Application and Request for Approval of Study Proposal

1.0 PROTOCOL TITLE: Military Continuity Project (MCP)

2.0 STUDY PERSONNEL: See Core Document 376024-34

2.3 ROLES AND RESPONSIBILITIES: See Core Document 376024-34

3.0 RESPONSIBILITIES OF THE PRINCIPAL/ASSOCIATE INVESTIGATOR IN HUMAN SUBJECTS RESEARCH: See Core Document 376024-34

4.0 LOCATION OF STUDY: See Core Document 376024-34

5.0 DURATION OF STUDY: See Core Document 376024-34

6.0 BACKGROUND AND LITERATURE REVIEW:

Date of Search: February 2011
Period Searched: Inconclusive
Sources Searched: PUB MED
Keywords Searched: caring letters, caring contacts, suicide intervention, suicide prevention, military suicide, text message, SMS, ETC. Additional relevant publications were identified from cited references in the articles reviewed.

Overview of Problem

Suicide prevention is an important mission. Suicide is a major leading cause of death in the United States (U.S.), costing approximately 30,000 lives per year [1]. Death by suicide is only part of the overall problem. Millions of Americans have suicidal thoughts and hundreds of thousands make suicide attempts [2]. Apparent increases in suicidal behaviors and death by suicide among active duty service members have gained considerable attention from the media, members of Congress, and the DoD. Indeed, data suggest that active duty males now carry—for the first time in history—a risk of dying by suicide that is greater than comparable male cohorts in the general population [3, 4]. This is striking because combat has been historically correlated with decreases in suicide risk among Service Members (refer to [4, 5]). These developments are particularly noteworthy considering that the military entrance process typically screens out individuals with serious mental illness prior to entry onto active duty. Moreover, rates of veterans' suicide attempts and completed suicides have also been a significant source of recent concern [6]. Data available prior to the most recent military conflicts (Operation Enduring Freedom [OEF] & Operation Iraqi Freedom [OIF]) indicated heightened suicide risk among the general veteran population, with estimates indicating that veterans are twice as likely to die by suicide, regardless of whether or not they were affiliated with the U.S. Department of Veterans Affairs [7].

Factors that contribute to increased risk in service members. There are many factors associated with suicide risk among service members and veterans. Military personnel serving in OEF/OIF are predominately young males; in the U.S. general population, young people aged 15–24 make the largest number of suicide attempts each year [8]. In addition, combat-related experiences have been shown to be associated with increased risk of suicide [9].

Mental and physical health problems following combat deployment that are associated with suicide are also more prevalent in military, relative to civilian populations. Preliminary evidence suggests that the mental health needs of those who have served or are serving in Iraq and Afghanistan are significant[10-12]. Recent studies of OIF/OEF veterans suggest that 5 to 17% of U.S. military personnel returning from deployments have symptoms of posttraumatic stress disorder (PTSD), and as many as 25% report some psychological problem. Almost 2 million U.S. military personnel have deployed in support of OIF/OEF. Estimates of the rate of PTSD and depression in this population indicate that approximately 100,000-300,000 OIF/OEF veterans are at significant risk for chronic mental health illness. Findings from the RAND study [13] have proposed that these numbers might actually be an underestimate of the true prevalence of PTSD and depression due to strict measurement criteria used in most studies, which suggests that the scope of the problem of mental health conditions and suicidality might not be fully recognized. This high rate of mental health problems observed among returning veterans is of grave concern, since mental health conditions are one of the most important risk factors for suicide, with almost every mental health diagnosis being associated with elevated mortality rates due to suicide [14] . Furthermore, approximately 90% of individuals who die by suicide have a diagnosable mental health disorder [15].

Physical injuries secondary to combat also likely contribute to increased risk of suicidality in service members. Recent work by Terrio et al. [16] suggested that 22.8% of Soldiers in one Brigade Combat Team (BCT) may have a history of clinician-confirmed traumatic brain injury (TBI), with 7.5% of these individuals continuing to endorse sequelae at post-deployment. Those with TBI are 3-4 times more likely than the general population to die by suicide [17]. Eight percent attempt suicide, while 23% report significant rates of suicidal ideation (23%) at some time during their lives [18]. At this point, the relationship between brain injury and suicidality is not well understood, partly due to the absence of a sound basis for estimating the prevalence of TBI, and differentiating it from PTSD. A recent qualitative study by Brenner and colleagues [19] of 13 veterans with a history of TBI and of clinically significant suicidal ideation or behavior noted shared precipitating factors including loss-of-self post-TBI, cognitive sequelae, and psychiatric and emotional disturbances. Other possible explanations for the increased risk of suicidal behavior in persons with TBI might include disruptions in executive functioning such as impulse control and attention regulation.

Suicidal ideation is also relatively common, as recent findings from Hoge et al. [20] indicated that an estimated 222,620 Soldiers and Marines (1.1%) reported "some" suicidal ideation and .2% reported "a lot." Furthermore, Service Members are at increased risk for suicide due to their access to lethal means[21]. In 2009, 59% of military suicides were by firearm, the highest rate of any method reported [4]. Research has also suggested that military service may increase the acquired capability for suicide [22, 23], which Joiner [24] posited is a prerequisite for a serious suicide

attempt and suicide due to reduced fear of death from repeated exposure to self-injury, risk, and other traumatic events. Finally, service members may be at particularly high risk of suicide without a previous history of suicidal behavior because the majority of service members are young men (a group at high risk to die by suicide [8] but lower risk of multiple suicide attempts [25]). **Therefore, identifying and intervening with individuals thinking of suicide (as well as those engaging in suicidal behavior) is key to preventing suicide in service members.**

Rates of aftercare for suicide in military populations are low. In 2006, 395,320 people were treated in emergency departments for self-inflicted injuries [26] and 165,997 people were hospitalized due to self-inflicted injury [27] (primarily suicide attempts). The lifetime cost of self-inflicted injuries in the US in 2000 was $33 billion, including $1 billion for medical treatment and $32 billion in lost productivity [28]. Recent studies have found that patients admitted to emergency departments following deliberate self-harm are at substantially increased risk of dying from suicide—ranging from 30 to 66 times the risk in the general population [29]. Suicidal service members frequently do not attend behavioral health outpatient care [20]. Evaluations in civilian populations [30-32] have documented this as well as demonstrating that those who do present for outpatient psychiatric treatment have a remarkable propensity to drop out of care shortly thereafter. Researchers have demonstrated early patient dropout rates of approximately 40-70% of cases seen in a variety of outpatient psychiatric settings over many years[33-35].

Caring Contact Interventions: A Simple, Low-Cost Treatment for Suicide An innovative intervention – caring contacts (e.g., letters, phone calls) - have efficacy showing they may be an important adjunct or alternative to outpatient care [36]. Only two inpatient or outpatient interventions have been found to be effective in preventing death by suicide in a randomized controlled trial – both were caring contact interventions.

Caring contact by letter. One of these interventions was the "caring letters" intervention developed by Motto [37, 38]. In this study, patients hospitalized because of a depressive or suicidal state and determined to be at high risk for subsequent suicide were contacted 30 days after discharge about their follow-up treatment. Patients who either refused follow-up care or had discontinued it were randomized to a contact vs. no contact condition (N=843). Those in the "caring letters" (i.e., contact) condition received brief, non-demanding caring letters every month for 4 months, every 2 months for 8 months, and every 3 months for 4 years. The cumulative number of suicides in the no contact group was more than twice that of the contact group in the first 2 years. Although the suicide curves were not significantly different when evaluated over the full 5 years, the significant differences during the first 2 years occurred both when the letters were most frequent and during the period when the highest suicide rates would be expected.

The caring letters intervention was replicated in a shortened form by Carter who sent postcards (in envelopes) to individuals who had been admitted to a toxicology unit for self-poisoning [39, 40]. In this design, the caring cards intervention group received 8 cards over the 12 months following the index admission and the control condition was usual care alone. A total of 777 participants were recruited and randomized to the caring cards intervention (n=379) or usual care alone (n=398) at the time of index hospitalization and regardless of subsequent treatment received. The primary outcome was number of episodes of deliberate self-poisoning in the 12 months following the index admission judged by a utilization database of all self-poisoning

admissions. Although there were no differences in proportion of each group who were hospitalized for self-poisoning, there were 195 episodes of repetition of deliberate self-poisoning in the control group – significantly more than the 101 events in the intervention group [39]. These differences in the incidence risk ratio have persisted over 5 years since the index self-poisoning [41]. During this time, 323 medical/surgical and 2557 psychiatric bed days were saved for the sample of 777 participants [41]. While the numbers are very small, there were 6 suicides in the initial 12 months of the study while letters were received (2 in caring letters and 4 in control condition) with an additional suicide in the control group in the follow-up year for a total of 2 in the caring letters and 5 in the control condition in 24 months (G. L. Carter, personal communication 3-1-2010).

Beautrais et al., [42] published a study of Carter's version of the caring letters intervention among individuals presenting with suicide attempt to an emergency room in Christchurch, New Zealand. The findings are challenging to interpret because of major methodological flaws: (a) recruitment was stopped well short of the estimated sample size of 700 participants (N = 327) due to clear evidence of caring letters effectiveness (using an interim stopping rule), but (b) simple randomization was used, and post hoc, notable group differences at baseline on prior hospital visits due to self-harm were discovered. The authors covaried these baseline differences, which then reduced or eliminated the treatment effect that led to the stoppage of the trial. Fundamentally (and unfortunately), this is a failed trial in which the trial was stopped with less than half of the pre-specified sample and serious treatment imbalance.

Recently Hassanian-Moghaddam and colleagues [43] replicated the Carter and colleagues postcard intervention (with minor modifications) in Iran with a sample of 2300 self-poisoners. Similar to the previous study they observed a significantly lower number of suicide attempts in the intervention group relative to a control group receiving treatment as usual (TAU) as well as the proportion of subjects who made a suicide attempt. In addition, this was the first study to evaluate subsequent suicidal ideation. Results indicated fewer individuals in the caring letters condition reported suicidal ideation relative to treatment as usual, suggesting that caring contacts reduce suicidal thinking as well as behavior.

Caring contact by phone or visit: A 5- site, multi-national World Health Organization RCT found a brief intervention following admission to emergency services reduced suicide in the subsequent 18 months[44]. The intervention included a 1-hour individual patient education session as close to the time of discharge as possible and, after discharge, 9 follow-up contacts (phone calls or visits, as appropriate) conducted by a person with clinical experience according to a specific time-line up to 18 months. At the 18-months follow-up, significantly fewer subjects had died from suicide in the brief intervention group compared to a usual care comparison group. The results did not show an effect for suicide attempts [45]. Vaiva and colleagues [46] in France examined a phone intervention using a single telephone contact at either 1 or 3 months vs. usual care for 605 participants discharged from an emergency department after attempted suicide by self-poisoning. In intent-to-treat analysis, the three groups did not differ significantly, but completer analysis showed there were fewer suicide attempts for those who received the 1-month contact than for those in usual care alone.

Caring letters and e-mails for suicidal service members: Based on these studies, Luxton and colleagues recently adapted the caring contacts intervention for military personnel who received inpatient psychiatric care at a large military medical treatment facility [47]. In this pilot study, the researchers utilized both letters and emails to deliver brief caring messages to participants. Data from the study indicated that most service members preferred to receive the follow-up contacts via email as compared to postal mail. The overall results of the pilot study support the feasibility of technology-based caring contact interventions. Based on these promising pilot data, Luxton and his group are beginning a large scale RCT (N = 4700) to determine if this caring email intervention might result in reductions in suicide deaths and suicidal behavior in service members and veterans who are receiving inpatient psychiatric care.

Thus, the caring contacts intervention is an innovative approach with distinct strengths: 1) it is one of only a handful of interventions to prevent suicide attempts and deaths as well as suicidal ideation, 2) it targets patients with non-demanding support regardless of whether they are lost to follow-up care, 3) the intervention specifically targets "thwarted belongingness," an important interpersonal risk factor for suicide, 4) this intervention has been piloted successfully with military populations, and 5) due to its low cost and simplicity, it can be delivered at a public health level (e.g., throughout entire organizations or systems of care, such as the U.S. Military).

Caring Text Messages: Expanding the Reach of Caring Contacts into the 21st Century

Text messaging or short messaging service (SMS) is a low-cost means of sending brief messages (160 characters) to any owner of a mobile phone. There are approximately 262 million mobile phone subscribers in the US [48]. Further, adolescents, young adults, disadvantaged populations, and those who frequently move are more likely than others to own a mobile phone [49]. According to the Pew Internet and American Life Project [50] in 2010, 72% of adults who owned a mobile phone had sent a text message. Of the adults surveyed who used text messaging, 90% reported sending at least one text message per day. Amongst 18-29 year olds (the age of the majority of service members) with cell phones, 88% reported sending a text message at least once and 54% reported sending a text message daily. Two-thirds of teens reported that they used their mobile phones to text rather than talk and half of teens reported sending at least 50 text messages each day [51].

Text messages can be sent and received by any mobile phone— that is typically carried at all times by the user — without delay anywhere in the world where mobile phone coverage is available. Given the highly transitory nature of service members, text messaging has advantages over mail because individuals can maintain their mobile phone number despite changing their mailing address. Texting offers advantages over email, as one does not need to own a computer or have internet access to receive a message, and text messages can be sent to mobile phones that do not support email access. The brevity of text messaging (160 characters) also allows for simple and clear communication with the recipient.

Text messages have been investigated as interventions for improving attendance to medical appointments and adherence to treatment in medical populations. In psychiatric populations,

texts have been used to conduct brief and frequent assessments (e.g., experience sampling method, ecological momentary assessment; [52]) and to deliver or support brief interventions [53, 54]. Brief interventions delivered, in part, by text message have correlated with reductions in difficult-to-change behaviors, such as smoking [55]. Across medicine, studies consistently support the feasibility, acceptability, and effectiveness of text messaging as a means for modifying behavior[56, 57]. Our group, Stoner and colleagues, have developed a text messaging intervention to increase medication adherence in the context of antiretroviral treatment of HIV among adults with alcohol use disorders [58]. The text messaging intervention is being adapted to enhance adherence to naltrexone, an alcohol addiction medication for heavy drinking, and an RCT evaluating the effectiveness of the text messaging intervention was scheduled to begin in July 2011.

Initial Pilot Data Support the Feasibility of Caring Texts with Suicidal Individuals: Chen and colleagues [59] recently completed a pilot study of caring messages sent via text messages. Participants were 15 adults who attempted suicide and were being treated in an emergency department in China. After a research assessment and discharge from the hospital participants were sent one caring text message weekly for four weeks. Eighty percent of participants reported that these messages were helpful and would like to receive more messages in the future. Results of this study provide initial evidence that text messaging is a feasible means for delivering caring contacts, even in a cultural context where aftercare for suicidal behavior is rare.

Caring Contacts: Possible Mechanisms for Change

Social isolation, lack of social network, lack of social support, and low social integration are strong and consistent risk factors for suicide. Social isolation and related constructs have been seen as risk factors for suicide for over 30 years [60] and are "arguably the strongest and most reliable predictor of suicidal ideation, attempts, and suicides among samples varying in age, nationality, and clinical severity" [61]. Many theories of suicide have included these constructs [62-64], most recently the interpersonal theory of suicide proposed by Joiner and colleagues [24, 61, 65]. The interpersonal theory proposes the highest suicide risk occurs with the simultaneous presence of three factors: a) thwarted belongingness, b) perceived burdensomeness, and c) an acquired capability to engage in suicidal behavior. The former is most important here. Joiner and colleagues [24] propose that social isolation, lack of social network, lack of social support, and low social integration are associated with suicidal behavior because these are observable indicators that a fundamental human need is unmet – the need to belong. When this need is unmet (i.e., thwarted belongingness) then the desire for death develops. Over 40 studies with a wide range of populations confirm the importance of such indicators of thwarted belongingness in predicting lethal and non-lethal suicidal behavior above and beyond demographic and diagnostic covariates[44, 63, 66-88].

Caring contacts may improve a sense of belonging and through this the desire to live. Joiner and colleagues [61, 65, 89] have proposed that caring contacts are a means of meeting the need to belong through repeated social contacts over a long term, and thus reducing the desire for death. The caring contacts intervention may work because it communicates integration (i.e.,

belonging, being part of, embedded in social structure of some kind) and support without requiring effort on the part of the individual. Indeed, the original intervention by Motto is based on his hypotheses that "forces that bind us willingly to life are mostly those exerted by our relationships with other people, whether they be intimately involved in our lives or influence us by other psychological processes"[38]. Thus, the caring contacts intervention may convey a message of integration and belonging that the individual does not receive in any other way.

Competing mechanisms of increased outpatient behavioral health services. Although this has not been specifically evaluated in previous trials, it has been hypothesized that caring contacts work because they lead to a more positive attitude toward outpatient behavioral health services, which lead the suicidal individual to access more care, which in turn reduces subsequent suicidal behavior [36]. This mechanism is also the basis for many public health and screening suicide prevention activities. We propose to evaluate both of these possible mechanisms in this study.

Summarized Results

In summary, caring contact interventions have been shown in previous studies to decrease suicidal ideation and behavior and initial pilot data have shown positive results in military populations. As our current military population is a young, mobile, and increasingly technologically savvy population, and with the growing support behind text messaging as a feasible and effective mode of behavioral intervention, the pairing of text messaging and caring contact interventions warrants further research.

7.0 PURPOSE:

We propose to utilize text messaging to create and investigate the efficacy of a ***Continuing Contacts via Text (CCVT)*** intervention that extends the continuity of care for service members who have engaged in suicidal behavior and/or reported suicidal ideation by sending them regular caring text messages over a 12-month period. This study is a fully experimental design. Random assignment of participating service members to one of the two treatment conditions (i.e., CCVT + TAU or to TAU alone) rules out other explanations for the results. We will include those who report suicidal ideation, in addition to those who have engaged in suicidal behavior, as service members are at an increased risk of dying by suicide without a history of attempts (i.e., predominately young males, access to lethal means) and the fact that suicidal ideation even without behavior is likely to result in significant impairment to the individual and his/her fellow service members (e.g., the individual may not be able to be deployed, resulting in reduced readiness). Measured endpoints will include death, suicide risk incident requiring medical evacuation or hospitalization, suicidal ideation as identified by the follow-up assessment battery, "thwarted belongingness" as identified by The Interpersonal Needs Questionnaire, and outpatient behavioral health care utilization.

7.1 HYPOTHESES/RESEARCH QUESTIONS:

Aim 1: To determine if the addition of 12 months of CCVT+TAU results in lower rates of suicidal ideation and behavior relative to TAU alone.

Hypothesis 1a: Participants assigned to CCVT + TAU compared to TAU alone will experience reduced suicidal ideation at 12 month follow-up.

Hypothesis 1b: Over the 12 months post-study enrollment, a smaller proportion of participants assigned to CCVT+TAU vs. TAU alone will have suicide risk incidents (i.e., those requiring medical evacuation or hospital admission).

Hypothesis 1c: Over the 12 months post-study enrollment, CCVT+TAU vs. TAU alone will have fewer total number of suicide risk incidents requiring medical evacuation or hospital admission.

Aim 2: To test two proposed mechanisms of action of CCVT outcome: 1) reduced "thwarted belongingness" and 2) increased engagement in behavioral health services.

Hypothesis 2a: The effect of CCVT compared to treatment as usual alone will be mediated by reductions in "thwarted belongingness" from pre to post-study.

Hypothesis 2b: The effect of CCVT compared to treatment as usual alone will be mediated by increased use of outpatient behavioral health services in the CCVT condition.

7.2 SPECIFIC AIMS/SIGNIFICANCE:

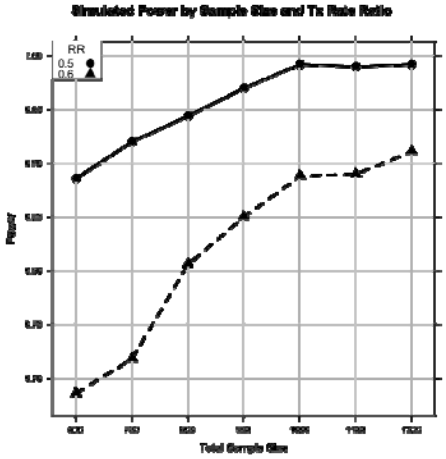
Suicide is a major leading cause of death in the United States (U.S.), costing approximately 30,000 lives per year [1]. Millions of Americans have suicidal thoughts and hundreds of thousands make suicide attempts [2]. Data suggest that active duty males now carry—for the first time in history—a risk of dying by suicide that is greater than comparable male cohorts in the general population [3, 4]. Suicidal ideation is also relatively common, as recent findings from Hoge et al. [20] indicated that an estimated 222,620 Soldiers and Marines (1.1%) reported "some" suicidal ideation and .2% reported "a lot." Furthermore, service members are at increased risk for suicide due to their access to lethal means [21]. Research has also suggested that military service may increase the acquired capability for suicide [22, 23], which Joiner [24] posited is a prerequisite for a serious suicide attempt and suicide due to reduced fear of death from repeated exposure to self-injury, risk, and other traumatic events. Finally, service members may be at particularly high risk of suicide without a previous history of suicidal behavior because the majority of service members are young men (a group at high risk to die by suicide [8], but at lower risk of multiple suicide attempts [25]). Therefore, identifying and intervening with individuals thinking of suicide (as well as those engaging in suicidal behavior) is key to preventing suicide in service members. These factors combined make a compelling argument for the necessity of identifying an effective intervention that can prevent suicidal ideation and behavior in suicidal service members and that could be easily disseminated. By investigating the effectiveness of this evidence-based intervention in a military population, using updated technology, and investigating the potential mechanisms of action of the intervention, we aim to identify such an intervention.

7.3 DESIGN:

Design type: Randomized controlled (i.e. fully experimental) trial of the efficacy of a ***Continuity Contacts via Text (CCVT)*** intervention with Treatment as Usual (TAU) compared to TAU alone.

- **Sample**
  - **Description of the population**
    - Active duty Service Members receiving services at a military clinic, hospital, or community-based service who present with suicidal behavior (thoughts or actions).
  - **Sample Size**
    - Based on power analyses, we seek to recruit 800 suicidal service members.
  - **Power Analysis**
    - Power analyses focused on H1c (i.e., number of suicide risk incidents requiring medical evacuation or hospital admission) and used effect sizes from Carter et al.[39]. Because these are end-point analyses (i.e., involving a single time point) and the proposed GLMM will use multiple assessments, the following estimates should be somewhat conservative. We are unaware of readily available sample size software for over-dispersed count regression, and thus, a simulation-based approach to power and sample size estimation was used (see Atkins[90] for discussion). Specifically, we used the counts of self-poisoning re-admission data from Carter[91] to simulate outcomes from an over-dispersed Poisson (technically, a negative binomial distribution) separately by treatment and gender as presented in Carter[91]). One thousand new datasets were simulated for each combination of sample sizes (from 600 to 1200) and treatment rate ratios (0.50 as reported by Carter, and 0.60 to use a more conservative estimate). Over-dispersed Poisson regressions were fit to each simulated dataset. The number of significant treatment effects represents a simulation-based estimate of power. The figure below shows that if the treatment effect size replicates that found by Carter (i.e., RR = 0.50), the study will be powered at 0.80 even at a total sample size of 600 (300 per arm). Power still for the current study of N=800 is sufficient with a somewhat smaller effect size (RR = 0.60, or a 40% reduction in treatment condition relative to control). Given this sample size and GLMM as the primary model, we are confident that the current design will be well powered for the suicide incident outcome. (Note that we did not attempt to directly estimate power using GLMM as the number of assumptions required to extrapolate the results presented by Carter using end-point analyses would be prohibitive.)

- Power was also calculated for the primary outcome of suicidal ideation.



- **Inclusion Criteria**
  - Active duty, Reserve, National Guard
  - 18 or more years of age
  - Identification to a behavioral health, counseling or medical service (inpatient, outpatient, or emergency) due to suicidal behavior - either suicidal ideation or a suicide attempt
  - Has current suicidal ideation as defined by the Scale for Suicidal Ideation-Current (SSI-C)
  - Has mobile phone or pager where he or she can receive 11 text messages in a year free of cost or at a fee they do not consider burdensome
  - Consents to participate in admission and follow-up interviews, possible further contact over the following year, and grants permission to review records for the previous and subsequent years.
  - Consents to randomization, participation, and the possibility of receiving texts for 12 months
- **Exclusion Criteria**
  - Does not speak and read English well enough to consent and to understand texts in English
  - Too cognitively impaired at best mental status during treatment to consent to participate (i.e., brain damage, psychosis, dementia, or other cause)
  - Treating clinician evaluates the intervention as contra-indicated (e.g., paranoia exacerbated by being contacted)
  - Prisoner or otherwise under judicial order where study participation could not be considered to be truly voluntary

- **Number of Participants:** 800 active duty Service Members receiving services at a military clinic, hospital, or community-based service who present with suicidal behavior (thoughts or actions).

- **Explanation of the process from consenting to data collection.**

- Identification of Potential Participants and Approach

At each of the 2 main bases involved in the study ([redacted] and [redacted]), a Continuity Clinician (CC) employed by the study will be hired to work on-site to facilitate the study (the CC based at [redacted] will also serve [redacted] and [redacted] bases, which are nearby). The CC will be based in the behavioral health outpatient clinic serving the largest number of service members at each base (or where otherwise decided with base staff). At [redacted], this will be the [redacted] clinic. The CC will be in contact with the providers for that clinic throughout the day about newly identified service members with suicidal ideation or behavior. On a regular basis throughout the week, the CC will also be in contact with clinicians at all behavioral medicine services (including inpatient, emergency department, and other outpatient services) as well as primary care and chaplains to assure they are identifying appropriate suicidal service members to the study and to problem-solve recruitment issues.

Recruitment to the study will be based on two steps being completed before the CC meets with the Service Member to discuss the study and conduct informed consent (these steps are captured in the MCP Clinician Approach Protocol).

(1) A base clinician treating the Service Member approves the Service Member as clinically appropriate to participate in the study and
(2) The Service Member's interest in talking with research staff about the study is confirmed.

Recruitment based on these two steps will occur in one of five ways that reflect the needs of a large number of clinics spread over the three bases hosting this study. The choice of procedures used by clinicians in each clinic will be made by that clinic's leadership:

(a) A base clinician will introduce the idea of the study to the suicidal Service Member he or she believes is appropriate and determine his or her interest in participating using the script in the MCP clinician approach protocol.
(b) A base clinician will introduce the idea of the study to the suicidal Service Member he or she believes is appropriate and determine his or her interest in participating using the Service Member Interest Form
(c) A base chaplain will introduce the idea of the study to the suicidal service member and determine his or her interest using the Service Member Interest Form. Service Members who indicate "yes" on Interest Forms will be reviewed with their treating clinicians for appropriateness using the MCP clinician approach protocol replacing #2 with the interest form completed with the chaplain. This will occur *prior* to the CC meeting with the Service Member to discuss the study and conduct informed consent..
(d) As the Service Member is enrolled in the base clinic, the Service Member Interest Form will be included with the other intake assessments. Service Members who indicate "yes" on Interest Forms will be reviewed with their treating clinicians for appropriateness using the MCP clinician approach protocol replacing #2 with the interest form completed at intake. This will occur *prior* to the CC meeting with the Service Member to discuss the study and conduct informed consent.
(e) Directly advertising to Service Members via a link on the website for the bases' clinics

and/or via posters/postcards/business cards. The posters/postcards/business cards about the study would be made available in common areas easily accessible to Service Members such as hallways, clinic lobbies, or restrooms. These locations are already used to advertise clinical services provide by the base as well as other research studies available to Service Members. When a Service Members contacts the CC based on the advertisement, the CC will follow three steps.

(1) The CC will provide the Service Member with a brief introduction to the study and explain that the study requires approval from their treating behavioral health or other service clinician to assure the study's appropriateness for the Service Member.

(2) The CC will ask the Service Member for their clinician's name and let the Service Member know that the CC will call back to follow-up based on the clinician's determination. If the Service Member does not want the CC to contact their clinician, then the SM will not be eligible to participate in the study.

a. If the Service Member does not have a treating clinician who is clinically responsible for that Service Member and able to determine clinical appropriateness for the study, then the CC will connect the Service Member with an intake clinician for the behavioral health clinic who can determine whether the Service Member is appropriate to the study as well as provide clinical care as appropriate.

b. If the Service Member does not have a treating clinician who is clinically responsible for that Service Member and able to determine clinical appropriateness for the study and refuses to interact with a behavioral health clinician at the installation, then the CC will explain that the Service Member will not be able to participate in the study. CC will also explain to the Service Member that they need to connect the Service Member with the Military Crisis line in order to ensure the safety and care of the Service Member. The CC will then use the 3-way calling feature to complete a warm hand-off.

(3) If the clinician approves, the CC will call the Service Member back to schedule a meeting to review the study and conduct informed consent. If the clinician does not approve, the CC will call the Service Member back to let them know this study is not the best fit.

a. If the study is not a good fit, the CC will assure that the Service Member knows which base clinician is the right fit and arrange for that contact, as directed by a base clinician or that base clinic's procedures.

(4) If the CC is contacted by someone other than the Service Member, e.g., a spouse, parent, or friend, the CC will answer questions about the study, but will not take the name or other identifying information about the Service Member. The caller will be directed to have the Service Member contact the CC or his/her clinician if he or she is interested in the study.

When both steps are completed (a base clinician treating the Service Member approves the Service Member as clinically appropriate to participate in the study, and the Service Member's interest in talking with research staff about the study is confirmed), the CC will meet with the Service Member, to explain the study, and if the service member remains interested, conduct

informed consent.

- Admission

At the time a participant completes the consent forms, the participant will be asked to provide contact information including his or her mobile phone number and email address (see Main Consent, Participant Tracking Consent, and Participant Information Form, Appendices B-D). To confirm that the participant is able to receive text messages, the CC will then send a test text message to the service member's phone. If at this point it becomes clear that the service member does not have a cell phone that is able to receive text messages and thus does not meet all eligibility criteria, the service member will not continue in the study. If the person does not have immediate access to his/her phone, the text will be sent and the admission process will continue. A single secure web-based CC Interface through [redacted] Corp, Inc will be used to input the data necessary to the texting intervention. (Data security further described in 12.0 HIPAA AUTHORIZATION section below.) Identifying information including name, date of birth, contact information, social security number (see section 12.0, HIPAA Authorization) will be direct-entered and stored electronically in a secure, password-protected database, separate from any study data. A third separately secured "bridge" database will house the link between the study and identifying data. Thus, the identifying information, study data, and link will be stored in three separate databases to maximize data security.

- Baseline Interview

At the beginning and end of the baseline interview, the CC will conduct the University of Washington Risk Assessment Protocol (UWRAP) protocol to assess and manage suicide risk during the course of the interview. The service member will be asked to complete the baseline interview, which includes a set of questionnaires. The interview and questionnaires assess psychiatric symptoms, suicidal ideation and behavior, psychiatric treatment utilization, and psychological constructs related to suicidal ideation and behavior (such as "thwarted belongingness"). (Please see "Participant Assessment Instruments" below for a list and description of instruments, and Appendix E for full-text instruments.) As stated in the Main Consent form, service members are free to choose not to answer any question or set of questions in the interview. The questionnaire portion of the interview will be self-administered and direct-entered into a secure participant interface by the participant. The participant interface does not allow the participant to view or edit any information except his/her own baseline assessment responses. The CC will be present during the self-assessment to proctor. Once the participant is finished, he or she will indicate so to the CC, who will log the service member out of the participant interface and complete the interviewer-administered instruments using paper forms.

Once the baseline interview is complete, the CC will use data about quality of life and life events collected during the interview to offer resources that may be beneficial to the participant, use the UWRAP to carry out any suicide risk management steps to assure the suicidal participant's risk is managed, and end the interview. The CC will then use a computerized randomization program to randomize the participant to either Continuity Contacts via Text Message + Treatment as

Usual (CCVT+TAU) or TAU only. Due to military regulation, participants will not be paid as compensation for baseline interviews.

- Intervention period

Participants in the CCVT+TAU condition will receive caring texts at 1 day, 1 week, 1, 2, 3, 4, 6, 8, 10, & 12 months, and on their birthday. Participants in both conditions will continue to receive usual behavioral health care according to standard operating procedures. Text messages will indicate a general concern for the individual and a link to a website with general resources including behavioral health and crisis services. Texts will be sent earlier in the day to allow maximum time for any responses while the CC is at the workplace and clinics are open. [redacted] has leased a shortcode which allows it to send and receive short message service (SMS; i.e., text messages) directly to participant's personal cell phone.

If the participant replies to the text, the direct SMS system will route that response to the CC's study cell phone. The [redacted] system allows input of additional cell phone numbers to route replies such that when the CC is not available, others on the clinical coverage team also receive and monitor responses from participants. For nights, weekends, and to cover vacations or illness, the CCs, Research Coordinator, and UW PIs will have a coverage system to assure someone is available at all times so that the response will be immediate in high-risk situations. Text message responses from participants will always be monitored, 24 hours a day. If a participant responds to a text with anything more descriptive in content than "I'm fine, thanks" , a response to that content will be incorporated into the next scheduled out-going text message. If a response is needed, but there is no indication of risk (e.g. request for resources or referral), a response will be crafted in coordination with Ms. Kerbrat or Dr. Comtois and as appropriate with base clinician(s).

CCs who receive replies indicating distress or suicidality will coordinate a response with the clinic when it is open and the base's after-hours service when not. Each base clinic will prescribe who the CC should contact during and after-hours. Drs. Comtois and Ries will provide supervision to the CCs in high-risk situations but clinical decision making for that Service Member will be as decided by their clinician or the after-hours service. Responses to texts from study participants who have separated from the military will be coordinated with warm hand-offs with the SAMHSA-run national suicide Lifeline, which routes to the crisis clinic in that participant's location, who can triage the case with the CC, intervene immediately if needed and provide resources for care, if not.

During the final intervention year following the close of recruitment on 20 Sept 2016, the clinicians will have concluded their work on-site and will shift to part-time work providing consultation (primarily regarding text responses from their participants and the replies to be sent back to them). Dr. Comtois and Ms. Kerbrat will take on 24/7 primary coverage of text replies during the final intervention year. Mr. [redacted] and Ms. [redacted] transitioned to this part-time role as of 20 Sept 2016.

In the course of collaborating with our behavioral and operations contacts in the Army and

Marine Corps, we have become aware that some deployment locations do not have text messaging available to the Service Member's personal cell phone. Therefore, we need an alternative contact method. Email is currently specified in the consent form as an alternative contact method. However, we have learned that email is not a reliable way to contact Service Members at some deployment locations. Therefore, we will replace text messages with either email or a brief greeting card, depending on what our base contacts consider the most effective method of contacting Service Members at that location. (To clarify, method of communication will be decided by deployment location and will be the same for all Service Members deployed to that location.) The content of the message will be the same as the scheduled text message but will be formatted to match standard email or greeting card formats.

- Text Message Content.

See Appendix F for an inclusive list of text messages.

- Follow-up Assessment

After the 12-month intervention period, participants receive an automated REDCap invitation to complete the self-administered follow-up survey items online. The self-administered survey portion will be the same as the one completed at baseline except for the omission of the demographic questionnaire. Once the self-administered portion is complete, the research assistant will call again to schedule the phone interview portion of the assessment. The interview will be the same as the interview conducted at admission except for (1) the addition of a short questionnaire regarding whether or not the participant received text messages from the study staff, and what his/her attitudes about the text messages were, to be answered if applicable, and (2) the omission of instruments assessing "lifetime" suicidal ideation and behavior (see Participant Assessment Instruments below).

To address suicide risk at follow-up interviews, the UWRAP protocol will also be used. Given that there might be risk during the self-administered portion at follow-up, the UWRAP risk ratings will be made at the beginning and end of this portion and, if the participant answers items showing risk is high, a "tripwire" in the data system will send a text noting the risk to the clinical coverage team as soon as the questionnaires are completed (this "tripwire" is active in the REDCap system). The clinical coverage team will then use the UWRAP protocol to manage risk and any needed interventions. More details managing risk can be found in the Managing Study Risks section below.

Participants who have separated from the military by this time will be paid $50 for participating in the 12-month follow-up assessment. These participants will be eligible to receive an extra $10 if they complete the assessment when originally scheduled, to encourage timely assessment.

To be sure contact information remains up to date, at 3 and 9 months, research staff will verify current contact information in military service records (permission to do this will be obtained from the service member during informed consent). At 6 months, research staff will call the participant's phone number to verify accuracy.

- Record review

Administrative medical records for military, VA, and Tricare for the year prior to study participation and year following recruitment will be reviewed for key outcomes such as admissions to inpatient medical and/or psychiatric care, utilization of emergency room or other crisis services, utilization of outpatient primary care or mental health treatment, and frequency of medical evacuations. Permission to review these records is included in the study consent process and form. Such analyses will provide validation of results by service member self-report. Electronic administrative medical records across Military Treatment Facilities, VA, and Tricare will be compiled by the Armed Forces Health Surveillance Branch (AFHSB) and shared with UW via [redacted] Site PI [redacted]. Specifics regarding security and file transfer are described in sections 12.0, vi-vii.

The UW research team will collaborate with the PI and Marines Corps collaborators to determine the most appropriate and effective means of providing additional data not included in AFHSB datasets, e.g., Marine Intercept Program data, to the UW research team for integration with participant interview data. (The Marine Intercept Program uses commanders to identify Marines at risk for suicide, who then receive ongoing outreach via telephone or face-to-face visits from a Marine Corps clinician; this intervention is captured by records maintained by Headquarters Marine Corps rather than by the electronic medical record.)

- **Data Collection Instrument**

All instruments were attached as Appendix E to the initial application and are described in detail below. All instruments are administered via direct entry using the REDCap (Research Electronic Data Capture; www.project-redcap.org) online interface except those noted below as "administered using a paper form."

***Participant Assessment Instruments*:**

Primary Outcomes and Mechanisms of Action.

The Scale for Suicide Ideation-Current (SSI-C)[92] is an interviewer-administered scale that measures a service member's suicidal ideation at its worst point in the past 2 weeks. This measure has been found to be a valid and reliable measure of 19 characteristics associated with suicidal ideation and intent[93, 94]. The Scale for Suicide Ideation-Worst (SSI-W)[95] will also be administered at baseline, focused on the worst two weeks of the service member's life, and at follow-up, focused on the worst period of time since enrollment. The SSI-W has shown better predictive validity for future death by suicide and may moderate the study effects. This scale is administered using a paper form.

The Suicide Attempt Self-Injury Count (SASI-Count)[96] is a brief two-page instrument determining the first, most recent, and most severe suicide attempt or non-suicidal self-injury (SASI) according to the definitions of Linehan et al[97] (i.e., using definitions of self-inflicted injuries which include situations of actual tissue damage and situations where tissue damage

would have occurred except for outside intervention or sheer luck [e.g., firearm jammed]). It assesses the date, method used, and intent to die (i.e., clear intent to die, ambivalent intent, no intent to die), highest level of medical treatment received (i.e., none, doctor/clinic visit, emergency room, and admission to a medical unit), and lethality of each of these. Following this, the number of SASIs for each of 11 methods of SASI is determined specifying the number with and without the intent to die, the number resulting in medical treatment, highest lethality, and the level of treatment received. A "Lifetime" version of the instrument administered at the baseline assessment assesses all SASIs during the service member's lifetime. A "Recent" version of the instrument assesses only those SASIs that occurred in the past year, both at baseline and follow-up assessments. This instrument is administered using a paper form.

The Suicide Attempt Self-Injury Interview- Short Form (SASII-SF) is a shortened version of the Suicide Attempt Self-Injury Interview (SASII) [97]. The SASII-SF will be used to gather more detailed data on suicide attempts identified on the SASI-C above. This measure includes more detail on attempt method and intent to assure a valid operationalization of suicide attempt. This instrument is administered using a paper form.

The Interpersonal Needs Questionnaire (INQ) was developed by Joiner and colleagues to measure beliefs about the extent to which individuals feel connected to others (i.e., belongingness) and the extent to which they feel like a burden on the people in their lives (i.e., perceived burdensomeness). Psychometric results indicated that the latent variable thwarted belongingness significantly predicted suicidal ideation scores providing support for the construct validity of the thwarted belongingness latent variable. Strong evidence for convergent and discriminant validity was also found for the thwarted belongingness[98, 99].

The Treatment History Interview (THI) uses a time-line follow-back method of assessment and will capture the subject's treatment history. This measure was designed for suicidal participants. We have modified a version to more appropriately capture the services service members are likely to receive, the Treatment History Interview – Military (THI-M). Part 1 describes the participant's involvement with professional psychotherapy, comprehensive treatment programs (e.g., substance abuse programs), case management, and other non-professional forms of treatment including number of sessions. Part 2 documents crisis and medical services, including the number of emergency room visits, number of psychiatric and medical hospital days, physician and clinic visits, paramedics or other emergency transport (i.e., medical evaluations), and wellness checks. Part 3 describes medications prescribed. Reliabilities for the THI are high. For participants who reported hospitalization in the past year, analyses revealed 90% agreement between participant report and hospital records for number of admissions per participant, $r = .99$, and 80% agreement for number of days per participant, $r = .99$. There were no false positives for participation in individual psychotherapy (verified by calling psychotherapists for interviews). Analyses of false negatives were not possible. There were no significant differences between therapists' records and THI self-reports of number of therapy hours in pilot studies[100]. This instrument is administered using a paper form.

Reasons for Termination- Client (RT-C) is a brief interview to determine the primary reasons for ending outpatient treatment and the relevant importance if more than one reason. This will help determine if the caring texts improve treatment acceptability. This instrument is administered using a paper form.

The Client Satisfaction Questionnaire (CSQ), a brief eight-item questionnaire, is used frequently for evaluating standard community mental health care [101-104]. The CSQ will help determine if the caring texts improve treatment satisfaction.

Additional measures.

In addition to measures of primary outcomes and proposed mediators, several additional measures will be used to collect important information characterizing the sample. These may also be used for exploratory analyses.

The Demographic Data Schedule (DDS) obtains a wide range of demographic data. High concurrent validity was established by comparing DDS responses to chart data for a sample of psychiatric inpatients[105].

The Mobile Phone Use Questionnaire A series of questions characterizing the service member's mobile and texting capacity and history will be included to determine that they are likely to receive the study texts and contextualize the receipt of these texts in terms of their frequency of text, phone, and other technology use.

The Acquired Capability for Suicide Scale (ACSS) is a 20-item measure designed to assess one's fearlessness about suicide. The ACSS has shown good to adequate internal consistency (α = -67-.83) as well as convergent and discriminant validity and it does not correlate with measures of depression or suicidal ideation[106, 107].

The Connor-Davidson Resilience Scale (CD-RISC) is a 25-item questionnaire that will be administered that asks about attitudes toward coping with adversity[108]. Conner and Davidson[108] reported a Cronbach's alpha of .89 for 577 general population subjects, and a test-retest reliability of .87 among 24 patients with either PTSD or generalized anxiety disorder who failed to respond favorably in a psychopharmacology clinical trial. Evidence for convergent and divergent validity include a positive correlation with a hardiness scale (r = 0.83) and a negative correlation with a perceived scale (r = 0.76).

The PHQ-9 is the 9-item depression scale of the Patient Health Questionnaire which is based directly on the diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual Fourth Edition (DSM-IV)[109]. In addition to making criteria-based diagnoses of depressive disorders, the PHQ-9 is a reliable and valid measure of depression severity[110].

The Alcohol Use Disorder Identification Test (AUDIT) will be administered to assess for alcohol use severity[111], as substance misuse is strongly associated with suicidal behavior.

The PTSD Checklist-Military (PCL-M) is a 17-item measure that will be used to measure PTSD symptoms. The PCL-M is widely used in the DoD and the VA and has excellent reliability and validity[113, 114] . Each item on the PCL-M corresponds to the DSM-IV diagnostic criteria for PTSD[115]. The PCL-M is scored on a 1 (not at all) to 5 (extremely) scale, and scores greater than 50 are considered clinically significant[116]. There are also three subscales (B, C, and D) that correspond to the criteria clusters in the DSM-IV. Previous research on the PCL-M indicated mean scores of 64.2 (SD=9.1) for PTSD and 29.4 (SD= 11.5) for non-PTSD participants[113].

The Bullying Survey was created from items in the Center for Disease Control (CDC)'s recent compendium of bullying assessment tools[117]. The survey assesses experiences with bullying during school-age years and in the workplace including items regarding frequency of

bullying, types of bullying behaviors experienced, perceived causes of bullying, and responses to bullying.

The Military Suicide Research Consortium Common Data Elements (MRSC CDE) includes items regarding suicidal behavior, behavioral health and TBI symptoms, substance use, and hopelessness that are to be included in all MRSC-funded studies. Many of these items are reflected in scales listed above. (The CDE items not already included in other measures are included in a separate form.)

The Life Events Questionnaire (LEQ) assesses stressful life events over the past year and whether those events are perceived to have contributed to participants' recent suicidality. The instrument also includes ratings of the extent to which each life event was a positive or negative event[118, 119].

The Exposure to Suicide Questionnaire assesses for possible contagion effects via a brief measure of each participant's exposure to suicide. The participants will be asked about family members or friends/co-workers who have died by suicide or made a suicide attempt and survived. Thus, we will be able to examine post-hoc any impact of exposure to suicide and suicide clusters on the intervention effects. This instrument is administered using a paper form.

The Text Message Reception Survey is a short questionnaire regarding whether or not the participant received text messages from the study staff, and what his/her attitudes about the text messages were, to be answered if applicable. This scale is administered using a paper form.

The University of Washington Risk Assessment Protocol. To manage suicide risk during assessments, the *University of Washington Risk Assessment Protocol (UWRAP*), developed by Marsha Linehan, Ph.D. and Co-PI, Comtois, will be utilized. This protocol has been recommended by NIMH and has been used successfully in 20 years of research by the Co-PI[120, 121]. This instrument is administered using paper forms. A summary of the UWRAP follows:

1. The protocol starts at the beginning of each session with (1) the location and contact information for the service member (unless interview is in person) and (2) four ratings of stress, intent to commit suicide, urges to self-injure, and urges to use drugs or alcohol (0 = Low to 7 = High).

   Because the questionnaire portion of the follow-up interviews will be completed by participants on their own, the questionnaires will also be bookended with the 0-7 ratings described above. The assessment team is automatically sent a text page if the service member indicates high risk for suicide (greater than 3 on the 0-7 scale). In this case, a team member will contact the service member and follow the protocol as described below and in Appendix E.

2. Following the 0-7 ratings described above, the interviewer conducts a Mood Improvement Protocol (MIP). This MIP helps the service member to identify strategies that could be used by the participant or the assessor during and after the assessment to manage any distress associated with the assessment. We have found it helpful to identify these strategies before the assessment starts (rather than at the end when the participant is focused on leaving).

3. After completion of the assessments, 0-7 ratings of stress, intent to commit suicide, and urges to self-injure and use drugs or alcohol are re-administered to determine current risk as well as whether risk has increased or decreased since the start of the interview. It is also possible for service members to be identified as at risk if they indicate current suicide risk in their responses to study assessments. Similarly, a spontaneous self-report of active suicide intent at any point during the assessment-treatment process will identify a patient as high-risk, requiring evaluation for possible crisis intervention.
4. If moderate or greater intent to die is reported on any of the above measures, the Suicide Risk/Protective Factors Assessment is conducted to assess and manage the risk.
5. If a service member is identified as at imminent risk, the continuity clinician will facilitate a clinical disposition from a range of options reflecting the severity and immanency of suicide risk which will be conducted in collaboration with the appropriate behavioral health clinician for active duty participants. Appropriate clinical disposition will be facilitated in consultation with Dr. Comtois and Ms. Kerbrat at follow-up (at which time the service member may have separated from the military).
6. For all assessments, the UWRAP concludes with a debriefing protocol, which makes use of the strategies identified in the MIP to assure the service member can manage any distress from the assessment. Additional strategies to improve mood, stabilize the situation, or involve others, if needed, are implemented prior to ending contact. If the service member is actively in treatment, the service member's therapist is the primary contact/referral for him or her. If not, crisis resources are provided to the service member in case of difficulties later on.
   (More information on the UWRAP and risk management can be found in the Managing Study Risks section below.)

- **Variables/Data Points**

Figure 1. Table of Variables/Data Points

Variable	Data Source
Suicidality and suicidal behavior	SSI-C, SSI-W, SASI-Count, SASII, MRSC CDE
Hypothesized Mechanisms of Action	INQ, ACSS, THI, RT-C, CSQ
Other possible moderators of effect	ACSS, CD-RISC, PHQ-9, AUDIT, PCL-M, MRSC CDE, LEQ, exposure to suicide and bullying
Demographic Data	DDS
"Dose" of intervention received	Text Message Reception Survey
Admissions to inpatient medical and/or psychiatric	THI, AFHSB compiled data from Military Treatment Facilities, VA Medical Record,

care, utilization of emergency room or other crisis services, utilization of outpatient primary care or mental health treatment, and frequency of medical evacuations	Tricare Medical Record
Death Records	Social Security Administration Records & National Death Index Records

8.0 DATA ANALYSIS:

Prior to inferential statistics, thorough univariate and bivariate descriptive statistics will be conducted to examine distributions of key variables and explore basic relationships. In addition, baseline differences across groups will be examined to ensure that randomization yielded approximately equal groups. Should there be any concerns about treatment group comparability, a propensity score approach will be used to adjust for imbalanced covariates[122].

All analyses will use an intent-to-treat approach, analyzing data as randomized regardless of actual treatment received. As noted earlier, attempts will be made to retain accurate contact information for all participants to ensure intervention texts are received. Moreover, primary outcomes will be assessed from military records. Thus, missing data (i.e., drop-outs) would only occur in the event that a participant is discharged from the military (i.e., there are no records for that individual post-discharge) and we are not able to contact them for the follow-up assessment. To prevent this, multiple strategies to prevent attrition described above, which have been used successfully by Dr. Comtois in other studies of suicidal participants, will be employed to assure complete follow-up.

Aim 1. Key outcomes include continuous (i.e., suicidal ideation), binary (i.e., whether there were any suicidal incidents), and count outcomes (i.e., number of suicide incidents). For H1a, a linear regression will examine treatment differences in 12-month suicidal ideation, controlling for baseline ideation, following Carter's reports from the previous caring letters intervention[39, 91]. For H1b and H1c, assessment data and military records will provide the number of suicide risk incidents (i.e., requiring medical evacuation or hospital admission), which will be summed over 3-month intervals during the year of the study, yielding 4 repeated measures of the proportion of individuals with any suicide risk incidents and the total number of suicide risk incidents per person, which will be modeled using generalized linear mixed models (GLMM)[123]. GLMM allows for non-normally distributed outcomes (e.g., binary and count outcomes) and models correlated data (e.g., repeated measures) via random effects. The basic GLMM for H1b and H1c will be:

$$Outcome_{ti} = \beta_0 + \beta_1(Tx)_i + \beta_2(Time)_{ti} + \beta_3(Tx)(Time)_{ti} + r_{0i} + r_{1i}(Time) \quad (1)$$

where t indexes time and i indexes individuals. The regression coefficients, predictors, and random effects are connected to the dependent variable through a link function: logit for binary outcomes and log for count outcomes. These link functions guarantee that predictions are within

the permissible range of the outcome (i.e., 0 and 1 for binary and 0 or greater for count). Moreover, the underlying probability model will be the binomial distribution for the binary outcome and Poisson for the count outcome. The Poisson distribution assumes that the mean is equal to the variance (called equi-dispersion), whereas data commonly show over-dispersion in which the variance far exceeds the mean. This can be accommodated in the Poisson GLMM via an extra over-dispersion term, which will be used in the proposed analyses. Because of the stratified randomization, treatment conditions will be balanced across site, i.e. [redacted], and the [redacted] Marine Corps Bases ([redacted], [redacted], and [redacted] will be considered one site together because [redacted] and [redacted] use the same CC as [redacted] and are expected to contribute too few participants to be independent sites without unbalancing the stratification) and history of suicidality divided into none, one lifetime suicide attempt, and multiple lifetime suicide attempts (gender is too imbalanced in a military sample to suggest stratification); nevertheless, each will be considered as potential covariates in all models. The key terms in the model above for the specific aims are β_2, which estimates the change across time in the outcome for the control group, and β_3, which estimates the difference in change across time for the intervention condition relative to control. In addition, planned contrasts using the model in equation 1 will test for treatment differences at 12 months. at one year post-index hospitalization will compare the proposed data with the results found by Carter[39, 91].

Aim 2. The second aim focuses on why the CCVT intervention might work – specifically, whether the intervention affects two intervening variables (thwarted belongingness and outpatient behavioral health services), which in turn impact the outcomes. To test these mediation hypotheses, we will use an extension of the classic Baron and Kenny[124] framework. Because the hypothesized mediators are available at 12 months, mediation analyses will focus on 12 month outcomes (i.e., for suicide risk incidents, a summary proportion and total number over 12 months will be used). MacKinnon[125] describes an extension of mediation to non-normal outcomes, and Shrout and Bolger[126] have recommended the bootstrap to estimate the indirect pathway of treatment to mediator and mediator to outcome. For both mediators (thwarted belongingness and behavioral health services), analyses will focus on changes in coefficients for the total treatment effect to a model that includes a mediator. In addition, indirect effects will be estimated via bootstrap resampling. Mediation models will be run for both mediators and each of the three primary outcomes in Aim 1.

Figure 2. Data Analysis Table

Statistical Test	Independent Variable/ Predictor Variables	Dependent Variable/ Outcome Variables	Aim
Regression Analysis	Treatment Group Baseline Suicidal Ideation	Suicidal Ideation at 12 months	Aim 1
Generalized Linear Mixed Model	Treatment Group Time (Assessment Period)	Suicide Risk Incidents (yes/no) Suicide Risk Incidents (total sum)	Aim 1

Mediation Analysis	Thwarted Belongingness Outpatient Behavioral Health Services	Suicidal Ideation Suicide Risk incidents	Aim 2

9.0 MILITARY RELEVANCE:

The proposed study has direct military relevance because: (a) it will be conducted on multiple military installations, (b) the study will be with active-duty military service members, (b) the study will use an evidence-based intervention approach specifically tailored for military personnel and (c) the study will utilize military service providers to function as continuity clinicians (funded by the study) to conduct baseline assessments, as well as send and respond to caring texts exactly as this model would be disseminated in military settings if it is found to be effective, and (d) we will develop the text messaging technology that will allow for rapid dissemination of this intervention throughout the military. Further, this intervention is designed to complement and enhance the treatment as usual that service members are already receiving by reducing risk of suicidal ideation and behavior and increasing mental health and resiliency. This intervention could be immediately disseminated throughout the military as an inexpensive and broad-reaching continuity of care intervention.

10.0 MEDICAL APPLICATION:

The proposed study has direct medical application because suicide is a significant problem in the military and caring contacts have been shown in previous studies to reduce suicidal ideation, behavior, and death. CCVT is designed to be implemented in Army and Marine Corps behavioral medicine or counseling services as an additional suicide prevention service if it is found to be effective in this study.

11.0 BUDGET:
Will any outside organization provide funding or other resources? Yes (X) No ( )

Funder: Military Suicide Research Consortium
The DoD, Assistant Secretary of Defense (Health Affairs) from the Defense Health Program Enhancement (DHPe) awarded the $17 million federal grant to Florida State University and the Denver Veterans Affairs Medical Center to establish the Department of Defense Military Suicide Research Consortium (MSRC). MSRC then put out a request for proposals and awarded the subcontract for this project to the University of Washington. At the end of 2015, the University of Washington received additional funds from the MSRC to keep recruitment open through September 2016.

Item	Cost	Additional MSRC funding	Total
Personnel	[redacted]	[redacted]	[redacted]
Supplies	[redacted]	[redacted]	[redacted]

Equipment	[redacted]	[redacted]	[redacted]
Travel	[redacted]	[redacted]	[redacted]
Other Direct Costs	[redacted]	[redacted]	[redacted]
Total Direct Costs	[redacted]	[redacted]	[redacted]

A Cooperative Agreement letter is attached in Appendix I.

12.0 HIPAA AUTHORIZATION: See Core Document 376024-34

12.1 BENEFITS:

- General benefits of this study to the military and society are noted in Specific Aims/Significance and Military Relevance above.
- The specific benefit to participants is that care in a research study is enhanced by the attention to treatment by the monitoring of study procedures.
- Enrollment into this clinical trial will also afford more extensive assessment and follow-up for all study participants by trained study personnel alert to the risks in this patient population regardless of group assignment.
- Those in the experimental condition will receive standard treatment plus CCVT which we hope, but do not know, will be more effective than usual care alone.
- However, there is no guarantee that participants will receive any benefit from taking part in the study. It is hoped that information gained from this study will improve treatment for other suicidal service members.
- If treatment is <u>not</u> found effective, it can either be modified with further evaluation or there will be evidence for its abandonment rather than continued use.

12.2 RISKS:

Likely Risks, but Not Serious

- Research study assessments may produce some discomfort or emotional upset as the participant describes his/her experiences, thoughts, images and feelings.
- There is a possibility that participants will report sensitive information that could require a report to state, local, or military authorities. This risk is inherent in all mental health care for military patients, and will be handled in a manner consistent with standard practices in [redacted] Department of Behavioral Medicine. Such situations will be discussed with participants upon enrollment as a routine part of the informed consent process that is standard for all mental health treatment with military personnel.

- A possible risk would be someone saw the text message other than the patient. However the texts are brief messages of general support that do not include information about the individual nor PHI. The texts refer to a website for more access to resources as well as the CC's first name. If someone other than the service member investigates the website, they will see a simple website titled Military Continuity Project with buttons for "If you are Army", "If you are Marines", "If you would like Veteran's resources" and "If you would like civilian resources". These buttons link to Military One Source or the VA resource page, or the SAMSHA resource page – all of which have clear buttons to link to suicide crisis resources but also many other types of non-mental health resources so the service member's privacy can be maintained. The CC's names, contact info, and bases will be listed in an administrative way on the main page so it can be seen they are simply staff on a military continuity project affiliated with resources. As this is the focus of the baseline interview as well, it fits with anything the service member would have described.

Rare, but Serious Risks:

- Both treatment conditions will require participants to talk about some things that might be painful or uncomfortable for them, which could cause increased emotional distress and the possibility of increased suicidal risk. Estimates indicate that as many as 40-47% of those receiving treatment (psychotherapy and medications) make an average of 2.5 suicide attempts during the first year of treatment following an index suicide attempt. One of the risks both in and out of treatment is therefore attempted suicide, which can result in death. The specific suicide attempt and death rate for PTSD, depression, and anxiety while in treatment is not yet known.
- With the handling of medical and research records, there is always the possibility of a breach of confidentiality.
- Finally, knowing that this intervention has been successful in two previous studies, a possible risk could be not sending letters to control group participants. However, this replication is being designed because these studies were in different health systems from those currently available in the US military and we feel there is still a need for further study before widespread implementation is appropriate.

Managing Study Risks.

All CCs as well as follow-up assessment interviewers at UW will be trained in research interviewing, Human Subjects procedures, HIPAA, and the UWRAP by Dr. Comtois as well as on the specific assessments. CCs and assessment interviewers will be closely supervised in the management of high-risk situations by Dr. Comtois and the clinical supervisor on site. The CCs (as well as the PI as needed) will work closely with the clinical supervisor on site and Dr. Comtois to assure all suicide risk situations during assessments are handled as agreed with Dr. Comtois and consistently with base protocol. Dr. Comtois has been conducting assessment and clinical trial research with suicidal individuals for more than 15 years and has taught over 25

research assistants to conduct these interviews and assess and manage risk during suicide risk assessments. She has been a member of the NIMH Data Safety Monitoring Board (DSMB) since 2001 as well as serving on two other DSMBs for clinical trials with high-risk participants.

The UWRAP,[121] used in this study to protect service members during assessment, has been used by UW suicide researchers, including Dr. Comtois, for over 20 years for both phone and in-person assessments. This protocol includes an assessment of suicide risk at the beginning and end of each assessment session in which the participant rates his/her stress, intent to kill him/herself, and intent to harm him/herself. For anyone with high ratings, there is an explicit series of steps starting with a suicide risk/protective factors assessment that is carried out by the assessor. Then strategies are used to reduce risk in the moment as well as to secure the individual in the longer term that start with putting the individual in contact with an existing clinician, coordinating contact with appropriate crisis response, up to having emergency personnel come to the participant's location for on-site evaluation, depending on the level of risk. This protocol has been used successfully at the University of Washington for over 20 years, including randomized clinical trials as well as in clinical epidemiology studies with no treatment provided. The protocol has been used with children and adults, men and women. A review of outcomes from the suicide risk assessment protocol[121] showed that this model is successful. It is also a recommended Risk Management Protocol by NIMH in their "Issues to Consider in Intervention Research with Persons at High Risk for Suicidality."

During follow-up assessments, to assure adequate contact information for participants in case an emergent response is needed, participants are asked to confirm (or update) their contact information at the beginning of each assessment including their current location if not at their home address.

Given that the participants in the study will live outside of the UW area, two strategies will be used if a participant is discovered to be a suicide risk during a follow-up assessment. The study assessment includes details about their current treatment providers. If they have a behavioral health provider and they are at suicide risk, we will follow our standard protocol and contact that provider to alert them of the participant's risk. If they are active duty but not in treatment at the time of the follow-up assessment, we will connect them to the appropriate behavioral medicine provider for screening. This method assures that the clinically responsible provider can decide the best course of action and actions are not taken that conflict with that provider's treatment plan. However, if the individual does not have a current behavioral health provider and are no longer active duty, they will be given the appropriate VA or civilian suicide crisis hotline number. These hotline systems routinely bridge at-risk callers to crisis centers in the closest geographic location to the caller, which are able to respond at multiple levels to acutely suicidal individuals. Decisions about handling such situations will be made by the assessor (and/or supervisor) and participant together whenever possible via three-way calling to coordinate an effective and appropriate response commensurate to the risk. If the participant refuses but the assessor and/or supervisor feel the inherent risk is high, they will contact the appropriate behavioral medicine clinician or hotline independently to take action.

There are several other steps we will take to reduce risks associated with this study. First,

in response to the risk that the interviews we conduct might be stressful or upsetting to the participants, we are limiting our assessments to questions regarding suicidal ideation and behaviors, related issues of belongingness and hopelessness, treatment services, behavioral health symptoms and quality of life which are similar to the evaluations they will already be receiving as part of the mental health care for which they have presented. The UWRAP includes ending ratings of suicide risk (with a "tripwire" in the self-administered section to alert the clinical coverage team that risk was identified there). Also, the UWRAP includes interventions to make assessments easier, including breaks and strategies after the assessment to improve the participant's mood.

Second, there is the possibility that the text messages may not help the participant. However, all participants, regardless of treatment condition, will be receiving treatment as usual per their command's standard operating procedures, and study procedures will not interfere in any way with their standard care.

Third, as in all trials of this nature, there is the possibility of unauthorized disclosure of confidential information. To minimize this risk, all staff will be trained to be sensitive to issues surrounding confidentiality and other forms of participant risk. We will emphasize the confidential nature of all data collected in this study to potential participants. We will also thoroughly explain our safe-guarding procedures.

Data Safety Monitoring Board (DSMB).

A Research/Medical Monitor (RM) and a DSMB, which includes the RM, will oversee and monitor the safety of study participants and the validity and integrity of the research endeavor. The RM's written acceptance of this role specifies that the RM will agree to make every effort to provide as much notice as possible if he/she is no longer able to fulfill the role (see "Research Monitor Acceptance Memo ([redacted]).pdf" submitted with [redacted]). For the remainder of the study, DSMB Chair Dr. [redacted] will also serve as the Research Monitor, in accordance with the specifications in section 3.0 of this protocol.

Upon establishing the DSMB, the relevant Institutional Review Boards (IRBs) will be informed of the operating protocol with regard to data and safety monitoring. The IRBs will evaluate the monitoring procedures and recommend modifications if necessary. An initial meeting of the DSMB and investigators will be scheduled prior to the start of the trial, thereafter members of the DSMB will meet at least once a year and more often as needed both with and without the investigators present. At least once a year, Dr. Comtois will send information to the DSMB on recruitment progress, participant retention, collaborative efforts and problems, and progress of data management and analyses. DSMB members will receive these data 2 weeks in advance of scheduled meetings.

The University of Washington IRB classifies suicide attempts and inpatient admissions in trials of highly suicidal participants as expected events and requires immediate reporting only on those which are unexpected in terms of severity *and* related to study participation *and* represent unanticipated risk to subjects or others, i.e., are indicative of an unexpected problem involving

risk to subjects or others (UPIRSO). More generally, UPIRSOs are defined adverse events that meet *all* of the following criteria: (1) the event is severe, e.g., is life-threatening, results in hospitalization; (2) the event was unexpected, altogether by nature, or in terms of frequency or severity; (3) the event appears to be related to study participation; (4) the event is indicative of increased risk to subjects or others. All adverse events reported after randomization to treatment condition are tracked and documented by the study team. Suicide attempts and inpatient admissions are reported in the annual IRB status reports and DSMB reports. In the event that a serious adverse event (SAE) (e.g., suicide, homicide, physical attack on staff) or a UPIRSO occurs, Drs. Comtois and [redacted] will notify the DSMB, including the RM, and IRB within 24 hours of learning of the event. The RM will promptly provide an unbiased written report of the event, commenting on the outcome of the event or problem, and in the case of a serious adverse event or death, commenting on the relationship to participation in the study, and whether the RM concurs with the details of the report provided by the study investigators.

Prior to each DSMB meeting, a DSMB report will be prepared and distributed that includes: (1) a review of recruitment, (2) the number, nature, and outcome of any adverse events which occurred during the review period and actions taken to mitigate them, (3) protocol violations and actions taken to mitigate them. Following each meeting of the DSMB, the DSMB Chair will prepare and send a brief summary report to Dr. Comtois including the date the review took place, the board's conclusions with respect to study progress, any need for modification of the study protocol or operating procedures, and approval/disapproval for the study to continue. Upon receipt of the report, Dr. Comtois will be responsible for transmitting a copy of the report to the IRBs and Consortium. We will, of course, accommodate any policy or procedures preferred by the Consortium or IRBs with respect to the DSMB.

12.3 HIPAA AUTHORIZATION WAIVER

If you wish to obtain and use identifiable protected health information for a study without obtaining written approval ("HIPAA Authorization") from the subject, please complete the HIPAA Authorization Waiver Form to provide justification for IRB review and approval. Contact wamcirbadmin@amedd.army.mil for assistance.

N/A.

13.0 WAIVER OF THE REQUIREMENT TO OBTAIN INFORMED CONSENT:

☐ **The research involves no more than minimal risk to the subjects and,**

☐ **The waiver will not adversely affect the rights and welfare of the subjects and,**

☐ **The research could not practicably be carried out without the waiver.**

☒ Not applicable

13.1 WAIVER OF THE REQUIREMENT TO DOCUMENT INFORMED CONSENT:

☐ 1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

☐ 2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

☒ 3. Not applicable.

14.0 REFERENCES:

1. Kung HC, Hoyert DL, Xu J, Murphy SL. Deaths: final data for 2005. *National Vital Statistics Report.* Apr 24 2008;56(10):1-120.

2. McIntosh J. USA suicide: 2003 Official final data. Fact sheet developed by the American Association of Suicidology from National Center Health Statistics: www.suicidology.org.; 2006.

3. Kuehn BM. Soldier suicide rates continue to rise: military, scientists work to stem the tide. *Journal of the American Medical Association.* 2009;301(11):1111-1113.

4. Luxton DD, Skopp NA, Bush N, Kinn J, Reger MA, Gahm GA. *Department of Defense Suicide Event Report: Calendar Year 2009 Annual Report. National Center for Telehealth & Technology (T2), Defense Centers of Excellence for Psychological Health & TBI (DCoE).* 2010.

5. Maris RW, Berman AL, Silverman MM, Bognar BM. *Comprehensive textbook of suicidology*. New York, NY: The Guilford Press; 2000.

6. Blue Ribbon Work Group on Suicide Prevention. *Report of the Blue Ribbon Work Group on Suicide Prevention in the Veteran Population.* Washington, DC 2008.

7. Kaplan MS, Huguet N, McFarland BH, Newsom JT. Suicide among male veterans: a prospective population-based study. *Journal of Epidemiology and Community Health.* Jul 2007;61(7):619-624.

8. Centers for Disease Control and Prevention. Trends in Suicide Rates Among Both Sexes, by Age Group, United States, 1991-2006. *Retrieved from: http://www.cdc.gov/violenceprevention/suicide/statistics/aag.html#3.* 2009.

9. Bullman TA, Kang HK. The risk of suicide among wounded Vietnam veterans. *American Journal of Public Health.* 1996;86(5):662-667.

10. Lineberry TW, Bostwick JM, Rundell JR. US troops returning home: Are you prepared? *Current Psychiatry.* 2006;5(1):12-30.

11. Milliken CS, Auchterlonie JL, Hoge CW. Longitudinal assessment of mental health problems among active and reserve component soldiers returning from the Iraq war. *Journal of the American Medical Association.* Nov 14 2007;298(18):2141-2148.

12. Seal KH, Bertenthal D, Maguen S, Gima K, Chu A, Marmar CR. Getting beyond "Don't ask; don't tell": an evaluation of US Veterans Administration postdeployment mental

health screening of veterans returning from Iraq and Afghanistan. *American Journal of Public Health.* Apr 2008;98(4):714-720.

13. Tanielian TL. *Invisible wounds of war: Psychological and cognitive injuries, their consequences, and services to assist recovery.* Santa Monica, CA: RAND Corporation; 2008.

14. Ilgen MA, Bohnert ASB, Ignacio RV, et al. Psychiatric Diagnoses and Risk of Suicide in Veterans. *Archives of General Psychiatry.* 2010;67(11):1152-1158.

15. Moscicki EK. Epidemiology of completed and attempted suicide: toward a framework for prevention. *Clinical Neuroscience Research.* 2001;1:310-323.

16. Terrio H, Brenner LA, Ivins BJ, et al. Traumatic brain injury screening: preliminary findings in a US Army Brigade Combat Team. *Journal of Head Trauma Rehabilitation.* Jan-Feb 2009;24(1):14-23.

17. Teasdale TW, Engberg AW. Suicide after traumatic brain injury: a population study. *Journal of Neurology, Neurosurgery, and Psychiatry.* Oct 2001;71(4):436-440.

18. Silver JM, Kramer R, Greenwald S, Weissman M. The association between head injuries and psychiatric disorders: findings from the New Haven NIMH Epidemiologic Catchment Area Study. *Brain Injury.* Nov 2001;15(11):935-945.

19. Brenner LA, Homaifar BY, Adler LE, Wolfman JH, Kemp J. Suicidality and veterans with a history of traumatic brain injury: precipitants events, protective factors, and prevention strategies. *Rehabilitation Psychology.* Nov 2009;54(4):390-397.

20. 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. *New England Journal of Medicine.* Jul 1 2004;351(1):13-22.

21. Mahon MJ, Tobin JP, Cusack DA, Kelleher C, Malone KM. Suicide among regular-duty military personnel: a retrospective case-control study of occupation-specific risk factors for workplace suicide. *American Journal of Psychiatry.* Sep 2005;162(9):1688-1696.

22. Nademin E, Jobes DA, Pflanz SE, et al. An investigation of interpersonal-psychological variables in air force suicides: a controlled-comparison study. *Archives of Suicide Research.* 2008;12(4):309-326.

23. Bryan CJ, Cukrowicz KC, West CL, Morrow CE. Combat experience and the acquired capability for suicide. *Journal of Clinical Psychology.* Oct 2010;66(10):1044-1056.

24. Joiner TE. *Why people die by suicide*. Cambridge, MA: Harvard University Press; 2005.

25. Kerkhof AJ. Attempted Suicide: Patterns and Trends. In: Hawton K, van Heeringen K, eds. *The International Handbook of Suicide and Attempted Suicide*. West Sussex, England: John Wiley & Sons, Ltd,; 2008.

26. Krug EG, Mercy JA, Dahlberg L, A Z, R. L. *World report on violence and health.* Geneva: World Health Organization; 2002.

27. Web-based Injury Statistics Query and Reporting System (WISQARS). 2007. www.cdc.gov/injury/wisqars/index.html. Updated Last Updated Date.

28. Corso PS, Mercy JA, Simon TR, Finkelstein EA, Miller TR. Medical costs and productivity losses due to interpersonal and self-directed violence in the United States. *American Journal of Preventative Medicine.* Jun 2007;32(6):474-482.

29. Cooper J, Kapur N, Webb R, et al. Suicide after deliberate self-harm: a 4-year cohort study. *American Journal of Psychiatry.* Feb 2005;162(2):297-303.

30. Suominen KH, Isometsa ET, Henriksson MM, Ostamo AI, Lonnqvist JK. Treatment received by alcohol-dependent suicide attempters. *Acta Psychiatrica Scandinavica.* Mar 1999;99(3):214-219.

31. Rudd MD, Joiner TE, Jobes DA, King CA. The Outpatient Treatment of Suicidality: An Integration of Science and Recognition of Its Limitations. *Professional Psychology: Research and Practice.* 1999;30(5):437-446.

32. van Heeringen C, Jannes S, Buylaert W, Henderick H, De Bacquer D, Van Remoortel J. The management of non-compliance with referral to out-patient after-care among attempted suicide patients: a controlled intervention study. *Psychological Medicine.* 1995;25(05):963-970.

33. Comtois KA. A review of interventions to reduce the prevalence of parasuicide. *Psychiatric Services.* Sep 2002;53(9):1138-1144.

34. Allan AT. No-shows at a community mental health clinic: a pilot study. *International Journal of Social Psychiatry.* 1988;34(1):40-46.

35. Baekeland F, Lundwall L. Dropping out of treatment: a critical review. *Psychological Bulletin.* Sep 1975;82(5):738-783.

36. Luxton DD, June JD, Comtois KA. Can Post-Hospitalization Follow-up Contacts Prevent Suicide?: A Systematic Review of the Evidence. Manuscript submitted.

37. Motto JA, Bostrom AG. A randomized controlled trial of postcrisis suicide prevention. *Psychiatric Services.* 2001;52(6):828-833.

38. Motto JA. Suicide prevention for high-risk persons who refuse treatment. *Suicide and Life Threatening Behavior.* 1976;6:223-230.

39. Carter GL, Clover K, Whyte IM, Dawson AH, D'Este C. Postcards from the EDge project: Randomised controlled trial of an intervention using postcards to reduce repetition of hospital treated deliberate self poisoning. *British Medical Journal.* Oct 8 2005;331(7520):805.

40. Carter GL, Clover K, Whyte IM, Dawson AH, D'Este C. Postcards from the EDge: 24-month outcomes of a randomised controlled trial for hospital-treated self-poisoning. *British Journal of Psychiatry.* Dec 2007;191:548-553.

41. Carter GL. Can we reduce suicide and attempted suicide? *Harborview Medical Center Psychiatry Conference*. Seattle, WA; 2009.

42. Beautrais AL, Gibb SJ, Faulkner A, Fergusson DM, Mulder RT. Postcard intervention for repeat self-harm: randomised controlled trial. *British Journal of Psychiatry.* Jul 2010;197(1):55-60.

43. Hassanian-Moghaddam H, Sarjami S, Kolahi AA, Carter GL. Postcards in Persia: randomised controlled trial to reduce suicidal behaviours 12 months after hospital-treated self-poisoning. *British Journal of Psychiatry.* Feb 22 2011.

44. Fleischmann A, Bertolote JM, Wasserman D, et al. Effectiveness of brief intervention and contact for suicide attempters: a randomized controlled trial in five countries. *Bulletin of the World Health Organization.* Sep 2008;86(9):703-709.

45. Bertolote JM, Fleischmann A, De Leo D, et al. Repetition of suicide attempts: data from emergency care settings in five culturally different low- and middle-income countries participating in the WHO SUPRE-MISS Study. *Crisis.* 2010;31(4):194-201.

46. Vaiva G, Vaiva G, Ducrocq F, et al. Effect of telephone contact on further suicide

attempts in patients discharged from an emergency department: randomised controlled study. *British Medical Journal.* May 27 2006;332(7552):1241-1245.

47. Luxton DD, Kinn JT, June JD, Pierre LW, Reger MA, Gahm GA. The caring letter project: A military suicide prevention pilot program. *Crisis: The Journal of Crisis Intervention and Suicide Prevention.* in press.

48. CTIA - The Wireless Association. *October 13th marks 25th anniversary of the first commercial cellular phone call [press release]*: Retrieved from http://www.ctia.org/media/press/body.cfm/prid/1781; 2008.

49. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. *American Journal of Preventative Medicine.* Feb 2009;36(2):165-173.

50. Pew Internet and American Life Project. *Cell phones and American adults*: Retrieved from http://pewinternet.org/Reports/2010/Cell-Phones-and-American-Adults.aspx; 2010, September 2.

51. Pew Internet and American Life Project. *Teens and mobile phones*: Retrieved from http://pewinternet.org/Reports/2010/Teens-and-Mobile-Phones.aspx; 2010, April 20.

52. Bopp JM, Miklowitz DJ, Goodwin GM, Stevens W, Rendell JM, Geddes JR. The longitudinal course of bipolar disorder as revealed through weekly text messaging: a feasibility study. *Bipolar Disorders.* May 2010;12(3):327-334.

53. Shapiro JR, Bauer S, Andrews E, et al. Mobile therapy: Use of text-messaging in the treatment of bulimia nervosa. *International Journal of Eating Disorders.* Sep 2010;43(6):513-519.

54. Spaniel F, Vohlidka P, Hrdlicka J, et al. ITAREPS: information technology aided relapse prevention programme in schizophrenia. *Schizophrenia Research.* Jan 2008;98(1-3):312-317.

55. Brendryen H, Kraft P. Happy ending: a randomized controlled trial of a digital multi-media smoking cessation intervention. *Addiction.* Mar 2008;103(3):478-484; discussion 485-476.

56. Depp CA, Mausbach B, Granholm E, et al. Mobile interventions for severe mental illness: design and preliminary data from three approaches. *Journal of Nervous and Mental Disorders.* Oct 2010;198(10):715-721.

57. Haller D, Sanci L, Sawyer S, Coffey C, Patton G. R U OK 2 TXT 4 RESEARCH?--feasibility of text message communication in primary care research. *Australian Family Physician.* Mar 2006;35(3):175-176.

58. Stoner SA. AGATE: Adaptive goal-directed adherence tracking and enhancement via mobile phone. Paper presented at: Poster presented at the 2010 mHealth Summit,, 2010; Washington, DC.

59. Chen H, Mishara BL, Liu XX. A pilot study of mobile telephone message interventions with suicide attempters in China. *Crisis.* 2010;31(2):109-112.

60. Linehan MM. A social-behavioral analysis of suicide and parasuicide implications for clinical assessment and treatment. In: Glazer H, Clarkin JF, eds. *Depression: Behavioral and Directive Intervention Strategies*. New York: Garland; 1981:229-294.

61. Van Orden KA, Witte TK, Cukrowicz KC, Braithwaite SR, Selby EA, Joiner TE, Jr. The interpersonal theory of suicide. *Psychological Review.* Apr 2010;117(2):575-600.

62. Baumeister RF, Leary MR. The need to belong: Desire for interpersonal attachments as a

fundamental human motivation. *Psychological Bulletin.* 1995;117(3):497-529.
63. Durkheim E. *Le Suicide: Etude de socologie.* Paris, France: F. Alcan; 1897.
64. Shneidman ES. Perspectives on suicidology. Further reflections on suicide and psychache. *Suicide and Life Threatening Behavior.* Fall 1998;28(3):245-250.
65. Joiner T, American Psychological Association. *The interpersonal theory of suicide : guidance for working with suicidal clients*. 1st ed. Washington, DC: American Psychological Association; 2009.
66. Appleby L, Cooper J, Amos T, Faragher B. Psychological autopsy study of suicides by people aged under 35. *British Journal of Psychiatry.* Aug 1999;175:168-174.
67. Beautrais AL. A case control study of suicide and attempted suicide in older adults. *Suicide and Life Threatening Behavior.* Spring 2002;32(1):1-9.
68. Brent DA, Johnson BA, Perper J, Connolly J. Personality disorder, personality traits, impulsive violence, and completed suicide in adolescents. *Journal of the American Academy of Child Adolescent Psychiatry.* 1994;33(8):1080-1086.
69. Cantor C, Slater P. Marital breakdown, parenthood, and suicide. *Journal of Family Studies.* 1995;1:91-102.
70. Conner KR, Britton PC, Sworts LM, Joiner TE, Jr. Suicide attempts among individuals with opiate dependence: the critical role of belonging. *Addictive Behaviors.* Jul 2007;32(7):1395-1404.
71. Conwell Y, Rotenberg M, Caine ED. Completed suicide at age 50 and over. *Journal of the American Geriatrics Society.* Jun 1990;38(6):640-644.
72. Dervic K, Brent DA, Oquendo MA. Completed suicide in childhood. *Psychiatric Clinics of North America.* Jun 2008;31(2):271-291.
73. Duberstein PR, Conwell Y, Connor KR, Eberley S, Evinger JS, Caine ED. Poor social integration and suicide: Fact or artifact? A case-control study. *Psychological Medicine.* 2004;34:1331-1337.
74. Fazel S, Cartwright J, Norman-Nott A, Hawton K. Suicide in prisoners: a systematic review of risk factors. *Journal of Clinical Psychiatry.* Nov 2008;69(11):1721-1731.
75. Gove W, Hughes M. Reexamining the ecological fallacy: A study in which aggregate data are critical in investigating the pathaological effects of living alone. *Social Forces.* 1980;58:1157-1177.
76. Groholt B, Ekeberg O, Wichstrom L, Haldorsen T. Suicide among children and younger and older adolescents in Norway: a comparative study. *Journal of the American Academy of Child and Adolescent Psychiatry.* May 1998;37(5):473-481.
77. Heikkinen M, Aro H, Lonnqvist J. Recent life events, social support and suicide. *Acta Psychiatrica Scandinavica. Supplementum.* 1994;377:65-72.
78. Hoyer G, Lund E. Suicide among women related to number of children in marriage. *Archives of General Psychiatry.* Feb 1993;50(2):134-137.
79. Koivumaa-Honkanen H, Honkanen R, Viinamaki H, Heikkila K, Kaprio J, Koskenvuo M. Life satisfaction and suicide: a 20-year follow-up study. *American Journal of Psychiatry.* Mar 2001;158(3):433-439.
80. Kposowa AJ. Marital status and suicide in the National Longitudinal Mortality Study. *Journal of Epidemiology and Community Health.* Apr 2000;54(4):254-261.
81. Maris RW. *Social forces in urban suicide*. Homewood, IL: Dorsey Press; 1969.

82. Miller M. Geriatric suicide: the Arizona study. *Gerontologist.* Oct 1978;18(5 Pt 1):488-495.
83. Murphy GE, Wetzel RD, Robins E, McEvoy L. Multiple risk factors predict suicide in alcoholism. *Archives of General Psychiatry.* Jun 1992;49(6):459-463.
84. Nickel C, Simek M, Moleda A, et al. Suicide attempts versus suicidal ideation in bulimic female adolescents. *Pediatrics International.* Aug 2006;48(4):374-381.
85. Obafunwa JO, Busuttil A. Clinical contact preceding suicide. *Postgraduate Medicine.* 2002.
86. Pokorny AD. Prediction of suicide in psychiatric patients. Report of a prospective study. *Archives of General Psychiatry.* Mar 1983;40(3):249-257.
87. Qin P, Nordentoft M. Suicide risk in relation to psychiatric hospitalization: evidence based on longitudinal registers. *Archives of General Psychiatry.* Apr 2005;62(4):427-432.
88. Rubenowitz E, Waern M, Wilhelmson K, Allebeck P. Life events and psychosocial factors in elderly suicides--a case-control study. *Psychological Medicine.* Oct 2001;31(7):1193-1202.
89. Joiner TE, American Psychological Association. *The interpersonal theory of suicide : guidance for working with suicidal clients*. 1st ed. Washington, DC: American Psychological Association; 2009.
90. Atkins DC. Using multilevel models to analyze marital and family treatment data: Basic and advanced issues. *Journal of Family Psychology.* 2005;19:98-110.
91. Carter GL, Clover K, Whyte IM, Dawson AH, D'Este C. Postcards from the EDge: 24-month outcomes of a randomised controlled trial for hospital-treated self-poisoning. *Br J Psychiatry.* Dec 2007;191:548-553.
92. Beck AT, Kovacs M, Weissman A. Assessment of suicide intention: The Scale for Suicide Ideation. *Journal of Consulting and Clinical Psychology.* 1979;47(2):343-352.
93. Beck AT, Brown GK, Steer RA. Psychometric characteristics of the Scale for Suicide Ideation with psychiatric outpatients. *Behavior Research and Therapy.* 1997;35(11):1039-1046.
94. Beck AT, Steer RA, Ranieri W. Scale for Suicide Ideation: psychometric properties of a self-report version. *Journal of Clinical Psychology.* 1988;44(4):499-505.
95. Beck AT, Brown GK, Steer RA, Dahlsgaard KK, Grisham JR. Suicide ideation at its worst point: A predictor of eventual suicide in psychiatric outpatients. *Suicide & Life-Threatening Behavior.* 1999;29(1):1-9.
96. Comtois KA, Linehan MM. Lifetime parasuicide count: Decription and psychometrics; 1999.
97. Linehan MM, Comtois KA, Brown ML, 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. *Psychological Assessment.* 2006;18:303-312.
98. Van Orden KA, Witte TK, Gordon KH, Bender TW, Joiner TE, Jr. Suicidal desire and the capability for suicide: tests of the interpersonal-psychological theory of suicidal behavior among adults. *J Consult Clin Psychol.* Feb 2008;76(1):72-83.
99. Van Orden KA. *Construct validity of the interpersonal needs questionnaire* [Dissertation]. Tallahassee: College of Arts and Sciences, Florida State University; 2009.
100. Linehan MM, Heard HL. Treatment History Interview (THI): Available Department of

Psychology, University of Washington, Seattle, WA; 1987.

101. Attkisson CC, Zwick R. The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. *Evaluation and Program Planning.* 1982;5(3):233-237.

102. Attkisson CC, Zwick R. The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. *Evaluation & Program Planning.* 1982;5(3):233-237.

103. Gaston L, Sabourin S. Client satisfaction and social desirability in psychotherapy. *Evaluation & Program Planning.* 1992;15(3):227-231.

104. Nguyen T, Attkisson C, Stegner B. Assessment of patient satisfaction: Development and refinement of a service evaluation questionnaire. *Evaluation and Program Planning.* 1983;6:299-314.

105. Linehan MM. Demographic Data Schedule (DDS). Seattle, WA: Available Department of Psychology, University of Washington; 1982.

106. Van Orden KA, Witte TK, Gordon KH, Bender TW, Joiner TE, Jr. Suicidal desire and the capability for suicide: tests of the interpersonal-psychological theory of suicidal behavior among adults. *Journal of Consulting and Clinical Psychology.* Feb 2008;76(1):72-83.

107. Bender TW, Gordon KH, Bresin K, Joiner TE, Jr. Impulsivity and suicidality: the mediating role of painful and provocative experiences. *Journal of Affective Disorders.* Mar 2011;129(1-3):301-307.

108. Connor KM, Davidson JR. Development of a new resilience scale: the Connor-Davidson Resilience Scale (CD-RISC). *Depression and anxiety.* 2003;18(2):76-82.

109. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders Text Revision (DSM-IV TR)*. Washington, DC: American Psychiatric Press; 2000.

110. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine.* Sep 2001;16(9):606-613.

111. Babor TF, de la Fuente JR, Saunders JB, Grant M. AUDIT: The Alcohol Use Identification Test: Guidelines for use in primary health care: World Health Organization; 1992.

112. Newcombe D, Humeniuk R, Ali R. Validation of the World Health Organization Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): report of results from the Australian site. *Drug Alcohol Rev.* 2005;24:217-226.

113. Weathers FW, Litz, B. T., Herman, D. S., Huska, J. A. & Keane, T. M. The PTSD checklist; reliability, validity & diagnostic utility. Paper presented at: Annual Meeting of the International Society for Traumatic Stress Studies.; October, 1993; San Antonio, TX.

114. Blanchard EB, Jones-Alexander J, Buckley TC, Forneris CA. Psychometric properties of the PTSD Checklist (PCL). *Behaviour Research and Therapy.* Aug 1996;34(8):669-673.

115. Association AP. *DSM-IV-TR : Diagnostic and statistical manual of mental disorders*. 4th ed., text revision ed. Washington, DC: AMERICAN PSYCHIATRIC PRESS INC (DC); 2000.

116. Weathers, F.W. PCL-M for DSM-IV. In: Huska, J.A., eds. Boston: National Center for PTSD--Behavioral Science Division; 1991.

117. ME H, KC B, AM V. *Measuring Bullying Victimization, Perpetration, and Bystander Experiences: A Compendium of Assessment Tools.* Atlanta, GA: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2011.
118. Sarason IG, Sarason BR, Potter EH, Antoni MH. Life events, social support, and illness. *Psychosomatic Medicine.* 1985;47(2):156-163.
119. Sarason IG, Johnson JH, Siegel JM. Assessing the impact of life changes: Development of the Life Experiences Survey. *Journal of Consulting and Clinical Psychology.* 1978;46(5):932-946.
120. Linehan MM, Comtois KA, Ward-Ciesielski EF. Assessing and Managing Risk With Suicidal Individuals. *Cognitive and Behavioral Practice.* in press(0).
121. Reynolds SK, Lindenboim N, Comtois KA, Murray A, Linehan MM. Risky assessments: participant suicidality and distress associated with research assessments in a treatment study of suicidal behavior. *Suicide Life Threat Behav.* Feb 2006;36(1):19-34.
122. Rosenbaum P. *Observational Studies*. New York: Springer; 2002.
123. Hedeker D, Gibbons R. *Longitudinal data analysis*. New York: Wiley; 2006.
124. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology.* Dec 1986;51(6):1173-1182.
125. MacKinnon DP. *Introduction to statistical mediation analysis*. Mahwah, NJ: Erlbaum; 2008.
126. Shrout PE, Bolger N. Mediation in experimental and nonexperimental studies: new procedures and recommendations. *Psychological Methods.* Dec 2002;7(4):422-445.

15.0 IMPACT STATEMENTS: See Core Document 376024-34

16.0 PRINCIPAL INVESTIGATORS' SIGNATURE: See Core Document 376024-34

17.0. ASSOCIATE INVESTIGATORS' SIGNATURE: See Core Document 376024-34

18.0 OTHER SIGNATURES FOR APPROVAL (REQUIRED): See Core Document 376024-34