CIRB # 20-06: Evaluating the Use of Peer Specialists to Support Suicide Prevention

Funding Agency: RR&D Small Projects in Rehabilitation Research

Principal Investigator/Study Chair: Matthew Chinman, PhD

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VA Central IRB Panel 2
Effective Date: March 8, 2022

Abstract

Preventing suicide is a top priority for the Veterans Health Administration (VHA). Suicide prevention efforts for high-risk patients focus on clinical (e.g., mental health) and service use (e.g., case management) factors. What has yet to be tested is an approach that targets factorsin community living, as it is not only mental and physical illnesses that heighten suicide risk in VHA patients, but also their struggles with a sense of self-worth, meaning, and social connections in the community. To help VHA patients with high risk of suicide, this application proposes to adapt and test a promising approach called PREVAIL, which uses 'Peer Specialists'(i.e., Veterans with psychiatric disabilities who have been trained to help others with similar conditions) as an adjunct to standard VHA care. This project proposes to use Intervention Mapping, a multi-method, systematic approach using diverse stakeholders, to adapt and pilot PREVAIL. The VHA is the single, largest employer of Peer Specialists and research shows that they can enhance standard clinical care in mental health, physical health, and rehabilitative outcomes. However, Peer Specialists have only just begun to be deployed in suicide prevention efforts. The primary aims of this study are to: 1) Use Intervention Mapping to identify which components of PREVAIL require adaptation to reduce suicidal ideation in high risk VHA patientsand to identify implementation strategies useful for the VHA system; and 2) Pilot test the feasibility and acceptability of the adapted PREVAIL, rehabilitative measures, and suicide- related outcomes for use in a rigorous prospective study. Needs assessment interviews with diverse VHA staff, Peer Specialists, and patients will be conducted to inform the adaptation. Based on results from the needs assessment and the literature on suicide prevention, psychiatric rehabilitation, and peer-based approaches, a steering committee will help adapt PREVAIL. Twelve high suicide risk Veterans with unipolar or bipolar depression will participatein a 3-month "pre-pilot" and provide feedback on how the adapted PREVAIL may be revised. After making any necessary modifications to the intervention, a second group of 12 high suicide risk Veterans with unipolar or bipolar depression will be recruited to participate in a formal pilot test to further evaluate the feasibility and acceptability of recruitment, retention, and assessmentprocedures. Patients and Peer Specialists will be from the VA Connecticut Healthcare System. All participants will receive standard VHA care from the Connecticut campuses while participating in this study. Participants will be assessed at baseline, post-intervention, and 3- month follow-up in their level of functional impairment and community integration; sense ofhope, quality of life, meaning, and purpose; and self-views and social support. Chart reviews willalso be completed at 3-month follow-up to assess for changes in health care visits involving suicidal behaviors. If acceptability (> 50% enrollment of eligible participants) and feasibility (> 70% of enrollees complete follow-up assessment) are demonstrated, this study will result in a novel rehabilitation-oriented suicide prevention intervention to test in a fully-powered randomized controlled efficacy trial.

VA Central IRB Panel 2
Effective Date: March 8, 2022

List of Abbreviations

Term	Abbreviation
C-SSRS	Columbia-Suicide Severity Rating Scale
INQ	Interpersonal Needs Questionnaire
IM	Intervention Mapping
PRFs	Patient Record Flags
PSs	Peer Specialists
QIDS	Quick Inventory of Depressive Symptoms
Q-LES-Q-SF	The Quality of Life Enjoyment and Satisfaction Questionnaire
QPR	Questionnaire about the Process of Recovery
SCS	Suicide Cognitions Scale
SDS	Sheehan Disability Scale
SPC	Suicide Prevention Coordinator
TUCP	Temple University Community Participation
VACT	VA Connecticut Healthcare System
VHA	Veterans Health Administration

VA Central IRB Panel 2
Effective Date: March 8, 2022

Contents

VA Central IRB Panel 2
Effective Date: March 8, 2022

Protocol Title: Intervention Mapping to Develop a Peer-based Rehabilitation Intervention for High Suicide Risk Veterans

1.0 Study Personnel

In addition to the Principal Investigator, the study team is comprised of several co-Investigators across the three project/performance site locations: VA Pittsburgh Healthcare System, VA Connecticut Healthcare System, and VA Ann Arbor Healthcare System.

2.0 Introduction

Background and Rational

Veteran suicide is a public health crisis: According to the most recent VA National Suicide Data Report: 2005-2016,[29] the Veteran suicide rate increased by 26%, as compared to 21% for non-Veteran adults. Although suicide rates rose more sharply for non-VHA Veterans (26%) than for VHA patients (14%), the suicide rate among VHA patients is higher than Veterans who are not receiving VHA care.

Suicidal ideation is a frequent precursor to non- fatal and fatal suicide attempts.[30] Suicidal ideation is reported by 3%-52% of Veterans, depending on the time frame (e.g.,past month vs. current) and population (e.g., general community, primary care, orurgent care psychiatric clinic).[31-33] Similar rates for suicide attempts are reported by Veterans (2%-48%). Despite increased relative risk of suicide among persons expressing suicide ideation, the absolute risk of suicide is low.[34,35]

Care for high-risk Veterans features increased contact but lacks a focus on key life domains: VHA patients who attempt suicide, report serious suicidal ideation, or exhibit other warning signs of acute suicide risk have a Patient Record Flag (PRF) placed in their medical record for no less than 90-days. The VHA maintains a list of

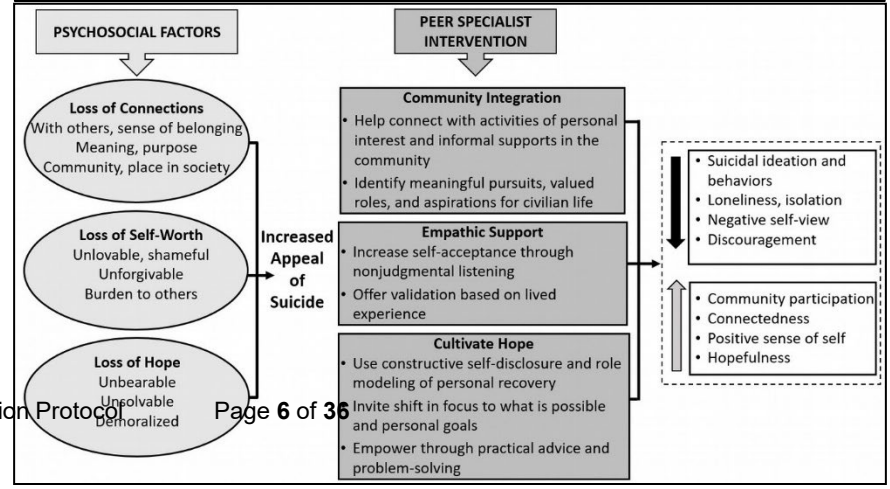
VA Central IRB Panel 2
Effective Date: March 8, 2022

active PRFs to alert all staff that increased follow-up and case management are required.[36] Patients with PRFs must have at least 4 clinical contacts within the first 30 days after the flag is placed or following discharge from the hospital. During these 30 days, they must be also assessed four times. Clinical care focuses primarily on safety planning, use of the Veterans Crisis Line, stepped-up mental health care, and additional case management support from the Suicide Prevention Coordinator,[37] rather than directly addressing needs in other life domains. Recent evaluations of the VHA suicide prevention initiatives observe deficits in tracking, safety planning, and care practices for high suicide risk Veterans.[38]

Peer Specialists (PSs) are a promising, but untested, adjunct to suicide prevention: PS-based approaches involve being supported or mentored by a trained non-professional who is living with the same challenge. PS models do not devalue clinical care but expand the sphere of interest and intervention to include rehabilitative tasks of building a life of self-respect, meaning, purpose, and connectedness in one's local community. These outcomes are achieved largely through offering empathy, hope, and practical advice based on one's personal experience of mental health recovery.[39] PSs and similar models can enhance standard clinical care in mental health, physical health multiple domains[5,11,14,40] and rehabilitative outcomes,[12,41] especially with increasing sense of empowerment and engagement.

PSs appear well suited to reduce certain psychosocial factors associated with suicide risk in VHA patients with PRFs. Research with Veterans show that feeling hopeless, shameful, or burdensome, or being disconnected from others and meaningful activities are predictive of suicide ideation and lower help-seeking behavior for mental health reasons.[42] Concerns about stigma, trust, and empathy are critical barriers to disclosing suicidal ideation to VHA providers.[43] Because PSs share patients' mental health and military history, they may be particularly helpful in this respect as patients often feel more accepted, connected, and hopeful when working with PSs than traditional providers

Figure 1: *Conceptual Model of Peer Specialist Rehabilitation Intervention*



VA Central IRB Panel 2
Effective Date: March 8, 2022

(Figure 1).[3,4] The VA National Strategy calls for peer services and testing of promising approaches to assist with suicide prevention efforts. One promising approach is PREVAIL, a peer-based intervention developed for reducing suicidal ideation in adult civilians recently hospitalized for suicidal thoughts or behaviors.[15] PREVAIL was developed for non-Veterans and needs to be adapted to "fit" the needs of VHA patients and health care setting.

Adapting PREVAIL involves identifying which components need to be tailored to target the rehabilitation needs of VHA patients and implementation context in the VHA: Intervention Mapping (IM)[16] is a systematic, multi-method approach to designing complex interventions and adapting them to new populations or settings. IM usesdiverse stakeholder involvement and theory to understand barriers and facilitators to implementation at the patient-, provider-, and organizational- levels. IM draws on systems-based and participatory models to understand a health problem and its causes by including diverse stakeholders to plan an intervention that targets the most effective leverage points to improving health. Each step of IM involves multiple activities that are iterative and inform subsequent steps culminating in a novel approach to a problem. IM has been used successfully to develop and adapt a range of rehabilitative programs, including suicide prevention practices in primary care.[44,45] In the VHA, similar multi-level approaches involving stakeholders have successfully yielded mental health and primary care programs[19] as well as roll out of PSs in mental health.[21]

Adapting interventions with IM involves identifying changes that need to be made to meet the needs of the new target population and to address differences between the original context and the new one in which it will be implemented. These steps include:
(1) assessing organizational capacity (e.g., readiness to adopt a new program and role of new program in existing organizational relationships); (2) assessing behavioral determinants (e.g., psychosocial factors that differ from original sample to produce the desired change) and environmental determinants (e.g., key differences in the organizational characteristics from those of the original sample); and (3) identifying indicated changes to essential elements (e.g., tailoring the content of format to fit the new population). We propose to use Intervention Mapping to adapt PREVAIL to supplement the clinical care of VHA patients with PRFs for acute suicide risk using PSs to increase hope, sense of purpose, and community connections as a mechanism to reduce suicide ideation.

Significance. The VA's National Strategy for suicide prevention calls for the development of peer-to-peer services to help those at risk for suicide. Our proposal is innovative because it proposes using PSs in a new priority arena, suicide prevention.

VA Central IRB Panel 2
Effective Date: March 8, 2022

This research has high impact because it seeks to reduce suicidal ideation among high suicide risk VHA patients. Our project is directly aligned with suicide prevention as a top priority for the VHA as well as RR&D major priority domains for implementing interventions and techniques designed to maximize psychological recovery. Data from this project will inform the development of an RR&D IIR proposal testing the rehabilitative PS-based suicide prevention intervention in a multi-site, randomized, controlled trial.

3.0 Objectives

Study Aims

The specific aims of the study are to:

1) Use Intervention Mapping to identify which components of PREVAIL require adaptation to reduce suicidal ideation in high-risk VHA patients and to identify implementation strategies in the VHA system.
2) Pilot test the feasibility and acceptability of the adapted PREVAIL, rehabilitative measures, and suicide-related outcomes for use in a rigorous prospective study.

Hypothesis

These data will inform the development of an RR&D IIR proposal testing the PREVAIL adaptation in a multi-center, randomized, controlled trial. The current intervention is innovative because it proposes using for the first time, VA Peer Specialists to improve rehabilitation of those who are suicidal. This research has high impact because it seeks to reduce suicidal ideation among VHA patients flagged for high suicide risk.

4.0 Resources and Personnel

VA Central IRB Panel 2
Effective Date: March 8, 2022

PRIMARY SITE: VA PITTSBURGH HEALTHCARE SYSTEM (VAPHS), PITTSBURGH, PA

The personnel at this site include the following:

Principal Investigator: The PI will be responsible for overseeing all aspects of the study including development, management and integrity of the design, conduct, and reporting of the proposed research, achievement of the project aims, and development and maintenance of productive collaborative relationships with operational partners and co-investigators. They will lead the meetings of the monthly steering committee. They will also ensure budgetary compliance, and oversee data collection, data analysis, and the preparation of all reports, presentations, and publications. They will monitor the safety of all participating human subjects. Finally, the PI will lead several dissemination efforts that include regular reports to Dan O'Brien-Mazza, MS, the National Director of Peer Support in the VA; delivery of EES cyber- seminars to VA administrators and clinicians; and publication of interim and final study findings via CHERP and MIRECC dissemination vehicles and peer-reviewed publications.

Co-Investigator: The Co-I will coordinate and manage the implementation and conduct of the study and serve as the qualitative methodologist. They will coordinate the efforts of the investigative team, develop the project manual of operations, develop the data tracking and management systems, assure the integrity of the data and protection of human subjects by directly working with the Central IRB, and help to manage the project budget. As described in the proposal, the Co-I will co-code 100% of the qualitative data (from the needs assessment and the interviews from the pre- and formalpilots) and lead the analysis of the qualitative data. They will oversee the developmentof documented coding audit trails and work with another Co-I to develop the qualitative codebooks. They will also contribute to the preparation of reports, presentations, and manuscripts related to the project. Finally, they will serve on the steering committee.

Research Assistant: In Years 1 and 2, they will be responsible for assisting withpreparing and submitting IRB documents for the Central IRB, at the Pittsburgh site, and helping with IRB documents at the other sites. They will also assist the Co-I and the transcriptionist with the qualitative coding and analysis.

Transcriptionist: A trained transcriptionist from the CHERP Qualitative Core who will transcribe verbatim all the qualitative interviews.

Transcriptionist - a Research Health Science Specialist in CHERP and a member of the Qualitative Core. They will verify all transcripts for accuracy.

VA Central IRB Panel 2
Effective Date: March 8, 2022

SITE #2: West Haven, Connecticut:

Site PI/Co-Investigator: The Site PI/Co-I will oversee the training of and provide weekly supervision to the peer specialists who will participate in the intervention arm of the proposed pilot study. They will also work closely with the Connecticut Suicide Prevention Coordinator who will provide names of potential patient participants to be approached for recruitment in the pilot study. They will facilitate collaborative relationships with operational partners in different VA care settings serving participating patients (e.g., acute care and outpatient settings) as well as with recruitment of participants for the needs assessment interviews in Year 1. The Site PI/Co-I will also assist with preparing reports, presentations, and publications.

Co-Investigator: The Co-I will co-code 100% of the data from the interviews and co-lead the analysis of the qualitative data with another Co-I. They will assist with development of documented coding audit trails and work with another Co-I to develop the qualitative codebooks.

Research Assistant (WOC): An experienced research assistant will be hired to work under the direction of the Site PI/Co-I and Co-I. They will start at 25% effort in the last 6 months of year 1. They will meet with potential patient participants to discuss the study, including activities, potential risks, and benefits; complete the consent process, and administer questionnaires at baseline, postintervention, and follow-up for the pilot. They will also coordinate the completion of the qualitative interviews. They will also facilitate the steering committee meetings, sending out agendas, read-ahead documents, and taking and circulating minutes. Finally, they will coordinate project meetings of staff from the three sites.

IPAs

Interagency Personnel Agreement – Yale University. The Co-I will oversee the day-to-day execution of the project activities in Connecticut and serve as a liaison with the West Haven PI. This will involve collaborating with them in their direct work with thepeer specialists and acting as the liaison between the Suicide Prevention Coordinator who will provide names of potential patient participants and Yale research assistant whowill approach participants for the consent process. The Co-I will also assist the PI with the IRB process, data analysis, and preparation of reports, manuscripts, and publications. They will also conduct the qualitative interviews as part of the needs assessment in the Intervention Mapping process and will also conduct the qualitative interviews of those who participated in the pre and formal pilots in West Haven.

VA Central IRB Panel 2
Effective Date: March 8, 2022

SITE #3: Ann Arbor, Michigan

Personnel

Site PI/Co-I: They will provide expertise to the development and implementation of the pilot intervention. In addition to meeting with Pittsburgh and West Haven staff as part of regular project meetings, the Co-I will also be a member of the steering committee.

Consultants: VA leadership and staff in the areas of Suicide Prevention, Peer Specialist Implementation, Behavioral Health, and other relevant areas will be invited to serve as consultants on the Steering Committee.

5.0 Study Procedures

5.1 Study Design

This study will be conducted in three phases. The first phase will involve the use of Intervention Mapping to identify which components of PREVAIL require adaptation to reduce suicidal ideation in high-risk VHA patients to identify implementation strategies in the VHA system. Needs assessment is the first step in IM.

Needs Assessment

A Co-I will conduct a total of 12 interviews at the West Haven VHA site to learn more about: (1) attitudes toward PSs involvement in suicide prevention efforts, (2) current involvement of PSs in clinical care and safety planning, (3) PSs' experiences working with persons with history of suicide ideation, (4) beliefs about how PSs can improve suicide prevention efforts, and (5) feedback on the focus, content, and process of the PREVAIL model. Interviews will be conducted with Veterans (n=3), PSs (n=3), and providers from primary care, behavioral health, rehabilitation, and emergency department settings (n=4). The Co-I will also interview clinical directors (n=2). Interviewswill focus on current clinical practices involving peer specialists and suicide prevention services in terms of: (1) degree of perceived helpfulness; (2) perceived barriers; and (3) areas of value and possible improvement. Information from the interviews will be usedto identify a range of potential barriers to the effective use of peer specialists in suicide

VA Central IRB Panel 2
Effective Date: March 8, 2022

prevention efforts and possible changes to PREVAIL.

Analyses of needs assessment data: Qualitative analyses of interviews from the needs assessment will be conducted with empirical phenomenological procedures used successfully by our team in previous studies.[57] Verbatim transcripts of audio recordings from the interviews will be distributed to two of the Co-Investigators. Each researcher will independently review, analyze, and code the transcripts for themes that characterize participants' experiences. After creating a narrative summary using the participants' own language, the Co-Investigators will review each of their summaries to compare/contrast the identified themes before coming to consensus about important themes. A synthesized report will summarize the overarching themes.

For *Step #2* of the IM process, the steering committee will review the themes that were identified in the needs assessment interviews and data from the suicide prevention literature, provided by the Co-I who conducted the interviews. Preliminary qualitative and quantitative data on the PREVAIL model have already provided support for the logic model but identified minor modifications in the training and supervision provided toPeer Specialists. Based on information from the needs assessment interviews, the committee will help determine whether further refinements are appropriate or unnecessary.

Pre-and Formal Pilot Testing

Adaptation of PREVAIL: Steps #3 and #4 of the IM process will be completed during the monthly steering committee meetings. As recommended for adaptinginterventions,[1,8,58] proposed changes to PREVAIL will based on stakeholder input from the needs assessment results, literature reviews, and guidance from the original developer. Based on a recent meta-analysis of evidence-based psychotherapies adapted to new populations and settings, when changes are "discrete, well-defined, andbased on sound theory and an understanding of the population for which the intervention is being adapted, they may result in better outcomes." (p.409).[59] To help inform potential changes to PREVAIL for the Veteran population, a Co-I will interviewthe PSs one two occasions. First, a focus group will be held on the last day of training inthe PREVAIL to solicit feedback on possible changes to the curriculum. A second focus group will be conducted after PSs have delivered the intervention during the pre-pilot, with the possibility of individual interviews helping to elucidate specific topics brought updduring the focus group. The conceptual model co-developed by Dr. Pfeiffer will be refined as needed by the needs assessment and steering committee, however, we do not anticipate any changes to this overarching structure based on preliminary feedback from the steering committee and needs assessment interviews.

VA Central IRB Panel 2
Effective Date: March 8, 2022

The PREVAIL intervention consists of weekly interactions over the course of 3-months using a flexible approach to accommodate Veteran's preferences and recovery needs over the course of the typical duration of a PRF. During weeks 1 and 2 of the intervention, Veterans meet twice weekly with a PS. During weeks 3 through 8, meetings are once weekly. During weeks 9 through 12, meetings typically occur once every other week. Over the course of the 3-month intervention, this approach bolsters the development of a strong therapeutic alliance in the beginning (weeks 1-2), followed by active teaching and reinforcing new skills (weeks 3-8), and then culminating with mastering new skills and preparing the Veteran for active self-management and sustained recovery. For a small number of PREVAIL participants, an additional 3 sessions were added over the span of the last 4 weeks to provide additional time to prepare for the end of the therapeutic relationship. A similar approach will be used for the current pilot.

Meetings between PSs and Veterans will be approximately 45-60 minutes and occur primarily in the community, home, clinic, by telephone, or VA-approved video calling platform (e.g. VVC, WebEx). Session content will be rooted in PSs offering nonjudgmental empathic support, active listening, and constructive disclosure and role modeling. A primary focus will be helping patients with PRFs to identify and strengthen connections with informal supports and participation in activities in their community that will enable them to feel more worthwhile as individuals and hopeful about their future.

The PREVAIL model uses a 4-step process as a guide to their interactions with patients each of the weekly meetings: (1) Invite discussion about hope- and belongingness-related topic; (2) Learn to find out more about what participants have already tried and what participants think might be helpful or relevant to their situation; (3) Share suggestions based on their personal experience or knowledge; and (4) Motivate "change talk," including how taking action might be helpful, how they might practicallygo about implementing changes, and whether they have made a commitment to change. The PREVAIL model also includes having PSs "check in" midway through the 3-month intervention to gauge the patient's preference for more- or less-structured conversations or sharing, and to remind participants they are half-way through the intervention so they anticipate and prepare for termination at the 3-month point.

The second phase will involve pilot testing the feasibility and acceptability of the adapted PREVAIL, rehabilitative measures, and suicide-related outcomes for use in a rigorous prospective study. To mirror recommendations for adapting interventions and pilot studies to help prepare for larger trials,[7,28] we will recruit 12 high suicide risk Veterans who will participate in a 3-month "pre-pilot" and provide feedback on how the

VA Central IRB Panel 2
Effective Date: March 8, 2022

intervention may be improved. Pre-testing adapted materials and using retrospective feedback from participants are recommended steps to identifying any further changes prior to further implementation.[7,8] After making any necessary modifications, for the third phase or 3-month "formal pilot", we will recruit a second group of 12 Veterans who are at high suicide risk to further evaluate the feasibility and acceptability of recruitment, retention, and assessment procedures to be used in a future randomized trial. We will draw upon the support and existing resources at the VA Connecticut campuses, which house on the largest PSs programs.

Veterans in both the pre-pilot and formal pilot will each meet with research staff for a Baseline Visit, Post-Intervention Visit, and a 3-Month Follow-Up Visit. All participants will also be invited to participate in an in-depth qualitative interview shortly after their 3- month follow-up assessments to assess their views of the intervention, including barriers, strengths, and recommended changes. All qualitative interviews will be recorded and transcribed. During the interviews, participants will be encouraged toavoid using names. If any name is recorded, it will be omitted from the written transcript (i.e., the transcript may read [name] in place of the actual name). Only the study team will have access to data collected by questionnaires, interviews, and medical record data.

Risks and Risk Minimization

Needs Assessment (Aim 1): There are no foreseeable physical or medical risks in this portion of the project. However, potential participants will be informed of the general nature of the study, what their involvement entails, the risks/benefits, and limitations to confidentiality prior to providing informed consent. The site PI for VA Connecticut and Co-I will contact key staff and make arrangements for interviews. Three Veterans will be identified pursuant to a HIPAA waiver, and a letter will be mailed to them invitingtheir participation.

We will minimize risks to interview participants by thoroughly explaining to them that participation in the project is strictly voluntary and that the decision not to participate will have no bearing on their employment. Individual names of employment settings and associated responses will not be provided to any other agency. In reports, publications, or presentations using project research data, we will report the data in aggregate form and/or change names and disguise the identity of any individual we describe or quote for purposes of illustration or example.

Pre-and Formal Pilot Testing (Aim 2): A potential risk to study participants is clinical deterioration of their mental health and/or an increase in suicidal thoughts or behaviors

VA Central IRB Panel 2
Effective Date: March 8, 2022

related to receiving the pilot intervention. This risk is anticipated to be minimal based on the outcomes of a R34 pilot study and ongoing R01 conducted by Co-I (developer of the PREVAIL model informing this project), where suicidal ideation improved for the whole population from baseline to 3 months, and no adverse events were attributed to study participation. Additionally, a 2018 paper[2] reports no iatrogenic effects from two intensive suicide research protocols involving Veterans.

Another potential risk to study participants is loss of confidentiality related to self-report assessment data, medical record data, or audio recorded sessions or interviews. The risk of an inadvertent breach of confidentiality is minimal (see below regarding protections against risk). Because of the study involves reducing suicide risk, it is necessary to obtain detailed information about past and current suicidal thoughts, plans and behaviors. Loss of confidentiality may also occur in the event that the participant is assessed by a study clinician to be imminent risk for harm to self or others therefore requiring a breach of confidentiality to ensure safety of self or others (e.g., contacting a participant's family member, law enforcement, or health care provider). Such a breach would only occur if there is no reasonably safe alternative. The informed consentprocess and documents will explain mandatory reporting requirements for information regarding intention to harm self or others prior to participating in the study.

There is also a minimal risk of psychological discomfort to study participants from the questions asked in the assessments. Participants may become anxious or uncomfortable as a result of being asked personal questions. The study team members conducting assessments are trained to respond to this emotional distress and to refer the participant to their mental health provider or other appropriate resources as necessary. All participants are free to terminate the assessments at any time or refuseto respond to any questionnaire item. Additionally, there is a popular misperception that inquiring about suicidal thoughts, plans or prior behaviors could increase the likelihood that an individual will make a suicide attempt. Research has not found that suicide assessments increase the risk of suicidal behaviors and this misperception has had the unfortunate consequence of decreasing research on potentially suicidal individuals. However, the study of individuals at elevated risk for suicide does require a clear set of procedures to manage potential crisis situations. These are reviewed in detail in the Data Safety and Monitoring plan.

Data Safety and Monitoring plan

Several steps will be taken to minimize the risk of breaches of confidentiality. Unique identification numbers will be assigned to all participants who complete the initial

VA Central IRB Panel 2
Effective Date: March 8, 2022

screening session. Chart reviews will be limited only to the data necessary for the research procedures (i.e., ICD codes for suicide ideation, self-harm). RAs completing the review will enter abstracted data directly into restricted-access databases keptbehind the VA firewall. Data will be identified only by a unique study ID. Every effort is made to ensure that all study data are always confidential, in terms of staff training and data storage, so that data cannot be linked to a particular person.

Unique identification numbers will be assigned to all participants who complete the initial screening sessions. Only individuals working on the actual data collection with the need to have access will be able to see the identifiers. Only the participant code will appear on the assessment forms and fidelity forms. All data forms and assessments will be coded with this number rather that with a name. All paper forms will be stored in lockedfile cabinets. All identified data will be behind the VA Firewall, and only current VA studystaff will have access to this data on an as needed basis. Consent forms and participantlist sheets will be stored separately from data, in locked cabinets because they contain identifying information and are linked to the participant ID. Only research team members will have access to the data. The identifiers will be maintained as long as data collection activities are ongoing, and up to 5 years following the completion of the study. Audio-recordings made on an approved, encrypted recorder will not include participant names and will be uploaded to a secure, password-protected server and deleted from the recording device after transcription. Transcriptions of audio-recordingsused for qualitative analyses will be reviewed to ensure all identifiers are deleted.

To minimize discomfort from study assessments or participation in the Peer Specialist sessions, we will train study staff in assessment and therapy techniques that are non-threatening, empathic, yet professional. In addition, Peer Specialists will receive training prior to the pre-pilot on topics such as therapeutic boundaries, self-care/compassion fatigue, and vicarious trauma. During weekly supervision, Peer Specialists will receive mutual support and ongoing assistance with a range of areas including case conceptualization, ensuring participant safety and self-care, and maintaining rapport/engagement to minimize potential therapeutic impasses. Peer Specialists will also be invited to share audio recorded segments from sessions to promote continued quality improvement. Study staff will also receive weekly supervision during the periods that baseline, post-intervention, and 3-month follow-up assessments are being completed. All study staff will be provided with specific suicide risk management protocols used in PREVAIL R34 in the case that a patient expresses severe distress or clinical deterioration (discussed below).

The Site PI in cooperation with the Site PI/Co-I will be responsible for ensuring training and weekly supervision to all research staff working with participants with regard to

VA Central IRB Panel 2
Effective Date: March 8, 2022

procedures for managing potential clinical deterioration, suicidal crisis situations, and/or adverse events. This training will include information regarding evaluating warning signs of acute suicidal ideation, planning, or intent that could occur during contact with participants, and means of addressing such issues. Peer specialists will inquire about suicidal ideation at every encounter (one visit per week) with participants, and participants complete self-report measures of suicidal ideation at baseline, postintervention, and 3-month follow-up assessments conducted by RAs. In the case that a participant indicates any level of suicidal ideation or recent attempt during encounters with any study staff (including peer specialists), a suicide risk management protocol will be used. The protocol is based on the same approach used in the R34 and ongoing R01 evaluation of PREVAIL and utilizes an algorithm of scripted risk assessment questions and "action steps" dependent on the participant responses (See Appendices A and B for peer specialist and research assistant versions, respectively). Similar but separate protocols were developed because peer specialists will not ask as many detailed questions as research assistants. This approach ensures peer specialistsstay out of a "risk assessment" role with the participants. For research assistants, they will be provided a more detailed risk assessment algorithm that involves an additional step for how to respond based on level of risk.

Based on the level of risk determined by the algorithm, study staff may perform one or more of the following. In the presence of elevated acute suicide risk, several steps will be taken to ensure participant safety (See Appendices A and B). First and foremost, should the participant disclose suicidal plan and/or intent OR recent suicidal behavior (e.g., suicide attempt or preparatory behavior in the past month) then the peer specialistor research assistant will conduct a warm hand off to a licensed mental health provider to further assess and intervene as appropriate (e.g., Safety Planning, hospitalization). Similarly, should the participant report these factors during a research interview on a self-report assessment (e.g., QIDS or C-SSRS), a warm hand off to a licensed mental health provider will be conducted. For lower, non-acute risk, steps taken by study staff include: a) recommend the participant call or be transferred to the Veteran Crisis Line orthe VHA Psychiatric Emergency Services b) notify the participant's primary Mental Health clinician and/or Suicide Prevention Coordinator regarding a non-imminent increase in suicide risk. When any suicidal ideation is reported, study staff will c) notify adesignated on-call study team clinician when the suicide risk management algorithmhas been activated, and when any questions arise regarding risk management. The on- call study clinician will be available via pager or cell phone at all times when there is potential contact between study staff (including peer specialists) and participants. Additionally, health and social service resources will be provided to the participant. This will include several resources, including suicide prevention resources which the participant can access. This will facilitate and enhance care on an ongoing basis among

VA Central IRB Panel 2
Effective Date: March 8, 2022

this population.

Participants will be instructed on how to contact the crisis hotlines, emergency services, or closest emergency department if they are experiencing a suicidal crisis. Peer specialists and study team members are not to further assess or manage suicide risk beyond the established protocol. Participants will be instructed to contact their clinicians or the Suicide Prevention Coordinator All outgoing voicemail messages on VA Connecticut phone lines are mandated to include instructions on how to contact crisis services. Due to policies associated with COVID-19, most meetings between peer specialists and participants will occur onsite at VA facilities in person or via VA Video Connect or WebEx during business hours. On the off chance of that meetings occur outside of regular business hours; clinician back up will be prearranged. Written safety procedures for conducting community-based meetings include use of public locations, during daylight hours, and mandatory call-in procedures. In our prior research, usingsuch procedures with similar populations, no incidents where staff safety concerns became an issue occurred during follow-up assessments. All safety concerns will be reported immediately to the PI.

Fidelity to the PREVAIL model will be evaluated by 'blinded' raters independent of the research team after participants complete their post-intervention assessment interview. A 20% random sample of audio recorded sessions will be assessed in terms of adherence to PREVAIL principles (i.e., interactions that follow the format of Invite, Share, Learn, Motivate) and assessment of suicidal ideation as well as demonstration of generalsupport skills.

Benefits

It is believed that research participants may be helped in a number of ways. Participants who take part in the peer specialist pilot may benefit from an improved sense of hope and belongingness as the intervention establishes a supportive relationship and helps restore community involvement. The peer specialists are trained and supervised to handle potential distress caused by participating in the intervention. The peer specialistswill have immediate "on call" access to a supervising mental health clinician at all times they are meeting with a pilot participant. The pilot intervention is an adjunct to standard care VHA treatment, including assessments, admissions, and referrals if deemed appropriate by the clinical staff. The potential benefits for the research are expected to outweigh the risks to participants.

Importance of Knowledge to be Gained

Veterans account for approximately 8% of the U.S. adult population yet account for roughly 14% of deaths by suicide. In fact, the age-adjusted suicide rate in 2015 for VHA

VA Central IRB Panel 2
Effective Date: March 8, 2022

Veterans was higher than both non-VHA using Veterans and non-Veterans. Preventing suicide is a top priority at the VA and new approaches to suicide prevention are critically needed as the VHA suicide rate has not reduced despite multiple VHA initiatives put into place over 10 years ago. Randomized controlled trials have shown that peer specialists are effective in improving symptoms of depression, reducing the likelihood of psychiatric hospital readmission, increasing hopefulness, and improving quality of life. However, the data are scant on the effectiveness of these approaches in suicide prevention. Developing an effective intervention for preventing suicidal behaviors would represent a major advancement given the few existing effective VHA interventions to date. This study will add to the knowledge base in this critical area. Given the potential for this study to improve the quality of life for patients with varying levels of access to evidence-based mental health services, the potential benefits outweigh the risks outlined above.

5.2 Recruitment Methods

Recruitment-Aim 1

We will recruit a diverse group of 12 individuals for the Needs Assessment phase of the project to inform the adaptation of PREVAIL. This group will be comprised of Veterans (3), Peer Specialists (3), Providers from behavioral health, inpatient and outpatient psychiatry, and other relevant departments (4), and Clinical Directors (2).

We will obtain a waiver of HIPAA authorization to identify Veterans to participate in the Needs Assessment. Once these Veterans are identified, they will be mailed a letter informing them about and requesting their participation in the Needs Assessment interviews. A member of the study team will follow-up with a telephone call approximately one week after the letter is the sent. The team members will attempt to reach the Veterans by phone 3 times and will leave no more than two messages. Providers, clinical directors, and Peer Specialists will either be sent an email or will be verbally invited in person to participate in the Needs Assessment.

Recruitment for the Steering Committee

The Steering Committee will be comprised of researchers and VHA leadership. The site PI will identify appropriate VA staff and other providers and will contact them by phone or email.

Recruitment-Aim 2

VA Central IRB Panel 2
Effective Date: March 8, 2022

We will recruit 4-6 Peer Specialists who are currently working in VA Connecticut Healthcare System (VACT) to receive training in the PREVAIL model and to deliver the intervention for the pre- and formal pilot. All of the selected Peer Specialists have been trained and certified, with multiple years of clinical experience working with Veterans in recovery, including those who have been at some point 'flagged' for suicide risk.

We will include a sample of up to 24 VHA patients identified as being high-risk for suicide at the VA Connecticut Healthcare System (VACT) to receive the pilot intervention as an adjunct to usual care. Patients will be considered high suicide risk if they have a Patient Record Flag (PRF) in their medical chart for a recent suicide attempt, serious suicidal ideation, or other warning signs of acute suicide risk. The VACT Suicide Prevention Coordinator maintains a list of patients with active PRFs.This population is targeted because they are at greatest risk for suicide and therefore most in need of intervention.

In addition to reaching out to Veterans on the high-risk list, we also will engage Veterans via the New Haven VA psychiatric Emergency Room, inpatient units, and individual New Haven clinicians. Specifically, we will engage with staff to find out if any Veteran has received a score on the Columbia-Suicide Severity Rating Scale Screen of 3 or greater in the last three months. This measure is used commonly in the VA. Such a score is known to be an optimal cut off score for identifying individuals who would likely attempt suicide. In a recent study of nearly 19000 patients, those scoring over the cut-off of $\geqslant$3 had almost four times the odds of dying by suicide within 1 week and 1 month, respectively, and doubled the odds of dying within a year[90]. We will also engage with individual clinicians to assess whether any of their patients have recently received a score of $\geqslant$3 on the Columbia measures. In addition, we will ask these staff about any Veteran who made a suicide attempt in the last three months. Thus, the additional recruitment criteria we are adding will be:

- Any Veteran from the New Haven VA psychiatric Emergency Room, the New Haven inpatient units, or from individual New Haven clinicians who received a score on the Columbia-Suicide Severity Rating Scale Screen of 3 or greater in the last three months
- Any Veteran from the New Haven VA psychiatric Emergency Room, the New Haven inpatient units, or from individual New Haven clinicians who made a suicide attempt within the last three months

Each month, there are approximately 105 VHA patients with PRFs for suicide risk at the CT VA campuses. In addition to those Veterans with a PRF, we also will be recruiting those Veterans with suicidal ideation or attempts. This pool of Veterans should be sufficient to recruit participants for the pre-pilot (n=12) and formal pilot (n=12). Assuming a 75% retention rate (as achieved in Dr. Pfeiffer's PREVAIL pilot)[15] this will yield a final sample of 18 patients with outcome data at post-intervention and 3-month follow-up. Thissample size will yield reasonably precise estimates of feasibility in terms of actual rates of recruitment, retention, compliance/fidelity to intervention, and completion of outcome assessments.

Once eligible Veterans are identified, they will be mailed a letter along with a study information sheet, inviting them to participate in Aim 2 of study. A member of the study team will follow-up with a telephone call approximately one week after the letter is the sent if they do not hear back from the Veterans. The team members will attempt to reach

the Veterans by phone 3 times and will leave no more than two messages.

Additionally, the site PI will work with providers of eligible Veterans seeking their help in recruiting these Veterans into the study and will also provide them with a study information sheet. Once the provider identifies an eligible Veteran, they will discuss the study with the Veteran and if the Veteran is interested in hearing more about the study, the provider will call the study staff with the Veteran present or will share the number of the study staff with the Veteran so that they may call the study staff at their own convenience. In the event that the provider facilitates the phone call with study staff, the provider will step out of the room to give the Veteran a chance to learn more about the study. for this to occur. If a provider or research staff cannot reach the Veteran by phone, they will follow-up with a CIRB-approved letter as described above.

Payments

Veterans who participate in the Needs Assessment interview will receive $25 for their time and effort. Study participants will receive $25 upon completion of each assessment interview (baseline, post-intervention, 3-month follow-up), for a total of upto $75. Additionally, Veterans who participate in the one-time interview will receive $25 for their time and effort.

5.3 Informed Consent Procedures

Veterans

Needs Assessment

Pursuant to a Waiver of HIPAA Authorization, the site PI will identify three Veterans appropriate for the Needs Assessment in discussion with clinical providers. Selected Veterans will be mailed a letter describing the participation and requesting that the Veteran respond about their interest by calling the number provided or mailing back the return letter in the stamped envelope provided. If the Veteran is interested in participating in the Needs Assessment, a member of the research team will arrange a time to discuss the study with them and obtain their written consent. The member of research team will then conduct the Needs Assessment interview following written consent or will schedule a mutually agreed upon time to conduct the interview.

Pre-Pilot and Formal Pilot

A face-to-face meeting (interview and/or focus groups) will be held with Peer Specialists who have been selected to participate in the proposed study. Research staff will obtain verbal consent, including the permission to obtain audio-recordings of interviews and/or focus groups conducted after they have completed training in the PREVAIL approach as well as after the pre-pilot to inform potential modifications to the intervention.

A face-to-face meeting will be held for Veterans who have been selected to participate in the pre-pilot and formal-pilot phases of the study. Research staff will administer written

informed consent (or Veteran assent along with consent of a conservator if applicable) and HIPAA authorization, including the permission to obtain audio- recordings, at the baseline visit. The ICF, HIPAA and other study materials will be submitted and approved by the CIRB prior to the start of any recruitment for the pre-pilotor pilot.

VA Staff

Needs Assessment Staff Interviews

Pursuant to a waiver of documentation of ICF for staff who are going to be interviewed for the Needs Assessment, a member of the research staff will read through the ICF for staff over phone, obtain verbal consent from the staff member, and record the name of the staff member and date of consent for tracking purposes.

Peer Specialist Interviews and/or Focus Groups

Pursuant to a waiver of documentation of ICF for Peer Specialists who are going to be interviewed via a 1:1 interview and/or focus group following their participation in the PREVAIL training as well as after the pre-pilot, a member of the research staff will read through the ICF for staff over phone or via MS Teams,obtain verbal consent from the staff member, and record the name of the staff member and date of consent for tracking purposes.

5.4 Inclusion/Exclusion Criteria

Inclusion Criteria for Aim 1 Veterans

1. Experience related to suicide
2. Voluntary informed consent (must be able to be given by the patient)
3. Age 18 and older
4. Fluent in English

Exclusion Criteria for Aim 1 Veterans

1. Active suicidal flag or currently hospitalized
2. Pregnant and/or incarcerated
3. Unable to provide voluntary, written informed consent for any reason (include incompetency)

Inclusion Criteria for Aim 1 Staff

1. Voluntary informed consent
2. Age 18 and older

VA Central IRB Panel 2
Effective Date: March 8, 2022

3. Peer Specialists with experience related to suicide (Peer Specialists only)
4. Staff members with experience related to treating Veterans with experience related to suicide (Staff members only)
5. Fluent in English

Exclusion Criteria for Aim 1 Staff

1. Unable to provide voluntary, written informed consent for any reason

Inclusion Criteria for Aim 2 Veterans

1. Voluntary informed consent (must be able to be given by the patient) or voluntary informed assent with consent of a conservator if applicable
2. Age 18 and older
3. High suicide risk evidenced by a Patient Record Flag in their medical chart.
4. Fluent in English

Exclusion Criteria for Aim 2 Veterans

1. Substantially cognitively impaired as indicated by a score of 10 or higher on the Blessed Orientation, Memory, Concentration (BOMC) Test
2. Unable to provide voluntary, written informed consent for any reason (include incompetency)
3. Determined by patient's attending psychiatrist that the peer-based intervention is not appropriate due to unstable psychosis, cognitive disorder, or severe personality disorder
4. Residing outside of the VA Connecticut catchment area
5. Pregnant and/or incarcerated

Inclusion Criteria for Aim 2 Peer Specialists

1. Voluntary informed consent
2. Age 18 and older
3. Employed by the VA as a Certified Peer Specialist

Exclusion Criteria for Aim 2 Peer Specialists

1. Unable to provide voluntary, verbal consent for any reason

VA Central IRB Panel 2
Effective Date: March 8, 2022

2. Determined by Peer Specialists' supervisor, attending psychiatrist, or other clinician that delivering the intervention is not appropriate due to prior trauma, clinical instability, or current concerns with suicide risk

5.5 Study Evaluations

Measures

The measures used to collect data for Aims 1 and 2 include data from the CPRS record as well as several rehabilitation and depression & suicide variables described in further detail below. Additionally, a study-specific form will be used to collect information about age, sex, race, ethnicity, employment, education, income, and marital status.

Rehabilitation Variables

Sheehan Disability Scale (SDS)[64]. The SDS uses 3 items to measure how much work, social life, and family life are impaired by mental health symptoms. The SDS has been widely used in diverse samples,[65-67] including Veterans,[68,69] and found to be psychometrically sound and sensitive to treatment effects.

Temple University Community Participation scale (TUCP)[71]. The TUCP is a 26-item measure of community inclusion in the past month. The TUCP has been used in previous studies with good reliability.[71-74]

Questionnaire about the Process of Recovery (QPR)[75]. The QPR contains 15 items that measure connectedness, hope, identity, meaning, and empowerment. The QPR has demonstrated high internal and convergent validity as well as sensitivity to change.[76,77]

Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-SF). The Q-LES-Q-SF consists of 16 items to assess life satisfaction in the past week. The Q-LES-Q-SF has been used extensively with Veterans as part of the National Health and Resilience in Veterans Study (NHRVS).

Depression and Suicide Variables

VA Central IRB Panel 2
Effective Date: March 8, 2022

Quick Inventory of Depressive Symptoms (QIDS)[79]. The QIDS consists of 16 questions to assess depression severity. The QIDS has demonstrated high reliability, validity, and sensitivity to treatment change,[80], including among Veterans.[81]

Columbia-Suicide Severity Rating Scale (C-SSRS)[82]. The C-SSRS is used to assess suicidal ideation (past 30 days) and behaviors (past 3 months). Suicide ideation items include: (1) wish to be dead, (2) non-specific suicidal thoughts, (3) suicidal thoughts with methods, (4) suicidal intent, and (5) suicidal intent with plan. The suicide behavior subscales include: (1) attempts (actual, aborted, interrupted), (2) preparatory behavior, and (3) non-suicidal self-injurious behavior. We will also use two measures of psychosocial variables that potentially mediate suicide risk and are hypothesized to be impacted by PSs.

Interpersonal Needs Questionnaire (INQ)[83]. The INQ uses 15 items to measure two underlying motives for suicidal desire (i.e., perceive burden and thwarted belonging). The INQ has established validity and reliability,[84] including on Veterans.[85]

Suicide Cognitions Scale (SCS)[86]. The SCS contains 18 items that assess thoughts of unloveability, unsolvability, and unbearability. The SCS has strong psychometric qualities in diverse samples (including Veterans) with incremental validity to predicting suicidal behavior beyond depression, INQ scores, prior attempts, and suicidal ideation.[87,88]

5.6 Data Analysis

Per SPiRE protocol and discussions with an RR&D Scientific Program Manager, calculations for power and estimated effect size are not required because our proposal involves piloting a rehabilitation intervention with a small, high risk sample of VHA patients (as opposed to determining effectiveness in large samples via inferential statistical hypothesis testing).

Aim 1

Qualitative analyses of interviews from the needs assessment will be conducted with empirical phenomenological procedures used successfully by our team in previous studies.[57] Verbatim transcripts of audio recordings from the interviews will be distributed to the Co-Investigators. Each researcher will independently review, analyze, and code the transcripts for themes that characterize participants' experiences. After creating a narrative summary using the participants' own language, they will review each of their summaries to compare/contrast the identified themes before coming to consensusabout important themes. A synthesized report will summarize the overarching themes.

VA Central IRB Panel 2
Effective Date: March 8, 2022

Aim 2

WOC employees from the Program for Recovery and Community Health (PRCH) will conduct the data analysis for this aim. In line with SPiRE guidelines and recommendations for pilot studies,[28,89] our focus will be on the feasibility of the intervention and assessment of outcomes. Therefore, quantitative analysis will be mostly descriptive in nature (e.g., frequencies, percentages, means, standard deviations) and will focus on the estimation of confidence intervals. This includes descriptive statistics on each of the measures at each assessment period, creation of confidence-intervals, and visual plotting of data to observe potential trends in the data associated with the intervention. Formal hypothesis testing will not be conducted as comparisons of outcomes would be unreliable estimates of any true effect given the small sample size. Instead, analyses will be used to evaluate the feasibility of measuring the primary outcomes and potential mediators as well as to inform decisions about power and sample sizes in a larger trial. Qualitative analyses of post-intervention interviews with Veterans will follow the same procedures as described for Aim #1. Qualitative analysis of interviews and/or focus groups with Peers Specialists conducted after completing the PREVAIL training and the pre-pilot of the intervention will also follow the same procedures as described in Aim #1.

5.7 Withdrawal of Subjects

As discussed in Section 5.1 of the protocol, the risk of clinical deterioration of mental health and/or an increase in suicidal thoughts or behaviors related to receiving the pilot intervention is anticipated to be minimal, therefore we believe that few participants will need to be terminated. Participants who are hospitalized during the project will not be withdrawn, but the intervention will continue, either during their stay if medically appropriate, or following their discharge.

If study staff becomes aware of Veterans who are incarcerated and/or become pregnant during the study period, the Veteran will be withdrawn from the study. Other potential reasons for withdrawal include if a participant relocates out of state or misses the first four scheduled sessions. Any participant may withdraw from the study at any time, as stated in the ICF. If a participant calls the research staff to withdraw, the staff member

VA Central IRB Panel 2
Effective Date: March 8, 2022

will thank the Veteran for their participation and ask whether the Veteran would like to schedule a behavioral health appointment related to their study participation or decision to withdraw. A note will be added to the Veteran's medical record indicating their decision to withdraw, and the behavioral health provider of record will be informed.

6.0 Reporting

Principal Investigators (PI), Co-investigators (Co-I), and all other study staff will monitor for adverse events (AE) and protocol deviations, and staff will notify the PI immediately of any AE or protocol deviation. CIRB guidelines will be strictly adhered to. The study staff member and PI will discuss the event in its entirety: (e.g. what happened, what caused it, if it was expected or unexpected, any ways to resolve or correct the issue,etc. The PI or project manager will file a report of all SAEs and protocol deviations with the Central Institutional Review Board (CIRB), and a copy of the report is kept on file in the project binder. When participants are consented into the study, they will be notified that they may leave the study at any time without repercussions to their regular care from the VA. In the event that a Veteran is incarcerated during the study they will be formally removed from the study and study staff will immediately notify the Central IRB (CIRB) of this event.

The Principal Investigator or site PI will be responsible for contacting the CIRB within 5 working days about any serious unanticipated adverse events or unanticipated problems involving risks to participants or others and completing any reports applicable. As necessary, either the PI or Site PI will submit Form 119 (CIRB Report of Unanticipated Serious Adverse Events and Unanticipated Problems) to the CIRB, and submit a copy to the other site, thus assuring that all parts of the study are well informedabout any events or problems.

They will also provide a summary report about adverse events and unanticipated problems that did not require immediate reporting to the CIRB at the continuing reviews and at study closure. The VA Central IRB table of reporting requirements time frames will be used in all cases.

Due to the pilot nature of this study and small sample size, this study will not have a Data Monitoring Committee.

7.0 Privacy and Confidentiality

Study related questionnaires will be identified with unique ID numbers for each participant and will be collected in paper format. After the written informed consent process (Aims 1 and 2) and the survey measures have been completed, the study documents will be kept in a locked file cabinet, within the locked office, within a locked building, of the study staff. Coded interview data will be manually entered by research staff into a database that will be stored on a VA server located behind the secure firewall. Windows integrated security will be used for all computer access. At the VA, all PCs, laptops, workstations, and remote devices are set to lock and are secured after being left unattended for 5 minutes or more, or by logging-off when the equipment willbe unattended for an extended period. User and role permissions will be defined at the computer, file, directory server and database level to ensure data security. Source documents with private information (e.g., consent document, payment form, etc.) will be stored in a locked file cabinet, within the locked office, within a locked building, of the research staff. Research records may be released or disclosed if required by federal law. Study participants will not be specifically identified in any publication of research results. Records will be kept according to current VA regulations.

All local policies will be adhered to for information security purposes. All identified data will be behind the VA Firewall, and only current VA study staff will have access to this data on an as needed basis. Research staff who leave the study will be removed from the study staff via the Study Staff Form and their access to the study drives and/or documents will also be terminated. If there is an improper use or disclosure of study data, we will notify the ISO and Privacy Officer immediately of said occurrence.

All research records will be maintained in accordance with the Veterans Health Administration (VHA) Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.

7.1 Communication Plan

The Principal Investigator ultimately will be responsible for monitoring the data and safety with involvement from all of the study investigators. They will ensure that all relevant CIRB policies, procedures and stipulations are being followed. They also will beresponsible for ensuring that other investigators and project staff adhere to the VA CIRB policies including: (1) all participants will understand, agree to and sign a written consent form before participating; (2) strict adherence to a participant's right to withdrawor refuse to answer questions will be maintained; (3) the assessments will be

completely confidential and no names will be associated with the assessment data; (4) consent forms and identifying information will be kept separate from the actual participant data; (5) all identifying information (consents, tracking data) will be kept locked at all times and computer files will be saved with passwords; (6) participants will be informed in writing in the consent form how to contact the PI, the study coordinator, and VA CIRB office with any questions and/or concerns.

The PI will directly supervise the data manager and the project coordinator and will be responsible for monitoring confidentiality procedures. Quality control and reliability of screening, baseline and follow-up assessments will be monitored by Dr. Chinman throughout the trial via regular meetings and observation of the project coordinator conducting standardized assessments.

VA Central IRB Panel 2
Effective Date: March 8, 2022

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Effective Date: March 8, 2022

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Effective Date: March 8, 2022

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VA Central IRB Panel 2
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