocol

Youth-Nominated Support Team for Suicidal Adolescents

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Project Summary

As highlighted in the Surgeon General's Call to Action to Prevent Suicide (1999), effective suicide prevention strategies are sorely needed. Despite substantial knowledge about adolescent suicide risk factors, there is a paucity of research on effective interventions. Few randomized controlled intervention trials have been conducted with suicidal adolescents, and treatment adherence among these adolescents is generally poor. This randomized controlled trial will investigate the efficacy of the Youth-Nominated Support Team Intervention (YST), a psychoeducational, social network intervention that targets two problems common among suicidal adolescents, poor treatment adherence and negative perceptions of family and social support. It targets these problems during a period of high risk for suicidal behavior, the 12-month period following psychiatric hospitalization. Suicidal adolescents (n = 532) will be recruited from the Child and Adolescent Psychiatric Hospital at the University of Michigan and Havenwyck Hospital, a large private psychiatric hospital. Adolescents will be randomly assigned to either treatment-as-usual (TAU) or treatment-as-usual plus YST (TAU+YST). Adolescents assigned to TAU+YST will nominate three or four adults from family, school, and community settings to function as support persons. Nominated support persons participate in a psychoeducation session that focuses on the adolescent's psychiatric disorder(s), individualized treatment plan, importance of treatment adherence, and suicide risk factors. During the 3-month YST intervention, support persons maintain regular contact with the adolescent to support treatment adherence and progress toward treatment goals. The YST intervention specialist maintains regular telephone contact with each support person to provide information and address concerns. Adolescents will be contacted for 6-week, 3-month, 6-month, and 12-month assessments. The efficacy of YST will be measured by reductions in (a) severity and frequency of suicidal ideation, (b) severity of depression and anxiety, (c) suicide attempts, (d) internalizing behavior problems, and by improvements in (e) perceived social support, (f) treatment adherence, and (g) adaptive functioning. Repeated measures analyses will test overall intervention effects, the hypothesized moderating effect of gender, and the extent to which intervention effects are maintained. Results of this study are expected to provide information about the effectiveness of YST for suicidal adolescents, addressing a critical gap in our understanding of strategies for improving treatment adherence and reducing suicide risk among these adolescents.

Performance Sites (organization, city, state)

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RESEARCH PLAN

Specific Aims

As highlighted in the Surgeon General’s Call to Action to Prevent Suicide (U. S. Public Health Service, 1999), effective adolescent suicide prevention and intervention strategies are sorely needed. Despite substantial knowledge about adolescent suicide risk factors and increasing public awareness of suicide, there is a paucity of research on effective interventions (Brent et al., 1997, Rudd et al., 1999). Few randomized controlled intervention trials have been conducted with adolescents, evaluated interventions have shown limited impact on suicidal ideation and behavior, and suicidal adolescents’ follow-through with treatment recommendations has generally been poor (Spirito et al., 2000). The proposed study has three specific aims:

Specific Aim #1: To conduct a randomized controlled clinical trial to evaluate the efficacy of a social network intervention, Youth-Nominated Support Team (YST), for suicidal adolescents post-hospitalization. Due to ethical considerations critical to treatment research with suicidal individuals, a randomized controlled design will contrast treatment-as-usual with treatment-as-usual plus YST.

Hypothesis 1a. Treatment-as-usual plus YST will be more effective than treatment-as-usual alone in reducing suicidal ideation, decreasing internalizing behavior problems, and improving adaptive functioning among suicidal adolescents.

Hypothesis 1b. Gender will function as a moderator of YST efficacy. The magnitude of intervention effects on suicidal ideation, internalizing behavior problems, and adaptive functioning will be greater for adolescent females than for adolescent males.

Hypothesis 1c. The effects of YST in reducing suicidal ideation, decreasing internalizing behavior problems, and improving adaptive functioning will be maintained over time. They will be evident at 6-month and 12-month follow-up.

Specific Aim #2: To determine the extent to which changes in perceived social support and treatment adherence function as mediators of YST efficacy. Primary hypotheses are as follows:

Hypothesis 2a. Perceived social support will improve more among suicidal adolescents in the treatment-as-usual plus YST group than among suicidal adolescents in the treatment-as-usual only group, and perceived social support will mediate YST efficacy (as defined by decreases in suicidal ideation and internalizing behavior problems, and improved adaptive functioning).

Hypothesis 2b. Treatment adherence will be better among suicidal adolescents in the treatment-as-usual plus YST group than among adolescents in the treatment-as-usual alone group, and treatment adherence will mediate YST efficacy (as defined by decreases in suicidal ideation and internalizing behavior problems, and improved adaptive functioning).

Specific Aim #3: To conduct preliminary analyses to determine whether or not treatment-as-usual plus YST will be more effective than treatment-as-usual alone in reducing suicide attempts and time until occurrence of a suicide attempt during the 12-month period following adolescents' psychiatric hospitalization. Although not evident in our feasibility study, it is believed that such effects will be found because of (a) a proposed improvement in YST (faster start-up post-hospitalization), (b) inclusion of an extended follow-up, and (c) increased emphasis on the importance of treatment adherence in psychoeducation sessions for support persons. Intervention-related reductions in suicidal ideation, documented in our preliminary study, are expected to translate into reductions in suicide attempts during the post-intervention follow-up period.

Hypothesis 3a. Treatment-as-usual plus YST will be more effective than treatment-as-usual alone in reducing suicide attempts during the 12-month post-hospitalization period.

Hypothesis 3a. Treatment-as-usual plus YST will be more effective than treatment-as-usual alone in reducing time until occurrence of a suicide attempt during the 12-month post-hospitalization period.

In addition to these focused analyses, we will conduct exploratory analyses to examine potential moderators and mechanisms of action. For instance, we will examine interactions between intervention efficacy and history of suicidality (repeat attempts, single attempt, suicide ideation only), presence of psychiatric disorders (e.g., substance dependence), depression severity, psychosocial impairment, and treatment-as-usual variables.
Background and Significance
Suicidal Ideation, Suicidal Behavior, and Completed Suicide among Adolescents

Completed suicide among youth is a continuing tragedy. During the forty-year period between 1956 and 1996, the suicide rate in the United States increased from 0.4 to 1.6 for the 10- to 14-year age group and from 2.3 to 9.7 for the 15- to 19-year age group (McIntosh, 2000). Recent data indicate that suicide continues to be the 3rd leading cause of death for these age groups (National Center for Health Statistics, CDC, 2000).

Suicidal ideation and suicide attempts are not uncommon among adolescents. The prevalence rates are striking. The 1999 Youth Risk Behavior Survey reveals that, nationwide, 19.3% of students had seriously considered attempting suicide, 14.5% had made a specific plan to attempt suicide, and 8.3% had attempted suicide one or more times during the previous 12 months (Kann et al., Centers for Disease Control and Prevention, 2000). In an epidemiological study of more than 1,700 14- to 18-year-old adolescents, Lewinsohn et al. (1996) documented lifetime prevalence rates of 12.9% for thoughts of hurting or killing self, 8.3% for reports of a suicidal plan, and 7.1% for reports of a suicide attempt.

Converging evidence indicates that suicidal ideation, suicide attempts, and completed suicide are distinct, yet overlapping. That is, they can be conceptualized on a severity continuum (e.g., Brent et al., 1988; King, 1997). Suicidal ideation is a significant predictor of suicide attempts (Andrews & Lewinsohn, 1992; Kienhorst et al., 1990), and intensity of suicidal ideation is meaningful as a specific predictor. In a large scale prospective study, Lewinsohn et al. (1996) found that 16.7% of adolescents with high suicidal ideation at baseline (based on number of items endorsed and frequency of occurrence) made a suicide attempt in the following year. This was in contrast to 6.7% of those with moderate suicide ideation and 2.8% of those with mild suicide ideation. These attempts are often recurrent. Ten to eighteen percent of youth hospitalized following a suicide attempt make repeat attempts in the six months following hospitalization (Brent et al., 1993a; King et al., 1997a). Approximately 1-4% of suicidal girls and 9% of suicidal boys become suicide victims in the four to ten years following hospitalization (as reviewed in King, 1997; Otto, 1972).

Significant psychopathology and continued severe psychosocial impairment is the rule rather than the exception for adolescents who express significant suicidal ideation or make suicide attempts (Brent et al., 1988; Marttunen et al., 1991; Shaffer et al., 1988). Suicidal ideation and behavior are common and often unremitting among youth with depressive disorders (e.g., Brent et al., 1993a; Myers et al., 1991; Pfeffer et al., 1991). Kovacs et al. (1993) identified a four- to fivefold increase in suicidal ideation and behavior among youth with depressive disorders as compared to youth with other psychiatric disorders. The often severe psychosocial impairment among suicidal youth is also associated with alcohol abuse (e.g., Marttunen et al., 1991), histories of antisocial behavior and conduct disorder (Kovacs et al., 1993), and patterns of aggression and impulsive violence (e.g., Pfeffer et al., 1988).

Preventive Strategies and Treatment Interventions for Suicidal Adolescents

Most large-scale suicide prevention efforts have focused on identifying at-risk youth. Screening measures have been carefully designed for school and community settings (e.g., Reynolds & Mazza, 1994; Shaffer & Craft, 1999), and efforts have been made to educate teachers and other "gatekeepers" about suicide risk factors (Mazza, 1997). These efforts have heightened "gatekeeper" awareness of the problem of youth suicide, providing them with important identification skills. Unfortunately, this universal preventive strategy is unavailable to the gatekeepers of many individual suicidal adolescents. Even when recognition and referral to a mental health professional does take place, the suicidal adolescent may not be effectively treated. Existing clinical prevention and intervention models have had limited success. In fact, there is an almost complete absence of empirically validated, effective treatments for suicidal behavior in youth. The limited state of our knowledge was highlighted in a practitioner review concerning the aftercare of suicidal adolescents (Brent, 1997) and in a recent review of randomized clinical trials designed to reduce suicidal behavior (Linehan, 1997). It is also discussed by Rudd et al. (1999) in a presentation of guidelines for the treatment of suicidality. The meager scientific basis available provides only tentative answers to some of the most fundamental questions concerning core interventions, effectiveness, and potential associated harm.

No randomized controlled study targeting suicidality in youth has clearly demonstrated efficacy in terms of reductions in adolescent suicide attempts, and few controlled studies have demonstrated reductions in suicidal ideation (Rudd et al., 1999). Rudd et al. (1996) evaluated the efficacy of a brief cognitive-behavioral treatment and demonstrated reductions in suicidal ideation among older adolescents and young adults. Their cognitive-behavioral intervention incorporated a strong emphasis on problem-solving, which is consistent with other interventions demonstrating reductions in suicidal ideation, depression, and hopelessness (as reviewed in Rudd et al., 1999). In a randomized trial of a home-based family intervention for youth who had deliberately poisoned themselves, Harrington et al. (1998) found no significant difference between “routine care” and family intervention groups in suicidal ideation, hopelessness or adolescent perceptions of family functioning at 2-month and 6-month follow-ups. This intervention consisted of an assessment session and four home visits to facilitate family problem-solving. Harrington et al. (1998) did find, however, that this intervention was linked with reduced suicidal ideation in the subgroup of participants without major depression. Taking a different approach, Cotgrove et al. (1995) randomized hospitalized adolescent suicide attempters to either a standard care or an experimental group that received a card allowing for immediate rehospitalization without question if the adolescent was feeling suicidal and felt hospitalization was needed. A nonsignificant reduction in suicide attempts was evident for the experimental group at one-year follow-up, suggesting that this may be a promising approach.

Other treatment studies targeting suicidal adults include a study of young adult females with borderline personality disorder. Linehan et al. (1991, 1993) compared a cognitive-behavioral intervention with treatment-as-usual
and found that those who obtained the cognitive-behavioral treatment had fewer suicide attempts and better treatment adherence. In a randomized controlled study of a “follow-up outreach” intervention for adult suicide attempters, Welu (1977) found a significant reduction in suicide reattempts among those assigned to the outreach program. Taken together, findings from studies with adolescents and adults suggest that cognitive-behavioral treatment focused on problem-solving and depressive cognitions may be helpful for depressed and suicidal persons (e.g., Brent et al., 1997; Linehan et al. 1991; Rudd et al., 1996) in addition to some type of follow-up outreach (e.g., Welu, 1977).

Treatments targeting the family unit are often considered to be a key component of interventions with depressed and suicidal youth because of well-established correlations between youth suicide attempts and family conflict, parent-adolescent communication problems, and parental psychopathology (Keitner et al., 1987; King et al, 1993a), as well as family histories of suicidal behavior (e.g., Shafii et al., 1985). In a clinical trial comparing three psychosocial treatments for adolescent depression, Brent et al. (1998) found that the efficacy of CBT for these adolescents “plummeted” in the presence of self-reported maternal depression, suggesting the need to assess and treat maternal psychopathology. A family therapy program called Successful Negotiation/Acting Positively or SNAP (Rotheram-Borus et al., 1994) was developed to target family functioning in families of youth suicide attempters. The program's primary goal is to increase positive family communication skills and improve the family's ability to use effective problem-solving strategies during conflict. This is a promising approach that suggests the possibility of positively impacting treatment adherence among female adolescent suicide attempters presenting to an emergency room (Rotheram-Borus et al., 1999).

**Treatment Adherence among Suicidal Adolescents**

The rate of treatment drop-out is extremely high for suicidal youth (Cohen-Sandler et al., 1982; Spirito et al., 1992; Trautman et al., 1993). Following resolution of a suicidal crisis, continued treatment may be neither prioritized by the family nor desired by the adolescent. Many of the adolescents who do seek help, at least initially, fail to comply with recommended appointments (King et al., 1997b; Spirito et al., 1992; Trautman, Stewart, & Morishima, 1993). Spirito and his colleagues found that 9% of suicidal adolescents treated in a psychiatric hospital failed to participate in any recommended outpatient treatment. At three-month follow-up, only 59% were participating in psychotherapy on a regular basis. In a study of outpatient follow-through among 10- to 18-year-old suicide attempters, Trautman et al. (1993) reported an overall dropout rate of 77%, with a median survival prior to drop-out of only three visits.

A growing number of empirical studies have investigated predictors of suicidal adolescents' adherence with recommended treatments post-hospitalization. Predictors include adolescent psychopathology, adolescent hopelessness, parent psychopathology, and type of outpatient intervention. Suicidal youth are often depressed and hopeless (e.g., Lewinsohn et al., 1996), and have a long history of family relationship difficulties (e.g., Brent, et al., 1994). Demonstrating the impact of parental psychopathology on adherence, King et al. (1997b) found that mothers' self-reported depressive and paranoid symptoms were negatively associated with adolescents' post-hospitalization adherence with individual psychotherapy, and that family dysfunction was a predictor of poor adherence with family therapy. In a study of treatment adherence among Latina female adolescent suicide attempters presenting to an emergency room, Rotherham-Borus et al. (1999) found that adolescents whose mothers reported more psychopathology attended fewer treatment sessions. Converging evidence indicates that parental psychopathology and family functioning have substantial influence on treatment adherence among suicidal adolescents. A naturalistic outcome study indicating that suicidal adolescents’ adherence with recommended family therapy (33.3%) was significantly less than adherence with medication follow-up (66.7%) and individual therapy (50.8%) also suggests the need for interventions that place a low demand on families to participate or that build in strategies for increasing adherence (King et al. 1997b).

**Rationale for the Youth-Nominated Support Team (YST) Intervention**

YST is a psychoeducational, social network intervention designed to supplement other more traditional or usual treatments (King et al., 2000). It targets two problems that characterize many psychiatrically hospitalized suicidal
adolescents, poor treatment adherence and negative perceptions of family support and helpfulness. And, it targets these problems during a period of particularly high risk for suicidality, the first 12 months following a psychiatric hospitalization for serious suicidal intent or a suicide attempt.

In a review of prevention and treatment programs for troubled youth, Kazdin (1993) emphasized the necessity of extending existing interventions and devising new models. Intervention strategies for suicidal adolescents must somehow grapple with the increased prevalence of parental psychiatric disorder and dysfunction in the families of adolescent suicide attempters (e.g., King et al., 1993a; Wagner, 1997) as well as with the relationship between parental psychopathology and treatment adherence (e.g., King et al., 1997b; Rotheram-Borus et al., 1999). We believe the YST intervention has the potential to broaden and strengthen the adolescent’s supportive network, including the parents and guardians. The relation between social support and wellbeing has been clearly documented (e.g., Leavy, 1983), and may be particularly important for suicidal adolescents. That is, YST has the potential to provide a compensatory function if the adolescent’s parents are unable to be sufficiently helpful or supportive of treatment adherence or if they need additional support to do so. Suicidal youth can nominate adults for participation from several spheres of their lives, including school, neighborhood, and community settings, as well as from their immediate and extended family. Although the relatively poor treatment adherence and outcomes of suicidal adolescents are often attributed to family disorganization or treatment resistance, it behooves us to revise our intervention models to better meet the needs of these adolescents and their families (e.g., King et al., 1997a).

Universal preventive approaches have not met the needs of many psychiatrically disordered and suicidal adolescents who require a more targeted and individualized intervention strategy. In addition, highly targeted hospital- and clinic-based interventions have often failed to meet the needs of these suicidal adolescents because they are generally office- and appointment-based, rely heavily on parent and family involvement, and are characterized by low rates of treatment adherence. The Youth-Nominated Support Team intervention (YST) was designed with consideration of what has failed in universal and targeted approaches to suicide prevention. It was designed to bridge the gap between community-based gatekeeper approaches and individualized office-based treatment approaches. By involving youth-nominated adults from different spheres of the adolescent’s life, YST extends the breadth of support available to the adolescent as well as the range of influences on treatment adherence.

YST offers psychoeducation for youth-nominated caring adults, providing them with information about the adolescent’s psychiatric disorder(s), the adolescent’s treatment plan and rationale for recommended treatments, the signs of increased suicide risk, and the availability of professional resources. YST is multi-systemic in its inclusion of nominated adults from home, school, and community settings, and its facilitation of regular contact between these adults and the suicidal adolescent. It is developmentally sensitive in its consideration of the adolescent developmental phase and its effort to positively empower and involve suicidal youth, giving them a “say” in their treatment, through the nomination of caring adults for participation as support persons. Cicchetti and Toth (1992) have highlighted the critical importance of taking developmental issues into account when designing new interventions and preventive strategies. YST provides ongoing consultation for nominated support persons to help them (1) understand the adolescent’s psychiatric disorder(s); (2) recognize "red flags" for increased suicide risk, and (3) support the adolescent’s adherence with recommended treatments and progress toward goals. It also facilitates ongoing communication between the adolescent and nominated adults. The objectives of YST are to: (a) increase suicidal adolescent's positive perceptions of adult social support; (b) increase suicidal adolescent's adherence with recommended treatments; (c) decrease severity of suicidal ideation, depression, and anxiety; decrease suicide attempts; and (d) improve adaptive functioning.

Psychoeducational Intervention Models

Psychoeducation has been used as an adjunct to pharmacologic interventions and as an adjunct to many psychotherapeutic interventions for children and adolescents (e.g., Brent et al., 1993b; Fristad et al., 1996; Geist et al., 2000, Goldberg-Arnold et al., 1999). Psychoeducation has the potential to improve treatment adherence (e.g., Rotheram-Borus et al., 1996) and outcome, particularly given the beneficial effects that have been demonstrated in studies of adult patients with affective disorders (e.g., Anderson et al., 1986; Clarkin et al., 1990). In a study that provided a 2-hour psychoeducation session to the parents of 34 affectively ill adolescents, Brent et al. (1993b) found that the psychoeducation was feasible, positively received by families, and resulted in significant improvements in knowledge. In a study of 25 female adolescents hospitalized with anorexia nervosa, Geist et al. (2000) compared the effects of family therapy and family group psychoeducation in a randomized trial. Weight restoration occurred in both groups following the 4-month treatment and family group psychoeducation was found to be as effective as family therapy. The psychoeducation program being developed for families of youth with mood disorders (e.g., Fristad et al., 1996; Goldberg-Arnold et al., 1999) is extremely promising. Following a six-session multi-family psychoeducation group, parents frequently reported increases in their knowledge about mood disorders and treatment options. Psychoeducational approaches warrant further consideration in efforts to help suicidal adolescents because of the data concerning feasibility and efficacy, the importance of parents as collaborators, and the relative cost effectiveness of educational approaches.

Gender as a Moderator of Intervention Efficacy

As discussed by March and Curry (1998), efforts to predict the outcome of treatment involve a consideration of the treatment itself as well as other variables that may moderate or mediate the effects of the treatment. Gender is a
potential moderator of the impact of the YST intervention. Gender differences in perceptions of social support are well-documented. Adolescent females tend to perceive higher levels of social support than do males (Slavin and Rainer, 1990; Stokes and Wilson, 1984; Leavy, 1983; Burke and Weir, 1978). Females perceive higher levels of support from peers (Burke & Weir, 1978; Slavin & Rainer, 1990) and nonfamily members (Slavin & Rainer, 1990). This has been found to occur across stages of adolescent development (Mahon et al., 1994). Studies also indicate that females are generally more satisfied than males with the social support they receive from parents, peers and other significant persons in their lives (Valery, 1997; Kuttler, 1999). Females tend to have more intimate relationships (Valery, 1997) and spend more time sharing feelings and personal concerns with others (Hirsh, 1980).

A common explanation for these consistent gender differences is the different socialization process for females and males (Leavy, 1983; Burke and Weir, 1978). The socialization of females tends to place a greater emphasis on expressiveness and comfort with intimacy (Stokes and Wilson, 1984). This is consistent with Piko’s findings (1998) that emotional support was perceived as being more important for adolescent female than males, and that informational or instrumental support was more important for males. In addition, according to identity development, females’ sense of identity is strongly tied to skill and success in interpersonal relationships, whereas the sources of sense of identity for males are more strongly connected with vocational or ideological identity achievement (Marcia, 1993 p.37). Given these differing developmental processes, adolescent males and females may have differing levels of investment in social relationships that translate into different perceptions of social support. Because the YST intervention is designed to enhance the suicidal adolescents’ support system with regular communication, emotional support, and encouragement rather than material or instrumental support, it is certainly possible that it will have a differential impact on adolescent males and females. This hypothesis is supported by our preliminary data (Preliminary Studies section).

Limitations of YST Intervention

The YST intervention does not target several adolescent suicide risk factors, including conduct disorder, alcohol/substance abuse, and the availability of firearms (Shaffer et al., 1988). The increased involvement of supportive adults with knowledge of these risk factors and the adolescent's treatment recommendations may be beneficial in addressing these problems. It is unlikely, however, that YST is sufficiently focused on these problems, or of sufficient intensity, to have significant impact on them. In addition, because YST is designed for suicidal adolescents who have been identified and are obtaining psychiatric services, it will not address the needs of at-risk adolescents in the community whose suicidality is either unrecognized or untreated. Finally, the YST intervention requires the parents of suicidal adolescents to allow other adults to have information about their adolescent's psychiatric disorder(s) and treatment plan, and to have regular supportive contact with their adolescent. It will not address the needs of those suicidal adolescents (approximately 10% in our preliminary study) whose parents refuse the involvement of other adults.

Research Design and Methods

Overview

This study is designed to examine the efficacy of the Youth-Nominated Support Team intervention (YST). This is an intervention for suicidal adolescents seeking mental health services in psychiatric settings that is intended to supplement usual services. The study incorporates a randomized control design with suicidal adolescents assigned to treatment-as-usual (TAU) or treatment-as-usual plus YST (TAU+YST).

Changes based on preliminary findings. Based on findings from our preliminary study, we have made several changes that are expected to strengthen the YST intervention and findings concerning its efficacy. These are as follows:

1. We will include only adults as support persons rather than adults and peers for the following reasons: a) There were no significant differences in outcome, on any measure of functioning, related to involvement or noninvolvement of a peer support person; b) The involvement of peers as support persons delayed intervention onset because of the extra step of obtaining written informed consent from each nominated peer’s parent or guardian; c) There was significantly more dropout among peer support persons than among adult support persons (see Preliminary Findings); and d) Evidence from other intervention studies suggests possible negative effects of involving peers in interventions with high-risk youth (Dishion et al., 1999). We believe this change will enable us to begin the YST intervention more quickly with suicidal adolescents, which may result in a significant reduction in suicide attempts as preliminary data indicate that 43% of attempts occurred during the first 6-weeks post-hospitalization.

2. We will include a 12-month post-hospitalization assessment. Because our preliminary study indicated a significant intervention effect on suicidal ideation at the 6-month follow-up assessment, it is possible that this will translate into a reduction in suicide attempts during the 6- to 12-month period post-hospitalization. This follow-up assessment is also critical to understanding the sustained impact of YST on other documented outcomes such as reductions in suicidal ideation and internalizing behavior problems, and improvements in adaptive functioning.

3. We plan a 3-month YST intervention period rather than a 6-month YST intervention period. We found no significant difference in SIQ-Jr. scores (suicidal ideation) at outcome between subgroups of adolescents assigned to TAU+YST who obtained 3-months versus 6-months of regular contact from nominated support persons. Preliminary data do indicate, however, that the feasibility of YST is enhanced if the intervention is employed for three rather than
six months. There was a 7-fold increase in the percentages of youth (from 6% to 42%) who were not contacted regularly (e.g., three of four weeks/month) by support persons between three and six months. Moreover, 94% of adolescents were contacted weekly by at least one support person and 75% were contacted weekly by two or more support persons for at least three months. In contrast, only 25% of participating adolescents were in contact with two or more support persons for six months. Our Intervention Specialists have also shared their experiences indicating that some families refused consent because they felt that it was too much to ask nominated support persons to be involved for six months on a regular basis. Intervention Specialists also report that nominated support persons become “less available” and “increasingly difficult to contact” from three to six months as compared to the period from onset to three months.

(4) We plan to place a stronger emphasis on the adolescent’s treatment recommendations and the importance of treatment adherence in the YST Psychoeducation sessions with support persons and during regular telephone check-ins with these support persons (Appendix A: YST Intervention Manual). Preliminary data indicate that treatment adherence is related to more positive outcomes (See Preliminary Findings section.)

Rationale for treatment-as-usual control. Because this study involves a high risk group of patients, suicidal adolescents, a design in which standard psychiatric treatments are neither withheld nor delayed is believed to be most appropriate. This is due to heightened safety and ethical concerns related to treatment research with suicidal patients, which have been summarized recently by the NIMH (NIMH Document, 2000). In addition, because YST is not intended as a primary or "stand alone" intervention, it is believed to be most appropriate to examine its efficacy as a supplemental intervention. Thus, this study will determine the extent to which YST enhances or improves upon usual psychiatric treatments for suicidal adolescents.

Based on our extensive preliminary data on TAU from the proposed clinical research sites, CAPH and Havenwyck Hospital, we anticipate that TAU will consist of psychoactive medication and individual therapy for the large majority of participants (see Preliminary Data section). In our preliminary study, we found that treatment adherence across the 6-month post-hospitalization period was approximately 60% for these treatments. TAU in the proposed project is also expected to consist of additional interventions such as family therapy and substance abuse treatment that will be recommended for individual adolescents as appropriate.

During each scheduled assessment, a brief clinical interview will be conducted with the adolescent and assessment instruments will be reviewed and scored before the adolescent leaves the site. In keeping with criteria listed in the Risk Management Protocol (Appendix C), Dr. King, or one of the project coinvestigators, Drs. Venkataraman and Quinlan, will be notified of any concerns related to risk status or safety. In addition, the Intervention Specialists will flag any information from weekly contacts with nominated persons that suggest increased suicide risk, and consult with the Principal Investigator immediately concerning appropriate next steps. The Data Safety Monitoring Board (DSMB) is an additional safeguard. It consists of three individuals, including one member internal to the University of Michigan (Gregory Hanna, M.D., Chief, Division of Child and Adolescent Psychiatry) and two external members from university and community-based settings. One of these external members, Mary Fristad, Ph.D., is a faculty member at Ohio State University with a specialization in psychosocial interventions for children and adolescents. The DSMB will convene on a regularly scheduled basis, a minimum of three times each year, to review ethical issues related to subject recruitment activities, assessments, and the clinical status of participating adolescents. The DSMB will also conduct telephone conference calls on an as needed basis if an adverse event occurs or if there is need to address a potential ethical dilemma. During the project’s 4-month development/startup phase, the DSMB will convene to review and recommend changes to the Risk Management Protocol (Appendix C).

Adolescents randomly assigned to treatment-as-usual (TAU) will have the option of participating in the YST intervention following their 12-month outcome evaluation. This strategy was chosen for ethical reasons, as preliminary data suggest that YST may be effective for suicidal adolescents, and because it may enhance subject recruitment. That is, the study incorporates a "roll-over" design wherein all recruited adolescents can potentially benefit from YST. In a sense, this is a modified wait-list design. It is believed to be critical, however, that no suicidal adolescents are required to "wait" for recommended psychiatric treatments.

The Subject Participation and Assessment Timeline (Appendix E) takes into account data indicating that the highest risk period for repetitive suicidal behavior among psychiatrically hospitalized suicidal adolescents is the initial 6- to 12-months post-hospitalization period (Goldston et al., 1999). Assessments will be conducted at baseline, 6 weeks’ post-hospitalization (mid-point of YST), 3 months post-hospitalization (following completion of YST), 6 months post-hospitalization, and 12 months post-hospitalization.

Sites

Study sites will be two psychiatric hospitals: (1) the Child and Adolescent Psychiatric Hospital (CAPH) at the University of Michigan Medical Center (UMMC); and (2) Havenwyck Hospital, a private psychiatric hospital serving southeastern Michigan. These hospitals serve as sites for the preliminary efficacy study of YST. The principal investigator has a longstanding history of successful subject recruitment at CAPH and a 2-year history of successful research.
Subjects

Study participants will be 532 adolescents, ages 13 to 17 years, who are psychiatrically hospitalized at CAPH or Havenwyck Hospital and meet inclusion criteria for suicidality. Based on our preliminary data, we expect the sample to be approximately two-thirds female and one-third male, which is consistent with the well-documented finding that adolescent females outnumber males in psychiatric hospitals (Borst and Noam, 1989). Inclusion criteria for suicidality (McIntosh, 2000; Steinberg and Silverberg, 1986) include (a) a history of one or more suicide attempts, (b) a report of recent suicidal ideation that is unrelenting, (c) reports of recent suicidal ideation and suicide attempts are at their highest levels, and (d) issues related to independence and autonomy are salient. By having adolescents nominate their own support team, YST is designed to enhance autonomy in the treatment process and to increase the likelihood of long-term treatment adherence.

Exclusion criteria. The adolescent is (a) unable to grasp the purposes or procedures such that informed assent is impossible; (b) unable to nominate a support team, even with parent/guardian and project staff facilitation; or (c) unable to participate in baseline self-report or clinician-administered assessments. The inability may be due to serious physical illness (needing immediate transfer to pediatric unit) or severe cognitive impairment (e.g., severe or profound mental retardation; incapacitating psychosis). A record will be maintained of (a) adolescents excluded from the study for the inability to grasp the purposes or procedures such that informed assent is impossible and (b) adolescents who are deemed by parents/guardians to be ineligible for participation in the study and reasons for refusal.

Procedures

Screening/Recruitment. Adolescent admissions to the psychiatric inpatient units at CAPH and Havenwyck Hospital will be reviewed each morning. An initial screening of admission records will be conducted to ascertain the patient's age and reasons for admission. The attending child psychiatrist or child psychiatry resident will be consulted to determine whether or not the adolescent seems to meet study inclusion and exclusion criteria. If screening information indicates that the adolescent definitely or probably meets study criteria, the adolescent and parent or guardian will be approached for informed consent without regard to gender, racial/ethnic group, or other criteria.

Several steps will be taken to recruit a higher percentage of eligible adolescents than we did in the preliminary study. By involving the child and adolescent incompetent director at CAPH and a primary child psychiatrist at Havenwyck Hospital as co-investigators, it should be possible to build a stronger culture of recruitment and acceptance for the project on the hospital units. The addition of two research associates at each site represents incremental staffing and will enable more time to recruitment. This extra time is essential due to the follow-up required with adolescents who are too frightened, angry, or overwhelmed the day of admission. Later in the evening or the next day these adolescents are often more open to the possibility of involvement. Additional staffing will also enable some flex-time arrangements for project staff that make it possible for some recruitment to take place in the evenings when parents are visiting their children.

Baseline assessment. The baseline assessment will be scheduled as two sessions and take place during hospitalization whenever possible. The Child and Adolescent Psychiatric Assessment (CAPA) and (Angold et al. 1995; Angold & Costello, 2000) Children’s Depression Rating Scale, Revised (CDRS-R; Poznanski, Freeman, & Mokros, 1985; Poznanski & Mokros, 1996) will be administered during the first session. These interviews are expected to require
professionals have the clinical skills necessary to implement YST consistently and flexibly.

Kramer, training and experience in the evaluation and treatment of suicidal adolescents. One of the Intervention Specialists, Anne

need to individualize psychoeducation in keeping with the varying psychiatric disorders and treatment recommendations

psychoeducation sessions with nominated persons. This manual is expected to enhance internal validity and treatment

reasonable. This offers t

preliminary data (see Preliminary Studies), an expectation of nine telephone contacts within a 12

day or evening. The nominated person also has the option of initiating the weekly contacts at a time of convenience to

communic

adolescent's psychiatric disorder(s) and psychosocial problems; (b) adolescent's treatment plan and rationale for

information about how to reach professional help 24 hours a day in case of an emergency.

is then scheduled. The role of the nominated person is described in Appendix A (YST Intervention Manual). The role is

greater detail

network intervention rather than a direct intervention with the suicidal adolescent.

Suicidal adolescents randomly assigned to YST are asked to identify adults who may be helpful in supporting

treatment follow-through and progress toward goals. Adolescents are encouraged to nominate at least three adults

(maximum of four), and are informed that their parents/guardians will need to approve each nomination. We have found

that we can facilitate the nominating process by encouraging adolescents to consider caring adults from all domains of

their lives, including school, neighborhood/community, and family. Following the nomination process, which takes place

in an individual meeting with the adolescent, the parent/guardian is invited to join the meeting (if at the hospital) or is

contacted by telephone to schedule a time to review the list of nominated persons, answer any additional questions

concerning YST, and obtain signed release of information forms (enabling YST staff to contact nominated persons). The adolescent and parent/guardian are given the option of making the initial contact with the nominated person themselves,

extending an invitation to participate, or of having the Intervention Specialist make the initial contact. We have found that

most, but not all, adolescents and families prefer us to make the initial contact.

The nominated persons (for whom parent/guardian release of information forms have been signed) are contacted

by telephone and given a brief description of the project, YST, and their role in relation to the adolescent if they choose to

participate. If the nominated individual is potentially interested, an appointment is scheduled to review the project in

greater detail and obtain written informed consent. For those who consent to participate, the YST psychoeducation session

is then scheduled. The role of the nominated person is described in Appendix A (YST Intervention Manual). The role is

clearly that of a support person who cares but is not responsible for the adolescent's behavior. That is, the support person

is not expected to function as a mental health professional. Nominated support people have regular telephone contact with the

Intervention Specialist, a mental health professional experienced in working with suicidal adolescents, and are given

information about how to reach professional help 24 hours a day in case of an emergency.

The YST psychoeducation sessions focus on relaying and discussing information concerning the following: (a)

adolescent's psychiatric disorder(s) and psychosocial problems; (b) adolescent's treatment plan and rationale for

recommended treatments; (c) suicide risk factors and warning signs of increased risk; and (d) strategies for

communicating with adolescents and encouraging treatment adherence. A collaborative plan for weekly telephone contact

with the Intervention Specialist and the availability of emergency services are discussed prior to the session end. The YST

Psychoeducation Manual is in Appendix A.

The Intervention Specialist maintains scheduling flexibility such that telephone contacts can be made during the
day or evening. The nominated person also has the option of initiating the weekly contacts at a time of convenience to

them. If no call is received within the 7-day period, the Intervention Specialist initiates the contact. Based on our

preliminary data (see Preliminary Studies), an expectation of nine telephone contacts within a 12-week period is

reasonable. This offers the nominated person reasonable allowance for special events, vacations, and illness, and is

consistent with the YST role of a helping and caring adult rather than the role of "responsible" professional.

Intervention fidelity. Several procedures will be used to enhance intervention fidelity.

(1) The YST Intervention Manual (King et al., 2000; Appendix A) provides explicit guidelines for the

psychoeducation sessions with nominated persons. This manual is expected to enhance internal validity and treatment

integrity (Kendall, 1994). It is a "flexible" manual that provides clear intervention guidelines while taking into account the

need to individualize psychoeducation in keeping with the varying psychiatric disorders and treatment recommendations

of suicidal adolescents.

(2) Intervention Specialists will be masters level social workers or licensed psychologists who have previous

training and experience in the evaluation and treatment of suicidal adolescents. One of the Intervention Specialists, Anne

Kramer, M.S.W., also has two years of experience with YST that she gained during its pilot phase. Thus, these

professionals have the clinical skills necessary to implement YST consistently and flexibly.
(3) YST training for Intervention Specialists from CAPH and Havenwyck Hospital will take place together at the
University of Michigan. A 4-month project start-up phase will allow sufficient time for this training, which will include
an overview and discussion of intervention components, role plays of psychoeducation sessions, role plays of weekly
telephone contacts, and consideration of multiple clinical and ethical dilemmas.
(4) Ongoing cross-site training and discussion will occur for Intervention Specialists from both sites at the
University of Michigan on a monthly basis. This will enable booster training and a joint discussion of special
circumstances and their practical resolution. It will also enable the project team to maintain an open line of
communication, reduce intervention drift, and develop an ongoing consistency in "clinical culture" and clinical "case law"
across sites (as discussed in Arnold et al., 1997; MTA study).
(5) The P.I. will conduct weekly site visits as well as weekly supervision sessions with Intervention Specialists at
each site. Dr. Venkataraman, Co-Investigator, will attend these sessions on a biweekly basis at Havenwyck Hospital, to
assure consistency in feedback. In a similar manner, Dr. Quinlan, Co-Investigator and Adolescent Inpatient Director, will attend these sessions on a biweekly basis at CAPH. Drs. Venkataraman and Quinlan will also provide regularly scheduled and "as needed" supervision for Intervention Specialists at Havenwyck Hospital and CAPH, respectively, to address
concerns related to system issues, recruitment, and evaluation of adolescent risk status.
(6) Checklists will be used to record the completion of project steps and self-reported adherence with the YST
Intervention Manual. One checklist is a participant tracking form that includes all project steps such as initial screening,
recruitment, random assignment, and assessments. For those adolescents randomly assigned to TAU+YST, this checklist
is also used to track the nomination of caring individuals, signed release of information forms, psychoeducation sessions,
and weekly telephone contacts. A second checklist includes YST Psychoeducation Topics. At the close of the
psychoeducation session, the Intervention Specialist and the nominated individual check those topics that have been
covered in the session. Both individuals sign this form.

...All YST psychoeducation sessions will be audiotaped. The principal investigator will review 20% of these audiotapes
for adherence. The P.I. will use a structure in reviewing these audiotapes, rating each in terms of the following: (a) clarity
of information presentation, (b) extent to which each of the four primary psychoeducation topics are covered, and (c)
responsiveness to nominated individual's questions and concerns. The P.I. will also review transcripts of audiotaped
sessions and minimize intervention drift. As discussed by Waltz and colleagues (1993), the issue of fidelity includes
attention to therapist's adherence to the treatment protocol and the competency with which treatment protocols are
implemented. The "experts" will rate the competency with which psychoeducation sessions are conducted in terms of

6-Week Assessment. This assessment will enable us to assess and review each adolescent's psychiatric status,
regardless of group assignment, to determine if needs for psychiatric treatment are being met adequately and to determine
if continued participation in the study is appropriate (in keeping with Risk Management Protocol; Appendix C). In
addition, it offers an important data point for studying hypothesized mediators (perceived social support, treatment
adherence) and understanding individual and group trajectories of change (Hinshaw et al., 1997). To the extent that
adolescents' functional status at 6 weeks, the midpoint of the YST intervention, predicts the eventual intervention
outcome, this would inform decisions about changes in the intervention that may be needed for those patients for whom it
is appearing to fail. That is, this intermediate assessment point enables us to conduct preliminary analyses to determine if
short-term data are predictive of adolescents’ status at the end of the intervention.

The 6-Week assessment includes the clinician-administered CDPRS-R (Poznanski & Mokros, 1996) and Critical
Incidents Checklist (King, 2000) in addition to the SIQ-JR (Reynolds, 1988), BHS (Beck & Steer, 1993; Beck et al.,
1974), Perceived Emotional/Personal Support Scale (PEPSS; Slavin, 1991), and Services Assessment & Review Record
(SARR; Preuss & King, 2000). It will require approximately one hour for adolescents and 30 minutes for parents.

3-Month Assessment. This primary assessment will coincide with the completion of the YST intervention for
those in the TAU+YST group. It will include all 6-week assessment measures in addition to a comprehensive diagnostic
interview with the adolescent and a partial diagnostic interview, concerning the adolescent, with the parent/guardian
(CAPA; Angold, 2000; Angold et al., 1995). Parents will complete the Critical Incidents Checklist (King, 2000), CAFAS
(Hodges, 1996), and SARR (Preuss & King, 2000), providing information about adolescents’ adaptive functioning and
treatment adherence. They will also complete the SCL-90R (Derogatis, 1977). Parents and adolescents in the TAU+YST
group will complete the Client Satisfaction Questionnaire-8 (Attkisson & Greenfield, 1996; Attkisson & Zwick, 1982;
Nguyen et al.). This assessment will require approximately 2 to 2-1/2 hours for adolescents and 1 to 1-1/2 hours for
parents/guardians. Adolescents’ school grade point averages and attendance records will also be obtained.

6-Month Assessment. This brief assessment will include the same measures as the 6-week assessment. By
providing an additional data point during a period of high risk for suicidal adolescent post-hospitalization (Goldston et al.,
1999), it will provide critical outcome data in terms of the multiple data points required to model "trajectories of change"
for individuals, subgroups, and treatment groups (Hinshaw et al., 1997). This assessment also will enable us to evaluate
adolescents' risk status (Risk Management Protocol; Appendix C).

12-Month Assessment. This primary outcome assessment will include the same battery of adolescent and parent
measures as the 3-month assessment. It takes place twelve months post-hospitalization, at the end of the high risk period
for suicidal adolescents post-hospitalization. The only exception to this is that the Client Satisfaction Questionnaire-I
assessing satisfaction with YST services will not be included in the 12-month assessment.

Roll-Over Design. Adolescents initially assigned to the TAU group will be invited to participate in YST,
beginning at the close of their 12-Month Assessment. Based on our conversations with participating families at the time of
the outcome assessments in the preliminary study, it is estimated that approximately 50% of those adolescents initially
assigned to the TAU group will choose to participate. These numbers are included in the Subject Participation and Assessment Timeline (Appendix E). They will be invited to nominate support persons, and the YST intervention procedures and assessments described above will be followed. Because these participants will not necessarily be “suicidal” at this time, according to our inclusion criteria, and because this involves a different sampling strategy, data from these participants will not be included in primary data analyses.

Subject Follow-Up and Strategies to Enhance Data Collection. Converging evidence from multiple studies attests to the difficulty in maintaining contact with suicidal adolescents in follow-up and naturalistic outcome studies (e.g., King et al., 1995). These data are consistent with the relatively poor treatment adherence of suicidal adolescents (e.g., Spirito et al., 1992; Trautman et al., 1993). Because of this difficulty, we plan to gather additional information at the time of consent, which will assist us in locating participants later. Consent forms will request the names and telephone numbers of two relatives and at least one family friend or neighbor to assist with locating the family for follow-up. This type of strategy has been used effectively in longitudinal and follow-up studies (Loeber et al., 1999). In addition, parent/guardian and adolescent drivers’ licenses (if they have them) and social security numbers will be requested on the consent form to facilitate locating participants at follow-up and so that it is possible to review the death registry at the close of the study. This step is necessary to determine whether or not any suicides occurred among those participants whom we are unable to locate.

We also plan to maintain frequent contact with participants and their parents/guardians. We will contact adolescents who are assigned to TAU+YST to nominate support persons, and adolescents’ parents/guardians will receive written informed consent, which will assist us in locating participants later. Consent forms will request the names and telephone numbers of two relatives and at least one family friend or neighbor to assist with locating the family for follow-up. These strategies are expected to reduce subject attrition due to the inability to locate families or families’ disinterest in further participation because of detachment from the research team. Monthly contact will also enable us to ascertain any parental concerns about the adolescent’s risk status. It is an opportunity to ask questions concerning risk factors and treatment follow-through that can guide the decision to recommend a face-to-face evaluation. This is consistent with NIMH recommendations for regular assessment of risk status when conducting intervention studies with suicidal persons (Issues to Consider in Intervention Research with Persons at High Risk for Suicidality, 2000).

To enhance participation and partially compensate adolescents and parents/guardians for their time, we will offer adolescents $20 for completion of baseline, 6-week, 3-month, and 6-month assessments and $30 for completion of the final 12-month assessment. We will offer each parent/guardian $20 for completion of the baseline and 14-16-week assessment and $30 for completion of the final assessment.

Data Collection/Management. Careful control and monitoring of patient diagnostic interviewing, assessments, and data collection procedures will be maintained across sites through cross-site training, weekly site visits, and regular telephone conversations. The assessors will be blind to participants’ conditions at each data point. The Project Coordinator will divide time between sites and maintain consistency in patient recruitment, interviewing, and coding procedures. All decisions concerning these procedures or special circumstances will be documented in writing so that standardized procedures will be followed.

Tracking records will be kept for each of the following: (a) percentage of adolescents at participating hospitals, 13 to 17 years of age, who are screened for study eligibility; (b) percentage of eligible adolescents with parent/guardian written informed consent and adolescent consent to participate; (c) percentage of participating adolescents with complete baseline evaluations; (d) percentages of participating adolescents assigned to TAU+YST who nominate at least two caring adults (with parental permission to contact them); (e) percentage of eligible youth for whom parental consent is obtained to contact caring persons; (f) percentage of nominated support persons who complete YST Psychoeducation session. Intervention specialists will also keep track of weekly contacts with nominated persons.

Efficient research management methods will be emphasized. The status of recruitment, monthly telephone check-ins, completed assessments, and data entry progress will be monitored by computerized checklists. Regular communication between interviewing/evaluating project staff and data management staff will ensure accuracy and improved understanding of instruments and methods. In addition, data accuracy will be promoted by the use of (a) different staff for scoring measures and checking/editing measures, (b) different staff for double-entry of data with verification and consistency checks.

Confidentiality and security of patient records will be a top priority. University of Michigan Hospital employees sign a pledge of confidentiality and are informed that their positions depend on adhering to the pledge. Techniques to safeguard confidentiality include the use of unique identification numbers, storage of data in locked files, maintaining identification numbers/names in a locked file and separate office from data files. Furthermore, no participant identifying information will be stored on the computer network. Despite the involvement of a large number of adolescents in our preliminary YST study during the past two years, we have had no instance of a security violation or lost data.

Measures

Table 4 lists the adolescent and parent/guardian measures that will be used and provides information concerning assessment domain, informant, and time points. In addition, copies of all measures are included in Appendix F. The major domains of assessment are adolescent functioning; adolescent perceptions of family and social support; parent psychiatric symptoms; mental health service utilization; consumer satisfaction; and support person functioning. In choosing these measures, a consideration was respondent burden, particularly given the difficulties that suicidal adolescents and their families have with scheduled appointments. We also took into account the relationship between length of the assessment battery and the risk of attrition (e.g., Chorpita et al., 1998). It has been our experience that a more extensive assessment
battery is possible with the adolescents because it can usually be completed while they are in the hospital. With their parents or guardians, however, we have found that it is critical to limit the assessment battery to a size that can feasibly be completed by the family during hospitalization. The interview is recorded by project staff (the CAPA) will be 

Adolescent functioning

Child and Adolescent Psychiatric Assessment (CAPA; Angold, Prendergast, Cox, Harrington, Simonoff, & Rutter, 1995; Angold & Costello, 2000). The CAPA is an interviewer-based psychiatric interview designed for youth between the ages of 9 and 17 years. It requires approximately 1 1/2 hours for administration. The interview guide provides a structure for posing questions to determine whether symptoms, as defined in a detailed glossary, are present or absent. The CAPA assesses the broad range of diagnoses in addition to information concerning onset dates, duration, frequency and intensity of symptoms. Its primary focus is on the 3-month period preceding the interview, although information is collected from nonrecent time periods. Each assessable symptom falls into one of 11 diagnostic subgroups. A composite psychosocial impairment by child self-report has been reported as 0.77 (Angold & Costello, 1995). The project coordinator and research associates will participate in the formalized CAPA training program.

The CAPA was chosen because of its solid psychometric properties, its feasibility of use with graduate student or masters’ level interviewers, its inclusion of detailed questions on “Suicide and Self-Injurious Behavior” and “Family Structure and Function,” and its extensive and wider measurement of impairment. A combination of impairment is list of diagnoses does not capture the extent of impairment that can be associated with comorbid conditions.

Parents/guardians will complete only sections of the CAPA. It has been our experience that respondent burden is particularly critical for parents when their child is psychically hospitalized. We have found that it is extremely difficult to have parents return for a second full evaluation session during a brief hospital stay. Because the adolescents are inpatients, it is much more feasible to involve adolescents in two full evaluation sessions. The CAPA Parent Interview sections incorporated in this study will include Depression, Suicide and Self-Injurious Behavior, Hypomania and Mania, Oppositional/Conduct Disorder (includes alcohol/substance use), and Psychosis. These were chosen because we believe affective disorder and suicidal behavior questions are particularly critical to hypothesized study outcomes, and because parents may be helpful as informants for externalizing behavior problems (e.g., Achenbach et al., 1987).

Child and Adolescent Functional Assessment Scale (CAFAS; Hodges, 1996; Hodges & Wong, 1996). The CAFAS assesses functional impairment in the areas of school/work, home, community, self-care/safety, behavior towards others, and caregiver resources. It has demonstrated high test-retest reliability, interrater reliability, construct related validity, and predictive validity. The CAFAS has been used in studies of youth mental health (e.g., Costello et al., 1996). Youth Self-Report (YSR; Achenbach, 1991). The YSR includes competence and behavior problem scales such as withdrawn, anxious/depressed, thought problems, delinquent behavior, and aggressive behavior. It has strong psychometric properties and provides a broad view of youth functioning. Scale development was based on 1,272 clinically referred youths and normed on 1,315 non-referred youths.

Suicidal Ideation Questionnaire-Jr. (SIQ-JR; Reynolds, 1988). The SIQ-Jr is a 15-item self-report questionnaire assessing the frequency of a range of suicidal thoughts. Total scores have excellent, well-documented psychometric properties (Reynolds, 1988, 1992). The SIQ-Jr total scores of psychiatrically hospitalized adolescents have been found to be predictors of suicidal thoughts and attempts 6-months post-hospitalization (King et al., 1997a).

Children’s Depression Rating Scale. Revised (CDRS-R; Poznanski & Mokros, 1996; Poznanski et al., 1985). This semi-structured interview will be administered to adolescents for the purpose of assessing depressive symptoms during the previous two weeks. Originally developed to assess depression in children 6- to 12-years of age, the CDRS-R has also demonstrated strong psychometric properties, including concurrent and predictive validity, in studies with adolescents (e.g., Emelie et al., 1997; Rintelmann et al., 1996; Shain et al., 1990). The CDRS-R includes 17 symptom areas, which provides a broad coverage of depressive symptoms and utility in evaluating change in depression severity. It requires approximately 20-30 minutes for completion. As a clinician-administered interview, the CDRS-R also offers the opportunity for a face-to-face clinical evaluation of participating adolescents’ risk status (in keeping with Risk Management Protocol, Appendix C).

Beck Hopelessness Scale (BHS; Beck & Steer, 1993). The BHS includes 20 true-false items and requires 5-10 minutes for self-administration. It has strong psychometric properties (Tardiff, Leon, & Marzuk, 2000), including evidence of predictive validity. The BHS has been shown to be a significant predictor of eventual suicide in psychiatric inpatients (Beck et al., 1985) and outpatients (Beck et al., 1990). It has been associated with adolescent suicidal in a number of empirical studies (e.g., Lewinsohn, Rohde, & Seeley, 1996).

Personal Experiences Screen Questionnaire (PESQ; Winters, 1991; 1992). This self-report questionnaire screens for alcohol and other substance abuse. It requires ten to fifteen minutes for completion. The PESQ has shown high sensitivity and specificity in identifying substance use disorders.

Multidimensional Anxiety Scale for Children (MASC; March, 1997; March, Parker, Sullivan et al., 1997). The MASC is a 39-item self-report rating scale designed to assess a broad spectrum of anxiety symptoms in children and adolescents. Each item is scored on a 4-point scale ranging from never to often. The MASC includes four factors (physical symptoms, social anxiety, harm avoidance, and separation/panic) and a Total Anxiety Index. The MASC has good internal reliability coefficients and test-retest reliability. It has shown high specificity and sensitivity in differentiating children with anxiety disorders from healthy control subjects as well as sensitivity to therapeutic effects (Miller &
Kamboukos, 2000). An assessment of anxiety is included because of its importance to our understanding of suicidal adolescents’ post-hospitalization functioning (e.g., Goldston et al. 1999).

Critical Incidents Checklist (CIC; King, unpublished). This checklist was developed for the preliminary efficacy study of YST (Appendix E). It consists of a list of incidents, including such incidents as school suspension, school expulsion, alcohol/drug related incidents (school expulsions for use or possession, driving under the influence, assault and battery), psychiatric hospitalization, running away, and suicide attempts. The checklist is coded in terms of whether or not each type of incident occurred since the previous assessment time point.

Table 4. Adolescent and Parent/Guardian Instruments

<table>
<thead>
<tr>
<th>Domain</th>
<th>Instrument</th>
<th>Informant</th>
<th>Time Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adolescent Functioning</td>
<td>Child and Adolescent Psychiatric Assessment (CAPA; Angold, 2000; Angold et al., 1995)</td>
<td>A, P (partial)</td>
<td>Baseline, 3mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Child and Adolescent Functional Assessment Scale (CAFAS; Hodges, 1996; Hodges &amp; Wong, 1996)</td>
<td>P</td>
<td>Baseline, 3mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Youth Self-Report (YSR; Achenbach, 1991)</td>
<td>A</td>
<td>Baseline, 3mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Suicidal Ideation Questionnaire-JR (SIQ-JR; Reynolds, 1988)</td>
<td>A</td>
<td>Baseline, 6wk, 3mo, 6mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Children’s Depression Rating Scale, Revised (CDRS-R; Poznanski &amp; Mokros, 1996)</td>
<td>A</td>
<td>Baseline, 6wk, 3mo, 6mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Beck Hopelessness Scale (BHS; Beck &amp; Steer, 1993)</td>
<td>A</td>
<td>Baseline, 6wk, 3mo, 6mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Multidimensional Anxiety Scale for Children (MASC; March, 1997; March et al., 1997)</td>
<td>A</td>
<td>Baseline, 3mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Personal Experiences Screen Questionnaire (PESQ; Winters, 1991, 1992)</td>
<td>A</td>
<td>Baseline, 3mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Critical Incidents Checklist (CIC; King, 2000)</td>
<td>A, P</td>
<td>6wk, 3mo, 6mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Grade Point Average/Attendance Record</td>
<td>School</td>
<td>Baseline, 3mo, 12mo</td>
</tr>
<tr>
<td>Family and Social Support; Parent &amp; Family Functioning</td>
<td>Perceived Emotional/Personal Support Scale (PEPSS; Slavin, 1991)</td>
<td>A</td>
<td>Baseline, 6wk, 3mo, 6mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Perceived Social Support from Family (PSS-FA; Procidano &amp; Heller, 1983)</td>
<td>A</td>
<td>Baseline, 6wk, 3mo, 6mo, 12mo</td>
</tr>
<tr>
<td></td>
<td>Brief Symptom Inventory (BSI; Derogatis, 1993)</td>
<td>P</td>
<td>Baseline, 3mo, 12mo</td>
</tr>
<tr>
<td>Mental Health Service Utilization</td>
<td>Services Assessment &amp; Review Record (SARR; Preuss &amp; King, 2000)</td>
<td>P</td>
<td>6wk, 3mo, 6mo, 12mo</td>
</tr>
<tr>
<td>Consumer Satisfaction</td>
<td>Client Satisfaction Questionnaire-8 (Nguyen, Attkisson, &amp; Stegner, 1983; Attkisson &amp; Greenfield, 1996)</td>
<td>A, P</td>
<td>3mo</td>
</tr>
</tbody>
</table>

**KEY:**  A=Adolescent  P=Parent

School Records. Parent informed consent and adolescent assent will be requested to obtain each adolescent’s grade point averages (GPA) and attendance record (# absences) for the most recent grading/recording period.
Interpersonal Orientation Scale (IOS; Hill, 1987). This 26-item scale measures interest in affiliation under stressful and uncertain conditions and reasons that social contact may be rewarding to individuals. The response format consists of a 5-point Likert scale. Reported internal consistency coefficients (.70 to .90) and test-retest coefficients (.66 to .90) are acceptable. Factor analyses support the scale’s multidimensional construct. Correlations with other personality measures and relationship with role-played behaviors support the concurrent validity of the scale’s four dimensions, social comparison (“seeking information about self from others”), emotional support, positive stimulation, and attention (“desire for attention and praise”). The IOS is included to explore the relationship between interpersonal orientation and YST efficacy in males and females.

Family and Social Support; Parent and Family Functioning

**Perceived Emotional/Personal Support Scale** (PEPSS; Slavin, 1991). This scale assesses emotional support that is operationally defined as the extent to which personal relationships are perceived as close, confiding, satisfying, and helpful. Respondents are asked to list three important relationships in each of three categories (family members, nonfamily adults, and friends). For each of the nine listed relationships, respondents rate how much they talk with the person about personal concerns, how close they feel to the person, and how satisfied they are with the help and support the person provides. Ratings are made on 4-point Likert-type scales ranging from “hardly at all” to “very much.” Ratings of relationships within each of the subscales are averaged to form subscales, each with a possible range of 1 to 4. Reliability and validity studies included 1697 adolescents, ranging in age from 13 to 19 years. Internal consistency (.87 for each subscale and .90 for test-retest reliability over a 2-week period/78 for family, 78 for nonfamily, and 79 for reasonably high, respectively).

**Perceived Social Support from Family** (PSS-Fa; Procida & Heller, 1983). This 20-item self-report scale assesses an individual’s perception of social support from family. It consists of declarative statements to which the individual responds “Yes”, “No”, or “Don’t Know.” The scale has excellent internal consistency (.88), test retest reliability (.85) over a 1-month interval, and factor analysis has revealed a single factor. A number of published studies attest to its concurrent validity in assessing adolescents’ general perceptions of support from family members (e.g., Cumsille & Epstein, 1994; Skinner & Hampson, 1998).

Mental Health Service Utilization

**Services Assessment Record – Parent Interview** (SARR; Preuss & King, unpublished). This assessment record has been specifically developed for this efficacy study to assess the nature of treatment-as-usual and the extent of suicidal adolescents’ treatment attendance during the 12-month period following psychiatric hospitalization. The structure and format of the SARR is modeled after the format of the Services Assessment for Children and Adolescents - Parent Interview (SCA-PI; Jensen et al., 1995), which has been used in the MTA study.

**Client Satisfaction Questionnaire -8** (CSQ-8; Hargreaves & Atkinson, 1978). The CSQ-8 is an 8-item, self-report form designed to assess client’s satisfaction with quality of service, type of service, outcome and overall satisfaction. Average administration time is 5-8 minutes. Each item is scored on a 4-point scale with individually specified anchors. The CSQ-8 has demonstrated high internal reliability coefficients across a number of studies and high correlation with other measures of global satisfaction. In addition, the CSQ-8’s brevity and ease of administration enhance the measure’s use for research purposes by not overburdening participating patients or staff.

**Exit Interview with Adolescents**. As part of the 3-month assessment, adolescents in the TAU+YST group will be asked to respond to open-ended questions concerning what, if anything, they found to be most and least helpful about YST. We will also ask them for any suggestions they may have for improving this intervention.

Nominated Support Person Information Form. This form is completed by the nominated person. It requests demographic information and information about the relationship of the support person to the youth (e.g., parent, school staff member, etc.).

**Family and Social Support; Parent and Family Functioning.”**

**Data Analysis Plan**

We aim to address the following specific aims: 1) At the end of the intervention, are program effects maintained over time? To address the first two questions, which pertain to Hypotheses 1.a. and 1.b. in the Specific Aims, we will separately analyze the suicide ideation, internalizing behavior, and adaptive functioning outcome scores obtained at the end of the intervention. For each of these variables, we will fit a general linear model that will allow us to test for main effects of intervention, gender, and site, as well as for intervention by gender and intervention by site interactions. In each of these models, the value of the dependent variable observed at baseline will be included as the primary covariate; additional baseline measures will also be considered for inclusion. The third question (Hypothesis 1.c. of Specific Aims) addresses whether or not program effects are maintained over time. We will investigate this question by using repeated measures analysis of variance models that will be analyzed using PROC MIXED in SAS (as discussed in
more detail below). In these models, we will analyze data from the three primary outcomes (3 months, 6 months, and 12 months). The primary independent variables will be the main effect for intervention, the main effect for time, and a time by intervention interaction effect. Other factors that will be considered include site, a site by intervention interaction, gender, a gender by intervention interaction, a gender by time interaction, and a gender by time by intervention three-way interaction. We will also consider the effects of suicidal ideation and suicide attempt. We believe that the effects of suicidal ideation and suicide attempt on the three primary outcomes can best be explored using repeated measures analysis of variance models discussed in conjunction with specific aim 1. The primary hypotheses of interest in these augmented models will be the significance of these two factors and of interactions involving these factors. It will be of interest to see if the inclusion of these factors meaningfully decreases the magnitude of the intervention effect. If this were to be the case, it would suggest that the primary program effect was obtained through program adherence and not from an intervention-induced increase in suicidal ideation or suicide attempt.

The preliminary study provides us with effect size estimates relevant to Specific Aim #1 and primary study purposes. We will approach this question by adding these two variables to the general linear model and repeated measures analysis of variance models discussed in conjunction with specific aim 1. The power available to detect gender by treatment interaction effects, we can use a two sample t-test to recruit 532 suicidal adolescents into the study. With an expected dropout rate of 10%, we anticipate a final participant sample size of 479 (239 in each group). This would include approximately 240 adolescents in the TAU and TAU+YST groups and approximately 239 adolescents in the TAU and TAU+YST groups. This would allow us to conduct sensitivity analyses using non-parametric data within each of the four treatment groups.

Secondary Analyses. Since the cost of carrying out a study like the one proposed is high and the marginal cost of collecting additional data is low, our plan is to obtain a rich data set that includes several measures for use as both covariates and dependent variables in exploratory analyses. An example concerns the use of information on psychiatric disorders and comorbid conditions. We will test whether or not, and the extent to which, participants with conduct disorder, substance abuse, or some other condition respond to the intervention by including main effects for diagnosis and an intervention by diagnosis interaction in models. Similarly, we will use information on treatment as usual variables observed outcomes or affects the success of the intervention. A final “secondary” analysis concerns the use of the clinical monitoring data collected during the intervention at 6 weeks. We will use general linear models to determine the extent to which program outcomes at 3 months can be predicted by the earlier data. If the ultimate outcome of the intervention can be predicted at an early stage, changes in the intervention could be implemented for those patients for whom it is appearing to fail. We will also conduct preliminary cost-benefit and cost-effectiveness analyses (Measures section: Preliminary Data on Intervention Cost) to include the results of these “secondary” analyses, we will suggest that the results are suggestive rather than conclusive because of the exploratory nature of these investigations.

Statistical Computing and Data Base Management. As soon as possible after a study measure has been filled out, it will be examined by a research staff person to check for obvious errors or omissions. This initial screening process will ensure that most data problems can be identified and fixed at a time when correct information can be obtained. Data entry will take place in batches with accuracy verified by two different staff members. We will carry out range checks on individual data items. We will compute and examine relevant summary measures. When these checks have been passed successfully, the data will be added to the raw data archive that will be stored on a “network” disk drive that is automatically backed up every week. Additionally, we will periodically copy all current data files onto a floppy (or Zip) disk that will be stored off-site for additional protection of the data archive.

We plan to use SPSS and SAS to carry out study analyses. Either system can carry out the requisite data base management tasks and compute the general linear model analyses but we will rely on SAS for analyses where we believe the implementations are more sophisticated. Specifically, we will use PROC MEANS in SAS for a general mean comparison and using PROC PHREG for Cox proportional hazard models.

Problems and Possible Solutions. The biggest problem we face concerns the fact that we will lose some participants. For Specific Aim #3, analyses of treatment adherence and social support will be based on tests concerning the significance of regression coefficients. With the anticipated final sample sizes of 240 per group, we will have substantial power to detect quite small effects. Specifically, in the context of a regression model with 10 variables which produce an
R-square of 0.20, if an additional variable increases the R-square value by 0.02 or 0.03, we will have, respectively, powers of 0.93 and 0.99 to detect this effect. Because our preliminary study analyses showed that social support was positively correlated with reduced depression severity (r = .36) and reduced internalizing behavior problems (r = .26), it is reasonable to assume that these variables will produce increases in R-square for which we will have adequate power.

For Specific Aim 3, we do not have preliminary data on suicide attempts over 12 months, but we anticipate that the treatment as TAU group will experience an 18% rate of attempts. This estimate is based on outcome studies of psychiatrically hospitalized suicidal adolescents (e.g. Brent et al. 1993b; King et al. 1995; Goldston et al. 1999), and our preliminary study that revealed an approximate rate of attempts of 12% during a 6-month period. If the TAU+YST group experiences rates of 9%, 10%, or 11%, the power which we will have to detect these changes will be, respectively, .90, .82, and .71.

Human Subjects

This study will involve recruitment of 152 suicidal adolescents at the Child and Adolescent Psychiatric Hospital, University of Michigan, and 380 suicidal adolescents at Havenwyck Hospital, a large, private psychiatric hospital serving a three county area in Southeastern Michigan. Recruited adolescents will range in age from 13 to 17 years and be seeking services at one of the two participating hospitals. The inclusion and exclusion criteria are discussed in the Research Design section. Adolescent males and females, and adolescents from all racial/ethnic groups will be recruited. The gender and racial/ethnic distribution is expected to be in keeping with the present demographic patterns at these hospitals and in the state of Michigan. At CAPH, it is expected to be approximately 88% Caucasian, 8% African-American, and 4% from other racial/ethnic backgrounds. These percentages are expected to be 76% Caucasian, 16% African-American, and 8% from other racial/ethnic groups at Havenwyck Hospital. All adolescents who present to the inpatient and outpatient units of these hospitals and who meet study inclusion/exclusion criteria will be screened for study participation.

Percentages of Minority Representation in Michigan (U.S. Bureau of the Census, 7/1/99) and in YST Preliminary Study

<table>
<thead>
<tr>
<th></th>
<th>American Indian or Alaskan Native</th>
<th>Asian or Pacific Islander</th>
<th>Black</th>
<th>Hispanic</th>
<th>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michigan Census Data</td>
<td>0.6</td>
<td>1.7</td>
<td>14.3</td>
<td>2.8</td>
<td>83.4</td>
</tr>
<tr>
<td>YST Preliminary Study</td>
<td>3.2</td>
<td>2.6</td>
<td>13.2</td>
<td>1.1</td>
<td>78.9</td>
</tr>
</tbody>
</table>


We anticipate that our recruitment and participation rates for minority groups will approximate that of the state of Michigan. As is evident in the table above, the participation rates in our preliminary study were relatively similar to the proportions reported by the U.S. Bureau of the Census for Michigan in 1999. We expect to recruit approximately 14-15% Black youth and 3% Hispanic youth for participation in this study. We plan to monitor these participation rates quarterly. If numbers fall below these expected proportions, extra effort will be extended to recruit these groups. As examples, to enhance recruitment of black youth, we would involve members of the inpatient social work staff who are of a similar minority background to meet together with a member of the research team and the family to discuss possible participation. Another strategy would be to accommodate the transportation or other needs of potential minority participants. Finally, we would make an effort to ask those who decline participation about what would have made participation or involvement more appealing to them.

Several human subject protection systems will be utilized in the proposed study. Before the project begins, Institutional Review Board approval will be obtained from the Institutional Review Board for Human Subject Research at the University of Michigan Medical School (IRBMED). The informed consent form will include all of the components recommended in the developing NIMH policy recommendations statement concerning intervention research with suicidal patients. The principal investigator of this study was a contributing author to that statement. We plan to secure “continuing approval” for the project each year and to notify the IRBMED committee if any adverse events occur in the conduct of the research. All members of the project team, including referring house officers and staff, the project coordinator, research associates, and the research assistant, will be mentored on the ethical conduct of research, human subject protections, regulatory policies and bodies, and requirements.

As an added protection because the proposed study involves a high risk group of patients, we will establish a Data Safety Monitoring Board (DSMB) that will address project-specific issues concerning human subject protections on an
ongoing basis. They will consider issues related to recruitment, participant risk monitoring, and the appropriateness of alternative treatments. Members of this board include Gregory Hanna, M.D., Director, Division of Child and Adolescent Psychiatry, Department of Psychiatry, University of Michigan, Mary Fristad, Ph.D., Associate Professor, Ohio State University Medical School, and Mary Leonardi, M.S.W., A.C.S.W. Dr. Fristad is a clinical and research expert in psychosocial interventions with children and adolescents. Ms Leonardi has over 25 years of experience working with suicidal individuals and survivors of suicide, and is board member emeritus of the Michigan Association of Suicidology. The study has a Risk Management Protocol (Appendix C) that the DSMB will review on an ongoing basis in terms of individual participants and in terms of whether or not changes should be made to the protocol. This includes guidelines to be followed if there is a change in any participant’s level of risk during the course of the study.

Written informed consent will be obtained from participating adolescents’ parent/guardian, and written informed assent will be obtained from the adolescents themselves. Parents and guardians will be approached first after their child has been admitted to the inpatient unit and they have participated in admission interviews. We will ask the parents if it is a good time to discuss this project with them. If they would prefer to do so at another time, this will be arranged. The principal investigator, co-investigator, project coordinator, or fully trained project intervention specialist will explain the project to families and remain available as long as needed to address questions and concerns. It will be clarified fully that participation is fully voluntary and that withdrawal from the study is possible at any time. Participants will be given the names, telephone numbers, and addresses of the principal investigator and co-investigator so that they may contact these individuals with questions or concerns during the course of the project. The consent form includes detailed information concerning reasons for maintaining or breaking confidentiality. In keeping with our Risk Management Protocol (Appendix C), we have found that this approach works well and helps to emphasize support persons’ roles as caring adults rather than mental health professionals.

The source of baseline and follow-up assessment information on participants and support persons will include self-report questionnaires and semi-structured interviews with adolescents and their parents or guardians. In addition, permission will be requested from adolescents and their parents/guardians to obtain grade point averages and school attendance records. Demographic information will be obtained from nominated support persons.

Potential risks during the study include changes in adolescents’ risk status that warrant more reevaluation, more intensive intervention such as psychiatric hospitalization, or study discontinuation. These changes may be due to a progression in the psychopathology unrelated to intervention, stress or losses in the adolescent’s life, some adverse effect due to the intervention, or some combination of these factors. Because YST is a supportive intervention, it is not anticipated that the intervention alone will have adverse impact. Nevertheless, the protocol includes several measures to maintain awareness of the adolescents’ risk status so that the project team can respond appropriately. These measures include monthly telephone check-ins with families to see if there are concerns about the adolescents’ status, in-person assessments of the adolescent at 8 weeks, 14 weeks, 6 months, and 12 months, and a Risk Management Protocol (Appendix C). This protocol describes policies that will be in place for all participating suicidal adolescents (attentive and empathic listening, initial comprehensive suicide risk assessment, ongoing risk assessment, team approach, full disclosure of suicide risk concerns with adolescent’s parent(s), accessible information on emergency services, and documentation). It also specifies indicators of high risk status and the additional measures that we will take with adolescents who meet these criteria. In addition, the Data Safety Monitoring Board will address issues related to our risk assessment monitoring in an ongoing manner. Two of the project co-investigators, Drs. Quinlan and Venkataraman, are closely affiliated with psychiatric inpatient units such that hospitalization will be readily available if needed.

A second potential risk is “burnout” among nominated support persons. It may be difficult for some support persons to maintain contact with troubled adolescents on a weekly basis. We have addressed this in several ways. In our preliminary study, we found that six months was too long for many nominated support persons. It was evident, however, that almost all of them maintained regular contact with adolescents for at least three months. Thus, we have reduced the intervention period to three months. We also make it clear to the support persons that they are not responsible for the adolescents’ behaviors and that they can discontinue their involvement at any time. We are also available to them for additional telephone or in-person consultations, and give them telephone numbers for 24-hour emergency services.

Data from this study will provide critically important information on a new intervention strategy for suicidal adolescents. There is a paucity of empirical data on effective interventions for these youth and new strategies are needed that address the substantial problem of treatment adherence among these youth. In sum, the potential benefits for the research outweigh the minimal risks for participants.

**Consortium/Contractual Arrangements**
The project includes a subcontract with Havenwyck Hospital to recruit 380 suicidal adolescents for subject participation. The subcontract includes funds for a project co-investigator at Havenwyck, two clinical intervention specialists, two research associates, and secretarial and administrative support. Please see the Budget justification section for more information about the subcontract components, the Resources section for more information about Havenwyck Hospital. Project procedures will be the same at Havenwyck Hospital and the other recruitment site, the Child and Adolescent Psychiatric Hospital at the University of Michigan.

**Consultants**

Consultants include external members of the Data Safety Monitoring Board, Mary Fristad, Ph.D., and Mary Leonhardi, M.S.W., A.C.S.W.. These individuals will attend three meetings each year to consult on issues related to subject recruitment, study implementation, and participant risk assessment monitoring. They will also participate in four regularly scheduled telephone conference calls each year and be available for additional conference calls as needed. Their duties include completion of required DSMB reports to the IRB and NIMH. Each consultant is paid $3,000 per year during the 5-year project period.
References


*Psychopharmacology Bulletin, 21,* 979-989.


