

**Veterans Coping Long Term with Active Suicide  
IRB Protocol  
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This application proposes to conduct a fully powered clinical trial evaluating the effects of an innovative, adjunctive intervention to reduce suicidal behavior in a sample of recently hospitalized military veterans. “Veterans Coping Long Term with Active Suicide Program” (CLASP) is an innovative, telephone-based intervention, which combines elements of individual psychotherapy, case management and significant other/family therapy. Two hundred patients admitted to the Providence VAMC inpatient unit for a suicide attempt or suicide risk will be randomized to either the CLASP intervention or a Safety Assessment and Eollow-up Evaluation (SAFE) control comparison, both delivered as adjuncts to VA treatment as usual. We propose to conduct follow-up assessments during both the end of the active intervention phase (3 and 6 months post-discharge from hospital) and again at 9 and 12 months post discharge.

**A. Objectives**

The primary objective is to test the efficacy of the CLASP intervention compared to a treatment as usual plus SAFE control condition. The following hypotheses will be tested:

**A1. Primary Hypothesis**

Fewer patients assigned to the CLASP intervention will have subsequent suicide attempts compared to those receiving SAFE.

**A2. Secondary Hypotheses**

When compared to patients receiving SAFE, patients assigned to the CLASP intervention will have: a) fewer re-hospitalizations due to suicide risk, and b) lower severity and chronicity of suicidal ideation.

**A3. Tertiary Hypotheses**

When compared to patients receiving SAFE, patients receiving the CLASP intervention will have: a) greater engagement in follow up psychiatric treatment, b) lower levels of overall psychiatric symptoms and c) greater overall psychosocial functioning.

**B. Background**

For the first time in recorded history, suicide rates in military Veterans have exceeded civilian rates [1, 2]. Suicide is one of the leading causes of death among military personnel [2], and in some branches of the military, suicide is the leading cause of death after combat-related incidents. Critically, the presence of a single episode of suicidal ideation or a single suicide attempt places an individual at a greatly increased risk of future suicidal behavior [3]. Research in civilian populations has found that suicide attempters are 38 more times likely than individuals in the general population to complete suicide in the future [4]. In the year following a suicide attempt, 0.8 – 2.6% of suicide attempters completed suicide, with that estimate increasing to as high as 5 – 11% after 9 years [5]. One estimate suggests that approximately 15% of all individuals with one or more suicide attempts will go on to complete suicide [6].

Rising rates of psychological disorders in Veterans has also increased their risk of suicide [7-9]. A 2010 Army report [10] found that the percentage of suicide deaths among soldiers with PTSD grew from 4.6% in 2005 to 14.1 in 2009 and that substance abuse was indicated in 1/3 of Army suicide deaths. Some estimates indicate that as many as 1 in 5 military Veterans who seek mental health treatment have contemplated suicide [11]. OEF/OIF/OND military personnel, on average, have more frequent deployments, increased operational demands, and insufficient quantity and quality of down time between deployments than do Veterans from previous military conflicts. All of these factors cause strain on interpersonal relationships and, consequently, may impact suicide risk [12]. For example, 65% of service members who complete suicide had a failed relationship (intimate, marital, or non-intimate relationships) prior to their death [13]. Other research has revealed a number of risk factors to suicide in military populations including, alcohol problems, relationship dissatisfaction, lack of unit cohesion and unity, and low social support [11].

**B1. Despite advances in treatment of psychiatric disorders, suicide rates have not decreased**

It has been estimated that over 90% of completed suicides are associated with mental illness [4, 14-17]. In their comprehensive meta-analysis of suicide research, Harris and Barraclough [4] reported that psychiatric illness and substance use disorders were closely associated with risk of completed suicide. Given the comorbidity between psychiatric disorders and suicidal behavior, one might expect a decline in suicidal behavior given recent advances in psychiatric care. Further, medication and psychotherapy treatments for psychiatric disorders are more widely available now than ever before. However, rates of completed suicide Nationwide have remained relatively stable over the past 50 years, and have even increased since the year 2000. Even though treatment of psychiatric disorders has made significant progress, the prevention of suicidal behavior in the United States has lagged behind. New treatments specifically developed to prevent suicidal behavior and designed to work in concert with traditional mental health treatment are clearly needed.

The military has been at the forefront in supporting research to understand and prevent suicide in Veterans. Yet, despite suicide prevention being highlighted as a top funding priority, military suicide rates have continued to rise over the last 10 years and in fact, have now surpassed civilian suicide rates for the first time in recorded military history [18].

### **B2. The time following discharge from the hospital is a period of high risk**

The period following discharge from a psychiatric hospitalization is a time of substantially increased risk for suicidal behavior [19]. The risk for suicide appears to be highest immediately after discharge and then declines over time, but remains high for at least the following year. The highest risk period appears to be in the first month after discharge [3, 20, 21]; yet elevated levels of risk for subsequent suicidal behavior remain up to one year post-discharge, with the risk of suicide increasing 30-60 fold in months 6-12 following discharge [3, 20, 22]. Taken together, this research suggests the period following hospital discharge is a time of uniquely high risk for suicidal behavior, and that for maximum effectiveness, preventative efforts should focus on the period immediately following hospitalization.

### **B3. What do we know about current treatments to prevent suicidal behavior?**

**B3.1 Relatively few trials have been conducted.** Despite the public health significance of suicidal behavior, relatively few controlled trials have evaluated interventions to reduce suicidal behavior, especially in the U.S. In their 2000 review of this literature for the Cochrane Library, Hawton et al [23] identified 23 controlled trials of suicidal behavior in adults. While there have been a few studies published after this review [24-29], it is clear that compared to the thousands of trials of treatments for depression or anxiety, treatment of suicide is a very under-studied area. Of even greater concern is the fact that only a minority (< 20%) of these trials have been conducted in the United States. In the past 10 years, there has been only one, well-powered published clinical trial evaluating an intervention to reduce suicidal behavior in adults, which was conducted in the US [30]. While there are a handful of trials currently underway, the lack of US based clinical trials focusing on suicidal behavior is striking.

**B3.2 Overall, the results of available studies have been mixed.** Virtually all reviews [26-31] have commented on the paucity of studies, small sample sizes, small effects and inconsistent results. The strongest findings have come from individually based psychotherapy that focus specifically on suicidal behavior, such as Dialectical Behavior Therapy [32, 33] and Cognitive Therapy for Suicide Attempters [25, 34]. Unfortunately, these treatments are intensive and require a significant commitment on the part of the patient. Since research indicates that Veterans tend to underutilize mental health treatments and report high levels of mental health stigma, these intensive treatments may be unsuccessful in engaging and retaining Veteran populations. Other types of interventions such as brief problem solving interventions, telephone outreach, and mailing of "caring cards", have been found effective in some studies but not in others [23][35][36][37][38][39-47].

## **C. Preliminary Studies/Work Accomplished**

### **C1. Pilot Trial**

We have conducted a pilot clinical trial using identical subject selection and procedures to the trial proposed in this application. 86 patients who were admitted to a private psychiatric hospital due to a suicide attempt (n=35) or suicidal ideation with intent (N=51) received treatment as usual in the

community plus randomization to one of two treatment conditions: 1) SAFE or 2) CLASP for a six month period. Assessments were completed during hospitalization, and 3 + 6 months post discharge.

### **C1.1 Subject Characteristics.**

Gender (% female)	68%
Age	43.7 years
Primary Diagnosis	Major Depression – 64%: Bipolar Disorder (depressed) – 24% Mood Disorder NOS – 3.5%: Depressive Disorder NOS – 3.5% Substance Use Disorder – 2.5%: Anxiety Disorder – 2.5%
Lifetime history of suicide attempt	74%
Lifetime history of multiple suicide attempts	47%
Lifetime history of any suicidal behavior (includes preparatory acts, interrupted and/or aborted attempts)	88%
Suicide attempt prior to hospital admission	38%
Any suicidal behavior prior to hospital admission	67%

**C1.2 Acceptability and Satisfaction.** A proportion of patients never engaged in their assigned treatment and were unable to be contacted after discharge from the hospital (24/86 = 28%). Similar proportions of these “non-engagers” were found in CLASP (10/39, 26%) and SAFE (14/47, 30%). Among those patients who did engage in the CLASP intervention, adherence was quite high with approximately 75% of the planned CLASP contacts (in-person and phone calls) completed to both patient and significant other. Satisfaction was also high among patients receiving CLASP, with scores on the Client Satisfaction Questionnaire almost uniformly high (CSQ total score = 29.2). On overall ratings of overall satisfaction, the mean was 3.6 on a scale of 1 (“quite dissatisfied”) to 4 (“very satisfied.”). Similar ratings of satisfaction were also found with the patients who received the SAFE condition (CSQ = 30.5). Although we did not do formal assessment of significant others’ satisfaction, our clinical sense is that significant others were also extremely pleased with their participation. Finally, community providers were quite acceptable to receiving the assessment reports as part of the SAFE procedures – with none of 149 community providers whom we contacted opting out of receiving reports.

**C1.3 Outcomes.** Our two main outcomes were subsequent: a) suicide attempts and b) re-hospitalization due to suicide attempt or risk. We collected six months of data from all possible sources, including follow-up assessments, b) chart reviews, c) significant other reports, and d) community clinician reports. In the table below, we present the conservative intent-to-treatment data, including all patients randomized to each treatment condition, even if they did not participate in the intervention. No patient in the study completed suicide.

# of patients with	CLASP	SAFE	Risk Reduction	95% CI	X <sup>2</sup>	p	Number Needed to Treat
Suicide attempt	3/39 (8.3%)	10/47 (21%)	13.8%	-.8 – 28%	2.1	>.07	8
Re-hospitalization	8/39 (20%)	17/47 (36%)	15.6%	-3 % - 34 %	1.83	> .09	7

**C1.4 Discussion.** The results from our pilot work are very encouraging. We have developed an innovative, structured, intervention which can be administered by relatively inexperienced clinicians with minimal training and which is acceptable to a majority of suicidal hospitalized patients. Even more importantly, our pilot data suggests that this intervention has the potential for significantly reducing subsequent rates of suicide attempts and re-hospitalizations, with the CLASP condition having only a third the number of patients who made suicide attempts and half the number of patients with re-hospitalizations as the SAFE condition. The size of differences in suicide attempts between the intervention and control conditions were slightly lower but similar to those reported by Brown et al [30] with a more intensive individual cognitive therapy intervention (18% risk reduction). However, given the relatively small sample size of our pilot study, the 95% confidence intervals are relatively large and include 0 (no difference). Thus, while our pilot data provide strong support for the efficacy of the CLASP intervention, a larger, more fully powered trial is necessary.

## **D. Research Design and Methods.**

## **D1. Overview**

Two hundred Veterans admitted to the Providence VAMC psychiatric inpatient unit or medical unit due to suicide attempt or suicidal ideation with any methods, plan, and/or intent to make an attempt will be recruited and randomly assigned to receive treatment as usual and either: a) SAFE or b) CLASP. The active interventions will begin during hospitalization and continue for 6 months post-discharge. After the intervention's end, patients will be followed for follow-up assessments for an additional 6 months (12 months post-discharge).

## **D2. Participants**

Participants for this study will consist of 200 inpatients from the Providence Veterans Affairs Medical Center and 100 identified significant others. **Inclusion criteria** for the Veteran participant will include: 1) suicide attempt or suicidal ideation with any methods, plan, and/or intent to make a suicide attempt within 1 week of hospitalization as indicated on the hospital chart and/or confirmed by administration of the C-SSRS [48]; 2) age greater than 18 years, 3) have a telephone, and 4) ability to speak, read, and/or understand spoken English sufficiently well to complete the procedures of the study. **Exclusion criteria** will include: 1) diagnosis of primary psychotic disorder based on chart review (e.g. Schizophrenia or Schizoaffective disorder), 2) diagnosis of borderline personality disorder (based on screening with MSI-BPD [49], followed by BPD section of SCID-II if MSI-BPD is positive), or 3) cognitive impairment which would interfere with adequate participation in the project (MMSE [50] < 20).

We will also enroll patients' significant others/family members for those assigned to CLASP intervention; n=100). Significant others will only be recruited to serve as a primary support person for the intervention. Their participation will be limited to 1 joint-family session with the Veteran participant and a series of phone sessions. All sessions will be focused on the Veteran participant. Significant others will not be asked to complete any questionnaires or interviews and no personal information other than name and phone number will be collected. **Inclusion criteria** for significant others will include: 1) age greater than 18 years, 2) have a telephone, & 3) ability to speak, read, and/or understand spoken English sufficiently well to complete the procedures of the study.

### **D2.1 Identification of potential participants.**

- 1) Chart review: Research staff will use CPRS to identify at-risk Veterans using the inclusion and exclusion criteria listed above. Potentially eligible participants will be approached on either the inpatient psychiatric unit or medical unit by a member of our research team and will be given information about the study. If they are interested in participating they will complete informed consent prior to any assessment or study participation. All informed consent of Veterans will occur in person while the participant is on the inpatient unit.
- 2) Physician and/or therapist referrals: Study personnel will provide study brochures and flyers to providers and staff on the inpatient unit. A member of the research staff will stop by the unit on a weekly basis to talk to any identified patients or answer questions about the study.
- 3) Referrals from the Providence VAMC Suicide Prevention Coordinator: Dr. Primack will provide study brochures and flyers to the local Suicide Prevention Coordinator and potential participants will be encouraged to contact the study if interested in participating.

**D2.2 Recruitment of Veteran patients.** There are several methods of recruitment that will be employed.

- 1) A recruitment brochure has been designed to reach eligible Veterans. Included on this brochure is contact information for the principal investigator for a screening. Brochures are distributed to inpatient physicians, the Suicide Prevention Coordinator and staff on the inpatient unit.
- 2) Presentations are made by the principal investigator to Veteran, inpatient staff, and the Suicide Prevention Coordinator to provide an opportunity for referring agencies, or potential participants, to inquire further.
- 3) VA clinicians who have patients interested in the study can obtain a release of information for our study to contact the patient directly.

**D2.3 Recruitment of family members or significant others.** Veterans randomized to the intervention arm of the study will be asked to identify a significant other to participate in the intervention with them. Significant others can be family members, partners, close friends, or other

identified support persons. In all cases, the Veteran patient will be asked to identify a significant other to participate with them prior to any contact between significant other and research staff. Several methods of recruitment for significant others will be used.

- 1) Once enrolled, patients will be asked to speak to their identified family member about the study. Research staff will provide enrolled patients with a brochure to give to family members about the study. Significant others who are interested in the study or who have questions can contact study personnel directly.
- 2) Research staff will be available to discuss the study with the patient's family member during visiting hours on the inpatient unit.
- 3) Enrolled patients will be asked to reach out to significant others and ask them to participate with them in the study. Patients will be able to coordinate with research staff to find a date for the joint Veteran-significant other session (typically scheduled during the inpatient hospitalization) and informed consent will be obtained at the beginning of the joint session.

### **D3. Screening**

Our team has developed effective procedures for recruiting from the inpatient milieu and Dr. Primack will consult with Providence Suicide Prevention Coordinator and inpatient staff to ensure the best methods for recruitment within the VA system. The research assistant will screen newly admitted patient charts for suicide risk and will conduct bi-weekly check-ins with the Providence VAMC Suicide Prevention Coordinator to identify potentially eligible participants. Patients meeting this initial criterion will be approached by research staff, provided a description of the study and study aims, and will be asked if they are interested in participating in the study. Informed written consent will be obtained prior to any assessment. The research staff member will be responsible for explaining the study and obtaining the participant's signed informed consent. Participants will be screened with the C-SSRS prior to any other assessment measures. Participants endorsing suicidality precipitating admission as indexed by the C-SSRS will be invited to complete the full initial assessment to determine eligibility for participation. Participants still meeting our inclusion criteria will be invited to participate in the full study.

### **D4. Informed Consent**

Written informed consent will be obtained while the Veteran patient is on the inpatient unit. Research staff will coordinate with inpatient staff to ensure that a) the patient is able to understand the study and research requirements and b) the informed consent, screenings, assessments, and intervention sessions are as minimally disruptive as possible.

All informed consent will be obtained in-person by a member of our research staff prior to the completion of any further screening or assessments. Informed consent will take place on the inpatient unit at Providence VA Medical Center located at 830 Chalkstone Avenue, Providence, RI 02908-4734. If the participant does not provide consent he/she will be informed that he/she is ineligible for the study, but will still be offered treatment referrals. If the Veteran would like to participate, the research staff member will obtain signed informed consent for the Veteran's participation.

### **D5. Assessments**

Participants will be assessed in-person at 5 time points: baseline, 3 months post-hospitalization, 6 months post-hospitalization, 9, and 12 months post-hospitalization. In addition to the usual demographic variables, we will assess seven areas: a) psychiatric diagnosis, b) suicidal ideation and behavior, c) hopelessness, d) social and family support, e) values, f) psychiatric symptoms, and g) treatment utilization. The specific measures to be used are listed in the following table. Detailed description of measures and their psychometric properties are limited to the references. Our assessment battery has been kept relatively brief in order to allow completion prior to hospital discharge and to enhance compliance at follow-up assessments.

We will make every effort to follow all subjects through the twelve-month period regardless of their continued participation in CLASP, SAFE or subsequent suicide attempts or hospitalizations. To reduce attrition, subjects will be paid \$50 in electronic funds transfer (EFT), cash, prepaid debit cards, or gift cards for completion of each follow-up assessment. If needed, we will conduct interviews by phone. Patients who are having continuing difficulties may feel discouraged and may fear that they have disappointed the experimenters. To encourage compliance among this group, patients will be

informed that the information they provide is extremely important regardless of how well they may feel they are doing.

	Baseline	3,6,9,12 month Follow-up
<b>Demographics</b>	X	
<b>Diagnosis and Cognitive Impairment</b>		
The McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD) [49]	X	
Mini-Mental State Exam (MMSE) [50]	X	
Structured Clinical Interview for the DSM-IV Axis I Disorders (SCID-I) [51]	X	
Structured Clinical Interview for the DSM-IV Axis II Disorders – Borderline Personality Disorder (SCID-II BPD) [52]	X	
PTSD Checklist (PCL) [53]	X	X
Quick Inventory of Depressive Symptomology (QIDS) [54]	X	X
Psychiatric Diagnostic Screening Questionnaire (PDSQ) [55]	X	
<b>Suicidal Ideation and Behavior</b>		
Columbia Suicide Severity Rating Scale (C-SSRS) [48]	X	X
Longitudinal Interval Follow-Up Evaluation (LIFE) [56]– suicidal ideation and behavior		X
Record review (hospital, state death registry, national death registry)		X
<b>Hopelessness</b>		
Beck Hopelessness Scale [57]	X	X
<b>Social and Family Support</b>		
Social Support Behaviors Scale (SS-B) [58]	X	X
<b>Values</b>		
Valued Living Questionnaire [59]	X	X
<b>Psychiatric Symptoms</b>		
Brief Symptom Inventory [60]	X	X
<b>Overall Functioning</b>		
WHODAS II [61]	X	X
<b>Treatment Utilization</b>		
Treatment History Interview [62]	X	X

At 3, 6, 9, and 12 month follow-up, the assessments will be administered by an evaluator blind to patient study condition. Note that all evaluators will be blind to study condition at baseline, as that assessment occurs before individuals are assigned to treatment groups. In order to maintain the integrity of the treatment blind: 1) blind evaluations will be conducted by personnel not otherwise affiliated with this study and whose office space is physically separate from the clinical offices of this project, 2) patients will be instructed at each visit that they are not to make any mention of their treatment condition while they are being interviewed by their assigned rater; and 3) at the beginning of each rating session, the rater will remind the patient that she/he is not to mention treatment condition during the interview with the rater.

## D6. Study Procedures

Research staff will approach potentially eligible participants during inpatient hospitalization in either the medical unit or the psychiatric inpatient unit. If interested, informed consent will be obtained and research staff will coordinate with the Veteran patient and inpatient staff in order to conduct the baseline assessment. Eligible patients will be enrolled in the study.

After enrollment patients will be randomized to 1) Safety Assessment and Follow-up Evaluation (SAFE) or 2) CLASP for a six month period. We will use the urn randomization strategy described by Wei [63] and Stout [64] to help insure balance among treatment groups. Urn randomization is a stratified randomization technique, which randomly assigns patients of a given subgroup to treatment conditions, but systematically biases the randomization in favor of balance among the treatment conditions on the stratification variables. For this study, we will be balancing the treatment groups on the following stratification variables: 1) gender of participant (male or female); 2) number of previous suicide attempts (zero, one, many) and 3) recent intake for suicidal ideation vs suicide attempt. We have successfully used the urn randomization procedure in several previous treatment outcome studies [65, 66] and have acquired an electronic file that contains the algorithm for urn randomization

[67]. This file also will provide the ability to monitor effectiveness of our stratification and randomization procedures. Patients assigned to the CLASP intervention will be asked to identify and reach out to a significant other to participate with them. For those in the CLASP intervention, research staff will attempt to complete 3 in-person individual sessions and 1 in-person joint session while the patient is hospitalized. In the event that the patient is discharged prior to the completion of in-person sessions, those sessions will be scheduled in the 1-2 weeks after the patient has left the hospital and will be conducted in assessment rooms in the Research building.

#### **D6.1 Treatments.**

- 1) *Description of CLASP.* CLASP differs from typical psychotherapy in that it involves a relatively unique combination of case management, with the implementation of both individual and family-based therapeutic strategies. The CLASP provider's primary role is in monitoring suicide risk areas, and if problems occur in these areas, to help facilitate the patient and significant other in resolving these difficulties. Thus, the CLASP provider's role is more of a treatment "advisor" than "therapist." For example, the CLASP provider would not attempt to provide psychotherapy to address increased depression, but would instead function more as an advisor, by exploring potential treatment options for depression with the patient and significant other. While the CLASP provider does provide some family and individual strategies, these types of interventions are: a) used sparingly, b) not the major focus of the CLASP telephone calls, and c) are done in the context of a more "facilitator or case manager" type relationship. For these reasons and in order to emphasize the difference between the CLASP provider and the patient's VA providers, the CLASP provider identifies him/herself to the patient as a "CLASP Treatment Advisor." Furthermore, the CLASP advisor is more proactive than typical clinicians. The CLASP advisor initiates the telephone calls to patient and significant other, and will continue to contact each as necessary, whereas typically, clinician attempts to contact patients may be limited, except in some specific types of treatment (e.g. DBT). Furthermore, unlike most outpatient treatments, CLASP involves both patient and significant other, providing consultation to both.
  - a. *Individual In-Person Meetings.* Meeting 1 focuses on rapport building. The advisor inquires about the events leading to hospitalization, emphasizing the links between identified risk factors and suicidality. The advisor assesses current risk behaviors. The advisor also provides brief psychoeducation about suicidality. Next, values clarification is introduced based on ACT to motivate change and instill hopefulness. In Meeting 2, the advisor reviews and finishes the values clarification discussion as needed and helps the patient define specific behavioral goals that are consistent with the values. The advisor helps the patient define a list of short-term, values-consistent goals. The majority of Meeting 3 is spent formulating an individualized "Life Plan." The Life Plan document contains various questions for the patient and advisor to discuss and record responses, such as "What is my plan of action for keeping safe?" and "How will I recognize my early warning signs so I can take action sooner?" The advisor and patient also formulate a specific safety plan to address any suicidality following hospitalization. Potential barriers to attending scheduled sessions within the VA post-discharge are discussed and the role of the Suicide Prevention Coordinator is discussed.
  - b. *SO In-Person Meeting.* Meeting 4 includes the advisor, patient, and a significant other (SO) following the FITT format. The advisor reviews the psycho-educational information with the patient and SO. The advisor asks the SO to discuss his/her perspective on the patient's recent hospitalization. The majority of the session is spent reviewing the patient's Life Plan. The advisor facilitates a discussion between the SO and patient about the role the SO can play in the treatment plan to support the patient's goals. If severe patient-SO conflict is identified referrals for family therapy are provided.
  - c. *Telephone contacts.* Following the in-person meetings, the advisor conducts Telephone Contacts 1-11 with the patient and their SO individually. To further personalize the intervention and decrease potential treatment burden, each session is 15-30 min in length based on the number and severity of clinical issues identified. Sessions are conducted on a schedule of decreasing frequency for a target of 11 sessions over 6 months. At the start of

each contact, the advisor conducts a quick assessment of risk factors (e.g., psychiatric severity, suicidality, treatment adherence, social support) since last contact. If suicidality is identified, this is discussed first and a safety plan is developed. The advisor facilitates problem-solving and communication between the patient and SO. The advisor discusses problems in terms of values strategies and in reference to the previously developed Life Plan document. If a problem develops that cannot be solved in this manner, the advisor may obtain permission to contact the patient's primary treatment provider directly or temporarily increase the frequency of the phone contacts during times of crisis. The SO phone contact proceeds in a similar manner. The VA Suicide Prevention Coordinator will be informed of any increase in risk.

2) *Description of Control Condition.* The choice of a comparison or control condition for suicide prevention research has been the subject of much debate [68]. For a variety of ethical, pragmatic and research concerns, the most commonly used control group has been some variant of "Treatment as Usual (TAU)." Although use of TAU as a control group has some limitations [69], it also has many advantages [70]. Since the CLASP intervention is designed to be an "adjunctive" intervention, the use of a variant of TAU seems particularly appropriate. Empirically, this decision allows for the evaluation of CLASP as a true adjunctive intervention, as we will be able to evaluate the additive benefits of CLASP over and above TAU. This design also reflects the manner in which CLASP would likely be implemented in the VA setting (i.e., to Veterans already identified as being at risk for suicide). However, given the high risk nature of this proposed sample, in order to provide an ethically appropriate "comparison" condition, we have developed and piloted a comparison condition which enhances "treatment as usual" with additional assessment and clinician feedback.

- a. The SAFE condition consists of clinical treatment as typically provided. Participation does not influence the patient's ongoing clinical care. However, in addition to treatment as usual, patients participating in SAFE receive enhanced assessment and monitoring services. The enhanced monitoring consists of regular assessments of suicidal ideation and risk factors on admission to the hospital, discharge, and follow-up assessments. We obtain releases to share information with the patient's clinician(s). At the baseline, 3, and 6 month assessment times, we provide the patient's clinician(s) with a standardized report based on these assessments that summarizes the patient's level of suicidal ideation and identified risk factors.

**D6.2 Advisor Supervision.** CLASP advisors will receive ongoing weekly supervision in a group format. Additionally, sessions are recorded for supervision purposes and regularly reviewed to prevent protocol "drift" throughout the study. Remedial training and practice is provided to advisors who do not maintain acceptable adherence and competency. Yearly "refresher" workshops are provided to advisors throughout the study to ensure continued adherence to the protocol

## **E. Early Termination**

If participants decide to withdraw from the program we will ask their permission to contact them for the assessment. We will provide additional referrals as needed or as requested if the participant decides to withdraw from the study.

## **F. Data Analysis**

### **F1. General Approach**

Analyses will be conducted using a combination of R [71] SPSS, and MPlus 6.12 [72]. Data initially will be examined for assumptions and appropriate estimation procedures will be applied as a function of data characteristics. As appropriate, maximum likelihood estimation with robust standard errors (MLR) will be applied, permitting analysis of data missing at random and non-normal distributions. Interpretation of results will be adjusted to account for number of tests performed using the step-down procedure of Benjamini and colleagues [73, 74]. Latent and longitudinal modeling (i.e. growth curve modeling) will be adopted wherever possible to permit simultaneous estimation procedures, maximize power, and allow comprehensive theoretically-informed tests of the aims.



## **F2. Baseline differences**

Chi-squares and t-tests will be used to assess the effectiveness of our randomization procedures, (i.e., compare CLASP to SAFE on demographic variables, diagnosis, suicide history and characteristics of previous attempt, and presence and severity of other suicide risk factors).

## **F3. Treatment Outcome (Primary, Secondary, and Tertiary Hypotheses)**

We will employ a similar analytic approach for all treatment outcomes. The primary focus of our treatment outcome analyses will be to identify differences between CLASP and SAFE for our major outcome measures (i.e. number of suicide attempts, severity and chronicity of suicidal ideation, rate of psychiatric hospitalization, psychiatric symptoms, psychosocial functioning and treatment engagement). The primary outcome analyses of the efficacy of the CLASP condition relative to the SAFE condition will assess subsequent suicidal behavior. Secondary analyses will focus on potential differences in psychiatric re-hospitalization, and suicidal ideation. Tertiary analyses will explore treatment engagement and potential differences in areas of psychiatric symptoms and psychosocial functioning.

### **F3.1 Operationalization of Outcomes.**

#### **1) Primary Outcome**

- a. *Suicide Attempts*. The number of patients who make a subsequent suicide attempt and total number of attempts will be assessed using 12 month data collected from all possible sources, including follow-up assessments (C-SSRS), b) hospital chart reviews, c) significant other reports, and d) community clinician reports.

#### **2) Secondary Outcomes**

- a. *Re-Hospitalizations due to Suicide Risk*. Although re-hospitalization may be function of multiple factors, including actual level of suicidal risk, it can provide a rough measure of subsequent risk, and is an important health services outcome. For these reasons, we will use the Treatment History Interview as well as hospital records and clinicians' reports to track # of subsequent psychiatric hospitalizations and reasons for these admissions
- b. *Suicidal Ideation*. Significant suicidal ideation will be operationalized through measures of severity and chronicity of suicidal ideation generated by the Longitudinal Interval Follow-Up Evaluation (LIFE). Using the methodology of the LIFE, at each assessment point, we will ask participants to rate their level of suicidal ideation in the preceding 13 weeks on a 6-point psychiatric status rating (PSR) scale. This methodology, which yields weekly scores, allows us to examine both the occurrence of significant suicidal ideation throughout the course of the study as well as the chronicity of suicidal ideation as an outcome, which we believe is a clinically relevant distinction from pre-post change in level of suicidal ideation. These methods have been successfully implemented in two NIMH-funded studies at Brown [75][76] and Dr. Miller is currently utilizing this methodology in a treatment development study of suicidal adolescents [77]. We will also assess severity of suicidal ideation more traditionally using the Suicidal Intensity subscale from the C-SSRS.

#### **3) Tertiary Outcomes**

- a. *Treatment Engagement*. Is defined here as the # of participants seeing a mental health professional in the month prior to a given assessment (i.e. 3-, 6-, 9-, or 12-month), as indexed by the Treatment History interview.
- b. *Psychiatric Symptoms*. We will utilize the Global Symptom Index from the BSI to assess overall severity of psychiatric symptoms.
- c. *Psychosocial Functioning*. We will compare CLASP vs. SAFE patients on relevant measures of psychosocial functioning, e.g. the WHO-DAS and SS-B.
- d. *Completed suicide*. Given the relatively low incidence of completed suicide, even in this high risk sample, we do not expect to have sufficient numbers of patients who complete suicide for meaningful analyses. However, since completed suicide is a critical outcome, we will track number of completed suicides, using all possible data sources, including significant other reports, chart reviews, community provider reports and reviews of state and national death registries.

**F3.2 Treatment Outcome Analyses.** Effect sizes between patients receiving the CLASP intervention and those receiving SAFE will be computed for each outcome measure. Specifically, for our primary dependent measure (proportion of patients who make suicide attempts), we will calculate an effect size of the difference in the proportions between CLASP and SAFE groups using an odds ratio and its associated robust confidence interval. Effect size estimates will be adjusted by significant covariates in analyses.

Supplanting this estimate will be an analysis of our graded ordinal measure of outcomes. We will employ Generalized Estimating Equations (GEE; [78]) to estimate the ordinal response at each follow-up assessment. GEE have the advantage of providing developed methods for the flexible handling of missing data under various assumptions [79]. Similar analyses will be conducted to obtain estimates for the CLASP effect on the total number of attempts in each treatment condition, suicidal ideation, completed suicide, re-hospitalization due to suicide, and treatment engagement. For continuous indices we will employ robust estimates of effect size obtained in two-level repeated measures analysis [80].

#### **F4. Change Trajectory**

We will use latent growth curve modeling to explore the trajectory of change in our outcome measures specified above. These models will initially be specified as parallel growth processes (i.e. simultaneous modeling of suicide attempts, suicidal ideation, and psychiatric hospitalization) to account for shared variance, but will be tested individually if a parallel growth model cannot be fit. Using data collected across our 5 assessments, we will estimate intercept (i.e. mean) and slope (i.e. linear rate of increase/decrease) for each of these latent suicide risk constructs. As we expect participants will show clinical improvements at the end of the CLASP protocol, with some participants deteriorating in the follow-up (with a similar, but more pronounced intensity of response for SAFE participants) we will also investigate quadratic slope (i.e. curvilinear change trajectory). To account for time, we will fix our initial two time points, and allow MPlus to estimate the remaining time parameters. We first fit unconditional models to identify the optimal change trajectory for each outcome.

Once the optimal growth trajectory has been identified, we then fit conditional growth models in which growth parameters (i.e. intercept, slope, quadratic slope) are regressed on selected predictor variables (i.e. treatment assignment, covariates, and/or moderator variables of interest). We chose this analytic approach because it permits us to both take advantage of the repeated suicide assessments and to model variations associated with the implementation and cessation of treatment. We will be able to add additional predictors to the model iteratively, to explore the unique and overlapping predictive utility of each measure. However, we recognize that as with any latent variable modeling approach, we may experience difficulty with model fit. In the event that we are unable to fit a model to the data, we will either modify our model (i.e. exclusion of a risk variable, inclusion of covariance between predictors, change in time parameterization, etc.) or employ a simplified multilevel modeling approach (i.e. HLM) or multiple linear regressions.

#### **F5. Statistical Power**

Statistical power was based upon effect size estimates derived from the CLASP pilot as well as our judgment about how large a difference would represent a clinically significant difference. In our pilot study, for suicide attempts, we found that 3 of 39 (~8%) individuals assigned to CLASP made a suicide attempt compared to 10 of 47 (~21%) randomized to control, yielding an effect size between small and medium ( $d = .38$ ; 95% CI: .31 - .45). Similarly, for psychiatric re-hospitalization, we found that 8 of 39 (~20.5%) individuals assigned to CLASP were re-hospitalized for suicide risk compared to 17 of 47 (~36%) randomized to control, yielding an effect size between small and medium ( $d = .35$ ; 95% CI: .28 - .41). Consequently, we believed that it was important to power the proposed study for effect sizes slightly larger than small ( $\sim d = .25$ ) to provide adequate coverage for the full range of expected effect sizes.

Sample size for effect size and odds ratio comparisons for the primary treatment outcomes was estimated using Fisher's Exact Test using our primary treatment outcome, # of suicide attempts. Assuming the proportions identified in the CLASP pilot,  $\alpha = .05$ , a one-tailed hypothesis test, and our projected sample of 200, our power estimate for this conservative test will be .82. It should also be noted that given the longer follow-up period in the current study, we hypothesize that the difference in

proportions obtained in our pilot study are likely to be higher due to the longer period of risk assessed. Consequently, the proposed study design should have ample power to test our primary hypothesis.

To estimate power for latent growth curve models, we used Zhang & Wang's [81] simulation procedure for SAS 9.1.3. Our simulation assumed five repeated measures assessments (Baseline, 3-, 6-, 9-, and 12-month), a moderate correlation between slopes and intercepts ( $r = .30$ ), a total missing data rate of ~30%, and 2500 simulation replications per sample size. We simulated sample sizes ranging from 50 to 300 in 10 participant intervals for our lower-bound effect size estimate ( $d = .28$ ). The proposed sample of participants ( $N = 200$ ) should be adequate (Power > .80) to detect even our lower-bound effect size for the full sample.

## **G. Human Subjects Consideration**

### **G1. Risk to Subjects**

**G1.1 Human Subjects Involvement and Characteristics.** Two hundred inpatient Veterans from the Providence Veterans Affairs Medical Center and 100 identified significant others will be recruited for this study. **Inclusion criteria** for the Veteran participant will include: 1) suicide attempt or suicidal ideation with any methods, plan, and/or intent to make a suicide attempt within 1 week of hospitalization as indicated on the hospital chart and/or confirmed by administration of the C-SSRS [48]; 2) age greater than 18 years, 3) have a telephone, and 4) ability to speak, read, and/or understand spoken English sufficiently well to complete the procedures of the study. **Exclusion criteria** will include: 1) diagnosis of primary psychotic disorder based on chart review (e.g. Schizophrenia or Schizoaffective disorder), 2) diagnosis of borderline personality disorder (based on screening with MSI-BPD [49], followed by BPD section of SCID-II if MSI-BPD is positive), or 3) cognitive impairment which would interfere with adequate participation in the project (MMSE [50] < 20). **Inclusion criteria** for significant others will include: 1) age greater than 18 years, 2) have a telephone, & 3) ability to speak, read, and/or understand spoken English sufficiently well to complete the procedures of the study.

**G1.2 Sources of Research Material.** All of the data for this project will be collected specifically for research purposes. Separate locked, secure files will be used to store study materials for each participant. Identity masking subject numbers assigned to each participant will be the only means by which collected information is labeled. Each participant will have his/her own assigned number. The only list that will link the names of the participants with their subject numbers will be kept in a secure, restricted computer account accessible only to the study staff.

Four sources of data will be included in this project. These include: (a) the initial screens, (b) questionnaires, (c) diagnostic interviews, and (d) audio-recorded intervention sessions.

- 1) *Screens:* Each potential participant will be interviewed separately by a member of our research staff to determine initial study eligibility while on the inpatient unit. All information from this screen will be identified with subject numbers only.
- 2) *Questionnaires:* Self-report questionnaire-based measures will be administered at baseline, and at 3, 6, 9, & 12 month post-hospitalization. All of this information will be identified with subject numbers only. Data collected from the pre- and follow up assessments will be stored in a locked filing cabinet in the offices of the Principal Investigator.
- 3) *Diagnostic interviews:* All information obtained from these interviews (SCID, C-SSRS) will be identified with subject numbers only and will be kept in a locked filing cabinet in the offices of the Principal investigator.
- 4) *Audio-recordings of sessions.* All sessions and phone calls will be audio-recorded. Recordings will be immediately uploaded to a restricted VA server and identified by participant number only. Recordings will be deleted from tape recorders immediately upon uploading to the server. Tape recorders will be kept in a locked filing cabinet in the offices of the principal investigator or research assistants.

**Data Disposition.** All data will be stored within Dr. Primack's offices in Building 32 at the Providence VA Medical Center located at 830 Chalkstone Avenue, Providence, RI 02908-4734. All hard copies of data will be kept in locked file cabinets in locked rooms accessible only by study staff. All digital and electronic data will be kept in restricted files on a secure server (\\vhaproappres01\V-

CLASP). Study data will be collected and managed using REDCap electronic data capture tools hosted on the VA Intranet [82]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Data will be stored by and accessible to study staff only. The study principal investigator acknowledges responsibility for assuring VA access accounts are terminated when a user no longer needs access or study personnel leaves the V.A.

For data analyses purposes we will create a database downloaded from REDCap with participant's responses to questionnaires and interview questions. All data in this database will be de-identified since none of the 18 potential identifiers listed on VAMC protocol will be entered into the spreadsheet. The only data entered into this spreadsheet will include subject number and responses on questionnaires. The only demographic data included in this spreadsheet will be age, gender, marital status, and race/ethnicity. This dataset will be kept in a restricted file on a secure server (\\vhaproappres01\V-CLASP), and will be kept in a separate file from any documents containing identifying information.

Phone intervention sessions will be audio-recorded for reliability and training purposes. Sessions will be immediately uploaded to a restricted file on a secure server (\\vhaproappres01\V-CLASP) and copies deleted from the audio-recorders upon upload.

In the event that theft, loss of other unauthorized access of sensitive data or storage devices and non-compliance with security controls occur, study staff have been instructed to follow the Providence VA Medical Center's standard operating procedure incidence reporting. All research data will be retained in accordance with the Veterans Affairs Record Control Schedule (RCS) 10-1.

### **G1.3 Potential Risks**

- 1) *Potential coercion*. It is possible that participants may feel coerced into participating.
- 2) *Confidentiality and loss of privacy*. We will be collecting personal information from the participants that may cause distress and psychological risk if released inappropriately. Furthermore, participants assigned to the intervention will be participating with significant others and intervention calls will require some sharing of information regarding patient safety.
- 3) *Increased distress* due to assessment or intervention procedures.
- 4) *Lack of symptom improvement or clinical deterioration*. It is possible that participants will fail to report any symptom improvement or, in some case, may report clinical deterioration.
- 5) The potential for adverse events during the study will be minimized by the following procedures.

## **G2. Adequacy of Protection from Risks**

**G2.1 Recruitment and informed consent.** The details regarding recruitment, screening, and consent procedures are described in the Procedures section. All potential participants will be provided with information regarding the nature of the study, the potential risks and benefits of the study, and the voluntary nature of participation. Informed consent will be required before the assessments are administered. Written informed consent will be obtained from all participants at the beginning of the in-person screening and assessment session.

### **G2.2 Protection against Risk.**

- 1) *Risk of coercion*: In order to minimize the risk of coercion we will fully explain the study procedures to all potential participants, with an emphasis on the fact that participation is optional and participants may withdraw from the study at any time. Participants will be told that their participation in this study will be independent of any other study. Although participants will be asked to identify a significant other to participate with them, failure to identify a significant other will not result in study termination. Participants will be allowed to participate even if they are unable to identify a significant other. All information will be outlined in the written consent form and we will explain all study procedures, risks, benefits, and alternatives to all participants.
- 2) *Confidentiality and loss of privacy*: All information will be collected by staff that are trained to deal with sensitive clinical information and will have completed all required human subjects training. All data will be treated as confidential and will only be available to research and clinical staff. Study data will be identified by participant code number only, not by participant name, and will only be

available to government regulatory agencies if required by law. All participants will be informed of the limits of confidentiality regarding suicidal or homicidal intent, child or elder abuse, or inability to care for self. All original paper copies of collected data will be stored in a locked cabinet at the Providence VAMC research building. Hard copy data will not leave hospital property. Computer files will be stored in password-only computer programs and there will be no electronic transmission of study data. All interviews will be conducted at the Providence VAMC research building and all paperwork will be maintained on hospital grounds. Audio files of the sessions will be immediately uploaded to a VA secure, restricted server. An approved flash drive will be requested to transfer a database, from which all identifiers have been removed, to research offices at Butler Hospital. The data will be encrypted to protect the database in the event that it is misplaced or stolen. Data will be analyzed using SPSS and Mplus computer software. The study statistician, Michael Arney, is a Butler Hospital psychologist and is in the process of obtaining WOC status at the Providence VA. Dr. Arney currently has the software on his computer. Dr. Arney will be added to this protocol as a statistician as soon as he has obtained WOC status and has completed all required VA research training. He will not have any involvement in the study until approved by the IRB. All software and licensing will be managed by Butler IT staff. Dr. Primack also has privileges at Brown University and Butler hospital and thus has access to both computer software (also managed by Butler hospital IT). In the event that the principal investigator is unable to obtain a VA approved flash drive, all data will remain at the VAMC and will be stored on the secure VA server (\\vhaproappres01\V-CLASP).

Veteran patients randomized to the CLASP intervention will be asked to identify a significant other to participate with them. One goal of the study is to increase communication and social support between patients and their family members. Patients and their significant others will be encouraged to share information from the phone calls and patients will be told to share specific information such as any new difficulties or safety issues with their participating significant others. Furthermore, Veteran patients will be told that the significant other phone calls are intended to a) increase social support, b) gain additional information on how the Veteran is currently functioning from the perspective of the significant other, and c) provide a backup in the event that the patient is feeling unsafe and needs support engaging in care. No questionnaire or interview data will be collected from any significant other and limits of confidentiality will be outlined in the consent forms.

- 3) *Distress as a result of completing the assessment procedures:* All assessments (including clinical assessments such as the SCID and C-SSRS, self-report questionnaire packet & treatment evaluation interview) will be administered by research personnel who are trained in the assessment battery and who have human subjects certification. Dr. Primack, a licensed clinician who will be available to speak with the participant in the event of any adverse event, will supervise all assessments and interviews. Participants who are ineligible for the study will be provided with a list of mental health referrals specific to their location. Individuals may also be referred to their current providers or emergency services as appropriate. While we do not anticipate that participants experience significant distress while completing the assessment measures, we will ensure that a licensed clinician is available during all assessments should participants experience any distress. Should any safety issues be raised during the assessment we will follow standard protocol (see section on safety monitoring and managing adverse events).

Individuals participating in the proposed study will be provided with a set of emergency contact numbers should they experience an exacerbation of depressed mood or suicidal ideation; however, any exacerbation of depressed mood would be expected to be of short duration. Subjects will be provided with contact numbers for local mental health care providers (Butler Hospital & Rhode Island Hospital) in addition to their VA providers. The VA National Suicide Prevention Hotline telephone number, 1-800-273-TALK (8255), will be provided to all Veterans on the consent form. Should our staff detect any serious suicidal ideation during intervention sessions or follow up assessments, it will be managed in accordance with the VA suicide risk management procedures.

- 4) *Lack of symptom improvement or clinical deterioration*: All participants will be receiving VA treatment as usual and therefore clinical deterioration is not expected. However, many patients are at high risk for subsequent suicide behavior. Although we hypothesize that participants in both the CLASP intervention and control condition will experience a reduction in suicide behaviors, in some cases it is possible that participants may experience a worsening of symptoms. In order to address this concern, all participants' symptoms (including suicidal symptoms) will be monitored at all assessment points and safety protocols will be implemented as needed according to VA policy.

If our staff identify an individual with significant clinical deterioration or who report any suicidal ideation with plan or intent they will contact Dr. Primack who will evaluate the patient over the phone or in person. Dr. Primack will generate a list of mental health services in case of emergency. In the event that a study participant reports significant deterioration but is not in immediate danger of hurting himself, we will take the following actions. First, we will inform the patient about the procedures for contacting emergency services should they find themselves at risk for self-harm. Second, for individuals stable on medications, we will request permission to contact their outpatient psychiatrist to inform them of their deterioration. Finally, the participant will be provided with additional mental health referrals. In the event that a participant is acutely suicidal, the research staff member will walk the Veteran over to interim care or the ER for immediate safety assessment. All adverse events will be immediately recorded and reported to the Providence VA Hospital IRB.

- 5) The potential for adverse events during the study will be minimized by the following procedures:
- Since the intervention being evaluated in this study is an adjunctive intervention, participation in the study will not prohibit involvement in any other type of treatment. All subjects will be allowed (and/or encouraged) to participate in whatever type or amount of treatment is thought to be clinically indicated for the patient. Thus, participation in the study will not cause any subject to be deprived of a clinically appropriate treatment.
  - All subjects in the study will receive enhanced monitoring of their clinical condition. As part of the SAFE intervention, we will obtain release of information forms and will routinely communicate the results of this monitoring to the patient's clinician(s). Further, patients will be informed that notes will be entered into CPRS and thus will be available to their VA treatment providers. CLASP advisors will routinely monitor levels of suicidal ideation and risk, as well as overall psychiatric symptoms, and take appropriate clinical action when necessary to reduce risk.
  - We will have procedures in place to respond to increased levels of suicide risk if reported. Briefly, if any patient manifests significant psychiatric symptomatology during study assessments, we will either: a) inform the patient's clinician and/or primary care physician, or b) if the patient is not currently in treatment, we will provide the patient with a referral to a qualified clinician and will contact the Providence Suicide Prevention Coordinator. In the event that a subject manifests significant suicidal or homicidal ideation or risk, we will take whatever steps necessary to insure the patient's and/or others' safety. Depending upon the specific situation, these steps may involve: a) escorting the patient to the hospital's admitting office for an emergency evaluation, b) alerting inpatient staff to the patient's level of risk, c) notifying patient's clinician, primary care physician, and/or family member or d) calling the appropriate police departments.
- 6) All serious adverse events will be immediately recorded and reported to the Providence VAMC IRB.

**G2.3 Procedures for Handling Suicidality.** Regarding imminent self- or other-harm, there is a specific protocol within the Providence VA Medical Center System for handling behavioral crises, which is contingent upon whether the person(s) is on-site or off-site when such emergencies arise. On site, we have "Team 3" buttons for each clinician or research assistant that are directly linked to the Providence VA Medical Center police department and additionally request a team of mental health workers trained in crisis management. If during the course of the assessment the participant reports suicidal ideation, the research assistant will immediately contact a study clinician. If the participants experience any crises between therapy or assessment sessions, they will be instructed to immediately

contact Dr. Primack at (401) 455-6336, Dr. Shea at (401) 444-1907 or (401) 273-7100 ext 6248, or their study therapist (if applicable) during working hours. If there is imminent risk to self or another, we will collaborate with Providence VA Medical Center's staff in Interim Care to triage the patient to receive the appropriate emergency services. If a participant is in crisis during working hours and cannot reach Dr. Primack, Dr. Shea, or their study therapist immediately, they will be instructed to call the Providence VA Medical Center hospital operator, who will put the patient in contact with the Interim Care at the Providence VA Medical Center. The clinical staff there will evaluate the need for emergency services, and triage the patient to receive the appropriate services. If participants have problems after hours, they are instructed to call the medical center at (401) 273-7100, dial 0 for the operator, and ask to be connected to the Emergency Department. The psychiatrist on call will evaluate the individual and take the necessary actions. If it is an emergency, they may choose to go the Emergency Department at the VA, or call 911 for the nearest Emergency Department. We will also provide a list of crisis hotline numbers and community resources that participants may access, for example, the Department of Veterans Affairs suicide prevention hotline number (800-273-TALK).

Relevant to risk for harm to self or others and suspected abuse or neglect of vulnerable persons (see below), participants are informed in the Informed Consent Procedures that these are circumstances in which confidentiality is not protected. These limits in confidentiality are also reviewed again in the first session of the therapy in the active treatment group. In addition, if a participant(s) has to be terminated from the protocol due to safety concerns, the study team will explore resumption of therapy with any referring clinician, and facilitate resumption of therapy through discussion with the therapist (with the client's consent). If there is no referring clinician and there is the need for referral, we will provide referral resources for the participant(s).

Participants in this study are considered a high-risk group in the sense that they are specifically enrolled in the study for suicide prevention. It is likely that participants may experience serious suicidal ideation at some point during the study period at a time when they are not being assessed in person. All participants will receive a card with important emergency contact information including the Veterans crisis line and the VA interim care. Those with imminent risk (intent with plan to act) will be escorted to the VA emergency department or interim care.

### **G3. Data and Safety Monitoring Plan**

**G3.1 Efficacy plan.** Data collected from screenings, assessments, and self-report questionnaires will be entered into a secure, restricted database. Twenty-five percent of all data will be reviewed and entered into the database a second time and files will be compared to check for accuracy of data entry. Ongoing checks of assessment techniques will be conducted in a process to assure calibration and prevent rater drift, while also obtaining inter-rater reliability.

**G3.2 Safety Plan.** As per HSR&D DSMB Charter Version 1.1, this study does not require a Data and Safety Monitoring Board (DSMB) to provide external monitoring of data and safety management.

Drs. Primack and Shea will conduct daily oversight of participant safety in the study. They will meet weekly with staff to review participant progress and their experience with the interventions, including adverse events. Any unexpected serious adverse events that are observed and/or reported will be reported to the DSMB and Providence VAMC IRB by written report within 24 hours of our receipt of information regarding the event. The DSMB will review all serious or unexpected adverse events and provide recommendations. We will inform the Department of Veteran Affairs of any significant action taken as a result of the DSMB's or IRB's findings.

*ClinicalTrials.gov.* This trial will be registered with ClinicalTrials.gov.

*Quarterly Data and Safety Review.* Drs. Primack and Shea will meet quarterly with our safety officer. During this meeting, we will evaluate the progress of this project, review data quality, recruitment, and study retention, and examine other factors that may affect outcome. We will review any and all adverse events to determine any changes in participant risk. A brief report will be generated quarterly for the study record and forwarded for review by the Providence VAMC Institutional Review Board. The scope of this project prohibits obtaining and maintaining an independent data and safety monitoring board.

**G3.3 Potential Benefits of the Proposed Research to the Subject and Others.** Potential benefits of the study for participants include a potential reduction in subsequent suicide behavior and rehospitalization. Pilot data indicated a support for the preliminary efficacy of the intervention. Secondary effects may include stronger social support, greater treatment engagement, and improved communication between Veteran, family members, and treatment team. We will likely publish the results of this trial.

**G3.4 Importance of Knowledge to be gained.** The proposed study would represent one of the few empirically supported interventions for suicide behavior in Veterans. Suicidal behavior is a significant public health issue. The evaluation of interventions to reduce suicidal behavior may have important benefits for multiple aspects of society. Thus, our results will have important implications for a variety of stakeholders, including patients, family members, healthcare providers, managed care organizations, health insurers, administrators, and policy makers. The program if efficacious could be easily disseminated and integrated into the VA system. Information gathered as a result of this study may help increase our knowledge regarding suicidal ideation in recently hospitalized patients, and provide the groundwork for a multi-site dissemination trial.

*Risk: Benefit Ratio.* We estimate that the potential risks associated with participating in this study appear to be minimal and the benefits appear to outweigh any potential risks. The major risks will be minimized by: a) emphasis and attention to the informed consent process, b) ensuring measures to protect participant confidentiality, c) periodic assessment of symptoms and risk, and d) provision of appropriate alternative mental health referrals in the event of acute risk behaviors or psychological distress. It is hypothesized that participants will experience an improvement in their mood and decrease in suicide ideation and behaviors. Participation in the research will provide all participants with information about suicide and will provide some tools with managing suicidal thoughts.



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