PROTOCOL

STUDY TITLE
Link Up: Facilitating use of the Veterans Crisis Line in High-Risk Patients

SPONSOR INFORMATION
VA HSR&D – IIR 14-103

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SPECIFIC AIMS

Reducing suicide is a national priority[1] and an urgent imperative within the Department of Veterans Affairs.[2] The passage of the Joshua Omvig Veterans Suicide Prevention Act highlights the importance that stakeholders, including Veterans groups, VA Central Office, and Congress, place on developing and implementing a comprehensive program to reduce suicide among Veterans.[3] Due, in part, to evidence that patients who utilize services from the Veterans Health Administration (VHA) are at significantly elevated risk for suicide compared to the general US population,[4] the VHA has invested heavily in programs designed to prevent suicide. Arguably one of the most visible products of VHA's investment in suicide prevention is the Veterans Crisis Line, an easily-accessible resource open around the clock to assist Veterans and their families during periods of crisis. Although not limited to VHA patients, the Veterans Crisis Line has the potential to directly impact VHA care and outcomes because Crisis Line staff have access to VHA medical records and can help coordinate care with local VHA providers and suicide prevention coordinators throughout the United States. By most measures, the Veterans Crisis Line has been enormously successful as a point of access for Veterans, with recent estimates indicating that it receives over 20,000 calls per month.[5]

However, despite high utilization of the Crisis Line, the overall rate of suicide among VHA patients has remained remarkably stable over recent years and since the Crisis Line's implementation.[6,7] Furthermore, the use of national crisis lines as a means to reduce suicide has not been rigorously tested and it is not feasible to study all-or-nothing access to the Crisis Line in a randomized controlled trial subsequent to its national availability. Additionally, the Veterans Crisis Line may not be used by individuals with the most acute risk for suicide. Our study team conducted a small survey of Veterans treated for recent suicidal crisis in a VHA inpatient psychiatric unit (one of the groups at highest risk for subsequent attempts and deaths) *and found that less than half had ever utilized the Veterans Crisis Line and less than a third had used it within the past year*.

In light of this context, we developed and gathered pilot data on a brief intervention designed to increase utilization of the Veterans Crisis Line among high risk patients, called *Crisis Line Facilitation (CLF)*. This single session therapist-delivered intervention addresses Veterans' perceived barriers and facilitators of crisis line use during periods of suicidal crisis. The CLF session culminates with the Veteran calling the Crisis Line with the therapist in the room as a way for the Veteran to practice the logistics of making the call and to have direct experiences that may counter any negative beliefs about Crisis Line use. Our small pilot study found significant increases in confidence in using the Crisis Line following completion of the CLF intervention. By increasing use of the Crisis Line among high-risk patients, this intervention could help VHA patients stay safe during a suicidal crisis. Conducting a larger randomized trial of CLF also provides a feasible approach to studying the efficacy of the Crisis Line in mediating reductions in suicide-related behaviors. **This is likely to be as close as it is possible to come to a randomized test of the efficacy of Crisis Lines and the results would have broad public health importance both inside and outside VHA.**

The present study will screen Veterans hospitalized for a recent suicidal crisis (significant ideation, plan and/or recent attempt requiring psychiatric hospitalization) at one of two VHA inpatient psychiatry units to determine whether they have previously called the Veterans Crisis Line. A sample of 500 participants who have not used the Veterans Crisis Line within the past year will be recruited for a randomized controlled trial to test the efficacy of CLF compared to enhanced usual care (EUC) on utilization of the Veterans Crisis Line, other mental health services, as well as subsequent suicide attempt(s). All participants will be re-assessed at 3-, 6- and 12-months post-baseline. The **Specific Aims** are to:

1) Test the impact of the CLF on Veterans Crisis Line utilization, as well as outpatient mental health treatment utilization, at the 3-, 6-, and 12-month follow-ups. **Hypothesis:** Suicidal Veterans who are randomly assigned to CLF will be significantly more likely to call the Crisis Line and initiate or continue outpatient mental health treatment compared to those assigned to EUC at 3-, 6-, and 12-month follow-ups.

2) Test the effect of CLF on likelihood of suicide attempts. **Hypothesis:** Suicidal Veterans who are randomly assigned to CLF will be significantly less likely to make a suicide attempt compared to those assigned to EUC at 3-, 6-, and 12-month follow-ups.

Secondary Aim 1: *Test the extent to which post-baseline use of the Veterans Crisis Line mediates the effect of CLF on suicidal behaviors*. **Hypothesis**: Post-baseline crisis line utilization will mediate the effect of random assignment to CLF vs. EUC on subsequent suicide attempts. ***Secondary Aim 2****: Understand barriers and*

facilitators of implementation of the CLF intervention, based on qualitative interviews with treatment providers and at-risk Veterans. This study is innovative as the first attempt to test the effect of connecting high-risk patients to a Crisis Line as a suicide prevention strategy. Developing a brief and effective approach to encourage use of the Crisis Line has the potential to have a significant and substantial impact on suicide rates within the VHA and could be modified and exported to other populations and settings.

RESEARCH PLAN

Background

Over 30,000 people die by suicide every year in the United States, making suicide the *fourth* leading cause of death in adults ages 18 to 65 and the *fifth* leading cause of years of potential life lost before age 65.[8] Over the past decade, identifying strategies to reduce the risk of suicidal behavior among members of the military and Veterans has become a high national priority.[9-11] Although it is unclear if Veterans, overall, are at elevated risk compared to the U.S. general population,[12,13] there are definitive data to show that individuals who use VHA services represent a high-risk group. More than 1800 suicides occur each year in VHA patients and, compared to general US population, rates of suicide in users of VHA services are 1.7 times (95% CI: 1.58, 1.74) higher in male VHA patients and 1.9 (95% CI: 1.35, 2.47) times higher in female VHA patients.[6] This heightened risk for suicide in VHA patients likely is due to the fact that users of VHA services are more likely to have characteristics generally related to higher risk of suicide, including demographic factors as well as higher levels of medical and psychiatric comorbidity[14-16] in addition to the potential lingering effects of military service. Of particular concern was our recent finding that, although service in Iraq and Afghanistan did not have an overall association with increased risk for suicide, among recent Veterans, the presence of a psychiatric condition was associated with a substantially greater risk of suicide than among other VHA patients.[17] Reducing suicide among VHA patients will likely require a multipronged approach that will simultaneously improve the availability and quality of specific mental health treatments while also designing services that could have a specific effect on risk for suicidal behaviors.

The Veterans Crisis Line. The VHA has undertaken a number of initiatives to reduce suicide among Veterans. This is reflected in a number of general changes to the system, such as significant hiring initiatives for mental health staff, as well as suicide-specific initiatives such as the hiring of Suicide Prevention Coordinators at each VHA facility, initiatives to improve local- and health system-level monitoring of fatal and non-fatal suicidal behaviors, and the development of the Veterans Crisis Line (formerly called the "National Veterans Suicide Prevention Line"). The Veterans Crisis Line first started receiving calls in July 2007 and has expanded steadily since that time. Currently, it receives over 20,000 calls per month and VHA estimates that approximately 3% are "rescues", or direct interventions by local services designed to save the life of Veteran callers determined to be at immediate risk. A key feature of the Veterans Crisis Line that distinguishes it from other suicide support hotlines is the ability for Crisis Line staff to directly access the VHA's electronic medical record for those Veterans receiving VHA care, and to reach out to local VHA facilities on behalf of the Veteran in crisis, often using the facility's suicide prevention coordinator as a point of contact. Thus, the Veterans Crisis Line can do more than provide support and intervene by sending the authorities in periods of acute crisis; it can function to directly coordinate care by linking Veterans to local treatment resources.[18,19]

The VHA has invested extensively in the Veterans Crisis Line. VHA has promoted the Veterans Crisis Line through national advertising campaigns as well as the widespread distribution of informational materials (fliers, magnets, key chains, etc.) to mental health and general medical providers throughout the VHA. However, there are no available national data on the extent to which these advertisement efforts are reaching those individuals at greatest risk for suicide or whether high-risk Veterans within the VHA system are using the Crisis Line.

Approaches to studying suicide prevention. It is difficult to scientifically study coordinated approaches to reduce suicide because suicide is a low base-rate phenomenon,[8] individuals who die by suicide are a heterogeneous group,[20] and suicide as an outcome likely reflects the influence of multiple causal pathways.[21] The Institute of Medicine[21] recommends using suicide reduction strategies that fall within three general categories: *universal* (those that target the population at large), *selective* (strategies focused on large groups of individuals who are at an increased risk because of a certain risk factor) and *indicated* (interventions focused on smaller groups of individuals at a clear proximal risk for future suicidal thoughts and behaviors). Suicide Crisis Lines fall within the category of universal interventions. Studying this form of intervention is challenging because, somewhat by definition, universal interventions are widely available, precluding the use of randomized controlled trial methods to establish efficacy**.**

Crisis Lines have a solid theoretical foundation because they are well-tailored to the transient nature of suicidal thoughts and plans.[22] Specifically, the 24-hour availability of Crisis Lines means that individuals can utilize this service for support in times of need. For many individuals, periods of suicidal crisis are highly transient, coming on suddenly and then dissipating. For example, estimates based on retrospective reports of suicide attempt survivors indicate that approximately 25% of all suicide attempts occurred with less than 5-30 minutes of planning, with even higher levels among individuals with substance use disorders.[23-25] This type of impulsive behavior is very difficult to prevent because, even for individuals who are receiving care from a mental health provider, a suicidal crisis can occur rapidly and before others can take steps to intervene. The key to suicide prevention is to help keep someone safe during these high-risk periods and, when that individual is safe, to utilize more intensive services to address some of the longer-term symptoms or problems that increase suicidal thoughts/behaviors.[19] Some observational data provides support for Crisis Lines indicating that suicidal ideation and/or distress decreased, on average, after calling a suicide crisis line.[26-28]

However, all of these studies are based on individuals who have already utilized Crisis Line services and none of the studies include a comparison group of those who could have benefitted, but did not use, the Crisis Line. More broadly, very little is known about the extent to which high-risk individuals utilize the Veterans Crisis Line or Crisis Lines more generally. With this in mind, we conducted a small survey of adults currently treated on a VHA inpatient psychiatric unit for a recent suicidal crisis. Participants were asked if they had ever used the Veterans Crisis Line and their perceptions of the Crisis Line. *In this small sample (n = 23), 52% (n = 12/23) reported that they had never used the hotline; 70% (n = 16/23) had not used the Crisis Line within the past year.* The most common reasons identified that interfered with Crisis Line use were practical barriers (e.g., not having the number), fears about the Crisis Line response (e.g., being "locked up"), and concerns about the potential helpfulness (e.g., crisis line could not help the situation; did not want help).

A similar dilemma related to understanding the impact of a universal intervention approach existed for the study of the impact of 12-step self-help groups (which, like crisis lines, are freely and widely available in the community) on substance use. The evidence base for 12-step groups was enhanced immensely when a novel therapy was developed, called Twelve Step Facilitation (TSF) that encouraged the use of 12-step groups as a resource for recovery.[29] In a landmark study of VHA patients, Timko and colleagues found that individuals who were randomized to TSF were more likely to utilize 12-step groups as a form of support and had better substance-related outcomes; in addition, 12-step meeting utilization mediated the effect of randomization to TSF on substance-related outcomes.[30] In his commentary that accompanied the Timko article, Humphreys stated that "methodologically the study is in the vanguard of a new generation of experimental evaluations of… 12-Step self-help groups."[31] The opportunity exists to apply a similar approach to conduct a randomized trial of an intervention designed to encourage greater utilization of Veterans Crisis Line services among high-risk individuals. This type of study could, similar to Timko's study within the area of addictions research, have far-reaching implications for the scientific study of Crisis Line and other universal suicide prevention approaches.

Indicated interventions following a suicide attempt. Thus, we sought to develop and pilot a Crisis Line Facilitation (CLF) approach. A randomized trial of a CLF approach would involve the use of an *indicated* intervention among a particularly high-risk group of VHA patients in order to facilitate use of the *universal* resource of the Crisis Line. In order to test the effects of an indicated intervention on suicidal behaviors in a randomized trial that is of reasonable size and scope, it is important to identify a group of individuals that are at significantly elevated risk for proximal engagement in suicidal behaviors. The period of time immediately following an inpatient psychiatric admission has the highest rate of suicide mortality of any period that has been examined.[32-34] For example, Dr. Valenstein found that rates of suicide among VHA patients with depression approached 570 per 100,000 person years during the first 12-weeks following discharge from an inpatient psychiatric unit and slowly decreased over the course of a year to around 100 per 100,000 person years – *a rate at one year that is clearly lower than the initial time period post-discharge but also significantly elevated relative to other VHA patients with depression.*[35] Unpublished data from our ongoing IIR of psychiatric inpatients at one of the study sites found that almost 20% of participants in a randomized trial of a phone-based continuing care intervention reported a suicide attempt or a significant suicidal crisis in the nine months after inpatient discharge. This is broadly consistent with estimates that up to 25% of those who are treated for a suicide attempt will make a repeat attempt with a year.[36,37]

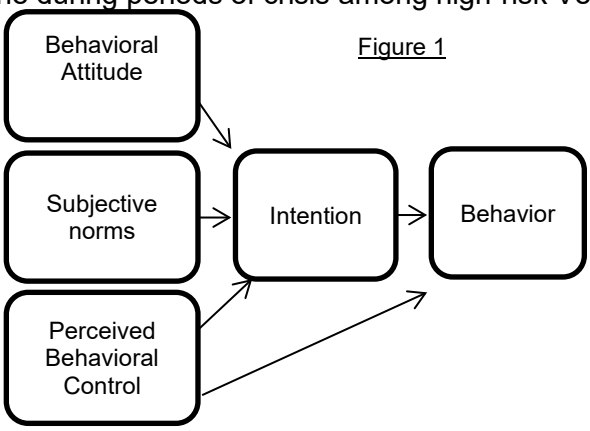
Several studies have been conducted during the time period either following inpatient psychiatric discharge or emergency treatment for a suicide attempt. As described in a 2013 review,[38] close to 10 studies have been

conducted of suicide prevention interventions; the methods of intervention have varied from calling participants, sending postcards, to using emails for interpersonal outreach. Some evidence supports the effectiveness of these approaches but, as noted by the authors,[38] more randomized trials are needed to determine the efficacy of post-treatment outreach methods. More broadly, these approaches involve outreach that occurs based on the interval that is pre-determined by the treatment provider. As noted previously, suicidal thoughts and plans are highly transient and even weekly contacts may fail to reach someone when they are in a suicidal crisis. Alternatively, an approach that effectively encourages use of a constantly-available resource, such as the Veterans Crisis Line, has the potential to provide resources to the individual during the period of time when it could be most useful. This is a core assumption of Safety Planning,[39] a suicide prevention approach, which is now widely available throughout VHA. However, efficacy data are not currently available on Safety Planning and there is the potential that the conversation about how to stay safe during a period of crisis, which is the core of Safety Planning, could be more effective if it is paired with behavioral practice of using a specific resource. This combined use of cognitive strategies to address concerns about the hotline use with practice calling the hotline is at the core of the CLF approach that this proposal is designed to study.

Crisis Line Facilitation. Our study group designed CLF in response to the need to identify strategies to link some of the highest-risk Veterans with the potentially valuable resource of the Veterans Crisis Line during periods of high need. Briefly, the CLF has three core components: (1) the presentation of psychoeducational information about the Crisis Line. This involves providing information about the Crisis Line, how to reach the Crisis Line, mission of the Crisis Line, etc.; (2) a discussion of the participant's perceived barriers and facilitators to future use of the Crisis Line. This discussion includes a conversation about practical barriers and strategies to overcome this (e.g., keeping a copy of the Veterans Crisis Line number in a wallet) as well as cognitive barriers (e.g., "I'll just be a bother to them", "they will only lock me up if I call"). *This portion of the intervention will be tailored to the specific needs of each participant, based on the specific challenges faced by the Veteran (e.g., unstable housing, hopelessness/depression, comorbid substance use, etc.) elicited during the baseline assessment and during the CLF session;* and (3) conducting a practice call with the Veterans Crisis Line. For this, participants will dial the Veterans Crisis Line with the therapist in the room. The participant and therapist will discuss the Veteran's thoughts/feelings about making the call prior to, and after completing the call. The participant will be provided with a list of common questions for the Veterans Crisis Line staff member as a way to start the conversation and gather more information. The goal is for the participant to talk with the Veterans Crisis Line for 5-10 minutes to counter misperceptions about the Crisis Line and increase comfort in future use of this service. If a participant is uncomfortable with making a practice call, they will be offered the option of viewing a demonstration of the use of the Veterans Crisis Line online web chat feature. The therapist will use the computer while the Veteran observes the practice conversation. *It is important to note that, during the CLF intervention, use of the Crisis Line is presented as an option for seeking care during periods of acute need not as a substitution for the existing treatment plan. This is consistent with the broader way in which the VHA conceptualizes and promotes the Veterans Crisis Line through marketing materials provided directly to patients and through inclusion of the crisis line number in suicide safety plans.*

Theory of Planned Behavior. The proposed intervention to encourage the utilization of the Veterans Crisis Line during periods of crisis among high-risk Veterans is based on the Theory of Planned Behavior(TPB).[40,41]

Figure 1



According to the TPB (see **Figure 1**), the likelihood of engaging in the target behavior (in this case, calling the Veterans Crisis Line) is guided by three core constructs: (1) Behavioral Attitudes (which are based on behavioral beliefs); (2) Subjective Norms (which are based on sense of social pressure/norms); and (3) Perceived Behavioral Control (based on the sense of self-efficacy to engage in the behavior). For behavioral attitudes, if behavioral beliefs suggest that engaging in the behavior will lead to a positive outcome, an individual will be more likely to engage in the behavior. For subjective norms, if an individual believes that engaging in the behavior is socially acceptable among his/her peers, the more likely s/he is to engage in the behavior. Perceived Behavioral Control produces a sense of self-efficacy in relation to a behavior, or sense that the individual can successfully complete the

behavior. CLF was designed to target all three cores of TPB.[41] Specifically, the initial discussion of perceptions of the Crisis Line is intended to highlight ways in which calling the Crisis Line could lead to positive outcomes for the individual and/or others important to him/her (targeting attitudes). Much of the psychoeducational information provided during CLF highlights the broad use of the Veterans Crisis Line by Veterans and the fact that many Veterans are employed by this service (targeting social norms). During practice calls to the Veterans Crisis Line, participants in CLF are encouraged to ask questions, through a list of sample questions about social norms and acceptability of use of the Crisis Line (e.g., "Is it a burden if I call late at night?", "What if I want to talk to another Veteran?"). Finally, the CLF session involves behavioral rehearsal of calling the Veterans Crisis Line (targeting behavioral control); behavioral rehearsal is one of the strongest predictors of increased self-efficacy to engage in a behavior.[42,43]

Summary. VHA patients are at significantly elevated risk for suicide and the Veterans Crisis Line was developed to provide easily accessible support during high-risk periods in order to prevent suicidal behaviors among Veterans and VHA patients. Although some observational data provide support for the appeal and utility of suicide crisis lines, more definitive efficacy data are lacking. More broadly, it is likely that the crisis lines are not used by many high-risk individuals who could benefit most from these services. The study team has developed a new intervention, CLF, which is based in the Theory of Planned Behavior and intended to enhance use of the Veterans Crisis Line among high-risk Veterans. The proposed study will evaluate the efficacy of CLF versus Enhanced Usual Care in increasing crisis line use and decreasing suicidal behaviors among high-risk VHA patients, those Veterans with recent inpatient hospitalization for a suicidal crisis.

Significance and Responsiveness to HSR&D Priority Areas

The proposed project is highly significant from the standpoint of the public health and the scientific community. The public health significance is clear given the high priority placed on suicide prevention in VHA as well as the general US population.[11,44] As noted by the former VA Secretary this past September "VA's highest priority is the mental health and well-being of the brave men and women who have served our Nation. Even one suicide is one too many."[45] VHA has invested extensively in the Veterans Crisis Line and has worked hard to market the Veterans Crisis Line in print and in media outlets. However, it is likely that many at-risk Veterans, even those well-connected to VHA services, are underutilizing the Crisis Line. Enhancing utilization of the Crisis Line among high-risk Veterans hospitalized for a recent suicide attempt could have a substantial impact on rates of suicidal behavior in this very high risk group. If found to be effective, the CLF approach could be easily expanded to other settings and could, over time, have a meaningful impact on VHA-wide rates of fatal and non-fatal attempts. *In the final year of the project, we will gather qualitative data on barriers and facilitators of utilization of the CLF intervention with the goal of informing future efforts to implement CLF.*

The scientific significance of the proposed project is based on the innovative use of an indicated approach to enhance use of the universally-available Veterans Crisis Line. There is the potential for Crisis hotlines to reduce suicide on a population level. However, no data currently support the efficacy of this approach despite substantial investment in the infrastructure of suicide crisis lines. The proposed study builds on work that has been done in the substance use disorders treatment field to develop a Crisis Line Facilitation approach as a way to test the link between crisis line use and subsequent suicidal behaviors. *In particular, the proposed meditational analyses will provide data on the extent to which use of the Crisis Line accounts for (fully or partially) the impact of the CLF intervention on suicide attempts.* This design has the potential to significantly advance the science supporting the potential utility of Crisis Lines which has broad-ranging importance for suicide researchers and policy-makers both inside and outside VHA.

The proposal is directly responsive to HSR&D Priority Area E - Mental and Behavioral Health, which encourages research to study best practices in suicide prevention research. Although some ongoing and planned QUERI research can provide some evaluation data about longer-term outcomes of Veterans Crisis Line callers, the RCT design of the proposed project will provide key data about the potential efficacy of efforts to encourage crisis line use in high-risk patients. The proposed project, with its aims focused both on service utilization and suicidal behaviors, and an intervention that is designed to be straight-forward and readily transportable to other settings and patient population, is consistent with the overall mission and goal of HSR&D to develop and test interventions with broad-reaching importance and the potential for broader implementation.

Research Design and Methods

Overview. All patients currently receiving treatment for a recent suicidal crisis (significant ideation, plan and/or recent attempt requiring psychiatric hospitalization) at one of two VHA inpatient psychiatry units will be screened

to determine whether they have used the Veterans Crisis Line within the past year. Individuals who report no past-year use of the Veterans Crisis Line will be randomized to either CLF or Enhanced Usual Care (EUC). These participants will receive a more detailed baseline assessment and be re-assessed for their use of the Crisis Line, other mental health services and suicidal thoughts, plans, and behaviors at 3-, 6- and 12-months post-baseline. *Finally, qualitative interviews will be conducted with key informants (including inpatient psychiatry staff, suicide prevention coordinators, and Veterans who participated in the CLF intervention) to characterize the potential barriers and facilitators of implementation of the CLF intervention*.

Preliminary Studies. The proposed study builds on the project team's substantial prior experience in studying strategies to improve the health and well-being of Veterans with mental health disorders. This includes: (1) examining risk for suicide among Veterans; (2) conducting randomized controlled trials of behavioral interventions; (3) studying individuals at significantly elevated risk for self-harm; (4) collecting pilot feasibility data on CLF; and (5) conducting qualitative data and measuring factors relevant to implementation of interventions.

Suicide and other mortality among VHA patients. Drs. Ilgen, Pfeiffer, Bohnert, and Britton have played a key role in the ongoing evaluation of the prevalence of, and risk factors for, suicide among VHA patients. Analyses of mortality data have yielded a number of memos and dispatches to the field as well as important publications on the rates of suicide in VHA,[4,6] psychopathology, and other medical conditions as risk factors for suicide[16-18,46-50] as well as risk factors for unintentional overdose and poisoning in VHA patients.[51-54] In addition, Dr. Britton conducted a study of the Veterans Crisis Line and found that approximately 59% of all callers received a referral for VHA services.[55] Overall, this work shows a familiarity with the key clinical and policy-related issues surrounding suicide in VHA and knowledge of methods for linking multiple data sources together to conduct applied suicide-focused research.

Conducting randomized controlled trials of behavioral interventions. Our research team (Drs. Ilgen, Pfeiffer, Bohnert, Chermack, and Britton) have frequently collaborated on randomized trials of behavioral interventions in VA and non-VA settings. For example, Dr. Ilgen has two recent or ongoing HSR&D-funded randomized trials, one (Ilgen PI; Bohnert Co-I) of a cognitive-behavioral pain management approach and one (Ilgen Co-PI; Chermack Co-I) of a telephone-based motivational interviewing intervention for patients with substance use and psychiatric disorders recruited from an inpatient psychiatric unit. This latter study recently completed recruitment and, for the only follow-up period that is nearly complete, the 3-month follow-up, over 81% of participants have completed the follow-up interview at the Ann Arbor site (the study site for the proposed study). Analyses of data from Ann Arbor for the other follow-up periods indicates that approximately 20% of participants report a significant suicidal crisis at either the 3- or 9-month follow-up. Dr. Chermack (PI) and Ilgen (Co-I) are currently conducting a HSR&D-funded trial of a cognitive-behavioral intervention to reduce interpersonal violence; again follow-up rates in available data up to 6-months post-baseline exceed 80%. Drs. Ilgen, Bohnert and Chermack also have other NIH-funded work that typically have follow-up rates exceeding 80%. Drs. Bohnert, Pfeiffer, and Britton all have funding for smaller pilot intervention trials that are currently ongoing. Overall, these experiences across investigators highlight our skills in refining the content of behavioral interventions for clinical trials research, reliably delivering the intervention, and achieving high follow-up rates even in potentially challenging patient populations.

Managing risk among high-risk patients. The proposed study team has been actively involved for many years in research involving data collection from individuals at elevated risk for harming themselves and others. This includes past work by Drs. Ilgen (PI) and Chermack, conducting a NIDA-funded R21 of a cognitive-behavioral intervention for suicidal individuals with substance use disorders as well as ongoing work with VHA patients recruited from inpatient psychiatric settings and VHA patients with addictive disorders at risk for interpersonal violence (Chermack PI). Also, Drs. Bohnert, Pfeiffer, and Britton are currently collecting data on pilot studies of patients: (a) preselected for their risk of unintentional overdose (Bohnert), (b) at high-risk for poor post-inpatient depression care and outcomes (Pfeiffer), or (c) repeated suicide attempt (Britton). The pilot study that serves as the base for the proposed study was conducted by the study team (with Dr. Pope as site PI in Battle Creek) in VHA patients receiving inpatient psychiatric treatment for a recent suicidal crisis. Overall, our work with high-risk patients has made it essential that we create clear and practical risk-management procedures for patients at elevated risk for harm to themselves or others. These risk management protocols involve unambiguous instructions for the therapists and research assistants in the field for when, and how, to reach out to doctoral-level study staff for support/consultation.[56] These methods will allow us to strike an appropriate balance of the need to conduct clinical trials to reduce the risk of self-harm while balancing important human subjects concerns in this

high-risk group.

*Pilot study of Crisis Line Facilitation***.** In preparation for this proposal and with a local grant from Ann Arbor's COIN, our study team conducted a small pilot study with two aims: (1) to gather preliminary data on crisis line use among VHA patients treated for a recent suicidal crisis and (2) to obtain information about feasibility and acceptability of CLF. This study was conducted at the Battle Creek VAMC with Dr. Pope taking the lead on coordinating the study protocol at that location. *Participants (n = 23) completed an initial screening survey indicating that 12/23 (~52%) had never previously utilized the Veterans Crisis Line; ~70% (n=16/23) reported that they had not used the Crisis Line within the past year. Thus, only 30% of participants being treated for a recent suicide attempt reported that they had utilized the Crisis Line within the past year. In addition, we delivered the CLF intervention to 9 participants who had not used the Crisis Line within the past year.* Self-reported ratings of satisfaction with the CLF session were extremely high with over 90% giving the session the highest possible score on a 0-10 scale of satisfaction. Despite the small sample, we found significant improvements from pre- to post-baseline on ratings of general confidence in the ability to stay safe during a future suicidal crisis; trends approaching significance (p's <.07) were found for improvements in self-efficacy to use the Veterans Crisis Line during a future crisis, and increased comfort with using the Crisis Line. *Consistent with current recommendations for pilot work,[57] this small pilot study was undertaken to demonstrate feasibility of recruitment, acceptability of the intervention, and to shape the design of the larger trial. This pilot demonstrated that recruitment was relatively easy, the study assessments and the intervention could be integrated into an existing episode of VHA inpatient care, the intervention was well-received by participants, and proximal changes were observed in the core domains that are hypothesized to drive the key outcomes of interest. Given that these goals were achieved, according to the framework proposed by Kraemer and colleagues, the collection of additional pilot data is not necessary and the next step is to progress to the larger randomized controlled trial of the intervention.*

The pilot study of CLF also strengthened our ties with Dr. Britton (Dr. Ilgen is also a mentor on Dr. Britton's CSR&D-funded CDA). As an investigator at the CoE for Suicide Prevention, Dr. Britton is stationed at the Canandaigua VAMC where the National Veteran Crisis Line is located. He has worked with Veterans Crisis Line leadership on multiple projects including a QUERI-funded evaluation of the Crises Line.[55] These experiences provide a clear link between the data collection portion of the pilot and proposed study with the Crisis Line management infrastructure based in Canandaigua, NY.

Qualitative data collection to inform implementation efforts. Drs. Ilgen, Bohnert, and Pfeiffer all have current or recent QUERI-funded qualitative work designed to understand the impact of policy changes in VHA on key outcomes (e.g., overdose) or related to the implementation of practice changes within VHA. For the proposed project, Dr. Forman will help guide the qualitative data collection and analysis efforts, including refining the interview guide. She has extensive experience leading the qualitative component of a large number of ongoing and recent VHA research projects at the Ann Arbor COIN.

Summary. The prior work of the study team highlights the depth and breadth of expertise in the study suicide in VHA patients, the evaluation of behavioral interventions for high-risk Veterans, experience delivering the proposed intervention to the target population at one of the study sites, *and experience gathering qualitative data designed to shape the future implementation of the intervention*. These efforts underline our ability to successfully carry out all of the key components of the proposed study.

Methods. The overall purpose of this project is to test the efficacy of a brief intervention designed to encourage use of the Veterans Crisis Line among high-risk VHA patients. All study procedures will be approved by the Institutional Review Boards at all study sites and a Certificate of Confidentiality has been obtained from NIH.

Description of study sites. The proposed study will recruit from two separate study sites in Southern Michigan: the inpatient treatment unit at the Battle Creek VA Medical Center (BC VAMC) and the inpatient treatment unit at the Ann Arbor VA Medical Center (AA VAMC). These sites were selected because they treat somewhat different patient populations yet they are approximately 90 miles apart allowing us to travel between sites to share resources and training, when needed. The following numbers are based on data from both units for all of 2012. Patients seen at the inpatient unit at the BC VAMC are 6% female; 73% are White, 22% are African American, and 5% are of another race (mainly Native American); less than 1% are Hispanic. This unit treats approximately 970 patients per year drawn from a wide geographic area that include the mid-sized cities of Grand Rapids and Kalamazoo as well as the predominately rural areas of Michigan. Patients seen at the inpatient unit at the AA VAMC are 9% female; 78% are Caucasian, 18% are African American, and 5% are of

another race (mainly Native American); less than 1% are Hispanic. The inpatient unit at the AA VAMC treats approximately 415 patients per year drawn from Southeastern Michigan and Northern Ohio which includes the cities of Flint, Toledo, Southfield, and Ann Arbor. We have recruited from both sites for recent research studies. Both sites are very supportive of this research project and will provide space to conduct research interviews and CLF sessions. These units have clear suicide risk management procedures as part of standard care that includes regular suicide assessments and Safety Planning. Estimates based on the current case load indicate that ~52% of patients have a recent suicidal crisis prior to admission.

Participants will include patients 18 years of age and over who are receiving care in an inpatient psychiatric unit at either the BC VAMC or AA VAMC who report a recent suicidal crisis (significant suicidal thoughts, plans, or attempts). Information about recent suicidal thoughts, plans and attempts will be obtained by screening the admission notes in the medical records of all patients admitted to either study site.

Inclusion criteria for screening (Part 1). (1) adults age 18 years of age or older receiving care in an inpatient psychiatric unit at either the BC VAMC or AA VAMC; (2) mention of a significant suicidal crisis within the intake note; (3) medically stable and able to provide informed consent; and (4) Mini-Mental State Examination (MMSE)[58] score greater than or equal to 21.

Additional inclusion criteria for the full randomized study (Part 2): (1) no reported use of the Veterans Crisis Line within the past 12-months; (2) report current suicidal ideation (BSS[59,60] greater than or equal to 5 during the past week) as reported during the screening interview.

Exclusion criteria for screening and full study: (1) patients who do not understand English; (2) prisoners; (3) patients deemed unable to provide informed consent as stated above; (4) profound psychotic symptoms and/or cognitive deficits that would prevent patients from understanding the content of the intervention and/or assessments; and (5) participants who recently received or are scheduled to receive electroconvulsive therapy (ECT). Similar to our ongoing IIR which recruited from VHA inpatient units, we do not have explicit exclusion criteria related to psychotic or cognitive disorders. Instead of relying on diagnoses, we will make judgments of appropriateness for the trial based on the clinical judgment of the study staff (supplemented with information in the clinical record). It has been our experience that patients often are unable to provide informed consent early in a psychiatric stay but their status will improve significantly prior to discharge. We attempt to recruit participants during this period of improved stability and will include individuals who meet the above inclusion/exclusion criteria at that time.

Recruitment / Informed Consent. Recruitment for the study will begin in month 7 of year 1 and continue through month 6 of year 3. Research staff will review the electronic medical record to identify patients with a documented recent suicide crisis associated with their inpatient admission. These patients will be approached (after verifying with clinical staff that the patient is sufficiently stable) by the research staff and recruited for the screening portion of the study. As part of the informed consent process, patients will: 1) have a brief mental status examination administered by the research staff to test the patient's orientation and judgment; and 2) be able to describe to the research staff the essential elements of the study. Patients who are notably sedated or confused at the time of screening may be re-approached later in their stay if they are still interested. Consent to participate will be obtained in writing, a copy given to the participant, and filed in a confidential research file (see Human Subjects Section). Informed consent will be obtained prior to screening and will outline the study in two parts (screening and full study participation) explaining that eligibility for the full study will depend on the answers provided in the screening survey.

Based on data from the study sites, we estimate that the two units treat approximately 2770 individuals over a two year period; approximately 50% (*or 1385*) will be treated for a suicidal crisis. *In order to use a conservative estimate for the purposes of this proposal, we have built our recruiting plan around a required sample of 1,042 (or 343 fewer participants than we anticipate will be eligible).* ***Figure 2*** *outlines how the 1,042 participants who are initially approached will yield our final study sample. We also used a conservative rate based on our prior work of 60% reporting no past-year use of the crisis line (the rate was ~70% in our pilot work).* Other exclusion criteria will be used but, based on our prior work, we anticipate that these will only account for the exclusion of 1-3% of participants. *We use a conservative estimate of 80% of those who are approached about consenting to participate. Based on our prior work, we anticipate that the actual rate may be somewhat higher. If the rate is lower than 80% we will need to screen a larger number of participants but this should be feasible given that have built our recruitment model around 1,042 individuals instead of the estimated 1,385 patients who will be treated on these units over the recruitment period.*

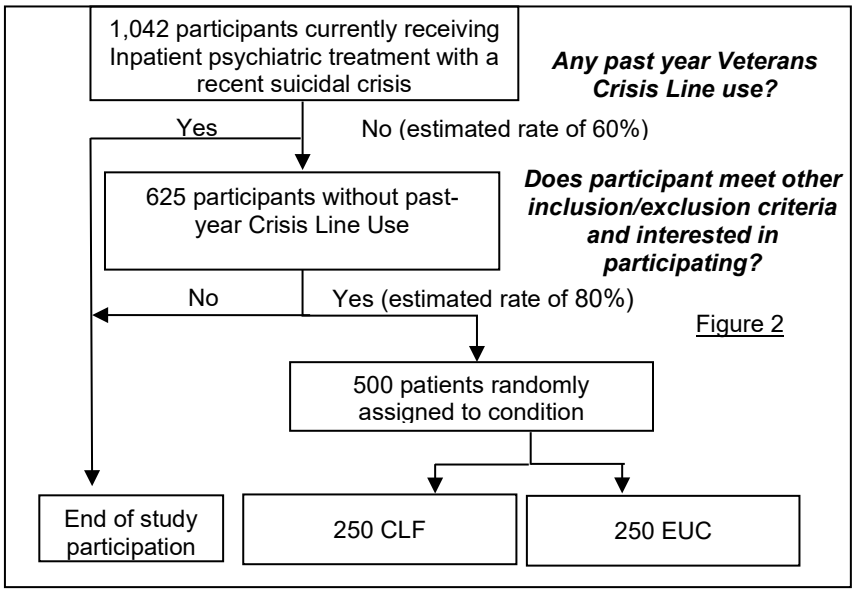


Figure 2

Screening Survey. After providing written informed consent, eligible participants will complete a brief screening survey which will ask about psychiatric symptoms, suicidal thoughts, plans, and behaviors, and Crisis Line and other service utilization. All participants who complete the screening procedure will receive remuneration of $10 which will be added to their personal items storage. We have used a similar approach in our pilot work and found it to be successful. In the event that a participant is discharged without receiving their research-related belongings, research staff will mail their belongings to the participant. Prior to mailing research staff will attempt to contact the participant by phone to obtain permission and an updated mailing address. Screening will take ~15-30 minutes.

Baseline Assessment. All patients who meet our inclusion/exclusion criteria will receive a baseline assessment to obtain more detailed information on psychiatric symptoms, service use, and perception of the hotline. The baseline assessment will also be conducted by self-report and clinical interview. Remuneration will be $25. The baseline assessment will take 45-60 minutes and will be conducted on the inpatient unit.

Randomization Procedures. Randomization to condition will be carried out blocking on gender and lifetime suicide attempt (none vs. one or more). Computerized randomization will proceed in blocks of randomly chosen and varying sizes, in order to equalize randomization over time and to prevent the possibility that staff could unwittingly manipulate subject assignment to conditions.

Follow-up Methods and Interviews. In order to contact participants at follow up, participants will be asked to provide contact information and identify additional contact persons at the baseline assessment. However it is likely that this contact information may change across follow-up. For all participants who signed a HIPAA form, in order to maintain up-to-date records, the research staff will access demographic information (e.g. address and phone number) in the medical records. Because not all local VA's have the ability to accept veterans for an inpatient psychiatric stay, many of the participants who are hospitalized at the Battle Creek and Ann Arbor VAMCs will receive the majority of their post-hospitalization medical care at other VA locations. In order to obtain the most up to date contact information, research staff will use VistAWeb to access the demographic information collected in the medical record at all VA locations where participants receive medical care. Participants will be contacted for follow-up assessments at 3-, 6-, and 12- months after the baseline assessment. The follow-up assessments will be conducted in person, whenever possible, and will take ~30-45 minutes. The 3- and 6-month follow-ups are intended to measure immediate suicidal behaviors and treatment utilization. *The use of a 12-month follow-up provides greater opportunity for suicide attempts to occur. Also, the 12-month follow-up will provide data on the longer-term engagement in suicidal behaviors and allow for secondary analyses on the*

effects of post-baseline Crisis Line utilization on subsequent symptoms. We anticipate a conservative follow-up rate of 80% even though we generally exceed this rate in our studies of adults with substance use disorders. Participants will be asked to come to the VA to complete follow-up assessments. In cases where this is not feasible for the participant, the research staff may arrange to meet the participant at a convenient location in the community (e.g. their home, a library, a restaurant, etc.) If we interview participants outside of the study site, we will typically arrange for at least two research staff members to go together for safety reasons. All research staff will be required to follow study check-in procedures when conducting follow-up assessments outside of the study site. As part of our recruitment and throughout the study, small items of insignificant value such as pop, water, water bottles, card holders, pens, magnets, etc. will be given to participants as necessary, and will not be used as a contingency of study participation. Participants who are unavailable to complete the assessments in person (i.e., move out-of-area) may be interviewed by phone at follow-up. In order to facilitate easy understanding of the survey questions and scales, if a participant schedules a telephone follow-up appointment, the research staff will mail a copy of the survey to the participant to use to follow along during the assessment. If a participant is unable to complete the follow up appointment by telephone or in person, they will be mailed a copy of the survey to complete at home. Clinical interviews will still only be conducted in person or over the phone.

Participant Remuneration and retention. Participants will be remunerated $30 for each of the 3-, 6- and 12-month assessments. Participants who complete the assessment over the phone or by mail will be mailed compensation for their participation. The following protocol to increase retention has been refined based on our prior work [61,62] and will be used as needed: 1) during the baseline, the name, address, and telephone number of up to three contact persons will be obtained; 2) reminder letters and telephone calls will be made prior to the next assessment; 3) appointment slips for their next research assessment will be handed to participants and 4) follow-up assessments will be scheduled at the participant's convenience including evenings and weekends.[63] VHA treatment records and public death records will be assessed for any patients lost to follow-up.

Description of CLF intervention. The CLF intervention will be delivered as soon as possible following randomization. The therapist will meet with the patient on the inpatient unit for approximately 45-60 minutes. The session will begin with a brief discussion of the patient's most recent suicidal crisis and how they have sought help during past times when they were feeling suicidal. This discussion will elicit feelings and cognitions about help seeking. The second portion of the CLF session will involve the therapist presenting some information about the Veterans Crisis Line (e.g., number of calls per day, the availability of Veterans to talk to callers, the types of support offered, the online Chat Line). The session then will focus on the participant's perceived barriers and facilitators to using the Veterans Crisis Line. Although the specific content will vary, in most cases, a portion of this discussion will be focused on evaluating and challenging cognitions about the hotline (e.g., "I would just be a bother if I called them", "all they would do is lock me up", "they can't do anything for me"). The therapist will work with the patient to develop specific challenges to these negative thoughts. The next portion of the CLF session will involve a discussion of practice strategies to help access the Veterans Crisis Line. These strategies include a discussion of how to find information online, where to store the number, how family members and/or friends can help, etc. The overall goals of these first components of CLF are to address potential concerns about using the Veterans Crisis Line and discuss practical strategies that would facilitate future Crisis Line use during periods of acute need. Technology will be incorporated in the CLF intervention in several ways.. During the intervention participants will be shown the online chat feature of the crisis line website. The session will culminate with the goal of having the participant directly call the hotline from a VA phone. The therapist and participant will review his/her immediate cognitions prior to making the call. Any negative cognitions will be re-evaluated based on the content of the prior discussions. The participant will be encouraged to tell the Crisis Line why s/he is calling (i.e., in a research study, currently hospitalized for a suicide attempt, and learning about the Crisis Line). S/he will also be given a list of questions as "conversation starters" and encouraged to talk with the Crisis Line for 5-10 minutes. Also, participants will be encouraged to think of their own questions to ask the Crisis Line therapist. The general goal of this portion of the CLF session is to increase self-efficacy in calling the Crisis Line and provide participants with a positive experience interacting with Crisis Line staff. If the participant is not comfortable reaching out to the Veterans Crisis Line by phone, the therapist will offer the option of demonstrating the use of the confidential online web chat feature. The therapist will type at the computer while the Veteran observes. The therapist may use the web chat to ask some of the questions discussed by the Veteran during the session. The goal is similar to the practice call in that it will hopefully increase self-efficacy in contacting the Crisis Line via online web chat and provide participants with a positive experience with the Crisis Line.

It is important to note that the CLF session presents the Veterans Crisis Line as an important resource to help supplement existing VHA services for psychiatric patients. Participants will be encouraged to discuss the Veterans Crisis Line with their inpatient and outpatient mental health treatment teams and to consider Crisis Line use within the broader context of their Safety Plan. They will be informed that it is a potentially useful additional tool and it should be used, as needed, in addition to, not in lieu of, other VHA mental health services.

It is also important to note that recruiting participants during their inpatient psychiatric hospitalizations creates a unique set of challenges that will require flexibility from the research project. For example the participant may be discharged from the hospital after consenting, and may choose to leave prior to completing portions of the baseline assessment or intervention. If the participant chooses to leave, but remain in the study, we may complete portions of the assessment or intervention at a later date by setting up an appointment for the participant to return to the VAMC.

Developing a training protocol for CLF providers. During the initial phase of the project, we will make minor revisions to the intervention content and the training protocol**.** The pilot intervention was delivered by a study Co-I (Dr. Pope) and an important step is to ensure that the intervention content is appropriate for masters-level study therapists. Trainings in the intervention will be co-led by Drs. Ilgen, Chermack, and Pope; Dr. Ilgen developed the intervention, Dr. Pope has experience delivering it as part of the pilot project and Dr. Chermack has extensive experience as a trainer of therapists for brief motivational interventions. Dr. Chermack will ensure that the content and practical expertise of Drs. Ilgen and Pope will be appropriately translated for the study therapists. Dr. Britton will ensure that the Veterans Crisis Line staff are aware of the study and will train them on how to respond to study callers. Study calls should not place an undue burden on the Crisis Line given that they field well over 20,000 calls per month, but Dr. Britton will work with them to make sure that they are receptive to study callers. For example, he will make sure that the phone numbers of the study sites will be placed on the list of "appropriate frequent callers" so that Crisis Line staffers understand the nature of the call.

CLF training will begin with a review of the literature on brief interventions and suicide risk factors, the rationale for the present study, as well as psychoeducation regarding suicide risk and treatment-seeking. Training will also involve a description of cognitive case conceptualization and examples of strategies to challenge maladaptive cognitions. Exercises will include role plays targeting treatment-related beliefs and suicidal thoughts. Role play sessions will be recorded and coded for fidelity (adherence and competence). Sessions will be reviewed in detail with Drs. Pope and Chermack, who will provide supervision and instruction. Providers will demonstrate proficiency, via role play practice, prior to delivering sessions to pilot participants.

Fidelity of the Intervention Conditions. Procedures for monitoring clinical adherence and competence include audio recording of all CLF sessions. For feasibility reasons, 25% of tapes in the CLF condition will be randomly selected and coded by two independent raters on the following scales. The *Condition-Specific Adherence Scale* will include a broad checklist of topics covered during the intervention. Instructions regarding item intent, examples, and scoring guidelines will be developed for intervention (e.g., discussing barriers, etc.). The *Clinical Skill/Competence Scale* will include Likert items based on modified items from the Yale Adherence and Competence Scale (YACS).[64,65] The measures will provide important information regarding the CLF session fidelity, and also will be used to maintain supervision and consistency of the interventions.

The Enhanced Usual Care Condition. The standard of care for all patients in either study site who are identified as having a recent suicidal crisis is to regularly assess for suicidal thoughts/plans, to retain participants who are at high immediate risk for suicide, and to develop a Safety Plan prior to discharge[39]. The proposed study will not attempt to directly shape the care provided during or after the episode of care during which the participant was recruited. This is true for both conditions. However, both conditions will provide additional information about the Veterans Crisis Line. Those in the EUC condition will receive some additional enhancement; they will be provided with materials that include the Veterans Crisis Line number and encouraged to seek help if they feel suicidal in the future. All participants will receive a list of numbers for VHA outpatient mental health clinic(s) within their community and encouraged to schedule an appointment. Most of this should be redundant with the services provided during standard care but all of this information is included as part of EUC to ensure that all participants receive this information about potential sources of support.

Management of acutely suicidal participants. Given the high-risk nature of this study, it is important that we have a clear protocol for suicide risk management. We have extensive experience studying high-risk patients in our VA- and NIH-funded work and have concrete plans to manage suicide risk (see Human Subjects Section). Briefly, because recruitment and the intervention will occur in a VHA inpatient psychiatric treatment unit,

participants will be mostly safe during these study activities. They will be informed during the consent process that we will need to inform treatment staff about any recent suicidal thoughts, plans or attempts. All efforts will be made to have the bulk of follow-up assessments occur within VHA facilities. These sessions will begin with a review of our need to inform others if the participant is determined to be at acute risk for suicidal behaviors. Determinations of high-risk status will be made through a review of the assessment measures, and discussions, when appropriate, with Drs. Ilgen, Pope and Pfeiffer. When it is determined that care is needed, the first choice is for participants to directly contact treatment providers. If the participant is unwilling to do so, study staff will contact local authorities. It has been our experience that this happens very rarely even when working with high-risk individuals. Also, we will use the VHA Crisis Line for support of patients deemed to be at high risk. This has the potential to influence the measurement of our key outcome. However, we feel that this is necessary for human subjects protection. Assessing our key outcomes is still feasible because risk management procedures are equivalent for participants in both conditions (and interviewers are blind to condition). Thus, this could hamper the ability to detect differences between conditions. We used conservative estimates of study effects for both our aims so as still have adequate power to detect effects.

Measures. Established instruments were chosen to measure key information for this study (**Table 1**). The study will also use other data sources (.e.g., chart reviews) which are described at the end of this section.

Demographics. The demographics assessment from the Diagnostic Interview Schedule (DIS) will be used to assess educational background, employment, income, ethnicity, and marital history. Additional background questions will assess military history, technology use and prior knowledge of the study.

Screen for suicidal ideation. The Beck Scale for Suicide Ideation (BSS)[60,66] is a 21-item self-report measure of respondents' suicidal thoughts, desire to attempt suicide, and preparation within the past week. The BSS has strong internal consistency (Cronbach alpha = .97) and moderate to high item-total correlations (.56 to .92 for each item); prior research indicates that a score of > 5 is a good indicator of elevated suicidal ideation.[60,66] The BSS is a self-report measure allowing us to rapidly screen a large number of participants; a more detailed suicide assessment will be conducted at baseline and used for the primary study analyses. The readiness to change and readiness to live ladders are 2 items that will also target suicidality. These items have been used in similar suicide prevention research conducted with Veterans by Dr. Britton (Co-I), and will be used to assess change across follow-up.

Prior experience with the Veterans Crisis Line. A series of questions will ask about use of the Crisis Line, reasons for prior use (or lack of use), and perceived barriers to future use of the crisis line. These items will be included in the screening assessment (to understand, in part, why participants who used the Crisis Line once may not have used it again) and the follow-up assessments (to document changes in perceptions and use of the Crisis line over time).

The Colombia Suicide Severity Rating Scale (C-SSRS)[67] is a low-burden, interview-based measure of both suicide-related ideation (e.g., "Have you wished you were dead or wished you could go to sleep and not wake up?") and behavior (e.g., "Have you made a suicide attempt?"). The C-SSRS will ascertain more complete information about suicide-related thoughts and behaviors, such as lethality associated with attempts and features of ideation (e.g., frequency, duration, controllability, deterrents to active attempt, and reasons for ideation). At baseline, the lifetime version of the C-SSRS will be used and, at follow-up, the *Since Last Visit* version will be modified to cover the interval since last assessment.

Psychiatric symptoms. Two measures will be used to assess current Axis I psychiatric disorders at baseline, including the PSTD Checklist (PCL-5) to assess post-traumatic stress disorder symptoms, and a subset of questions from the Behavior and Symptom Identification Scale (BASIS-24) to assess symptoms of psychosis. The PCL-5 is a brief 20 item scale that measures various symptoms of PTSD, and is widely used throughout military and Veteran populations.[68] The BASIS-24 is a self-report tool developed to assess a variety of mental illnesses, and has good validity and reliability.[69]

Depression. The Patient Health Questionnaire (PHQ-8) will be used to measure depression and suicidality. The PHQ-8 is a widely used measure of depressed affect with strong psychometric properties that has been utilized in numerous psychiatric and medical patient populations.[70]

Alcohol and drug use. Alcohol and drug use will be measured using a subset of questions from the Brief Addiction Monitor (BAM).[71] This instrument is a self-report measure designed to assess substance use as well as risk factors and protective factors related to substance use.

Mental health treatment utilization. Questions about treatment utilization will be based on modified items from the Treatment Services Review.[72] Information on treatment will be collected including whether a session was scheduled/attended, the number of sessions attended, type and location of provider (primary care doc, therapist, etc.), and type of treatment received (therapy vs. medications). Questions have been added to assess for use of the Veterans Crisis Line and any other Crisis Line services. Questions have also been added to assess participants' use of safety plans.

Table 1 Assessments	Screening	Baseline	Follow-ups
Demographics	X		
BSS (Suicidal ideation and lifetime attempt)	X		X
Prior experience with the Crisis Line	X		X
C-SSRS (Detailed suicide assessment Interview)		X	X
Treatment Services Review	X		X
Hoge (Perceptions of Services)	X		X
Readiness to Live/Change	X		X
Safety Plan	X		X
PHQ-8 (Depressive symptoms)		X	X
PCL-C (PSTD symptoms)		X	X
BIS-Brief (Impulsivity)		X	X
INQ-10 (Interpersonal needs)		X	X
CTS2 (Experience of violence)		X	X
PEG (Pain)		X	X
Basis-24 (Psychotic symptoms)		X	X
BRFSS – HRQoL (quality of life)	X		X
BAM (Substance use/addiction)		X	X
TLFB (Suicidal crisis timeline interview)		X	X
PIQ (Post intervention questionnaire) ALSO AFTER INTERVENTION or CONRTOL		X	
Chart Abstractions (Diagnoses, medication, utilization)		X	X

Perceptions of Services. An Adaptation of the Hoge scale will be administered to all participants in order to assess beliefs about mental health treatment. The Hoge will measure key perceptions and potential barriers to service use. The Hoge has also been used previously in Veterans.[73]

Impulsivity. The Barratt Impulsivity Scale (BIS) is one of the most commonly used self-report measures for assessing impulsivity. This 8-item, brief version of the BIS has been found to have high construct validity compared to the original 30-item version.[74]

Thwarted belongingness and perceived burdensomeness. The Interpersonal Needs Questionnaire (INQ-10)[75] is a brief measure that will assess for thwarted belongingness and perceived burdensomeness, two important pieces in the interpersonal theory of suicide.

Experience of violence. The Conflict Tactics Scale (CTS2)[76] is a broad and commonly used measure of interpersonal violence. A subset of items from this scale will be used to assess conflict both within relationships and in general interactions.

Pain. Information about participants' experiences with chronic and acute pain will be collected using the PEG, a measure focused on average pain intensity (P), interference with enjoyment of life (E), and interference with general activity (G). Items in the PEG come from the well-established Brief Pain Inventory (BPI), and have both high reliability and construct validity.[77]

Quality of Life. The Behavioral Risk Factor Surveillance System (BRFSS) is a large national survey sponsored by the CDC, VHA, and SAMHSA. A subscale within this long-standing and well-recognized survey targets health related quality of life (HRQoL)[78], and will be used to assess changes in perceived quality of life across follow-up.

Suicidal crisis timeline interview. The Timeline Follow-Back Assessment (TLFB) protocol has primarily been used to examine daily alcohol and other drug consumption over specified time intervals (e.g., 90-180 days) using monthly calendars. Several studies have demonstrated the reliability and validity of this method of assessing alcohol use using test-retest and convergent methodologies,[79,80] and a recent study supports the reliability and validity for assessing drug use.[81] This measure has been adapted to assess suicide attempts and calls to the Veterans Crisis Line. This Timeline Follow-Back Assessment for suicidality also resembles a subsection of the Suicide Attempt Self-Injury Interview (SASII), a widely used instrument designed to assess the factors involved in nonfatal suicide attempts and intentional self-injury.[82] *Post-intervention questionnaire.* The Post-intervention Questionnaire will be comprised primarily of Likert items assessing the relevance and helpfulness of the informational materials (EUC) or the therapy intervention (CLF). Dr. Chermack (Co-I) and several other CCMR investigators have used similar measures to target these constructs in prior research.

Medical Record Abstraction and Administrative Data Extraction. We will abstract VHA records for information regarding Veterans Crisis Line use, inpatient psychiatric admissions, outpatient mental health service utilization, as well as any recorded suicidal thoughts, plans and attempts. These reviews will cover the year prior to treatment participation as well as the entire follow-up interval. A randomly-selected 25% of charts will be double-coded to allow Kappas to be calculated as a measure of the chart coding. This will capture all health care utilization within the VHA system; outside treatment use will not be captured. Thus, chart abstraction will supplement the self-report measures of service use but chart data will not be examined as a separate outcome. Medical record abstractions will only give the study utilization data contained in the Battle Creek and Ann Arbor medical records. Since many of the participants in this study will receive the majority of their medical care at their local VA locations, we also plan to extract data from the CDW Production Domains, CDW MCA (formerly DSS) NDE, MedSAS Files including VetsNet Files and CAPRI/VistAWeb. Access to real SSN data is needed in order to link the extracted administrative data to data from chart reviews, and in order to use VistAWeb. Data will be extracted over follow-up to assess VHA service use (e.g. information regarding Veterans Crisis Line use, inpatient psychiatric admissions, outpatient mental health service utilization, etc.), diagnoses, medication use, the results of all screening assessments, and mortality (from the Beneficiary Identification Records Locator Subsystem of Vital Status; mortality will also be measured by information that comes from the contacts nominated by that participant or records databases and obiturary listings). CAPRI/VistAWeb will be used to check for external appointments. VHA service use, diagnoses and other medication use will be extracted from CDW Production Domains, MedSAS files and CAPRI/VistAWeb. We have found that the Veterans Crisis Line only puts contact data into the CPRS medical chart if a consult is required with a suicide prevention coordinator. To collect all VCL contact data, we will be working with the Veterans Crisis Line to create a data use agreement, where we will specify the information we are requesting and send identifying data to link that information to our study participants, have the VCL link the data for us, and we access that data in VINCI.

Assessment of barriers and facilitators of implementation. The goal of the qualitative component is to inform modifications to the CLF intervention that will facilitate future implementation and scaling-up, and to help explain quantitative findings related to efficacy and mechanisms of action of CLF. *One of the primary goals of this phase of the project is to identify potentially effective and testable implementation strategies for a QUERI phase 2 hybrid effectiveness/implementation study.*

Sampling: We will conduct individual semi-structured interviews, at each site with: (1) inpatient psychiatry staff (physicians, nurses, and social workers); (2) suicide prevention coordinators; and (3) Veterans who participated in the CLF intervention (after they have completed the 12-month assessment). Veterans who were randomized to the CLF condition will be purposively sampled based on whether the Veteran made a suicide attempt during the follow-up interval. We anticipate recruiting 10 Veterans (5 with and 5 without a subsequent attempt). Data analysts will create envelopes for each participant to be opened at or after the 12-month follow up, with information regarding randomization group (CLF vs. EUC) and if there were any suicide attempts post-baseline. At or after the 12-month in-person or phone assessments RAs will open these envelopes to determine eligibility, while the participant is completing the survey. If eligible, the RA will inform the participant and deliver the recruitment script. All participants who are enrolled in the study were notified at the initial consent they may be contacted for further participation in this study after completing their 12-month assessment. We will also be recruiting eligible participants via phone/mail in one of two ways. 1. After completing the 12-month assessment via phone, RAs will use the recruitment script to ask eligible participants if they are interested in the qualitative interview portion of the study. Those that are interested will be mailed consent and HIPAA forms, a return envelope, and letter explaining this portion of the study and next steps if interested. 2. We may contact eligible participants who have previously completed their 12-month follow up in person or via phone. We would do this by mailing the consent and HIPAA forms, a return envelope, and a letter detailing the qualitative interview portion of the study and next steps. For both options, approximately one week later, RAs will call these participants to consent via phone, if the participant is interested. Participants will be asked to send the consent and HIPAA forms back via the return envelope, or by meeting with the RA in person at an upcoming appointment, if they prefer. Once the RA receives the documents, they will call the participant to complete the interview over the phone. Suicide prevention coordinators and inpatient psychiatric unit providers will be sent an email asking if they are interested in participating in an interview about the intervention session. We will send up to 2 follow-up emails if no response is received. These providers have collaborated with the study team thus far, and given their busy workload may not be responsive to email. If this is the case, a study team member may stop by the office of a

provider to mention the interview in person. A recruitment discussion will cover the same content as the email script. Data Collection: We have developed interview guides tailored to each group of participants. Interviews with inpatient staff will cover perceptions of how CLF impacted care on the unit and what might facilitate broader implementation of CLF. Interviews with suicide prevention coordinators will cover their impressions of CLF and ideas to extend use of CLF to other clinical settings. Interviews with the participants in the CLF intervention will cover their experience participating in CLF, and will solicit ideas for making CLF more convenient and appealing. Veterans will be asked to identify potential strategies to address barriers to engagement. Participants who are treatment providers will be recruited by e-mailing relevant stakeholders. No incentives will be provided to VHA staff; however, per recommendation from the ACOS of Mental Health, clinicians will be excused from clinical duties to participate. Veteran participants will be recruited for the qualitative component of the study following their 12-month assessment. They will go through a separate process of providing consent and will be remunerated $30 for their participation in the qualitative interviews.

Dr. Forman will help guide the qualitative data collection and analysis efforts, including refining the interview guide. These interviews will be conducted in a private study office or in another mutually convenient private location. Each interview will last about 30 minutes, and, with participants' permission, will be audio-recorded. Qualitative data are ideally collected until the point of thematic saturation is reached; that is, when no new themes are identified. Because the required sample size cannot be known in advance, we have estimated sample size based on prior experience with similar studies.[84] We anticipate that this will result in approximately 10 patient interviews (5 from each site) and approximately 8 staff interviews (4 from each study site) with an inpatient psychiatrist, nurse, and social worker, and a suicide prevention coordinators.

Research Electronic Data Capture (REDCap)

Study data will be managed using REDCap (Research Electronic Data Capture). REDCap is a secure web application approved by the VA Office of Information & Technology (OI&T), and designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system was developed by a multi-institutional consortium which includes the Department of Veteran's Affairs and was initiated at Vanderbilt University. The database is hosted on VA Informatics and Computing Infrastructure (VINCI) virtual servers. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the Denver MIRECC Data and Statistical Core. This iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap is flexible enough to be used for a variety of types of research and provides an intuitive user interface for database design and data entry.

VA Informatics and Computing Infrastructure (VINCI)

We will request data extracts from the VHA Corporate Data Warehouse (CDW). VINCI is a partner with the Corporate Data Warehouse and hosts all data available through CDW. As VA and VHA research progresses, large amounts of data are being collected into databases maintained by a variety of investigators, studies, and locations. Individual investigators and multiple databases may lack sufficient resources to ensure consistency and quality control, or a long-term commitment to data storage and access. Therefore, there are less consistent standards for the protection of Veterans data, data quality, and data access compared to a centralized repository. A centralized research data repository, such as the VA Informatics and Computing Infrastructure (VINCI), offers a number of important advantages: Consistent, defined, and transparent security and standards for access to data; a common point of entry for all investigators who use the data; tools for analysis and reporting; tighter and more consistent control over the standards and quality of the data included; and the ability to standardize and update terminology and format as technology and methodology improve. VINCI is a partnership between the VA Office of Information Technology (OI&T) and the Veterans' Health Administration Office of Research and Development (VHA ORD). VINCI provides the storage and server technologies to securely host suites of databases integrated from select national data. These servers reside at the Austin Information Technology Center (AITC), located in Austin, Texas. To ensure the protection of Veterans data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources will be approved in accordance with the requirements of National Data Systems (NDS), VHA

Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. Researchers and Operations staff will access the data along with the tools for analysis and reporting in the secure, virtual working environment through a certified VHA network computer using the VA INTRANET (NOTE: VINCI is not accessible through the INTERNET). If not working within a VA or VHA hosted office environment containing VA network access, researchers may access VINCI through an approved Virtual Private Network (VPN) and Remote Desktop application. The remote computing environment will enable data analysis to be done directly on VINCI-CDW servers located at the Austin Information Technology Center, thus keeping all data from being transmitted to local PC hard drives.

VINCI Data Collection

VA provides care to veterans at over 1,400 points of care. At the core of virtually all care processes is a broadly scoped and extensively used electronic health record system known as the Veterans Information System Technology Architecture (VistA). VistA provides a longitudinal view for patients receiving care nationwide including diagnosis, procedures, pharmacy, orders, labs, microbiology, physiologic measurements, and text documents. VA uses 128 VistA implementations to provide longitudinal electronic health record services nationwide for more than 25 million veterans historically. The aggregate content of these 128 VistA systems includes just over 1.03 Billion documents (e.g., Progress Notes, Discharge Summaries, Reports) accumulating at a rate of 638,000 each workday; 1.65 Billion orders (+955,000 each workday); 590 Million images (+884,000 each workday); 1.06 Billion vital sign measurements (+729,000 each workday) and 850 Million medication administrations (+607,000 each workday).

VA Informatics and Computing Infrastructure (VINCI) aggregates data sources from individual VistA systems, data from the Regional Data Warehouses for all 4 VA regions, the VA Corporate Data Warehouse, and the VA Health Data Repository and prepares them for research use. Other data published by the VHA Decision Support System (DSS) and Inpatient and Outpatient Medical SAS (MedSAS) can be requested through VINCI. VA National Data Services and other data stewards regulate the right to use the data, but VINCI facilitates the process. VINCI servers for data, applications and virtual sessions are physically located in the VA Automation Center in Austin, Texas. This secure enclave with 20 racks of high-performance servers and 72 terabytes of high-speed data storage has multiple layers of security to prevent data loss. When study data requested through VINCI is approved for use, it is extracted from source databases and placed in SQL tables accessible only to the research team and VA Automation Center OI&T operations personnel.

VINCI Natural Language Processing (NLP)

The VINCI application library has a suite of Natural Language Processing (NLP) tools for extracting information from unstructured text. The ability to create textual reports offers flexibility to clinicians for describing symptoms, vital signs, behaviors, attitude, instructions, patient and family history, and much more; but free text is not a data format well suited to the analytical tools familiar to researchers.

VINCI has an NLP “Pipeline”, a collection of configurable NLP modules available as a Service Oriented Architecture (SOA) within the VINCI processing environment. This SOA pipeline, named V3NLP, is more easily configured than other NLP pipelines and it is easier to adapt existing GATE or UIMA NLP modules to the SOA environment. VINCI and their customers have adapted V3NLP to data patterns specific to the VA and V3NLP has been used for several clinical use cases.

Data analyses

Data Management. The project’s data manager will conduct all data management and analysis activities under the supervision of Drs. Ilgen and Bohnert. When data entry is required, research staff will use double entry procedures and reconcile discrepancies. Data cleaning will be conducted throughout the data collection period to ensure the production of a final dataset for analysis. SAS (Statistical Analysis System) will be used to examine and prepare data for the analysis.

General analytic approach. Hypotheses will be planned a priori, and will be limited to the examination of a limited number of outcomes. We will utilize an “intent-to-treat” approach and conduct all analyses in models. All analyses will use two-sided tests because it is possible that the intervention participants might have worse outcomes compared to EUC participants.

Analyses will begin with descriptive data analyses to determine distributions of key variables, to collapse categories, if necessary, and to review data for outliers and clear anomalies. Tests for linearity, independence, missingness, and distributional assumptions will also be performed. Normalizing transformations of the dependent variables will be utilized, if necessary. We will validate the randomization scheme by comparing the

initial groups on key variables that could be associated with the outcomes. Where we identify significant differences between groups, we will either adjust for these variables or conduct stratified analyses. Prior to fitting any analytic models, a graphical exploration of the outcome variables will be conducted.

Missing data. Every effort will be made to minimize missing data. Where we have missing covariates that are necessary for analysis, we will perform multiple imputation of missing data and combine the results from 5 imputations based on Rubin's method to produce an estimate and the corresponding confidence interval accounting for missing data uncertainty.[85] For follow-up attrition, the proposed mixed-effects regression model will allow the use of data from all participants (not just those with complete follow-up) and provide unbiased parameter estimates that account for missing data under the missing-at-random assumption.[86] We will examine for non-random attrition, and if we find, for example, attrition rates to depend on a baseline covariate, we will include this covariate in the model. If we find attrition to depend on treatment use or ideation at prior assessments, we will utilize an appropriate pattern mixture model or multiply impute data based on an appropriate pattern mixture model assumptions based on the observed missing data pattern.[87]

AIM #1: *Test the efficacy of the CLF on Veterans Crisis Line utilization, as well as outpatient mental health treatment utilization, at the 3-, 6-, and 12-month follow-ups.* Data Analysis for Aim 1: The primary purpose of Aim 1 is to examine the impact of the intervention on crisis line utilization. We will use regression analyses, specifically, logistic regression models, to examine group status (CLF vs. EUC) as a predictor of crisis line utilization (coded as yes/no for any use). A positive and significant parameter estimate for the CLF will indicate that the intervention is effective at increasing the likelihood that participants will call the crisis line.

A goal of the crisis line service is to link callers to mental health services. Consequently, we will also use regression analyses to determine whether participants who are randomly assigned to the intervention condition generally have significantly greater use of mental health treatment compared to those assigned to the control condition. A dependent variable will be created based on the measures of mental health service use that indicates whether or not mental health treatment was initiated (defined as at least one visit) at any point in the year of follow-up. Consequently, logistic regression will be used to examine group status (CLF vs. EUC) as a predictor of mental health treatment initiation. To examine the outcome of continuation of treatment, we will use a dependent variable based on the number of sessions of mental health treatment attended in each three month period (1-3, 4-6, 7-9, and 10-12 months) following the baseline from data provided at each follow-up visit on the mental health service use measures. Because this dependent variable is a count, depending on the distribution (proportion of zeros and degree of skewness), Poisson regression or one of the modified Poisson regressions, such as negative binomial or zero-inflated models, will be used. This analysis will be implemented using a generalized linear model with a generalized estimating equation to account for the potential correlation in repeated measures over time.[88] If the intervention is effective, the CLF group will have a significantly greater mean number of sessions attended over follow-up period than the EUC group. Additional exploratory analysis will include three indicators for four three-month periods and interaction terms between indicators of periods by study group, which will explore if the CLF effect varies as a function of time.

AIM #2: *Test the efficacy of CLF on likelihood of suicide attempts.* Data Analysis for Aim 2: We will again use a regression framework. Initial analyses will examine the distribution of suicide attempt data over follow-up in order to select an appropriate outcome measure, such as a count of suicide attempts over each follow-up period (which will require use of Poisson regression or a related method) or a dichotomous indicator of any suicide attempts vs. none during a follow-up period (requiring logistic regression). We will again use a generalized linear model with a generalized estimating equation to incorporate repeated follow-up assessments in one model.[88] The primary explanatory variable will be the group indicator (CLF vs. EUC group). We will explore potential variation in the effect of the intervention over time by including interaction terms of the group (CLF vs. EUC) by time indicators.

Secondary Aim 1: *Test the extent to which post-baseline use of the Veterans Crisis Line mediates the effect of CLF on suicidal behaviors*. *Data Analysis for the Secondary Aim: We hypothesize that the primary mechanism of action of the CLF intervention is that it will facilitate greater use of the Veterans Crisis Line, which will prevent suicidal behaviors. If this hypothesis is true, then Crisis Line use would mediate the effect of CLF on suicidal behaviors.* In order to establish temporal ordering, we will examine whether Veterans Crisis Line use during the first 6 months post-baseline mediates the effect of random assignment on 6- and 12-month measures of suicide attempts.[89,90] We will first determine the whether study condition is associated with Veterans Crisis Line use over the first six months of follow-up and check for a direct effect of Veterans Crisis Line use in the first 6 months on

suicide attempts as measured at 6- and 12-months follow-up. We will estimate the indirect effect of the intervention on suicide attempts through Crisis Line use and conduct significance testing of this effect using macros created by Preacher and Hayes.[91]

Secondary Aim 2: *Understand barriers and facilitators of implementation of the CLF intervention, based on qualitative interviews with treatment providers and at-risk Veterans.* Interviews will be used anecdotally and may be transcribed by study RAs. Study staff will review audio tapes to identify themes and other relevant information regarding the delivery and implementation of CLF sessions. We may choose to conduct a thematic analysis[92] using a combination of deductive and inductive coding, beginning our analysis with preliminary codes based on the domains in our interview guides. We may use QSR NVivo 10 software[94] to organize the data. To inform and facilitate future spread of the intervention, we will compare data from the two sites to gain insight on the effect of organizational context on implementation. We may also analyze Veteran interview data by sub-group to identify differences, if any, between the experience of Veterans with and without suicide attempts during the follow-up interval.

Power Analyses

It is expected that 80% of participants will be retained (n=400). We conservatively have estimated power without accounting for methods that will allow inclusion of participants with partial follow-up data or the gains in power generated by the use of repeated measures in some analyses. The powerlog procedure in Stata was used to calculate power for logistic regression; for Poisson regression G*Power 3.1.5 software was used. For Aim 1 sample size calculations, we assume that basic usual care practices could increase utilization of the Veterans Crisis Line among previously non-utilizers to approximately 30%, similar to our estimate in our pilot data of the overall level of past-year Veterans Crisis Line use among Veterans treated for a suicide attempt. We achieve 80% power to detect a difference of 7.5% in the intervention group (i.e., 37.5% calling the crisis line), assuming a two-sided alpha of 0.05, based on logistic regression. This corresponds to an odds ratio of 1.4. For Aim 1, we will also examine overall mental health treatment utilization. Based on preliminary data collected as part of our on-going trial recruiting from psychiatric inpatient units, we estimate that 80% initiate outpatient mental health treatment in the first three months after discharge. To detect an increase in proportion initiating treatment to 84% in the intervention group (equivalent to an odds ratio of 1.3), the sample size of 200 per group will achieve greater than 80% power using a two-sided 0.05 level test, based on a logistic regression. To examine treatment utilization (number of mental health clinic visits), we assumed a mean rate of 1.2 visits per person in each 3-months-period in the EUC group, based on data collected in the above-mentioned on-going trial. The proposed sample size of 200 per group will provide 80% power to detect an effect size of 1.3 in each 3-months-period using a two-sided 0.05 level test, based on Poisson regression. For Aim 2 sample size calculations, we estimate that 20% of EUC participants will attempt suicide based on data from our ongoing trial of psychiatric inpatients. For the purpose of estimating power, we assume that a dichotomous outcome variable (any suicide attempt vs. none) will be used. We achieve 80% power to detect a difference of 4.5% in the intervention group (i.e., 15.5% attempting suicide), which corresponds to an odds ratio of 0.7. Thus, the proposed study is powered to detect moderate effect sizes for all aims, which is consistent with the low-intensity intervention approach used in CLF that can result in substantial improvements in suicide outcomes at a population level.

Dissemination and Implementation Plan

Members of the research team are well-positioned to inform VHA policy on suicide prevention. The Canandaigua COE (site of Dr. Britton) was funded as a part of ongoing VHA efforts to study and reduce Veteran suicides and Ann Arbor (site of Drs. Ilgen, Chermack, Pfeiffer and Bohnert) has played a central role in the evaluation and monitoring of suicide mortality in the VHA. Study staff regularly interact with VHA leadership in Operations and Services about how to improve system- and individual-level responses to Veterans at high-risk for suicide. Overall, we are acutely aware of the health system's priorities related to suicide reduction and are well-positioned to rapidly disseminate key study findings.

We will publicize our results to researchers, practitioners, and policymakers using tailored content and multiple methods. First, we will disseminate research findings through journal publication and presentations at conferences. We will submit at least three manuscripts to peer-reviewed journals geared toward health services researchers and/or mental health practitioners (e.g., *Psychiatric Services*), and submit at least one presentation per year targeting researchers and clinicians (e.g. the American Association of Suicidology, the VA's Annual Mental Health Meeting). We will also seek out opportunities to utilize VHA cyber-seminars to reach VHA researchers and clinicians. Importantly, we will directly disseminate our findings to clinicians and policy leaders

within the VA. For example, the findings may be of particular relevance to Suicide Prevention Coordinators throughout the VA. Because the education of Suicide Prevention Coordinators is coordinated by the COE in Canandaigua, study investigators could easily keep leadership apprised of study findings and work to shape training efforts for these key treatment providers. Similarly, the VA's Veterans Crisis Line is based at the Canandaigua COE and study findings could shape how the Crisis Line trains call center staff.

It is also worth noting that the project was designed with broader dissemination of the intervention in mind. Delivery of the brief CLF intervention could be added to other treatment planning activities that typically occur on inpatient psychiatric units. Although the study is based within inpatient psychiatric units, this setting was chosen as a way to examine suicidal behaviors as outcomes because of the high-risk of post-baseline attempt in this population. However, if CLF is found to be effective, the intervention could be easily modified for use in other settings ranging from new patient mental health appointments, to Emergency Department visits, to sessions with the Suicide Prevention Coordinator. *To increase the likelihood of broader use of CLF, the proposed project will use qualitative methods to identify barriers and facilitators of implementation of the CLF intervention in other settings. If the intervention is found to be effective, we plan to partner with VHA leadership to identify unique settings in which the CLF intervention could be delivered to reach high-risk Veterans.*

Project Management Plan

Project time line. The project will take four years to complete (See **Table 2** below). The first six months will be used to hire and train the study staff and finalize study protocols. Starting in month seven, we will begin screening and baseline assessments as well as the delivery of the intervention. This will last through the end of month six in year three. Follow-up assessments will begin with the first of the 3-month assessments delivered at the start of month 10 in year one. Follow-up assessments will continue until the end of month six in year four. *Key informant interviews will occur in the first 9 months of year 4*. Data entry, cleaning and/or analysis will begin at the start of month seven in year one and continue through the end of year four. Dissemination of findings and report writing will begin with analyses of the screening data around month 10 of year one and continue through the end of the project.

Resources: Facilities and equipment and key personnel roles. The majority of project personnel will be located at Center for Clinical Management and Research (CCMR; Drs. Ilgen, Bohnert, Chermack and Pfeiffer) or the Canandaigua COE (Dr. Britton) where office space and equipment for them will be provided. Project staff will have access to computing, telecommunication, and administrative research support through the Battle Creek VA, CCMR in Ann Arbor or the Canandaigua COE. CCMR and the Canandaigua COE have extensive information systems support and access to the VHA administrative data. The inpatient unit at the AA VAMC will provide space, with a telephone, to conduct the research assessments and to conduct the CLF. Recruitment will also occur at the Battle Creek VAMC. Project staff (Dr. Pope, RAs and therapist) will be provided with an office, telephone and computer. Also, the inpatient unit at the BC VAMC will provide space, with a telephone, to conduct the research assessments and to conduct the CLF. Key roles for all study personnel are described in the budget justification. Project staff in Ann Arbor and Battle Creek will have frequent telephone calls/videoconferences to ensure that the study is progressing at both study sites. In addition, study staff will have regular meetings to discuss logistical and larger scientific issues.

Table 2	Year 1				Year 2				Year 3				Year 4			
	Months				Months				Months				Months			
	0-3	4-6	7-9	10-12	0-3	4-6	7-9	10-12	0-3	4-6	7-9	10-12	0-3	4-6	7-9	10-12
Hiring and training																
Screening/baseline																
Follow-ups																
Key informant interviews																
Data cleaning and analysis																
Dissemination & Implementation																

Data management and safety. Dr. Ilgen will be responsible for the safety and security of patient-level data. All study data will be stored on firewall-protected servers at either CCMR, the Canandaigua COE or the Battle Creek VAMC. A Master's-level data manager within CCMR will conduct the initial data linkage and be responsible for preparing, cleaning, and analyzing the data. Project staff in Canandaigua and Battle Creek will create a shared study folder that can be directly accessed by study staff in Ann Arbor. All data obtained during the chart reviews will be stored directly into this shared server. Double data entry and initial file cleaning will occur on an ongoing

basis. The Master's-level data manager within CCMR will work to further clean this file and merge these data with other study data. Once the final file is completed in year four, in accordance with current regulations articulated by the 1996 HIPAA Privacy Rule, private health information will be stripped with the exception of ages and dates and kept physically separate on the secure VA network.

HUMAN SUBJECTS

Risks to Human Subjects

Human Subjects Involvement and Characteristics. Data will be collected from Veterans, men and women, ages 18 years and older, recruited from the inpatient psychiatric units at the Ann Arbor VAMC or Battle Creek VAMC. *After obtaining a HIPAA Waiver of Authorization, research staff will review the electronic medical record to identify and approach potentially eligible patients*. After providing written informed consent, participants will complete a brief screening survey. Based on data from the study sites and our pilot study, we anticipate screening 1,042 participants to generate our sample size of 500 participants who will meet inclusion/exclusion criteria and participate in the randomized control trial. Based on data from the proposed study sites, we anticipate the gender composition of the sample to be approximately 7.5% female

and 92.5% male; we expect the following racial composition of the sample: approximately 20% African American, 75% Caucasian, and 5% other (i.e., Asian, American Indian, Native Hawaiian or Other Pacific Islander). We also expect that 1% of adults at the study sites will identify as Hispanic ethnicity.

Inclusion criteria for screening (Part 1)*:* (1) adults age 18 years of age or older receiving care in an inpatient psychiatric unit at either the Battle Creek VAMC or Ann Arbor VAMC; (2) mention of a significant suicidal crisis within the intake note; (3) medically stable and able to provide informed consent; and (4) Mini-Mental State Examination (MMSE)[58] score greater than or equal to 21.

Additional inclusion criteria for the full randomied study (Part 2): (1) no reported use of the Veterans Crisis Line within the past 12-months; (2) report current suicidal ideation (BSS greater than or equal to 5 during the past week) as reported during the screening interview.

Exclusion criteria for screening and full study: (1) patients who do not understand English (less than 1% in our prior work); (2) prisoners; (3) patients deemed unable to provide informed consent as stated above; (4) profound psychotic symptoms and/or cognitive deficits that would prevent patients from understanding the content of the intervention and/or assessments; and (5) participants who recently received or are scheduled to receive electroconvulsive therapy (ECT). Similar to our ongoing IIR which recruited from VHA inpatient units, we do not have explicit exclusion criteria related to psychotic or cognitive disorders. Instead of relying on diagnoses, we will make judgments of appropriateness for the trial based on the clinical judgment of the study staff (supplemented with information in the clinical record). It has been our experience that patients often are unable to provide informed consent early in a psychiatric stay but their status will improve significantly prior to discharge. We attempt to recruit participants during this period of improved stability and will include individuals who meet the above inclusion/exclusion criteria at that time.

After providing written informed consent, and if they are eligible based upon the screening survey,, participants will be randomized into either the Crisis Line Facilitation (CLF) condition or enhanced usual care (EUC) condition.

The Crisis Line facilitation condition includes a brief (i.e., 45-60) minute session in which the participant and therapist will discuss the perceived barriers to using the crisis line, the therapist will provide information regarding the Veterans Crisis Line, and the participant will practice calling the Veterans Crisis Line. Participants in the EUC condition will be provided with materials that include the Veterans Crisis Line number and encouraged to seek help if they feel suicidal in the future. In addition, all of these participants will receive a list of numbers for VHA outpatient mental health clinic(s) within their community and encouraged to call and schedule an appointment. All participants who choose to participate in the study will complete a baseline assessment and three additional follow-up assessments (i.e., 3-, 6-, 12-months post baseline). These four assessments will contain interview and self-report questionnaires. The baseline and post-baseline surveys will be self-administered or administered by the study staff, depending on the desires of the subject. After completion of the 12-month post baseline assessment, 10 participants from the CLF condition will be selected for key informant interviews. After providing written informed consent, brief interviews will be conducted one-on-one with trained staff in a private location.

Involvement of special classes of subjects:

Inclusion of pregnant women, human fetuses, and neonates: This protocol allows for currently pregnant women to be included in the study for the following reasons: 1) There is no increased risk to the pregnant woman or fetus with this study; 2) The CLF intervention and associated surveys and interviews represent no risk to the fetus; 3) Consent of the pregnant woman will be obtained; 4) The pregnant woman providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate, which is expected to be none; 5) This protocol does not include the participation of minors; 6) No inducement, monetary or otherwise, will be offered to terminate a pregnancy from anyone on the study staff; 7) Research staff will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and 8) Research staff will have no part in determining the viability of a neonate.

Sources of Research Material. Data will be obtained by means of interviews and self-report inventories specifically for research purposes. Primary sources of data for this study will be gathered from an initial eligibility screening assessment, baseline assessment, and follow-up assessments (i.e., 3-,6-, and 12 months post baseline). To supplement self-report measures, we will abstract VA records for health services information such as regarding Veterans Crisis Line use, inpatient psychiatric admissions, outpatient mental health service utilization as well as any recorded suicidal thoughts, plans and attempts. Information will pertain to treatment prior to participation (i.e., one year prior) and over the course of study participation. Crisis Line Facilitation sessions will be audiotaped to monitor clinical fidelity (adherence and competence).

Potential Risks. There is a minor potential risk to confidentiality of assessment data and audio-recorded sessions. The risk of a violation of confidentiality exists because human participants will be disclosing personal information, both in assessments and intervention sessions. This risk is related to the damage that could be caused by an inadvertent release of sensitive information (e.g., psychiatric symptoms, substance use, etc.). Our research team has considerable experience in maintaining the confidentiality of study datasets and will have procedures in place to ensure data confidentiality. (See details of protections below.) All investigators have completed training in the requirements for handling protected health information as outlined by the Health Insurance Portability and Accountability Act (HIPAA). Participants will be informed of the procedures taken to protect their confidentiality. The focus of this study is not on child abuse or intention to harm others. However, because of the nature of the study (i.e., at-risk for suicide), these issues may arise. The consent form will contain a statement explaining mandatory reporting requirements for information regarding child abuse and intention to harm self or others prior to participating in the study.

There is also a slight risk of psychological discomfort to study participants as a result of being asked personal questions, particularly during the assessments. Participants may also become anxious or upset during discussions of their thoughts about mental health treatment that occur during intervention. Study staff will be trained to respond to this emotional distress and to refer participants to appropriate resources as necessary. All participants will be free to terminate the assessments at any time or refuse to respond to any questionnaire item.

In addition, there is a small risk that the intervention might upset participants. The project will utilize a cognitive behavioral intervention, which is a therapeutic approach that targets a change in the beliefs. The therapy is designed to be collaborative and avoid the use of any statements that could be perceived as coercive by participants. It has been the experience of the project's investigators that these approaches dramatically diminish risks to participants from the study's intervention. Still, unexpected events are always possible in intervention research. The investigators of this project will establish protocols for study staff to guide them in responding to crisis or potentially harmful situations.

Adequacy of Protection against Risks

Recruitment and Informed Consent. Research staff will review the electronic medical record to identify patients 18 years of age and older who have a documented recent suicide crisis associated with their inpatient admission. These patients will be approached (after verifying with clinical staff that the patient is sufficiently stable) by the research staff and recruited for the screening portion of the study. Those interested in participating in the study will be informed of the general nature of the study, what their involvement entails, the risk/benefits, and limitations to confidentiality. Participants will be informed that based upon their answers to the screening survey, their participation may be over, or they may be eligible for the rest of the study (Part 2). In addition to the above information, the consent will describe the randomization, intervention conditions including tape recording, and baseline and follow-up assessments. As part of the informed consent process,

patients will: 1) have a brief mental status examination administered by the research staff to test the patient's orientation and judgment; and 2) be able to describe to the research staff the essential elements of the study for which they are providing consent. Patients who are notably sedated or confused at the time of screening will be re- approached later in their stay if they are still interested. All participants will be told that participation is voluntary, that they can withdraw at any time, and that this will not impact their treatment. The limits of the NIH Certificate of Confidentiality will be explained in the consent form, but study staff will also verbally explain the limits of confidentiality. The screening survey will commence after the participants provide written informed consent. Only participants who meet eligibility criteria will take part in the randomized controlled trial portion of the study. When providing written informed consent, participants will be given a copy of the consent form and the original will be filed in a confidential research file.

Protections against Risk. Several steps will be taken to minimize the risk of breaches of confidentiality. First, every effort will be made to ensure that study data are always confidential, in terms of staff training and data storage, so that data can be linked to a particular person. Training of staff will include information about the importance of confidentiality and techniques to maintain confidentiality of all information reported by research participants.

Risks will be discussed with individuals choosing to participate as part of the informed consent process. Throughout the study, IRB and HIPAA guidelines will be followed to ensure privacy of patient data. Unique identification numbers will be assigned to all participants who complete the assessments. The participant code will appear on assessment forms and abstracted audio taped forms/recording. All data forms and assessments will be coded with this number, rather than with a name. Participants' names and other identifying information will be kept separately from study data on a secure server with restricted access and/or in a locked cabinet in a locked room; and only participants' unique ID number will be kept in the database. All research data will be presented in aggregate form only. Additionally, we will apply for a Certificate of Confidentiality from the NIH to protect the confidentiality of our participants.

Because there is a small risk that participants may experience some distress or psychological discomfort when answering assessment questions participants will be made aware of their right to refuse to answer any questions that make them uncomfortable or that they do not wish to answer, and they will be informed of their right to withdraw from the study at any time without penalty. Participants may also be informed that they can take breaks. Additionally, study staff will be trained extensively to respond to emotional distress and to discuss concerns and issues should they arise. More specifically, study staff will be trained to perform attentive and empathic listening as well as exhibit calmness during the interview. To minimize this risk, research staff will be available during and following participation in the intervention condition and during assessments to manage (i.e., discuss and refer as needed) any unexpected issues that may arise. These include increased arousal or distress that answering questions about suicide and risk factors may have caused. It has been the experience of the project's investigators that these approaches dramatically diminish risks to participants from the study's intervention. For those participants who are unable to complete a phone or in person follow-up assessment, a cover letter will be included with the mailed survey that reminds participants that participation is voluntary and that they can skip any questions that make them uncomfortable. They will also receive a survey insert reminding them that the survey is not an appropriate way to reach out for help, and offers several resources (911, local Emergency Department, Veterans Crisis Line, etc.) for seeking more immediate help.

It is possible that some participants will report levels of suicidal thoughts and plans that will require further intervention. At the beginning of each session, participants will be reminded of the need to inform others if the participant is determined to be at acute risk for suicidal behaviors. This reminder is included in the mailed survey insert for those participants who are unable to complete the follow up assessment in person or over the phone. We will have a detailed suicide risk assessment protocol and, if research staff determines that a participant is at acute suicide risk, we may ultimately need to inform treatment staff at the VA. However, VA staff will not be informed about every participant who reports suicidal ideation. Instead, research staff, in consultation with Drs. Ilgen, Pope, or Pfeiffer will evaluate if the participant is at acute risk of suicide based on the presence of a coherent plan and a desire to act. If a participant requires any services for a suicidal crisis, study staff will not make any attempt to influence the care or clinical disposition.

In cases in which a participant may be likely to hurt themselves over the next few days (as indicated through responses to survey instruments, discussion, and clinical discretion), our suicide risk assessment

protocol will be enacted. During the screening, a suicide assessment will be conducted with all participants that are eligible for the intervention portion of the study. During follow-up appointments, participant responses, discussion, and clinical discretion will determine suicide risk assessment necessity. For individuals that trigger the need for a suicide assessment, research staff will inquire about plan, severity, and risk factors. If a participant's answers on a mailed survey trigger a risk assessment, the research staff will attempt to follow up with the participant by phone within 72 hours of receiving the survey. Drs. Ilgen, Pope, or Pfeiffer will be contacted for individuals that are at high risk (i.e. distinct and/or immediate plan to harm oneself). Drs. Ilgen, Pope, or Pfeiffer will make a decision about appropriate next steps, including the need for emergency or follow-up evaluation, requesting the participant to contact a family member or friend, contacting a facility/hospital staff member (i.e., psychiatrist on call, participant's provider) before the study staff member leaves the location, performing a warm handoff with the Veterans Crisis Line, contacting local authorities, etc. If Drs. Ilgen or Pope indicate the level of risk suggests the need for a professional or emergency evaluation, the study staff member will assist in facilitating the next step. All participants will be given mental health referral information. Still, unexpected events are always possible in intervention research.

Potential Benefits of the Proposed Research to Human Subjects and Others

It is believed that research participants may be helped in a number of ways. All participants will be regularly assessed for suicidal thoughts/plans during study interaction and receive additional information about the Veterans Crisis Line, such as how to contact the line. Participants randomized to the crisis line facilitation (CLF) condition will receive a single-session intervention aimed at addressing perceived barriers and

facilitators of crisis line use. They will also have the direct experience of practicing the logistics of and making a call to the Veterans Crisis Line to help counter any negative beliefs about Crisis Line use. Those in CLF condition may also benefit from learning about an additional resource to help manage a future suicidal crisis. Because this project is intended to identify and intervene with individuals who have experienced a suicidal crisis, it is important to provide an enhanced usual care (EUC) condition. Participants in the EUC condition will be provided with materials that include the Veterans Crisis Line number and encouraged to seek help if they feel suicidal in the future. In addition, all of these participants will receive a list of numbers for VHA outpatient mental health clinic(s) within their community and encouraged to call and schedule an appointment.

Others may also benefit from this potential research. Developing a brief and effective intervention, aimed at providing additional support and resources, that can be utilized in various settings, can have a significant and substantial impact on suicide rates. This study has the potential to enhance service delivery to Veterans experiencing a suicidal crisis and assist with coping during a potential future suicidal crisis, while posing few physical risks beyond those associated with usual care. In sum, the potential benefits for the research far outweigh the risks to participants.

Importance of Knowledge to Be Gained

Reducing suicide is a national priority and an urgent imperative within the Department of Veterans Affairs. There is a clear need to link individuals at risk for suicide with readily available resources. Despite significant investment in, and marketing of, the Veterans Crisis Line, many high-risk Veterans are not utilizing this service. This study is one of the first attempts to directly test the effect of connecting high-risk patients to a Crisis Line as a suicide prevention strategy. More so, this RCT will evaluate the feasibility and effectiveness of a low-cost and easy-to-deliver intervention designed to encourage the use of existing crisis support resources. Developing a brief and effective approach to encourage use of the Crisis Line has the potential to have a significant and substantial impact on suicide rates within the VHA and could be modified and exported to other populations and settings.

Data and Safety Monitoring Plan (Now the DSMP is its own document, separate from the main protocol)
Inclusion of Women and Minorities

Our study is open to participants of any racial or ethnic background. We will recruit any eligible Veteran who provides informed consent, regardless of race, ethnicity, or gender. We expect the study population to reflect the racial, ethnic, and gender distribution of the study sites. Every effort will be made to recruit racial minority patients and women. Representation of those groups will be monitored throughout the project and if it appears they are underrepresented among participants, significant efforts will be made to boost their enrollment. These efforts will include meeting with providers who have large panels of racial/ethnic minority and women Veterans to get their input on barriers to recruitment and asking women and minorities who are not participating for informal feedback to understand barriers to participation and learn new strategies for increasing representation in those groups.

REFERENCES

1. Office of the Surgeon General. *The Surgeon General's Call to Action to Prevent Suicide*. Washington, DC: Department of Health and Human Services, U.S. Public Health Service; 1999.
2. VA Office of Inspector General. *Implementing VHA's Mental Health Strategic Plan Initiatives for Suicide Prevention (report No. 06-03706-126)*: Department of Veterans Affairs; 2007.
3. Public Law 110-110. *Joshua Omvig Veterans Suicide Prevention Act*2007.
4. McCarthy JF, Valenstein M, Kim HM, Ilgen M, Zivin K, Blow FC. Suicide mortality among patients receiving care in the Veterans Health Administration health system. *Am. J. Epidemiol.* 2009;169(8):1033-1038.
5. Website for Veterans Crisis Line. Accessed November 1, 2013.
6. Blow FC, Bohnert ASB, Ilgen MA, et al. Suicide mortality among patients treated by the veterans health administration from 2000 to 2007. *Am. J. Public Health.* 2012;102(S1):S98-S104.
7. Website for VHA 2012 Suicide Data Report. Accessed November 1, 2013.
8. Web-based Injury Statistics Query and Reporting System: Leading Causes of Death Reports. Centers for Disease Control and Prevention; 2013. Accessed November 1, 2013.
9. Suicide and Risk Management Surveillance Office. *Army Suicide Event Report.* Tacoma, WA: Army Behavioral Health Technology Office;2007.
10. Blue Ribbon Work Group on Suicide Prevention in the Veteran Population. Report of the Blue Ribbon Work Group on Suicide Prevention in the Veteran Population. 2011; http://www.mentalhealth.va.gov/suicide_prevention/Blue_Ribbon_Report-FINAL_June-30-08.pdf. Accessed January, 2011.
11. Joshua Omvig Veterans Suicide Prevention Act, (2007).
12. Kaplan MS, Huguet N, McFarland BH, Newsom JT. Suicide among male veterans: A prospective population-based study. *J. Epidemiol. Community Health.* 2007;61(7):619-624.
13. Miller M, Barber C, Azrael D, Calle E, Lawler E, Mukamal K. Suicide among US veterans: A prospective study of 500,000 middle-aged and elderly men. *Am. J. Epidemiol.* 2009;170(4):494-500.
14. Lambert MT, Fowler DR. Suicide risk factors among veterans: risk management in the changing culture of the Department of Veterans Affairs. *J. Behav. Health Serv. Res.* 1997;24(3):350-358.
15. Agha Z, Lofgren RP, VanRuiswyk JV, Layde PM. Are patients at Veterans Affairs medical centers sicker? *Arch. Intern. Med.* 2000;160:3252-3257.
16. Ilgen MA, Kleinberg F, Ignacio RV, et al. Noncancer pain conditions and risk of suicidenoncancer pain conditions and risk of suicidenoncancer pain conditions and risk of suicide. *JAMA Psychiatry.* 2013;70(7):692-697.
17. Ilgen MA, McCarthy JF, Ignacio RV, et al. Psychopathology, Iraq and Afghanistan service, and suicide among Veterans Health Administration patients. *Journal of Counseling and Clinical Psychology.* 2012;80(3):323-330.
18. Britton PC, Ilgen MA, Rudd MD, Conner KR. Warning signs for suicide within a week of healthcare contact in Veteran decedents. *Psychiatry Research.* 2012;200(2–3):395-399.
19. Knox KL, Kemp J, McKeon R, Katz IR. Implementation and Early Utilization of a Suicide Hotline for Veterans. *American Journal of Public Health.* 2012/03/01 2012;102(S1):S29-S32.
20. Modan B, Nissenkorn I, Lewkowski SR. Suicide in a heterogeneous society. *Br J Psychiatry.* Jan 1970;116(530):65-68.
21. Institute of Medicine. *Reducing Suicide: A National Imperative*. Washington, DC: National Academies Press; 2002.
22. Joiner TE, Jr., Walker RL, Rudd MD, Jobes DA. Scientizing and routinizing the assessment of suicidality in outpatient practice. *Professional Psychology: Research and Practice.* 1999;30(5):447-453.
23. Conner KR, Hesselbrock VM, Schuckit MA, et al. Precontemplated and impulsive suicide attempts among individuals with alcohol dependence. *J. Stud. Alcohol.* 2006;67(1):95-101.

24. Simon OR, Swann AC, Powell KE, Potter LB, Kresnow MJ, O'Carroll PW. Characteristics of impulsive suicide attempts and attempters. *Suicide Life. Threat. Behav.* 2001 2001;32(1 Suppl):49-59.
25. Wojnar M, Ilgen M, Czyz E, et al. Impulsive and non-impulsive suicide attempts in patients treated for alcohol dependence. *J. Affect. Disord.* 2009;115(1-2):131-139.
26. King R, Nurcombe B, Bickman L, Hides L, Reid W. Telephone Counselling for Adolescent Suicide Prevention: Changes in Suicidality and Mental State from Beginning to End of a Counselling Session. *Suicide and Life-Threatening Behavior.* 2003/12/01 2003;33(4):400-411.
27. Kalafat J, Gould MS, Munfakh JL, Kleinman M. An evaluation of crisis hotline outcomes. Part 1: Nonsuicidal crisis callers. *Suicide and Life Threatening Behaviour.* 2007;37(3):322-337.
28. Gould MS, Kalafat J, Harrismunfakh JL, Kleinman M. An evaluation of crisis hotline outcomes. Part 2: Suicidal callers. *Suicide and life-threatening behavior.* 2007;37(3):338-352.
29. Project MATCH. Project MATCH (Matching Alcoholism Treatment to Client Heterogeneity): rationale and methods for a multisite clinical trial matching patients to alcoholism treatment. *Alcohol. Clin. Exp. Res.* Dec 1993;17(6):1130-1145.
30. Timko C, DeBenedetti A, Billow R. Intensive referral to 12-Step self-help groups and 6-month substance use disorder outcomes. *Addiction.* 2006;101(5):678-688.
31. Humphreys K. The trials of Alcoholics Anonymous. *Addiction.* 2006;101(5):617-618.
32. Ho TP. The suicide risk of discharged psychiatric patients. *J. Clin. Psychiatry.* 2003;64(6):702-707.
33. Goldacre M, Seagroatt V, Hawton K. Suicide after discharge from psychiatric inpatient care. *The Lancet.* 1993;342(8866):283-286.
34. Qin P, Nordentoft M. Suicide risk in relation to psychiatric hospitalization: Evidence based on longitudinal registers. *Arch. Gen. Psychiatry.* 2005;62(4):427-432.
35. Valenstein M, Kim HM, Ganoczy D, et al. Higher-risk periods for suicide among VA patients receiving depression treatment: Prioritizing suicide prevention efforts. *J. Affect. Disord.* 2009;112(1–3):50-58.
36. Cedereke M, Monti K, Öjehagen A. Telephone contact with patients in the year after a suicide attempt: does it affect treatment attendance and outcome? A randomised controlled study. *European Psychiatry.* 2002;17(2):82-91.
37. Beautrais AL. Further Suicidal Behavior Among Medically Serious Suicide Attempters. *Suicide Life. Threat. Behav.* 2004;34(1):1-11.
38. Luxton DD, June JD, Comtois KA. Can Postdischarge Follow-Up Contacts Prevent Suicide and Suicidal Behavior? *Crisis: The Journal of Crisis Intervention and Suicide Prevention.* 2013;34(1):32-41.
39. Stanley B, Brown G. Safety Planning Intervention: A brief intervention to mitigate suicide risk. *Cogn. Behav. Pract.* 2012;19(2):256-264.
40. Ajzen I. The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes.* 1991;50:179-211.
41. Ajzen I. Perceived Behavioral Control, Self-Efficacy, Locus of Control, and the Theory of Planned Behavior. *Journal of Applied Social Psychology* 2002;32:665-683.
42. Bandura A. Self-efficacy mechanism in human agency. *Am. Psychol.* 1982;37(2):122-147.
43. Bandura A. *Self-efficacy: The exercise of control*. New York, NY: W.H. Freeman 1997.
44. U.S. Surgeon General and of the National Action Alliance for Suicide Prevention. National Strategy for Suicide Prevention: Goals and Objectives for Action. 2012.
45. Website for VA press release entitled "VA Focuses National Attention on Suicide Prevention". Accessed November 1,, 2013.
46. Ilgen MA, Bohnert ASB, Ignacio R, et al. Psychiatric diagnoses and risk of suicide in patients yreated by the Department of Veterans Affairs. *Arch. Gen. Psychiatry.* 2010;62:1152-1158.
47. Ilgen MA, Conner KR, Roeder KM, Blow FC, Austin K, Valenstein M. Patterns of treatment utilization prior to suicide in male Veterans with substance use disorders. *Am. J. Public Health.* 2012;102:S88-S92.
48. Ilgen MA, Conner KR, Valenstein M, Austin K, Blow FC. Violent and Nonviolent Suicide in Veterans With Substance-Use Disorders *Journal of Studies on Alcohol and Drugs.* 2010;71(4):493-479.

49. Ilgen MA, Zivin K, Austin KL, Czyz EK, Valenstein M, Kilbourne AM. Severe pain predicts greater likelihood of subsequent suicide. *Suicide Life. Threat. Behav.* 2010;40(6):597-608.
50. Pfeiffer PN, Ganoczy D, Ilgen M, Zivin K, Valenstein M. Comorbid anxiety as a suicide risk factor among depressed veterans. *Depression and Anxiety.* 2009;26(8):752-757.
51. Bohnert ASB, Fudale S, Ilgen MA. Increasing Poisoning Mortality Rates in the United States, 1999–2006. *Public Health Rep.* 2010;125(4):542–547.
52. Bohnert ASB, Ilgen MA, Galea S, McCarthy JF, Blow FC. Accidental Poisoning Mortality Among Patients in the Department of Veterans Affairs Health System. *Med. Care.* 2011;49(4):393-396 310.1097/MLR.1090b1013e318202aa318227.
53. Bohnert ASB, Ilgen MA, Ignacio RV, McCarthy JF, Valenstein M, Blow FC. Risk of Death From Accidental Overdose Associated With Psychiatric and Substance Use Disorders. *Am. J. Psychiatry.* 2012;196(1):64-70.
54. Bohnert ASB, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA.* 2011;305(13):1315-1321.
55. Britton PC, Bossarte RM, Thompson C, Kemp J, Conner KR. Influences on Call Outcomes among Veteran Callers to the National Veterans Crisis Line. *Suicide and life-threatening behavior.* 2013;43(5):494-502.
56. Pearson JL, Stanley B, King CA, Fisher CB. Intervention research with persons at high risk for suicidality: safety and ethical considerations. *Journal of Clinical Psychiatry.* 2001;62:17-26.
57. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Archives of General Psychiatry.* May 2006;63(5):484-489.
58. Folstein MF, Folstein SE, McHugh PR. Mini-Mental State: A practical method for grading the state of patients for the clinician. *J. Psychiatr. Res.* 1975;12:189-198.
59. Beck AT, Steer RA. Beck scale for suicide ideation manual. San Antonio, TX: Harcourt Brace; 1991.
60. Beck AT, Steer RA, Ranieri WF. Scale for Suicide Ideation: psychometric properties of a self-report version. *J. Clin. Psychol.* 1988 Jul 1988;44(4):499-505.
61. Cunningham R, Walton M, Zimmerman M, et al. SafERTeens: Computerized Screening and Brief Intervention for Teens At-risk for Youth Violence. *Acad. Emerg. Med.* 2007;14(5 supplement 1):S106.
62. Walton M, Blow F, Booth B. Diversity in relapse prevention needs: gender and race comparisons among substance abuse treatment patients. *Am. J. Drug Alcohol Abuse.* 2001 May 2001;27(2):225-240.
63. Faden V, Day N, Windle M, et al. Collecting longitudinal data through childhood, adolescence, and young adulthood: Methodological challenges. *Alcohol. Clin. Exp. Res.* 2004;28(2):330-340.
64. Carroll KM, Nich C, Sifry RL, et al. A general system for evaluating therapist adherence and competence in psychotherapy research in the addictions. *Drug Alcohol Depend.* 2000;57(3):225-238.
65. Morgenstern J, Morgan TJ, McCrady BS, Keller DS, Carroll KM. Manual-guided cognitive-behavioral therapy training: a promising method for disseminating empirically supported substance abuse treatments to the practice community. *Psychol Addict Behav.* Jun 2001;15(2):83-88.
66. Beck AT, Steer RA. *Beck Scale for Suicide Ideation Manual*. San Antonio, TX: Psychological Corporation; 1993.
67. Posner K, Brown GK, Stanley B, et al. The Columbia-Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry.* 2011;168(12):1266-1277.
68. Hoge CW, Riviere LA, Wilk JE, Herrell RK, Weathers FW. The prevalence of post-traumatic stress disorder (PTSD) in US combat soldiers: a head-to-head comparison of DSM-5 versus DSM-IV-TR symptom criteria with the PTSD checklist. *The Lancet Psychiatry.* 2014;1(4):269-277.
69. Eisen SV, Normand S-L, Belanger AJ, Spiro III A, Esch D. The revised Behavior and Symptom Identification Scale (BASIS-R): reliability and validity. *Med. Care.* 2004;42(12):1230-1241.

70. Kroenke K, Spitzer RL, Williams JB. The PHQ – 9: validity of a brief depression severity measure. *J. Gen. Intern. Med.* 2001;19:606-613.
71. Cacciola JS, Alterman AI, DePhilippis D, et al. Development and initial evaluation of the Brief Addiction Monitor (BAM). *J. Subst. Abuse Treat.* 2012.
72. McLellan AT, Alterman AI, Cacciloa J, Metzger D, O'Brien CP. A new measure of substance abuse treatment: Initial studies of the Treatment Service Review. *Journal of Nervous and Mental Disease.* 1992;180:101-110.
73. Hoge CW, Castro CA, Messer SC, McGurk D, Cotting DI, Koffman RL. Combat Duty in Iraq and Afghanistan, Mental Health Problems, and Barriers to Care. *N. Engl. J. Med.* 2004;351(1):13-22.
74. Steinberg L, Sharp C, Stanford MS, Tharp AT. New tricks for an old measure: The development of the Barratt Impulsiveness Scale–Brief (BIS-Brief). *Psychol. Assess.* 2013;25(1):216-226.
75. Bryan CJ. The clinical utility of a brief measure of perceived burdensomeness and thwarted belongingness for the detection of suicidal military personnel. *J. Clin. Psychol.* 2011;67(10):981-992.
76. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised conflict tactics scales (CTS2) development and preliminary psychometric data. *Journal of family issues.* 1996;17(3):283-316.
77. Krebs EE, Lorenz KA, Bair MJ, et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. *J. Gen. Intern. Med.* 2009;24(6):733-738.
78. Andresen EM, Catlin TK, Wyrwich KW, Jackson-Thompson J. Retest reliability of surveillance questions on health related quality of life. *J. Epidemiol. Community Health.* 2003;57(5):339-343.
79. Sobell LC, Maisto SA, Sobell MB, Cooper AM. Reliability of alcohol abusers' self-reports of drinking behavior. *Behav. Res. Ther.* 1979;17(2):157-160.
80. Sobell LC, Sobell MB, Leo GI, Cancilla A. Reliability of a timeline method: assessing normal drinkers' reports of recent drinking and a comparative evaluation across several populations. *Br. J. Addict.* Apr 1988;83(4):393-402.
81. Fals-Stewart W, O'Farrell TJ, Freitas TT, McFarlin SK, Rutigliano P. The timeline followback reports of psychoactive substance use by drug-abusing patients: psychometric properties. *J Consult Clin Psychol.* Feb 2000;68(1):134-144.
82. Linehan MM, Comtois KA, Brown MZ, Heard HL, Wagner A. Suicide Attempt Self-Injury Interview (SASII): development, reliability, and validity of a scale to assess suicide attempts and intentional self-injury. *Psychol. Assess.* 2006;18(3):303.
83. Thorpe KE, Zwarenstein M, Oxman AD, et al. A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *Journal of Clinical Epidemiology.* 2009;62(5):464-475.
84. Sandelowski M. Sample size in qualitative research. *Res Nurs Health* 1995;18:179-183.
85. Little RJ, Rubin DB. *Statistical analysis with missing data*. New York: Wiley & Sons; 1987.
86. Laird NM, Ware JH. Random-Effects Models for Longitudinal Data. *Biometrics.* 1982;38:1-15.
87. Little R, Yau L. Statistical techniques for analyzing data from prevention trials: Treatment of no-shows using Rubin's causal model. *Psychol. Methods.* 1998;3:147-159.
88. Littell M, Milliken G, Stroup W, Wolfinger R, Schabenberg O. *SAS for mixed models (2nd ed.)*. Cary, NC: SAS Institute Inc.; 2006.
89. Kraemer HC, Stice E, Kazdin A, Offord D, Kupfer D. How do risk factors work together? Mediators, moderators, and independent, overlapping, and proxy risk factors. *Am. J. Psychiatry.* 2001;158(6):848-856.
90. Kraemer HC, Wilson GT, Fairburn CG, Agras WS. Mediators and moderators of treatment effects in randomized clinical trials. *Arch. Gen. Psychiatry.* 2002;59(10):877-884.
91. Preacher KJ, Hayes AF. SPSS and SAS procedures for estimating indirect effects in simple mediation models. *Behavior Research Methods, Instruments, & Computers.* 2004;36:717-731.
92. Forman J, Damschroder LJ. Qualitative Content Analysis. In: Jacoby L, Siminoff L, eds. *Empirical Research for Bioethics: A Primer*. Oxford, UK: Elsevier Publishing; 2007:39-62.

93. Sandelowski M, Barroso J. Writing the Proposal for a Qualitative Research Methodology Project. *Qualitative Health Research.* July 1, 2003 2003;13(6):781-820.
94. NVivo qualitative data analysis software: QSR International Pty Ltd; Version 10, 2012.