Official Title: Reengaging rural patients in VA mental health care after VA-community care network referral

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Title
Reengaging rural patients in VA mental health care after VA-community care network referral.

Investigators
Natalie Riblet, MD, MPH is the Principal Investigator of this study.

Specific Aims/Purpose
Rural patients who receive mental health treatment through VA-Community Care Networks (VA-CCN) represent a special population of high-risk patients because they have demonstrated an acute mental health need yet are not routinely included in VA suicide prevention programming. This is a critical gap in care. We have previously developed a suicide prevention intervention to decrease suicide risk in patients during high-risk transition scenarios. The intervention is called the VA Brief Intervention and Contact Program (VA BIC) and is an adaptation of the successful World Health Organization Brief Intervention and Contact Program (WHO BIC). VA BIC aims to prevent suicide by educating VA patients around suicide risk, promoting treatment engagement, and increasing social connectedness. Our pilot work with VA BIC in VA inpatient and outpatient settings suggests that VA BIC may decrease suicidal ideation, reduce hopelessness, increase social connectedness, and improve treatment engagement. A quality improvement project of BIC at six rural VA facilities also found that on average, patients rate BIC as excellent and site staff perceive that BIC is implementable.

Building off our pilot work with VA BIC, we propose a two-year project arc to address current gaps in care by adapting the VA BIC intervention to promote re-engagement in VA care for VA-CCN patients and prevent suicide. Our project will consist of three phases. **In Phase 1**, we will develop a reliable method to incorporate our VA BIC intervention into care processes for rural patients who are discharged from VA-CCN mental health treatment settings. This adaptation will extend VA BIC to the VA-CCN. Our adaptation will be called the **B**uilding VA **E**ngagement, **S**elf-efficacy, and **S**ocial Support **T**o Prevent Suicide (BESST) intervention. During Phase 2, we will pilot test the BESST intervention in a cohort of patients. Finally, during Phase 3, we will conduct a randomized trial of BESST versus usual care to determine whether BESST improves re-engagement in VA-provided mental health services and suicide-related outcomes in the VA-CCN population

Study Objectives and Specific Aims
The overall goal of our proposed work is to develop a key resource for rural VA facilities to use to keep patients who are referred to (and discharged from) VA-CCN mental health treatment settings involved in VA care and to prevent suicide. To achieve our overall goal, we intend to pursue the following aims:

Aim 1: During phase 1, we will determine a reliable method to incorporate our VA BIC suicide prevention intervention into care processes for rural patients discharged from VA-CCN mental health treatment settings.

Hypothesis: We will develop a reliable method to incorporate VA BIC into care processes for rural patients discharged from VA- CCN mental health treatment settings. The adaptation will be called the **B**uilding VA **E**ngagement, **S**elf-efficacy, and **S**ocial Support **T**o Prevent Suicide (BESST) intervention.

Aim 2: During phase 2, we will pilot test the BESST intervention in four to six rural patients who are referred to (and discharged from) a VA-CCN mental health treatment setting.

Hypothesis**:** We will obtain data on the feasibility of studying the BESST intervention in rural patients who are referred to (and discharged from) a VA-CCN mental health treatment setting. We will identify any further modifications that may be required prior to studying BESST in this population.

Aim 3: During phase 3, we will conduct a randomized trial of the BESST intervention versus usual care in rural patients who are referred to (and discharged from) VA-CCN mental health treatment settings. We aim to determine whether the BESST intervention can improve suicide-related outcomes in this population.

Hypothesis**:** We will determine whether the BESST intervention reduces suicidal ideation and hopelessness and improves social connectedness and treatment engagement in rural patients who are referred to (and discharged from) VA-CCN mental health treatment settings.

Note**:** As show in **Table 1**, we will develop a reliable method to incorporate our VA BIC intervention into care processes for rural patients who are discharged from VA-CCN mental health treatment settings.

Table 1: Proposed phases of study of the BESST intervention in rural patients.

Phase	Aim	Proposed study activities during phase of work
Phase One	Aim 1	• Recruit three rural VA facilities and their affiliated VA-CCN sites. • Use an interview guide to interview site staff about current VA-CCN processes of care and to determine a reliable method to incorporate VA BIC into these processes. The adaptation will be called BESST.
Phase Two	Aim 2	• Pilot study of BESST in 4 – 6 patients who access VA-CCN care. • Finalize the BESST manual.
Phase Three	Aim 3	• Use results of Phase 1 and 2 to inform the design of a pilot, randomized trial of the BESST intervention for VA-CCN mental health settings.

BESST = **B**uilding VA **E**ngagement, **S**elf-efficacy, and **S**ocial Support **T**o Prevent Suicide; VA BIC = VA Brief Intervention and Contact Program; VA-CCN = VA Community Care Networks;

Scientific Rationale and Significance

A growing number of rural patients receive portions of their care in VA Community Care Network (VA-CCN) settings. In fact, VA researchers have observed that nearly 40% of recipients of VA-CCN services live in rural areas.[1] In Fiscal Year (FY) 2021, the

White River Junction VA Medical Center (WRJ VAMC) reported over 300 VA-CCN inpatient and residential mental health stays among its patient panel. Growth in VA-CCN use is concerning because **rural patients may experience worse outcomes in VA-CCN settings due to problems such as breakdowns in communication**.[2] Importantly, this may prompt patients to disengage from VA-delivered care following a VA-CCN stay.

Rural patients are at the highest risk for suicide following an inpatient or residential mental health stay for the treatment of mental health conditions or substance use disorders (SUD).[3, 4] Several factors may contribute to this finding such as poor social support,[5] limited engagement in care[5] and poor access to care.[5, 6] The VA has developed a suite of strategies to address suicide risk in patients following a mental health discharge.[7, 8] The **VA suicide prevention program, however, does not extend to patients who are treated in VA-CCN mental health treatment settings**. In fact, there is no evidence-based approach to assist rural patients with re-engaging with VA care after a VA-CCN discharge and to mitigate their suicide risk. These findings highlight a crucial gap in the VA's efforts to keep rural patients engaged in VA care and to prevent suicide.

We developed a suicide prevention strategy called the VA Brief Intervention and Contact Program (VA BIC).[9-11] A key goal of VA BIC is to mitigate suicide risk by helping rural patients to stay engaged in VA care after mental health discharge from a VA treatment program.[9-11] Our pilot work and testing of VA BIC at the White River Junction VA Medical Center suggests that VA BIC may reduce suicidal ideation and hopelessness and improve social connectedness and treatment engagement.[9-11] Based on our positive results**, we believe that VA BIC can be adapted to meet the needs of rural patients who are referred to (and discharged from) VA-CCN mental health settings**. Our VA BIC adaptation will be called the Building VA Engagement, Self-efficacy, and Social Support To Prevent Suicide (BESST) intervention. The BESST intervention will aim to increase engagement in VA care among rural patients and to decrease their suicide risk. Ultimately, our work will lead to the development of a key resource for rural VA facilities to use to keep patients who are referred to (and discharged from) VA-CCN mental health settings involved in VA care and to prevent death by suicide.

Preliminary Studies

Several brief interventions have been developed to address the risk for suicide following psychiatric and emergency room discharge.[12] In a meta-analysis of randomized controlled trials (RCTs) of suicide prevention strategies, Riblet et al. (2017) identified a single intervention, the World Health Organization Brief Intervention and Contact (WHO BIC) Program, that is proven to prevent suicide following psychiatric discharge.[12] The WHO BIC (1) facilitates patient engagement through educating patients about suicide risk and (2) provides patients with regularly- scheduled professional support after discharge by helping patients adhere to their discharge care plan through in-person and telephone contact.[13] The WHO BIC also aims to ensure continuity of care after discharge by facilitating the communication of emergent patient

needs and concerns to their outpatient providers. Yet, the WHO BIC has not been studied in high-income countries or in U.S. veterans. Our pilot work demonstrated that the WHO BIC may address systematic vulnerabilities in the discharge process and align with hospitalized veterans' preferences for treatment.[9-11]

We conducted a pre-post study of an adapted version of WHO BIC (called *VA BIC)* in nine psychiatrically hospitalized Veterans at the White River Junction VA Medical Center (WRJ VAMC).[10] We found that rural Veterans exposed to VA BIC experienced significant and clinically meaningful improvements in suicidal ideation at one and three months after discharge. We also observed significant improvements in related measures of suicide risk including hopelessness and connectedness. Patients had high treatment engagement after discharge. Subsequently, we performed a pilot RCT of VA BIC in 19 psychiatrically hospitalized Veterans.[9] Aligned with the results of our pre-post study, we found that VA BIC had a medium or large effect on suicidal ideation, hopelessness, social connectedness at one month after discharge. Furthermore, the effect on social connectedness remained large at three months. VA BIC also had a medium effect on treatment engagement.

The study of VA BIC during other high-risk transition scenario settings has also yielded promising results. We performed a pilot RCT of VA BIC in 19 Veterans who presented to a primary care mental health walk-in clinic for a new mental health intake appointment and were at risk for suicide.[11] We identified that it was feasible to conduct a virtual trial of the intervention in this population. Moreover, the results suggested that Veterans assigned to the intervention may experience improvements in suicidal ideation as well as higher treatment engagement. We are also currently completing a study of the VA BIC in Veterans who are admitted to a VA residential treatment program for the management of substance use disorder. We were able to meet our recruitment goal of 20 Veterans. The results of this study are not yet available. Finally, we collaborated with the VA Office of Rural Health, the VA National Center for Patient Safety, and the VA Office of Systems Redesign in a quality improvement (QI) project that examined the BIC program in six, rural VA facilities.[14] The results of the QI work suggested that Veterans on average rate the BIC program as excellent and VA providers perceive that BIC is implementable.

To the best of our knowledge there have been no studies of targeted interventions for rural patients that address suicide risk and treatment engagement after discharge from VA-CCN mental health treatment settings. The VA BIC (or any related adaptations) have also not been tested in these settings. Therefore, as a next step, we propose to determine current processes of care for rural patients who are referred to (and discharged from) VA-CCN mental health treatment settings. We will then develop, and pilot test a VA BIC adaptation (called the BESST intervention) that is optimized to meet the needs of rural patients who are referred to (and discharged from) VA-CCN mental health treatment settings.

Finally, we will conduct a randomized trial of the BESST intervention versus usual care in rural patients who are referred to (and discharged from) VA-CCN mental health treatment settings. The results of our work will ultimately lead to the development of a key resource for rural VA facilities to use to keep patients who are referred to (and discharged from) VA-CCN mental health treatment settings involved in VA care and to prevent death by suicide.

Note we report here only on the portion of the protocol that relates to the pilot RCT that is registered at clinicaltrials.gov at the number listed on the first page. Thus, pages 6-12 are intentionally excluded from the document as they pertain only to aims 1 and 2 of the larger project.

Project Proposal, Phase 3, Aim 3

To test our hypotheses as described above, we propose to conduct an assessor - blinded RCT comparing the BESST intervention plus standard care to standard care alone. We will enroll up to 25 patients who are 18 years or older and are being discharged from a VA-CCN mental health treatment setting. The primary aim is to determine whether the BESST intervention reduces suicidal ideation at one and three months after discharge. The secondary aim is to evaluate the impact of the BESST intervention on other related measures of suicide risk including hopelessness, social connectedness, fatal/non-fatal suicide attempts and treatment engagement.

Randomization: Prior to the start of study enrollment, the study team otherwise not involved in recruitment will independently prepare allocation cards using a permutated block schedule. The same study staff member will then put these prepared allocation cards into sealed, opaque, numbered envelopes. After obtaining consent and completing the baseline assessment (see description below), the study staff member will take the next numbered envelope from the box (described above) and open the envelope to determine the patient's assignment. In the event that the patient has been assigned to the intervention, the study staff will notify the intervention staff in order that the intervention staff can initiate the intervention. Otherwise, the patient will be informed that they have been assigned to usual care.

Baseline Assessment

The study assessor will meet with each eligible patient as close to the time of discharge as possible. The study assessor will conduct the visit by phone or VA Video-Connect (VVC). The study assessor will obtain informed consent from the patient and then administer the baseline assessments, which are described under the outcome measures (see below). The baseline visit will take approximately 90 minutes to complete.

BESST Intervention Description: Patients assigned to the BESST intervention will receive the BESST Intervention plus the standard care. The BESST intervention is an adaptation of the VA BIC intervention and designed to meet the unique needs of Veterans receiving care in a VA-CCN mental health treatment setting **(see BESST Manual**).[9-11] BESST can be delivered by a trained mental health staff member, such as a mental health nurse, social worker, psychologist, or psychiatrist. The intervention targets the needs of patients who are being discharged from a higher-level care setting (e.g., acute inpatient, residential). The intervention incorporates aspects of motivational interviewing (MI) techniques. Because the intervention is intended to complement and enhance standard care, patients assigned to the BESST intervention will continue to have access to care (described below). There are no restrictions on the types of treatments that patients may pursue after discharge from the VA-CCN mental health treatment setting.

Brief Educational Intervention: Patients receive a one-hour, one-on-one, brief educational intervention on suicide prevention. The session is performed by a intervention staff member. The intervention will be delivered virtually either by telephone or VVC. We expect that this visit will occur approximately within 1-2 weeks after study entry. Because the intervention staff member will not be able to visit with the patient in person because patients may be admitted to VA-CCN units across several states (e.g., NH, MA, ME, and CT), the staff member will send the patient any associated educational handouts as shown in the manual by U.S. mail. In addition, the handout will also be available to the patient through a Qualtrics survey link (web-based) which the intervention staff member will give to the patient at the time of the session. The Qualtrics survey platform is being used for the sole purpose of making sure that the patient can see the educational materials while the intervention staff member walks through them. The patient will not answer any questions on the survey link (i.e., the link contains no questions). The patient will not put in any personal information on the website (i.e., the link contains no mechanism to enter personal data or information). The Qualtrics survey link only contains uploaded educational materials that are generic to the prevention of suicide in a Veteran population. The survey link does not contain any PHI.

The educational session is designed to meet the information needs of Veterans receiving VA-CCN mental health care and to address patient barriers to follow-up. The education includes a discussion of the patient's safety plan. The sessions are highly interactive, allowing time for questions and providing patients with written materials that they can keep for future reference.

Regular Contact: The patients will maintain regular contact with the intervention staff member for a total of seven contacts over the course of the three months after discharge. At each of these contacts, the intervention staff member will monitor the patient's symptoms, assess treatment adherence, review the safety plan with the patient, and, if necessary, assist the patient with engaging in care. The contacts are designed to be highly interactive, allowing time for questions and providing patients with written materials that they can keep for future reference. Depending on the patient's preference, the regular contacts will be delivered over the phone (or VA Video Connect) or in-person in a private office on the grounds of the WRJ VAMC. These visits last roughly 15-30 minutes.

Standard Care: Regardless of study assignment, all patients will have access to standard care. This includes recommendations for mental health follow-up as deemed appropriate by the discharging treatment team. Patients may also be offered specific treatments to address their mental health symptoms after discharge. It is also conceivable that a patient may be on the High Risk for Suicide List. Patients on the High Risk for Suicide List receive enhanced oversight as

outlined in VA policy. This includes a requirement that the treating provider schedule the patient to be seen four times within the first 30 days following discharge. The primary care or mental health provider is also expected to tailor the patient's treatment to address his/her unique risk factors for suicide. The suicide prevention coordinator places a pop-up flag in the medical record to alert providers of the patient's high-risk status. The continued need for the patient to remain on the High Risk for Suicide List is reassessed by the suicide prevention coordinator. Finally, the treating provider is expected to complete a safety plan with the patient.

Table 2: Overview of Standardized Assessment Measures and Timing of Assessment

	Measurement Methods				Timing of Assessment		
Outcome	Instrument	Cronbach's α	Length	Time*	0M	1M	3M
Suicidal Ideation	**BSS**	**0.87 – 0.97**	**21 items**	**10**	**X**	**X**	**X**
Hopelessness	**BHS**	**0.87 – 0.93**	**20 Items**	**10**	**X**	**X**	**X**
Self-Efficacy	**GSE**	**0.76 - 0.90**	**10 items**	**3**	**X**	**X**	**X**
Connectedness	**INQ-15**	**0.89 – 0.91**	**15 items**	**5**	**X**	**X**	**X**
Connectedness	**MSPSS**		**12 items**	**5**	**X**	**X**	**X**
Engagement	**SRCS**	**0.89**	**17 items**	**5**	**X**	**X**	**X**
Suicide Attempts	**CSSR-S**	**N/A**	**7 items**	**5**	**X**	**X**	**X**
Substance Use	**TLFB**	**N/A**	**6 items**	**2**	**X**	**X**	**X**
Estimated time (in minutes) to complete assessments					**45**	**45**	**45**

BHS = Beck Hopelessness Scale; BSS = Beck Scale for Suicidal Ideation; CSSR-S = Columbia Suicide Severity Rating Scale; GSE = General Self-Efficacy Scale; INQ-15 = Interpersonal Needs Questionnaire-15; M = months; MSPSS: Multidimensional Scale of Perceived Social Support; N/A = Not applicable; SRCS: The Suicide-Related Coping Scale; TLFB = Timeline follow-back

*Time is described in minutes

Outcome Measures: As outlined in **Table 2**, we will use several standardized instruments to collect information on primary and secondary outcomes throughout the study. Copies of the assessment tools are available in the Assessment Manual.

Baseline Characteristics: We will collect socio-demographic data from the electronic medical record such as age, sex, marital status and service history (e.g., branch, era, combat exposure). We will also collect diagnostic information using either the MINI International Neuropsychiatric Interview (MINI), which has been validated against the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM). The MINI is a short, structured diagnostic interview that, on average, takes about 15 minutes to administer.[25] We will ask about any history of suicide attempts using the validated Columbia Suicide Severity Rating-Scale (C-SSRS).[26] The C-SSRS includes a seven-item subscale that assesses for actual and interrupted suicide attempts.

Primary Outcome (Suicidal Ideation): The primary outcome will be assessed using the Beck Scale for Suicidal Ideation (BSS) (Specific Aim 1).[27-29] Patients will be asked about their current suicidal ideation (i.e., past week) at baseline and at the one-month and three-month follow-up

assessments. The BSS is a self-reported questionnaire that assesses severity of suicidal ideation. The BSS measures attitudes, behaviors, and plans to die by suicide. Each item on the BSS is scored on a scale from 0 to 2 and the first 19 of the 21 items are used to calculate a total score ranging from 0 – 38. The BSS has high reliability and is a valid measure of suicidal ideation. The BSS may be a measure of risk of suicide.[30] There is evidence that the BSS is measurement invariant across time.[29]

***Secondary Outcome (Patient Engagement)*:** We will measure patient engagement in treatment at baseline and at follow-up assessments in two ways. First, we will examine healthcare utilization in the first three months after discharge. We will look at the amount of contact with mental health providers as well as the time to first mental health appointment after discharge. We will also evaluate evidence of disruptions of care such as no-show and cancelled appointments. We will abstract these measures from the electronic medical record. Since it is possible that some patients may receive portions of their care outside of the VA system, we will also ask patients to self-report on non-VA care. To gather data regarding the patient's sense of self-efficacy around managing their suicide risk after discharge, we will administer the validated Suicide-Related Coping Scale (SRCS).[31] This SRCS includes 17 questions related to a patient's perception of their ability to cope with suicidal thoughts. Each item is assessed using a 5-point Likert scale and the measure has been developed based on two studies of suicide prevention strategies conducted within Veteran populations. The scale includes two subscales including an External Coping subscale and an Internal Coping Subscale. Both subscales have shown good acceptable internal consistency. The two factors are also sensitive to change over time. Higher scores on the scale suggest better coping. In addition to the SRCS, we will also measure the patient's general sense of self-efficacy using the General Self-Efficacy Scale (GSE).[32] This is a valid scale of self-efficacy that is designed for the general population (12 years or older) and it has been tested in various countries.

Secondary Outcome (Hopelessness): We will assess hopelessness at baseline and at follow-up assessments using the Beck Hopelessness Scale (BHS). The BHS is a 20-item self-report scale that assesses hopelessness over the past seven days,[33] Patients report on feelings about the future, loss of motivation, and future expectations. Total scores range from 0 to 20, with higher scores suggesting more hopelessness. The BHS has good reliability and validity and is sensitive to change.[28] There is some evidence that the BHS may be a measure of risk of suicide.[28]

Secondary Outcome (Connectedness): We will measure social connectedness using the Interpersonal Needs Questionnaire-15 (INQ-15). The INQ-15 is a 15-item self-report scale that measures thwarted belongingness and perceived burdensomeness. Each item is measured on a 7-point Likert scale, with higher scores suggesting lower perceived connectedness.[34] The INQ-15 may be a measure of risk of suicide.[35] In addition, we will add also administer the Multidimensional Scale of Perceived Social Support (MSPSS).[36] The MSPSS is a 12-item self-reported scale that is designed to ask about support from several sources including friends, family and significant other. The scale has been shown to have good internal and test-retest reliability as well as good validity.

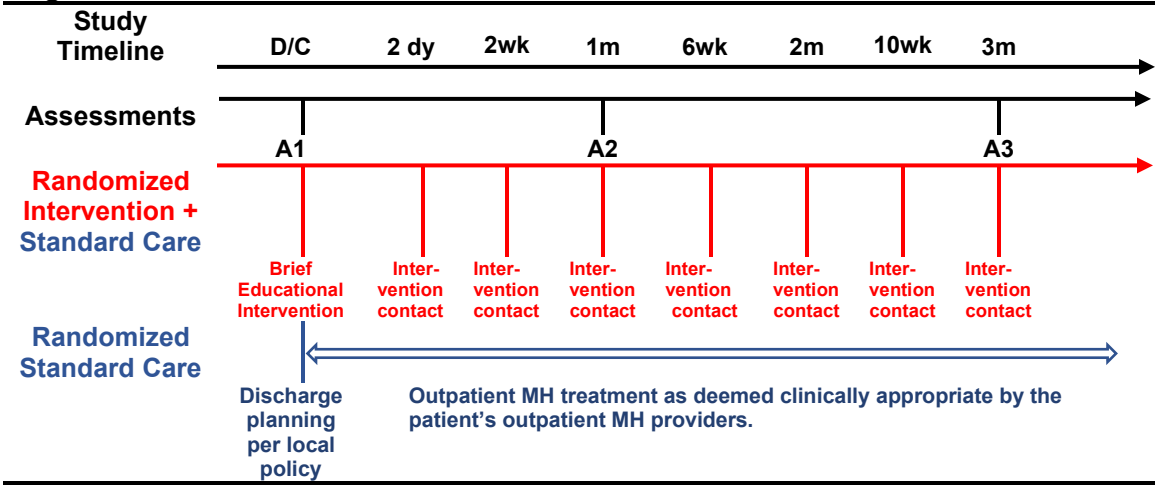
***Secondary Outcome (Suicide Attempts)*:** We will assess for non-fatal and fatal suicide attempts at one and three months after discharge using the C-SSRS.[26] The C-SSRS is a valid and reliable scale that includes a seven-item subscale that asks patients to self-report on actual attempts, interrupted attempts, aborted attempts, and preparatory acts or

behaviors. The scale asks the assessor to document the actual and potential lethality of these behaviors. The C-SSRS is widely used in the VA.

Secondary Outcome (Substance use): We will assess substance use at baseline and follow-up assessments using a timeline follow-back approach. This method is commonly used in research studies to assess substance use patterns.[37]

Study Design: As shown in **Figure 3** below, patients allocated to the BESST intervention will meet with the intervention staff around the time of discharge. During this visit, the patients will receive a brief educational intervention. Depending on patient preference, this visit will occur over the phone (or VA Video Connect). Depending on patient preference, the regular contacts will occur in a private office on the WRJ VAMC campus, or the contacts will occur over the phone (or VA Video Connect).

Figure 3. Schedule of Assessments and Interventions.



BIC= VA Brief Intervention and Contact Program; D/C = discharge; dy = days; m = months; MH = Mental Health; T0, T1, T2 = assessment time points; wk = weeks

All patients (including patients randomized to the intervention) will have access to standard care. Furthermore, regardless of study assignment, all patients will undergo outcome assessment at baseline (0M), one month (1M), and three months (3M). These assessments will be conducted by the independent outcome assessor. We anticipate that, in most cases, the baseline assessment will occur around the time of discharge. However, because patients will be recruited remotely, we anticipate that the baseline assessments may in some cases happen a few weeks after discharge. Depending on patient preference, the independent outcome assessor will conduct the follow-up assessments in a private office on the WRJ VAMC campus, over the phone, or using VA Video Connect. The assessors will be blinded to study assignment and the patients will be instructed to not reveal their status to the assessor.

Because we are recruiting patients from a large geographic area (New Hampshire, Maine and Vermont), we anticipate that several enrolled patients will prefer phone (or VA Video Connect) over in-person follow-up. Fortunately, the assessment instruments that we selected for this study can be administered over the phone or in person.

Statistical Analyses: We will conduct the analysis based on the intention-to-treat principle. Below, we have outlined the specific analysis plan for assessing each of the primary and

secondary aims of interest of this study. We will assess for statistically significant differences in baseline study characteristics such as age, sex, race, and mental health diagnosis, between study arms using *t*-tests for continuous measures and chi-squared tests for dichotomous variables. We will report these results using 95% confidence intervals (CI) and *P*-values. We will define statistical significance as a *P*-value < 0.05.

Specific Aim 1: We will generate descriptive summary statistics (e.g., means and standard errors, medians) and graphical displays for the BSS total scores at baseline and at each of the follow-up assessments. In the case of the pilot study of the BESST intervention in up to six patients, we will use a repeated measures analysis of variance (ANOVA) test to assess for changes in continuous variables in the first three months after discharge. Second, if the repeated measures ANOVA suggested a significant difference in means across time, we will perform a post-hoc, pair-wise comparison of means at baseline and at each follow-up using a two-sample t-test.

With regards to the RCT of the BESST intervention, we will use a generalized linear mixed model to assess for changes in continuous variables in the first three months after discharge. We will consider allocation of study arm (categorical measure) and time (continuous measure) as fixed effects. Random effect will be used to account for correlation that arises from repeated measures of the same individual. We will assume a linear effect and model changes in suicidal ideation over time. We will calculate 95% CI and *P*-values and will define a *P*-value of < 0.05 to be statistically significant. We will use the maximum likelihood ratio to account for any missing data. Based on available evidence, we hypothesize that the BESST intervention plus standard care will lead to a significant reduction in suicidal ideation after discharge.

Specific Aim 2: We will generate descriptive summary statistics (e.g., means and standard errors, medians) and graphical displays for our secondary outcomes of interest at baseline and at each of the follow-up assessments. In the case of the pilot study of the BESST intervention in up to six patients, we will use a repeated measures analysis of variance (ANOVA) test to assess for changes in continuous variables in the first three months after discharge. Second, if the repeated measures ANOVA suggested a significant difference in means across time, we will perform a post-hoc, pair-wise comparison of means at baseline and at each follow-up using a two-sample t-test.

With regards to the RCT of the BESST intervention, we will use a generalized linear mixed model to assess for changes in continuous variables in the first three months after discharge. We will calculate the associated 95% confidence intervals and *P*-values. As with the BSS, we will consider allocation of study arm (categorical measure) and time (continuous measure) as fixed effects. Random effect will be used to account for correlation that arises from repeated measures of the same individual. We will assume a linear effect and model changes in suicidal ideation over time. We will define a *P*-value of < 0.05 to be statistically significant. We will use the maximum likelihood ratio to account for any missing data. Based on available evidence, we hypothesize that the BESST intervention plus standard care will lead to a significant reduction in our secondary outcomes after discharge.

For the categorical measure of healthcare utilization, we will use chi-squared tests to compare findings between study arms.

Specific Aim 3: We will not be powered to detect a statistically significant difference between study arms with regards to suicide deaths and suicide attempts. These events are very difficult to examine in a clinical trial. A study would need to recruit well over 1,000 patients. Because we assume that few events will be observed in either arm, we plan to summarize our results by

providing basic descriptive statistics regarding the number of events in each arm at one-and three-month follow-ups.

Sample Size: Based on our prior work,[9-11] we believe it is useful to choose suicidal ideation as our primary outcome. In our pilot study of VA BIC, which included nine Veterans undergoing the VA BIC intervention, we found a greater than five-point improvement in the Beck Scale for Suicidal Ideation (BSS) over the three months following inpatient mental health discharge. Five points is a clinically meaningful improvement on the BSS as it represents the mean difference in suicidal ideation between ambulatory and hospitalized psychiatric patients.[2] Furthermore, in our pilot RCT of VA BIC on a VA inpatient unit we were also able to detect a statistically significant difference in BSS scores in a sample of 19 enrolled Veterans. Therefore, we will have sufficient power in this current pilot RCT to show a significant improvement in suicidal ideation if we enroll up to 25 patients.

Study Population and Recruitment

We will coordinate with staff at the WRJ, Togus or Manchester VAMCs to gain lists of patients referred to or discharged from VA-CCN mental health treatment settings. Acquiring these lists is the most comprehensive and effective way to garner this group of patients. We may also coordinate with staff at the sites mentioned in staff meetings such as interdisciplinary rounds (IDR) to learn of eligible patients for our study. Once a patient has been identified, we will then go into the patient's medical record to confirm eligibility criteria are met and to obtain contact information including telephone numbers and street addresses. In addition, if feasible, the staff may also inform the patient about our study and ask the patient's permission for our study team to contact the patient to provide further information about the study. In this case, if permission is obtained, the staff member will document this information in the patient's medical record.

We will request a HIPAA waiver for screening purposes. For patients identified via medical records, study staff will mail them a brief letter explaining the study. We will then follow-up via phone approximately one week after mailing the letter. If patients are interested in the study, study staff will read a consent document to the patient, and the patient will decide whether they would like to participate. If they agree to participate, verbal consent will be obtained and recorded on the telephone consent document. For patients who are referred to us by treating mental health providers, we will call the patient to further discuss the study. The VA staff will document in the medical record that the patient has given permission for the study staff to contact the patient and to provide further information about the study. If the patients are interested in participating, study staff will complete the consent process via telephone or VVC.

In the case of the RCT, study staff involved in the recruitment and consent process will be blinded at the time of study allocation. During the course of the study, it will be impossible to blind the intervention staff or patients to treatment allocation; however, the outcome assessor will remain blind to study assignment throughout the trial. Patients will be instructed not to reveal their study assignment to the outcome assessor.

Inclusion Criteria:

- The patient was recently discharged from a VA-CCN mental health treatment setting
- The patient is at risk for self-harm based on expressed symptoms such as suicidal ideation of any severity, suicide attempt, or self-harm or the patient has been diagnosed with a mental health condition that is a known risk factor for suicidal behavior (e.g., depression, substance use disorder).
- Be a patient connected to the WRJ VAMC, the Togus VAMC, or the Manchester VAMC;

- Be a Veteran;
- Be 18 years or older;
- Be able to speak English;

Exclusion Criteria

- Unable to provide informed consent;
- We do not plan to enroll any potentially vulnerable populations including prisoners, institutionalized patients, or involuntarily committed patients.
- Study physician deems the patient not clinically appropriate (e.g., patient is acutely, medically unstable). Note it is possible that a patient's clinical status could improve to the point where a patient could be approached about the study. This decision will be left to the clinical discretion of the study PI.

Informed Consent

We are requesting an alteration of consent. Because we are recruiting patients from VA-CCNs that are located across several states (many of which are located at a sufficient distance from the WRJ VAMC), it is not feasible for us to recruit patients in person to obtain their written consent. Furthermore, we wish to mitigate potential delays in recruiting patients because the goal of the intervention is to address the needs of patients around the time of discharge. Therefore, we will only be able to recruit patients virtually and conduct the consenting process virtually. Because this is a minimal risk intervention, it is appropriate to obtain a telephone consent or consent via VA-Video Connect (VVC) from the patient, with plans to send them a copy of the consent form by U.S. mail. This approach also reduces the burden on the patient, especially if they do not have access to technology and could otherwise not participate in the study because they can't sign a form electronically.

Risks and Side Effects

Potential Risks

Because the study population is known to be at high risk for suicide and the study outcomes include suicidal ideation, suicide attempts, and suicide, we will treat these events as anticipated adverse events during the course of this study. We will also consider hospitalizations or emergency room for worsening psychiatric symptoms or suicidal behavior as anticipated adverse events.

We fully expect that patients may report worsening suicidal ideation or suicidal behaviors at the study assessments (i.e., baseline, one-month, or three-month,) regardless of whether they are assigned to the intervention or control condition. In addition, patients who receive the intervention may report worsening suicidal ideation or suicidal behavior during an intervention visit. We also expect that patients could be seen in the emergency room or be hospitalized because of any of the aforementioned events. Thus, we anticipate for the patients to continue with the study unless the patient requests to be removed from the study. In addition, as described in our **Safety Alert Protocol**, the study staff will immediately follow the safety alert protocol in response to any reports of worsening suicidal ideation or behaviors. If deemed clinical necessary, the patient will be connected immediately with required clinical treatment. All patients will continue to have access to standard-of-care of treatment during the study irrespective of their study assignment. Furthermore, all patients may continue any treatments that they were getting as part of their routine care prior to enrolling in this study.

Additionally, the population that we will recruit for this study are also at higher risk for substance misuse because these are very common conditions among patients who are treated in acute inpatient or residential treatment settings. Therefore, we will treat substance misuse (e.g., alcohol use disorder) as well as admission to a detox facility as anticipated adverse events. Related to these concerns, we also expect that patients may be incarcerated, especially due to drug use, while participating in the study. We will capture this as an adverse event, and we will consider it to be anticipated, particularly if related to drug or alcohol use. No study-related procedures will be conducted while a patient is incarcerated. Participants may choose to continue with the study upon their release, under the discretion of Dr. Riblet. Dr. Riblet will determine together with the study staff whether the patient needs to be reconsented prior to continuing in the study. If any study visits occurs when the patient is incarcerated, the visit will be captured as "missed" (i.e., that particular visit will be skipped).

Therapeutic Risks

During the study, the research staff will ask patients questions about how they are feeling and their interactions with other people. Patients will be exposed to these therapeutic risks during the baseline and each follow-up assessment. In addition, patients who receive the intervention condition will also be exposed to these therapeutic risks at the intervention visits (brief education visit plus seven contact visits after discharge). In some cases, patients can feel embarrassed, nervous, bored, or generally uncomfortable when they are asked to answer these types of questions. However, because we have sufficient safeguards in place to mitigate these potential risks, we believe that the overall therapeutic risk from this study to enrolled patients is very low.

Research Risk

During the course of the study, we will collect from enrolled patients protected health information including name, social security numbers (in order to process participant payments), phone numbers (for contact purposes), sociodemographic information (e.g. age, race), psychiatric diagnoses (e.g. Alcohol Use Disorder, Substance Use Disorder, Depression), mental health treatments received, and psychiatric symptoms (e.g. responses to standardized questionnaires). Therefore, there is some risk that a patient's confidentiality or protected health information could be compromised due to study participation. As we have sufficient safeguards in place to mitigate this risk (see Protection Against Risk below), we believe the overall research risk in this study is very low. We will also make every effort to conduct study-related procedures in a private setting.

Protection Against Risk

Study Population Safety Risk

At each study assessment time point (i.e., baseline and one-month, and three-month follow-up), patients will be assessed for symptoms of suicidal ideation and suicidal behavior because these are *a priori* study endpoints. In addition, for patients receiving the intervention, patients may report worsening suicidal ideation or suicidal behavior in the context of the intervention visits. Regardless of whether the patient is receiving the intervention or is assigned to usual care alone, the study staff will be ethically bound to take appropriate action if the patient is at imminent risk for self-harm. The Safety Alert Protocol outlines the process that study staff members will take in order to ensure the safety and well-being of all enrolled patients regardless of whether they are receiving the intervention or usual care alone. In the case that a safety alert is met, the research staff member will contact Dr. Natalie Riblet (or the mental health physician covering for her) or, if necessary, the patient's mental health provider. As part of this risk assessment, the assessing clinician will immediately complete a comprehensive evaluation of

the patient's risk and determine the most appropriate next level of care for the enrolled patient. The next level of care may include psychiatric admission, emergency room referral, or an outpatient follow-up with the patient's healthcare provider. Please see **the Safety Alert Protocol** for a full description of all safety alerts and required actions by study staff members.

Therapeutic Risk
Patients will be given sufficient time to answer questions and complete visits in order to reduce any discomfort they may experience as part of being enrolled in the study. Patients will also be made aware that if any of the questions make them feel uncomfortable, they should feel free to report this to the study staff member and have this concern addressed immediately. At any point during a study visit, a patient can take a break or refuse to answer a question.

Research Risk
Every effort will be made to ensure that we maintain the privacy and confidentiality of the patient. All in-person, study visits will occur in a private office on the WRJ VAMC campus to ensure privacy. If a visit or assessment is done via a phone call, the research staff will conduct the phone call in a private office. All assessments that can be collected electronically will be stored on a secure, password-protected file on a secure, local researcher server. All staff associated with the study will complete required security training prior to the start of the study in order to be permitted access to this server. Furthermore, all study staff will adhere to the required annual training (by the WRJ VAMC) necessary to maintain their access to the server. All paper copies of study-related data, including consent and HIPAA forms, will be kept in a locked file cabinet, in a locked office, dedicated to this study. Only the research staff will have access to this locked cabinet.

Benefits:
All of the patients who participate in this study will receive standard of care and will be able to continue all treatments and mental health care that they would otherwise have access to outside of the study. In addition, some patients may receive the intervention in addition to standard care. The intervention is designed to enhance care that patients receive by helping to connect them with available mental health resources and educating them about suicide prevention after discharge. Although the intervention is adapted from a successful suicide prevention strategy (WHO BIC) and has also been studied in VA treatment settings, it is unknown whether the intervention significantly reduces suicide risk after discharge relative to standard discharge practices in patients who access VA-contracted community care inpatient or residential treatment. The work from this proposed study will be able to more definitively address whether the intervention is an effective suicide-prevention strategy in patients who access VA-contracted community care inpatient or residential treatment. This is important, given that suicide remains an important problem in the Veteran population. Because the overall risks associated with this study are minimal and the anticipated benefits and knowledge to be gained are clinically relevant, there is sufficient reason to conduct this proposed study.

Protected Health Information:
We will administer several validated instruments to all enrolled patients at baseline and follow-up (one- and three-month follow-ups). These instruments ask various questions related to self-harming thoughts or behavior and social connectedness. We will also ask patients to report on any non-VA healthcare utilization at one- and three-month follow-ups. Demographic data and other baseline characteristics will be collected from the patient's electronic medical record at baseline. Information on VA healthcare utilization will be

collected from the patient's electronic medical record at three-month follow-up. All data will be collected solely for the purposes of this study. All study data will be collected using an electronic data-capture system. These data are stored on a local, secure research server that only study staff will have access to. All paper copies of study-related data, including consent and HIPAA forms, will be kept in a locked file cabinet, in a locked office, dedicated to this study. Only research staff will be able to access this locked cabinet.

Multi-Site Study Concerns This project will be conducted at WRJ VAMC. All study procedures will be conducted by staff affiliated with the WRJ VAMC. While staff at the Togus VAMC or the Manchester VAMC may inform us of potential study subjects, these sites are not engaged in research per VA Policy No. 151-806. The three VA facilities are also all members of the VA Institutional Review Board of Northern New England (VINNE). Therefore, we do not foresee any issues in conducting this phase of the work.

Resources Available

Dr. Riblet will oversee and lead this project with the help of research staff, which includes:

- An interventionist (75% Year 2)
- A research coordinator (50% Year 2)
- A study assessor (75% Year 2)
- Administrative support (25% Year 2)

Subject Compensation:

We will compensate enrolled patients as follows: baseline: $100; one-month follow-up: $100; and three-month follow-up: $100. We chose this payment schedule so that patients are sufficiently reimbursed for their time and effort in the study. We will make every effort to compensate participants, however, if a participant refuses payment or does not provide the required information for payment purposes, study staff will pursue the following process: In the event that the patient has completed all assessments and/or interventions, and still has not provided the required information to pay them, the study staff will make reasonable efforts to obtain the information from the patient. If the patient still does not provide the required information to be paid, we will classify this patient as "unable to be paid".

Privacy and Confidentiality:

Please see *Protection Against Risk* above.

Data and Safety Monitoring Plan

Monitoring and Interim Analysis Plan: We will seek oversight for the RCT portion of our proposal. Specifically, we will request that the Dartmouth Data Monitoring Committee (DSMB). The DSMB will meets annually. The DSMB will focus on ensuring safety and feasibility, including participant accrual and retention, adverse events monitoring, and data analyses. Based on these findings, the DSMB may recommend: (1) continued approval (unconditionally or with conditions to be addressed); (2) probation; or (3) possibly termination, if there are problems with enrollment or safety concerns.

Study Safety & Monitoring:

Enrolled patients will be monitored for any unanticipated problems or adverse events during the course of the study. Unanticipated death possibly related to research will be orally reported to VINNE immediately with a written report submitted via IRBNet within 5 business days. Possibly study-related unanticipated problems involving risk to subjects or others; serious adverse events; and deviations/non-compliance will be reported within 5 business days to VINNE.

Adverse events will be reported with continuing review. Information security or privacy incidents will be reported to the ISSO or PO within one hour of discovery. As described above, we consider that the following events are anticipated adverse events: suicidal ideation, suicide attempts, suicide, hospitalizations or emergency room for worsening psychiatric symptoms or suicidal behavior, drug or alcohol relapse or admission to a detox facility, or imprisonment.

Reasons for stopping assigned treatment and follow-up:
We will consider that he following events are reasons to stop assigned treatment and or follow-up of an enrolled patient: (1) death because the patient would no longer be accessible to study staff; or (2) patient requests to withdraw from the study. In the event that the patient is assigned to the intervention, we will ask the patient if they are willing to continue with the outcome assessments but respect his/her wishes if he/she chooses to withdraw entirely from the study.

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