Study Protocol

Title: Suicide Prevention in Rural Veterans During High-risk Care Transition Scenarios

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Suicide Prevention in Rural Veterans During High-risk Care Transition Scenarios

Investigators
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Specific Aims/Purpose
The overall goal of our proposed work is to develop and implement an effective suicide prevention intervention for rural VA facilities to decrease suicide risk in veterans living in rural settings. To achieve this goal, we propose to study our VA adaptation of the World Health Organization Brief Intervention and Contact Program (WHO BIC) (which we will refer to as VA BIC) in rural veterans during high-risk care transition scenarios. Please see the VA BIC Manual for a full description of the intervention (**Appendix 1**). We will study the effectiveness of VA BIC in four high-risk care transition scenarios common to rural VA facilities: 1) any patient being discharged from an inpatient mental health unit, 2) patients being discharged an inpatient medical unit after receiving a psychiatric consultation, 3) any patient discharged from a residential substance treatment facility, and 4) patients being discharged from an emergency room after presenting with a mental health concern. By evaluating the intervention in each of these four scenarios, we will be able to guide rural VA facilities to the target populations most likely to benefit from the VA BIC intervention. We are initially requesting approval to conduct the VA BIC clinical trial enrolling patients from the first high-risk care transition scenario (any patient being discharged from an inpatient mental health unit). Once we reach our enrollment goal, we will submit a protocol amendment for the subsequent high-risk care transition scenarios. Because the VA BIC Manual may be adapted throughout the trial to target each transition scenario, completing a protocol amendment for each enrollment phase will be most logical and effective.

In **Year 1**, we plan to confirm our pilot findings suggesting that VA BIC is effective in reducing suicide risk after psychiatric hospitalization by conducting a small, randomized trial of VA BIC plus standard care versus standard care alone on the White River Junction (WRJ) VA Medical Center (VAMC) inpatient mental health unit (see Preliminary Studies section below). In addition, we plan to further adapt VA BIC for veterans experiencing three other high-risk care transition scenarios described above. During **Years 2 and 3**, we will sequentially conduct randomized trials of VA BIC plus standard care versus standard care alone for the other three high-risk care transition scenarios. If our findings indicate that VA BIC is an effective intervention in one or more of these high-risk care transition scenarios, we will spend **Year 4** working with three other rural facilities to develop materials for dissemination of VA BIC and assisting them with implementation at their sites. These materials would be used for broad dissemination in future work. Based on both our pilot work with the VA BIC and the results of the original international WHO BIC study, we are highly confident that our intervention will be helpful for rural VA facilities in decreasing suicide risk in at least one of the high-risk care transition scenarios. However, we feel that taking the preliminary steps in Years 1-3 will result in the most practical and effective program for rural VA facilities in Year 4.

Because of our promising pilot work,[1] we believe it is appropriate to choose suicidal ideation as our primary outcome. In our pilot study, 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, with this sample size and level of improvement, we were able to demonstrate a significant difference in improvement in suicidal ideation compared to a matched group of historical controls participating in a post-mental health discharge qualitative study.[3] Therefore, we believe that we will have sufficient power to show a clinically meaningful improvement in suicidal ideation overall and for each of the four high-risk care transition scenarios at one and three months after discharge if we enroll a total of 100 veterans (25 per transition scenario) over 3 years. We will also assess other important measures of suicide risk including hopelessness, connectedness, fatal/non-fatal suicide attempts and treatment engagement.[4-7] Please see the Assessment Manual for all assessment templates (see **Appendix 2**). We will assess post-discharge treatment engagement by evaluating continuity of care and disruptions of care (including missed appointments). We will abstract these data from the electronic medical record. In addition, we will ask veterans to report on any treatment they may have received outside of the VA healthcare system. We will use a standardized data

collection form to collect information on non-VA treatment. We have already piloted this data collection form in our current pilot study. We will include three measures of continuity of care including intensity of treatment, regularity of care, and continuity of care across organizational boundaries. These measures of continuity of care have been shown to be associated with improved mental health outcomes.[8] Because the focus of our project is on generating practical clinical results for rural VA facilities rapidly and cost-effectively, we will limit our longitudinal assessment to these outcomes. Finally, travel to appointments is a notable concern for veterans living in rural areas. We will give patients the choice to participate in VA BIC contact visits in-person, by telephone or via VA Video Connect. This approach aligns with the VA's goal to expand the use of telehealth services.

Study Objectives

1) To adapt the VA BIC for use during high-risk care transition scenarios including emergency room care, medical hospitalization and acute treatment in a drug dependence rehabilitation program.
2) To confirm that the VA BIC is effective at reducing suicidal ideation and other related measures of suicide risk during high-risk care transition scenarios including psychiatric hospitalization, emergency room care, medical hospitalization and residential substance treatment facility.
3) To disseminate the VA BIC to other rural VA facilities and assist these facilities with implementing VA BIC at their local sites in order to reduce the burden of suicide in rural veterans during high-risk transition care scenarios.

Our specific aims and hypotheses are as follows.

Specific Aim 1: The primary aim of the study is to determine whether the VA BIC program plus standard discharge care reduces suicidal ideation after discharge from an acute care setting compared to standard discharge care, alone.

Hypothesis: Based on available evidence, we hypothesize that the VA BIC program plus standard discharge care will lead to a significant reduction in suicidal ideation after discharge from an acute care setting. We believe that the effect of VA BIC on suicidal ideation will be the greatest at the three-month follow-up because the greatest intensity of follow-up care provided through VA BIC occurs within the first three months after discharge.

Specific Aim 2: The secondary aim of our study is to determine the effect of the VA BIC program on other related measures of suicide risk.

Hypothesis: Based on available evidence, we hypothesize that the VA BIC program plus standard discharge care will reduce hopelessness and improve patient engagement and perceived connectedness after discharge compared to standard discharge care.

Specific Aim 3 (exploratory): We plan to conduct an exploratory analysis on the number of suicide attempts (fatal and non-fatal) that occur after discharge in the VA BIC plus standard discharge care arm compared to standard discharge care alone.

Scientific Rationale and Significance

Suicide is a major public health concern.[9] U.S. veterans account for a sizable proportion of all U.S. suicide deaths, with approximately 14% of suicide deaths in the U.S. each year being attributed to a veteran.[10-11] The rate of suicide in the veteran population is more than two times that of non-Veteran U.S. adults.[9,11] The average number of suicides in veterans who use VA services has risen from four suicides per day in 2001 to six per day in 2015.[9,11] Veterans who live in rural areas may be at even higher risk for suicide than their urban counterparts.[12-13] For example, McCarthy *et al* reported that the risk for suicide among veterans in rural areas was 22% higher than those in urban areas.[13] There is a critical need to develop targeted interventions to address suicide risk in veterans in rural areas.

In order to have the greatest impact on suicide in rural veterans, it is important to develop effective interventions that target periods of highest risk. Available evidence indicates that **suicide risk is most**

concentrated during high-risk care transition scenarios such as discharge from an inpatient mental health unit or emergency room.[14-18] For example, in a study of psychiatrically hospitalized male veterans, Britton et al. (2017) found that patients who lived in a rural setting were at 20% higher risk of suicide after discharge compared to urban patients.[17] Similarly, patients who are discharged from an emergency room after presenting with suicidal behavior have a high risk for suicide in the months following discharge.[18] Yet, despite this known risk, patients discharged from an emergency room setting (after suicidal behavior) have very high rates of non-adherence with post-discharge care (ranging as high as 70%).[18] There is also some evidence to suggest that a subset of patients are at increased risk for suicide after medical hospitalization.[19-24] For example, Riblet et al. (2018) found a three-times higher risk of death by suicide among veterans with an against medical advice (AMA) discharge from a VA general medical ward, compared to those discharged routinely from the same wards.[20] This underscores the importance of looking beyond typical mental health settings, as AMA discharges from general medical wards occur most frequently among Veterans with substance abuse and mental health problems.[25] Finally, a substance use disorder is a strong risk for suicide and substance use disorders are highly prevalent in the veteran population.[26-27] Bohnert et al. (2017) found that male veterans who were diagnosed with a substance use disorder were at nearly two times greater risk for suicide, even after adjusting for age and medical and psychiatric comorbidity.[28] Studies have suggested that engagement in treatment (or lack thereof) plays an important role in clinical outcomes in veterans with substance use disorder. In particular, poorer continuity of care after discharge from VA residential substance treatment facilities may negatively impact patient engagement in care and outcomes.[29-30] This observation is particularly important given that rural veterans in general face more challenges accessing substance abuse treatment.[27] Our own recent review of root-cause analysis (RCA) reports of suicides following discharge from a VA residential substance treatment facilities (2002 – 2015) found that RCA teams reported contributing factors to suicide after discharge include poor engagement in care and fragmented care.[31]

Several brief interventions have been developed to address the risk for suicide following psychiatric and emergency room discharge.[32-33] 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.[32] 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.[34] 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.[3]

Preliminary Studies

We conducted a pilot study of an adapted version of WHO BIC (called *VA BIC)* in psychiatrically hospitalized veterans at the White River Junction VA Medical Center.[1] 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 continuity of care after discharge. To the best of our knowledge there have been no studies of targeted interventions for rural Veterans that address suicide risk during other high-risk care transition scenarios including discharge from an emergency room, inpatient medical stay or residential substance treatment facilities. The VA BIC has also not been pilot tested in these settings. Because of our promising pilot work, we believe it is appropriate to choose suicidal ideation as our primary outcome. In our pilot study, 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, with this sample size and level of improvement, we were able to demonstrate a significant difference in improvement in suicidal ideation compared to a matched group of historical controls participating in a post-mental health discharge qualitative study.[1,3] Therefore, we believe that we will have sufficient power to show a clinically meaningful improvement in suicidal ideation overall and for each of the four high-risk care transition scenarios at one and three months after discharge if we enroll a total of 100 veterans (25 per

transition scenario) over 3 years. We will also assess other important measures of suicide risk including hopelessness, connectedness, fatal/non-fatal suicide attempts and treatment engagement.[4-7] Please see the Assessment Manual for all assessment templates (**Appendix 2**). We will assess post-discharge treatment engagement by evaluating continuity of care and disruptions of care (including missed appointments). We will abstract these data from the electronic medical record. In addition, we will ask veterans to report on any treatment they may have received outside of the VA healthcare system. We will use a standardized data collection form to collect information on non-VA treatment. We have already piloted this data collection form in our current pilot study. We will include three measures of continuity of care including intensity of treatment, regularity of care, and continuity of care across organizational boundaries). These measures of continuity of care have been shown to be associated with improved mental health outcomes.[8] Because the focus of our project is on generating practical clinical results for rural VA facilities rapidly and cost-effectively, we will limit our longitudinal assessment to these outcomes. Finally, travel to appointments is a notable concern for veterans living in rural areas. We will give patients the choice to participate in VA BIC contact visits in-person, by telephone or via VA Video Connect. This approach aligns with the VA's goal to expand the use of telehealth services.

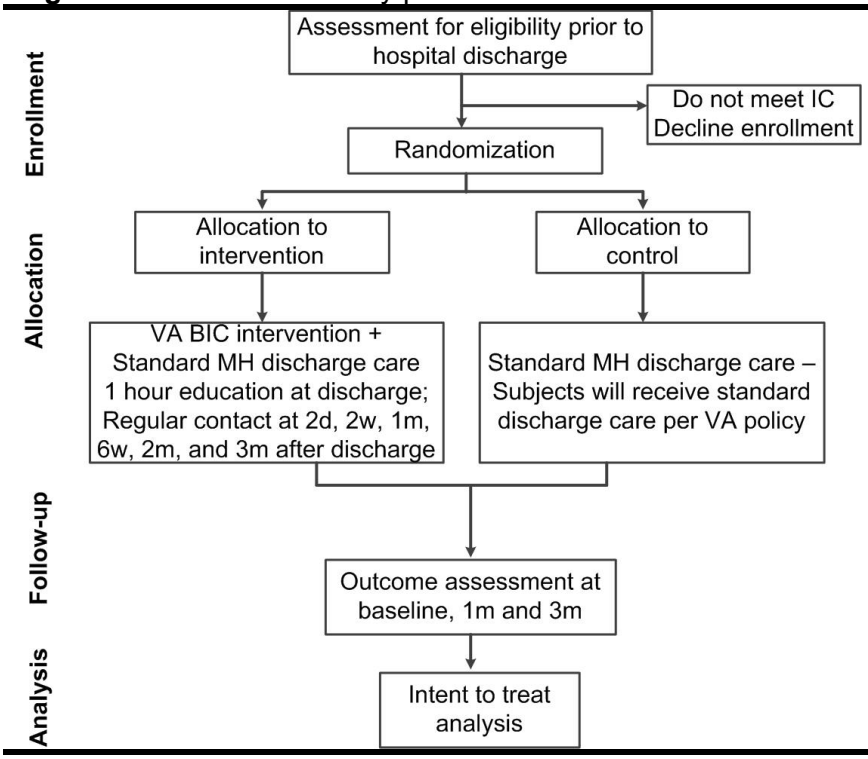
Our pilot work lends support that **VA BIC holds great promise for preventing suicide in a high-resource, rural, VA setting.** The VA BIC targets key factors that may contribute to suicide risk during high-risk care transition scenarios including problems with patient engagement in treatment and fragmented care in the post-discharge period.[3,18,19,31] As a next step, it is important to confirm the effectiveness of VA BIC in addressing suicide risk in psychiatrically hospitalized veterans in rural settings and to determine whether VA BIC shows similar effectiveness during other high-risk care transition scenarios in rural veterans such as emergency room care, medical hospitalization, and residential substance treatment facilities. Results of our work will serve as an important resource for rural VA facilities to draw from in order to develop and implement effective programs to mitigate suicide risk in Veterans living in rural settings at their facilities.

Research Design and Methods

Study Protocol for Patients Recruited from Ground East

As described in the Specific Aims section above, the proposed study will occur over the course of a total of four years with the funding of the study starting October 1, 2019. In year one of the study, we will first conduct a randomized trial of the intervention on Ground East. We made this decision because we have established experience conducting a small pilot of the intervention on the same unit. Therefore, it is it reasonable to first conduct a full clinical trial in a location where we the greatest experience and can gain important insights that will be helpful when we spread the study to other areas of the medical facility. Accordingly, we are requesting at this time from the IRB/R&D to open the study only on Ground East. Our plan is in then subsequently over the course of the years to submit amendments as appropriate to expand the study to additional locations with the WRJ VAMC as described in the protocol. For each additional site, we will modify the protocol and submit relevant consent forms because these will differ modestly across locations. The additional sites of interest includes the residential rehabilitation substance

Figure 1. Flow chart of study procedures



d=days; IC = inclusion criteria; m= months; MH = inpatient mental health; w = weeks

abuse program (RRC), the medical-surgical unit (specifically patients who were consulted by mental health and identified as being at risk for suicide), and the emergency room.

This section outlines the study protocol for the clinical trial of VA BIC on Ground East.

Overview of the VA BIC Intervention and RCT Design
As shown in **Figure 1 (see previous page),** to test the aforementioned hypotheses, we propose to conduct a single-site, assessor-blinded RCT at the WRJ VAMC comparing the VA BIC plus standard psychiatric hospital discharge care to standard psychiatric hospital discharge care alone. The trial will enroll patients 18 years and older who are being discharged from the WRJ VAMC inpatient mental health unit. The primary aim is to determine whether the VA BIC reduces suicidal ideation at one and three months after psychiatric hospitalization. The secondary aim is to evaluate the impact of VA BIC on other important measures of suicide risk including hopelessness, connectedness, fatal/non-fatal suicide attempts and treatment engagement.

Baseline Assessment and Randomization: Prior to the start of study enrollment, the statistician will independently prepare allocation cards using a permutated block schedule. The statistician will the put these cards into sealed, opaque, numbered envelopes. The box of envelopes will be stored in a locked cabinet in the study coordinator's locked office.

The study coordinator will meet with each eligible patient in a private room on GE around the time of discharge. The study coordinator 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. After obtaining consent and completing the baseline assessment, the study coordinator 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 coordinator will notify the VA BIC 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.

VA BIC Intervention Description: Patients assigned to the VA BIC intervention will receive the VA BIC plus the standard psychiatric hospital discharge care. The VA BIC is an adaptation of the successful WHO BIC intervention and designed to meet the unique needs of Veterans receiving care in the VA medical system **(see VA BIC Manual, Appendix 1**). VA BIC can be delivered by a trained mental health staff member, such as a mental health nurse, social worker, or psychiatrist. The VA BIC targets the needs of patients who are being discharged from a VA inpatient mental health unit after having been admitted because of acute suicide risk. The VA BIC incorporates aspects of motivational interviewing (MI). Since the VA BIC is designed to enhance the standard hospital discharge care that patients receive as part of psychiatric hospitalization, patients assigned to the VA BIC will continue to have access to standard discharge care (described below). There are no restrictions on the types of treatments that patients may pursue after discharge.

- *Brief Educational Intervention:* Patients receive a one-hour, one-on-one, brief educational intervention on suicide prevention. The session is performed by a VA BIC intervention staff member and takes place on the inpatient mental health unit around the time of discharge. We anticipate that, in most cases, the patients will receive the intervention the day prior to discharge. The education is designed to meet the information needs of Veterans receiving mental health care in the VA 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 same VA BIC intervention staff member for a total of six contacts over the course of the three months after psychiatric hospitalization. At each of these contacts, the VA BIC 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 contact sessions will be systematic and structured. The contacts are designed to be highly interactive, allowing times 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 Psychiatric Hospital Discharge Care: Patients assigned to the VA BIC intervention as well as the control condition will receive the standard VA hospital discharge care that occurs as part of psychiatric hospitalization. VA current standard psychiatric hospital discharge care includes five core elements. First, patients and their outpatient providers are required to be involved in discharge planning. Second, patients should be offered evidence-based treatments to address their mental health symptoms. Third, the inpatient team should work with the patient to complete a safety plan prior to discharge. Fourth, the inpatient team should arrange two follow-up care visits within 30 days of discharge. Fifth, the inpatient team in conjunction with the Suicide Prevention Coordinator (SPC) assess whether patients are appropriate to be placed on the High Risk for Suicide List. Patients who are placed on the High Risk for Suicide List receive enhanced oversight as outlined in VA policy. More recently, this enhanced care was renamed the Suicide Prevention Pathway. The SPC oversees the following elements of the Suicide Prevention Pathway: 1) The SPC reminds the mental health provider that the patient should be scheduled to be seen four times within the first 30 days following hospitalization; 2) The primary care or mental health provider is expected to tailor the patient's treatment to address his/her unique risk factors for suicide; 3) The SPC places a pop-up flag in the medical record to alert providers of the patient's high-risk status; and 4) The continued need for the patient to remain on the High Risk for Suicide List is reassessed by the SPC every three months. Of note, at the clinical discretion of the inpatient treatment team and the SPC, some patients may be assigned to the Suicide Prevention Pathway but may not meet criteria for the High Risk for Suicide List. Per VA policy, SPCs are not required to provide clinical care.

Outcome Measures: As outlined in Table 1, 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 (**App 2**).

Table 1: 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**
Patient Activation	**PIH**	**0.82 – 0.88**	**12 items**	**5**	**X**	**X**	**X**
Hopelessness	**BHS**	**0.87 – 0.93**	**20 Items**	**10**	**X**	**X**	**X**
Connectedness	**INQ-15**	**0.89 – 0.91**	**15 items**	**5**	**X**	**X**	**X**
Suicide Attempts	**CSSR-S**	**N/A**	**7 items**	**5-10**	**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; INQ-15 = Interpersonal Needs Questionnaire-15; M = months; N/A = Not applicable; PIH = Partners in Health;
*Time is described in minutes

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). With regards to diagnostic information, we will administer the MINI International Neuropsychiatric Interview (MINI) at study entry. The MINI is a short, structured diagnostic interview that takes about 15 minutes to administer.[35] It has been validated against the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM). We will inquire about any history of suicide attempts using the validated Columbia Suicide Severity Rating-Scale (C-SSRS).[36] 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).[2,37] Patients will be asked about their current suicidal ideation (i.e., past week) at baseline and at 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. There is also evidence that the BSS is measurement invariant across time.[38] The BSS is widely used in clinical trials, is

sensitive to clinical change, and unlike most other measures of suicidal ideation, higher scores on the BSS are associated with death by suicide. While there is no established BSS cutoff score to classify suicide risk as high, low, or none, there is evidence that higher scores on the BSS correspond to more severe suicidal ideation.[2,39] There is evidence that an improvement of five points or more on the total BSS scores may be clinically relevant. [2]

***Secondary Outcome (Patient Engagement)*:** We will measure patient engagement in treatment at baseline and at follow-up assessments. Patient engagement is a complex phenomenon to measure.[40] The term 'patient engagement' encompasses various aspects of care related to a patient's motivation and intent to be an active participant in addressing their healthcare needs.[40] To date, there is no agreed-upon measure in the literature that incorporates all aspects of the experience of 'patient engagement.[40] In the field of mental health, there is some notion that 'patient engagement' should mean that a patient experiences collaborative care, feels supported during their treatment, and adopts 'good practices' or behaviors that support their overall well-being.[40-41] Therefore, only assessing whether a patient attended a mental health appointment may not adequately reflect treatment engagement. There is also evidence that symptom severity can preclude patients from engaging in care.[42] Pfeiffer *et al*. found that, despite improvements in timely outpatient follow-up after VA psychiatric hospitalization, there were no significant changes in readmission or antidepressant treatment.[43] In fact, Bernet *et al.* found that appointment intensity was higher in Veterans who reattempted suicide after discharge versus those who did not reattempt.[44] Thus, we conceptualize that engagement includes continuity of care and activation.

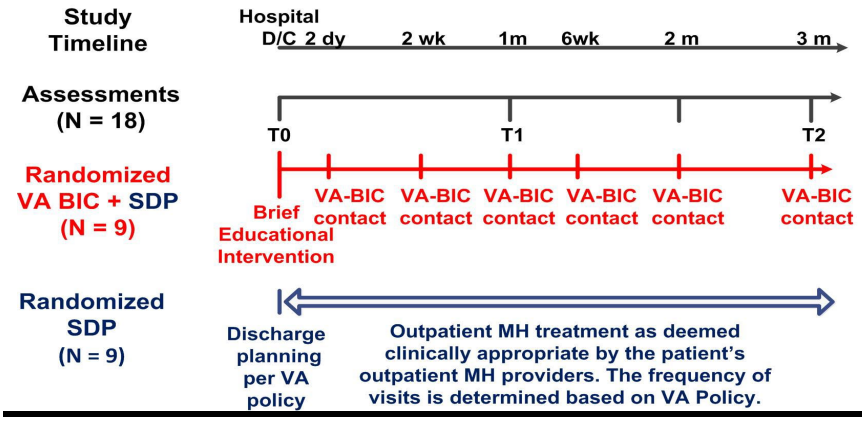
- Patient activation: Patient activation is defined as "an individual's knowledge, skill and confidence for managing their health and health care."[45-46] Individuals who demonstrate higher degrees of patient activation have been found to be more likely to engage in health-promoting behaviors and to experience better outcomes.[47] We will measure activation using the validated Partners in Health (PIH) scale.[48] The PIH is a 12-item generic instrument that is used to measure patient self-management of chronic conditions.[48] It includes three domains of self-management including knowledge of condition, partnership in treatment, and coping with the condition. It has good reliability and validity in patients with chronic conditions.[49-50] The psychometric properties of the PIH in Veterans have not been studied.
- Continuity of care: There is some evidence that improved continuity of care may lead to better mental health outcomes.[51-52] However, a single, valid, standardized measure of continuity of care for mental health has not been described in the literature. Work by Greenberg *et al.* in Veterans who were discharged from a VA inpatient mental health unit provides sufficient evidence that three aspects of continuity of care after psychiatric hospitalization (regularity of care, continuity of treatment across organizational boundaries, and intensity of treatment) are associated with improvements in overall mental health.[8] We will use the three measures of continuity of care as validated by Greenberg *et al.* This includes:
    a) Continuity of care: Measure of whether a patient discharged from the inpatient MH unit received any MH outpatient treatment in the first month and between 1 – 3 m after discharge.
    b) Regularity of care: The number of months in the 3 m after the initial assessment in which the patient attended at least 1 MH visit (Range 0 – 3 m), and
    c) Intensity of care: Measure of the total number of MH visits between initial entry into the study and the last study assessment).

  In addition, we will also evaluate evidence of disruptions of care including 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.
- Hopelessness: To gather clinical evidence of treatment engagement, 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.[53] Patients comment on feelings about the future, loss of motivation, and future expectations. Total scores range from 0 to 20, with higher scores suggesting more hopelessness. Higher scores on the BHS are associated with increased suicide risk.[39] The BHS has good reliability and validity and is sensitive to change.[39]

The psychometrics of the BHS in the Veteran population have not been studied, but the BHS has been used in other studies of the Veteran population.[54]

- ***Secondary Outcome (Connectedness):*** We will also include a measure of connectedness, 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.[5] The INQ-15 has good reliability and validity in the Veteran population. Higher scores on the INQ-15 have been associated with suicide risk.[5-6]
- ***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.[36] 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. The psychometrics of the C-SSRS in Veterans is unknown.
- **Study Design:** As shown in **Figure 2**, patients allocated to the VA BIC intervention will meet with the VA BIC intervention staff prior to hospital discharge. During this visit, they will receive a brief educational intervention, which will be delivered in a private office on GE. After hospital discharge, patients will participate in six regular contacts with the VA BIC intervention staff over a period of three months. 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 2. Schedule of Assessments and Interventions



BIC = VA Brief Intervention and Contact Program; dy = days; m = month
MH = Mental health; SDP = Standard psychiatric discharge practices;
T0, T0, T1, T2 = assessment time points; wk = weeks

- All patients (including patients randomized to VA BIC) will have access to standard psychiatric hospital discharge 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. The independent outcome assessor will conduct the baseline assessment in a private office on GE around the time of discharge. We anticipate that, in most cases, the baseline assessment will occur on the day before discharge. Depending on patient preference, the independent outcome assessor will conduct the follow-up assessments in a private office on the WRJ VAMC campus or over the phone (or VA Video Connect). The assessor will be blinded to study assignment and the patients will be instructed to not reveal their status to the assessor.
- As the WRJ VAMC is a rural medical center that serves a large geographic area (New Hampshire 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. Furthermore, our decision to allow patients to participate in study follow-up by phone (or VA Video Connect) or in person is consistent with the study methods of the original WHO BIC trials.

Summary of Project Work/Deliverables over the 4 year study period

1) **Year 1:** We will complete four deliverables during the first year:
   A) Enroll 25 veterans in a randomized trial of VA BIC for patients being discharged from an inpatient mental health unit. (<u>As described in the study</u>

protocol above for patients recruited from Ground East)

B) Develop an adapted version of the VA BIC for patients being discharged from an inpatient medical/surgical unit after receiving psychiatric consultation.

C) Pilot an adapted version of VA BIC in 3 veterans being discharged from an inpatient Medical/surgical unit after receiving psychiatric consultation. *(We will submit a study amendment prior to conducting this work*)

D) Develop an adapted version of VA BIC for patients being discharged from a residential substance treatment facility

2) **Year 2:** We will complete six deliverables during the second year: (*We will submit a study amendment prior to conducting the work described below)*

A) Clean and analyze data from trial of VA BIC for patients being discharged from an inpatient mental health unit.

B) Finalize VA BIC manual for patients being discharged from an inpatient mental health unit based on results.

C) Enroll 25 veterans in a randomized trial of VA BIC for patients being discharged from an inpatient medical/surgical unit after receiving psychiatric consultation.

D) Pilot an adapted version of VA BIC in 3 veterans being discharged from a residential substance treatment facility.

E) Enroll 13 veterans in a randomized trial of VA BIC for patients being discharged from a residential substance treatment facility.

F) Develop an adapted version of VA BIC for patients being discharged from an emergency room after presenting with a mental health concern.

3) **Year 3:** We will complete seven deliverables during the third year: (*We will submit a study amendment prior to conducting the work described below)*

A) Clean and analyze data from trial of VA BIC for patients being discharged from an inpatient medical/surgical unit after receiving psychiatric consultation.

B) Finalize VA BIC manual for patients being discharged from an inpatient medical/surgical unit after receiving psychiatric consultation based on results.

C) Enroll 12 veterans in a randomized trial of VA BIC for patients being discharged from a residential substance treatment facility.

D) Clean and analyze data from trial of VA BIC for patients being discharged from a residential substance treatment facility.

E) Finalize VA BIC manual for patients being discharged from a residential substance treatment facility.

F) Pilot an adapted version of VA BIC in 3 veterans following discharge from an emergency room after presenting with a mental health concern.

G) Enroll 25 veterans in a randomized trial of VA BIC for patients being discharged from an emergency room after presenting with a mental health concern.

4) **Year 4**: We will complete ten deliverables during the fourth year: (*We will submit a study amendment prior to conducting the work described below)*

A) Clean and analyze data from trial of VA BIC for patients being discharged from an emergency room after presenting with a mental health concern.

B) Finalize VA BIC manual for patients being discharged from an emergency room after presenting with a mental health concern.

C) Integrate VA BIC trial data across high-risk care transition scenarios and analyze results.

D) Develop integrated VA BIC manual including all four high-risk care transition scenarios.

E) Identify three rural sites interested in implementing VA BIC.

F) Disseminate VA BIC to 3 rural VA facilities

G) Work with the three rural sites to adapt materials for their settings and assist facilities with implementation.

H) Track use, success, and challenges of VA BIC implementation at the three rural sites.

I) Develop a generalizable VA BIC manual that is adaptable to any rural VA facility.
J) Propose additional dissemination work to Rural Health Resource Center Eastern Region.

Please see Table 2 below for a study timeline for the 4 year period.

Table 2: Gantt Chart Representing Each of the Proposed Project Activities

Calendar Year	2019				2020				2021				2022			
Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Development and testing of VA BIC in 4 High-Risk Care Transition																
Scenarios Transition Scenario 1: *Patients Being Discharged from an Inpatient Mental Health Unit*																
Enroll 25 veterans in a RCT of VA BIC																
Clean and analyze data																
Finalize VA BIC manual for mental health discharges																
Transition Scenario 2: *Patients Being Discharged from an Inpatient Medical Unit after Receiving Psychiatric Consultation*																
Develop adapted version of VA BIC for patients being discharged from an inpatient medical unit after receiving psychiatric consultation																
Pilot adapted version of VA BIC in 3 veterans being discharged from an inpatient medical unit after receiving psychiatric consultation																
Enroll 25 veterans in an RCT of VA BIC																
Clean and analyze data																
Finalize VA BIC manual for patients being discharged from an inpatient medical unit after receiving psychiatric consultation																
Transition Scenario 3: *Patients Being Discharged from a Residential Substance Treatment Facility*																
Develop adapted version of VA BIC for patients discharged from a RST																
Pilot adapted version of VA BIC in 3 veterans discharged from a RST																
Enroll 25 veterans in an RCT of VA BIC																
Clean and analyze data																
Finalize VA BIC manual for patients discharged from a RST																
Transition Scenario 4: *Patients Being from an Emergency Room after Presenting with a Mental Health Concern*																
Develop adapted version of VA BIC for patients discharged from an ER after presenting with a mental health concern																
Pilot adapted version of VA BIC in 3 veterans discharged from an ER after presenting with a mental health concern																
Enroll 25 veterans in an RCT of VA BIC																
Clean and analyze data																
Finalize VA BIC manual for patients discharged from an ER after presenting with a mental health concern																
Integration of Findings from VA BIC Use in 4 High-Risk Care Transition Scenarios																
Integrate VA BIC trial data																
Analyze results																
Develop integrated VA BIC manual																
Write up Manuscript of Work																
Dissemination of VA BIC Findings to Rural VA Facilities																
Identify 3 rural VA facilities interested in implementing VA BIC																
Work with 3 rural VA facilities to adapt VA BIC material locally																
Assist 3 rural VA facilities with implementation of VA BIC																
Track use, success, and challenges of VA BIC implementation by facilities																
Develop a generalizable manual that is adaptable to any rural VA facility																
Propose additional dissemination work to RHRCER																
Manual Development and Testing Work	Integration Work								Dissemination Work							

Note. ER = Emergency Room; RCT = Randomized controlled trial; RHRCER= Rural Health Resource Center Eastern Region; RST = Residential Substance Treatment Facility; VA = Veterans Affairs; VA BIC = VA Brief Intervention and Contact Program

Statistical Considerations

Statistical Analyses: To maintain blinding, the statistician who is otherwise not directly involved in the study 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. If we identify any variables for which there are significant differences across study arms, we will control for these confounders in the analysis of the aims.

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. For each of the four acute care settings included in our study, we will perform simple statistical tests. First, 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 one- and three-month follow-up using a two-sample t-test.

We will perform a more complex analysis for the entire study sample at the end of the four years because we will have adequate power to do so. The following outlines are specific approach: Based on available evidence, we hypothesize that the VA BIC program plus standard hospital discharge care will lead to a significant reduction in suicidal ideation after discharge from an acute care setting. We believe that the effect of VA BIC on suicidal ideation will be the greatest at the three-month follow-up because the greatest intensity of follow-up care provided through VA BIC occurs within the first three months after discharge. 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. Because BSS scores are typically over dispersed, it is not appropriate to use standard parametric statistics. Therefore, we will treat the BSS scores as count data and use negative binomial regression. Specifically, we will use a generalized linear mixed model. 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.

Specific Aim 2: First, we will perform an analysis to demonstrate whether there are greater improvements in patient engagement, hopelessness, and perceived connectedness over time in patients assigned to the VA BIC intervention versus control condition at one, three months after discharge. For continuous variables measuring patient engagement (PIH, Hopelessness, Regularity of Care, Continuity of Care across Organizational Boundaries, and Intensity of Care) and perceived connectedness (INQ-15), we will generate descriptive summary statistics (e.g., means and standard errors, medians) and graphical displays for each measure at baseline and at each of the follow-up assessments. Second, using analysis of covariance (ANCOVA), we will calculate mean differences in scores for each of our continuous measures at the one-and three-month follow-up, as well as the associated 95% confidence intervals and *P*-values. For the categorical measure of disruptions in care, we will use chi-squared tests to compare the proportion of patients experiencing disruptions in care between the two study arms at one- month and three-months after discharge.

Specific Aim 3: While suicide deaths and suicide attempts are important clinical endpoints, this single-site trial will not be powered to detect a statistically significant effect between study arms. Furthermore, because we assume that few events will be observed in either arm, we plan to summarize our findings by providing basic descriptive statistics regarding the number of events in each arm at one-and three-month follow-ups.

Randomization: Prior to the start of study enrollment, the statistician will independently prepare allocation cards using a permutated block schedule. The advantage of this approach is that it ensures that an equal number of participants are assigned to each arm.[56] The statistician will the put these cards into sealed, opaque, numbered envelopes. The box of envelopes will be stored in a locked cabinet in the study coordinator's locked office.

Sample Size: Because of our promising pilot work,[1] we believe it is appropriate to choose suicidal ideation as our primary outcome. In our pilot study, 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, with this sample size and level of improvement, we were able to demonstrate a significant difference in improvement in suicidal ideation compared to a matched group of historical controls participating in a post-mental health discharge qualitative study.[1,3] Therefore, we will have sufficient power to show a clinically meaningful improvement in suicidal ideation overall and for each of the four high-risk care transition scenarios at one and three months after discharge if we enroll a total of 100 veterans (25 per transition scenario) over 3 years.

Study Population and Recruitment

As described in the Specific Aims section, the proposed study will occur over the course of a total of four years with the funding of the study starting October 1, 2019. In year one of the study, we will first conduct a randomized trial of the intervention on Ground East. We made this decision because we have established experience conducting a small pilot of the intervention on the same unit. The first stage of the study will be conducted at the WRJ VAMC and will recruit patients hospitalized on Ground East (GE), the facility's 10-bed inpatient mental health unit. GE staff includes an inpatient psychiatrist and psychologist, nursing staff, a social worker, and trainees from these disciplines. We aim to recruit a total of 25 patients from Ground East. Study staff will communicate on a daily basis (Monday-Friday) with the inpatient treatment team in order to identify potentially eligible patients who can be approached about study participation. The inpatient team and attending psychiatrist will make the determination as to when and whether it is clinically appropriate for study staff to approach potentially eligible patients. After approaching eligible patients, study staff will make them aware of the study and determine if they are interested in participating in the study. If patients are interested in the study, study staff will obtain informed consent using a written informed consent document prior to enrolling the patient into the study. 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 VA BIC 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:

- Per the unit psychiatrist, hospitalization was due to concerns about acute risk for self-harm including suicidal ideation, suicide attempt, and/or admitting provider deemed the patient was at imminent risk for self-harm;
- Be a Veteran eligible to receive VA services; 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.

Informed Consent

Eligible participants who are interested in participating in this study will complete the informed consent process. Study staff will inform the patient about the study and provide them with the informed consent document. Patients will have the option to review the document with their doctor, family, and/or friends prior to signing if they choose. Upon signing, they will be provided with a photocopy of the document. We do not anticipate a waiting period between informing the patient of the study and obtaining informed consent, but participants may

choose to wait. To ensure understanding of the study purpose and procedures, the patient will be encouraged to ask questions if there is anything they do not understand. Additionally, the informed consent document is written in easy-to-understand language to facilitate comprehension.

Risks and Side Effects:

Potential Risks

Since the study population is known to be at high risk for suicide and study endpoints include suicidal ideation, suicide attempts, and suicide, these events would be considered anticipated adverse events during the course of this study. Similarly, we also consider that psychiatric hospitalizations or emergency room for worsening psychiatric symptoms or suicidal behavior are anticipated adverse events.

As described above, it is expected that patients may report worsening suicidal ideation or suicidal behaviors at the study assessments (i.e., baseline, one-month, or three-month follow-up) regardless of whether they are assigned to the intervention or control condition. It is also possible that patients assigned to the intervention arm may report worsening suicidal ideation or suicidal behavior during an intervention visit. It is also possible that patients could be seen in the emergency room or be hospitalized because of any of these events. Thus, it is expected for the patients to continue with the study unless the patient requests to be removed from the study. Furthermore, as outlined in our **safety alert protocol (Appendix 3)**, study personnel will immediately follow the safety alert protocol in response to any reports of worsening suicidal ideation or behaviors. If necessary, patients will be connected immediately with required clinical treatment. All patients will continue to have access to standard-of-care treatment during the course of the trial regardless of study assignment. Furthermore, all patients may continue any treatments that they were receiving as part of their routine care prior to enrolling in the study.

Therapeutic Risks

During the trial, 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 follow-up assessments at one- and three-month follow-ups. In addition, patients assigned to the intervention condition will also be exposed to these therapeutic risks at the intervention visits (brief education visit plus six contact visits after discharge). Sometimes, patients can feel embarrassed, nervous, bored, or generally uncomfortable when they are asked to answer these types of questions. However, because there are sufficient safeguards in place to mitigate these potential risks, the overall therapeutic risk from this study to enrolled patients is very low.

Research Risk

During the course of the trial, 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) will be collected from all enrolled patients. Thus, there is some risk that a patient's confidentiality or protected health information could be compromised due to study participation. As there are sufficient safeguards in place to mitigate this risk (see Protection Against Risk below), the overall research risk in this study is very low.

Protection Against Risk

Study Population Safety Risk

At each study assessment time point (i.e., baseline, 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 assigned to the intervention, patients may report worsening suicidal ideation or suicidal behavior in the context of the intervention visits. Regardless of whether the patient is assigned to the intervention or control condition, the study staff will be ethically bound to take appropriate action if the patient is at imminent risk for self-harm. **T**he safety alert protocol (**Appendix 3**) outlines the process that study staff members will follow in order to ensure the safety and well-being of all enrolled patients regardless of whether they are assigned to the intervention or control condition. In the event 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 risk evaluation and determine the most appropriate next level of care for the patient. The next level of care may include psychiatric admission, emergency room referral, or an urgent outpatient appointment with the patient's healthcare provider. Please see **the safety alert protocol (See Appendix 3)** for a full description of all safety alerts and required actions by study staff members.

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

Research Risk
Every effort will be made to ensure that the privacy and confidentiality of the patient is maintained. All 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 research staff will have access to this locked cabinet.

Benefits:
All patients participating in this trial 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, depending on study assignment, some patients may receive the VA BIC intervention. The VA BIC 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 psychiatric hospitalization. Although the VA BIC is adapted from a successful suicide prevention strategy (WHO BIC),[32,34] it is unknown whether the VA BIC significantly reduces suicide risk after psychiatric hospitalization relative to standard discharge practices. The work from this proposed study will be able to more definitively address whether the VA BIC intervention is an effective suicide-prevention strategy in patients following a psychiatric hospitalization. This is important, given that death by suicide after psychiatric hospitalization remains an important problem in the Veteran population despite the VA's multiple suicide-prevention strategies. Since the overall risks associated with this trial are minimal and the anticipated benefits and knowledge to be gained are clinically important, there is sufficient reason to conduct this 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 one- and three-month follow-ups. 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 have access to this locked cabinet.

Multi-Site Study Concerns
In Year 4 of the study, we will identify three rural sites interested in implementing VA BIC and work with these

sites to implement VA BIC locally. Prior to conducting this work, we will submit a study amendment to VINNE.

Resources Available

This project will be conducted at WRJ VAMC. For the first phase of the study, recruitment of 25 participants will take place on Ground East. Over the next phases of the study, we will be recruiting 25 participants from each of the following locations including inpatient medical/surgical services, residential drug treatment program (RRC) and the emergency room. Drs. Shiner and Riblet will oversee and lead this project with the help of research staff, which includes:

- A VA BIC interventionist (100% Year 1, 2, 3; 50% Year 4)
- A study coordinator (100% all 4 Years)
- A statistician (10%, Year 1, 2, 3; 20% Year 4)
- An independent assessor blinded to study arm (50% in Years 1-3)
- An implementation scientist to aid Drs. Shiner and Riblet to work with 3 rural VA facilities and develop generalizable materials to disseminate VA BIC broadly in rural VA facilities through future work.

Subject Compensation:

We will compensate enrolled patients as follows: baseline: $50; one-month follow-up: $100; three-month follow-up: $150. This schedule ensures that patients are sufficiently reimbursed for their time and effort in the study. Furthermore, the staggered schedule of higher payments over time accounts for the additional burden of committing to the study for three months. Finally, higher payments have been shown improve study retention, while not being unreasonably coercive.[57-58]

Privacy and Confidentiality:

Please see *Protection Against Risk* above.

Data and Safety Monitoring Plan

Monitoring and Interim Analysis Plan: We have formed an independent Data Safety Monitoring Board (DSMB) comprised of Peter Mills, PhD (has expertise in ethics and has previously served on a DSMB), Yinong Young-Xu, ScD (statistician who has experience serving on the Dartmouth-Hitchcock DSMB), and Bradley V. Watts, MD MPH (who has experience in mental health and suicide prevention). The independent DSMB will provide independent data and safety monitoring for this study. 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. We will also ask that the DSMB perform an independent, interim statistical analysis on our data on an annual basis. Dr. Young-Xu has experience performing these types of analyses. This will allow us to identify whether the treatment has greater benefits or risks than anticipated and make necessary changes to the trial including changing the trial or terminating the trial.

Study Safety & Monitoring:

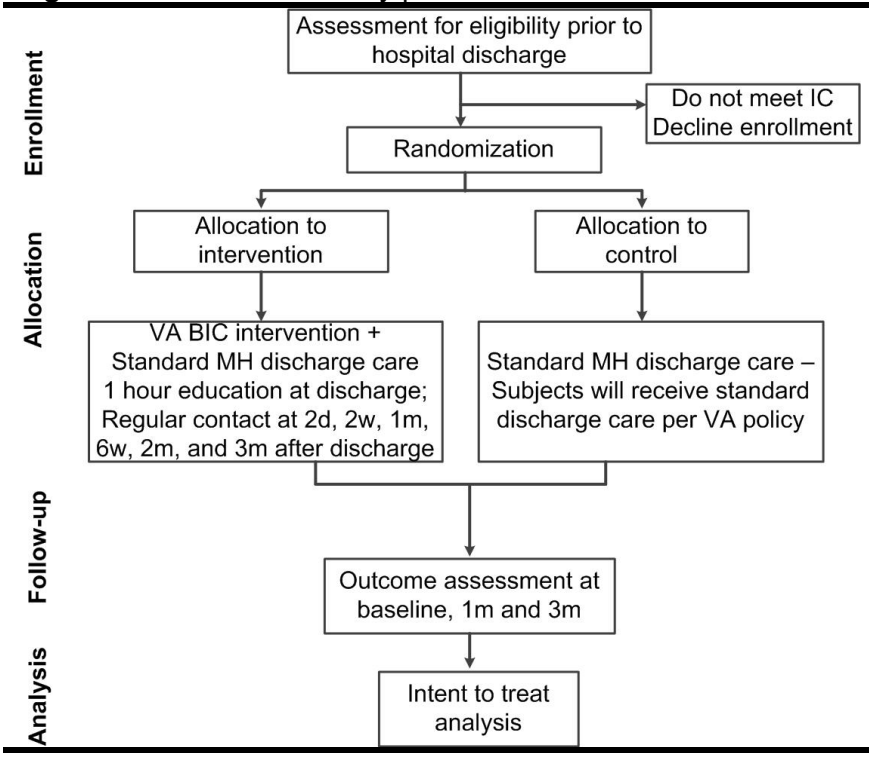
Enrolled patients will be monitored for any unanticipated problems or adverse events during the course of the study. Unanticipated death possibly related to research will be orally reported to VINNE immediately with a written report submitted via IRBNet within 5 business days. Possibly study-related 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 ISO 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, and psychiatric hospitalizations or emergency room for worsening psychiatric symptoms or suicidal behavior.

Reasons for stopping assigned treatment and follow-up:

The following events will be considered 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 from the study.

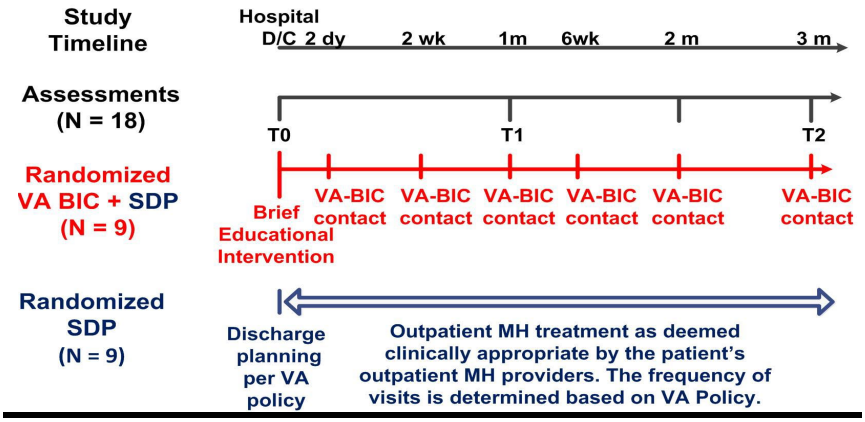
Figure 1. Flow chart of study procedures



d=days; IC = inclusion criteria; m= months; MH = inpatient mental health; w = weeks

Step-by-Step Guidance on Conducting the Study

Figure 2. Schedule of Assessments and Interventions



BIC = VA Brief Intervention and Contact Program; dy = days; m = month MH = Mental health; SDP = Standard psychiatric discharge practices; T0, T0, T1, T2 = assessment time points; wk = weeks

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