Protocol and Statistical Analysis Plan

Study Title
Increasing Help-Seeking Behavior Among Transitioning Veterans at Risk for Suicide With Online Gatekeeper Training

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Title

VAPORHCS/OHSU J: Increasing Help-Seeking Behavior Among Transitioning Veterans At Risk For Suicide With Online Gatekeeper Training: A Pilot Study Of PsychArmor S.A.V.E.

Specific Aims/Purpose

Transitioning Veterans (those who have recently separated from the military) are a high-risk group for suicide. A key component to advancing suicide prevention efforts among at-risk Veterans is to address low levels of help-seeking and engagement in clinical care.

Gatekeeper training is a type of intervention with the potential to substantially increase help-seeking, and thereby contribute to "upstream" suicide prevention efforts. Gatekeeper training teaches individuals the skills needed to identify signs of suicide risk and connect others to professional treatment. PsychArmor S.A.V.E. is a recently-developed form of brief online gatekeeper training and has been tailored to Veterans and their close supports.

We propose to conduct a pilot randomized controlled trial (RCT) of PsychArmor S.A.V.E. Using a targeted advertisement campaign on social media, we will reach and recruit transitioning Veterans and their close supports (family and friends) into this online study. Participants will be randomized 1:1 to PsychArmor S.A.V.E. or to a "sham" online training. We will use a mixed methods evaluation of website administrative data, surveys, and interviews, including follow-up over six months. This pilot will inform a subsequent, larger RCT to determine if PsychArmor S.A.V.E. improves trainee behaviors and reduces rates of suicide behaviors.

Our **Specific Aims** are:

1. **Determine the feasibility of recruiting participants via social media, engaging them to participate in an online gatekeeper training program, and retaining them in an online intervention study.**
2. **Determine the acceptability of PsychArmor S.A.V.E. in a pilot RCT, and evaluate measures for use in a future larger-scale RCT.**

Three key deliverables from this project will be: 1) empirical data on study feasibility (recruitment flow, training participation, and loss to follow-up); 2) a mixed methods evaluation of the acceptability of PsychArmor S.A.V.E.; and 3) measurement characteristics of key outcome variables for use in design of larger-scale RCT. If successful, this project will seamlessly link outreach via social media outreach to an online training in suicide prevention skills. This line of research has major potential for implementation and impact due to its broad reach and scalability.

Hypothesis:

This study has three hypotheses related to Aim 1:

- **Hypothesis 1.1**: Twenty participants per week, on average, will enroll in the study
- **Hypothesis 1.2**: At least 50% of eligible individuals will enroll in the study
- **Hypothesis 1.3**: Loss to follow-up at the study endpoint will be less than 50%

And one hypothesis related to Aim 2:

- **Hypothesis 2**: Participants will complete on average at least 70% of the PsychArmor S.A.V.E. training.

Scientific Rationale and Significance

Suicide prevention among Veterans not engaged in Veterans Health Administration (VHA) care and Veterans transitioning from military service is an urgent priority. An estimated 70% of Veterans who die by suicide have not recently used any VHA services.[1] The latest data further show that suicide rate among Veterans who do not use VHA care increased by 12% between 2016 and 2017.[1] As a consequence, addressing lack of help-seeking has been called one of the top three short-term research objectives in suicidology.[2] Addressing this barrier is especially critical among young Veterans transitioning from military service to civilian life who may face disruption in their social networks and challenges establishing care with VHA.

Veterans' close supports—which includes include family members and friends, as well as Veteran peers—have a vital role to play in increasing help-seeking and treatment engagement among Veterans at risk of suicide. Support and encouragement from Veterans' close supports is a key facilitator of help-seeking.[3] In addition, suicidal individuals are most likely disclose their thoughts to a close social network member.[4] Individuals having frequent social contact with at-risk individuals have the greatest potential to impact suicide prevention.[5]

Veterans' close supports are likely to have the opportunity to intervene on behalf of a Veteran at risk of suicide and seek training in how to help. A study of 971 National Guard personnel found that 65% reported knowing someone who had died by suicide, and on average, participants knew three suicide decedents.[6] Another study of 931 Veterans found that younger Veterans had an even higher chance of interacting with peers at risk of suicide, suggesting that transitioning Veterans may be an especially good target for suicide prevention efforts.[7] National data suggest that Americans "overwhelmingly agree they have an important role to play in preventing suicide – and most (78%) are interested in learning how they might be able to play a role in helping someone who may be suicidal."[8] However, few have ever received training in suicide prevention. Even among groups most often targeted for training (e.g., college students), just 8-10% have had any exposure to training.[9]

Gatekeeper training is a community-based, public health suicide prevention strategy. Gatekeeper training is explicitly designed to provide close supports with training in how to help a person at risk of suicide. It can be delivered outside of the healthcare system, and thus reach Veterans not engaged in VHA care who are most at risk of suicide. Further, it can be useful for both selective and universal prevention.[10] In this proposal we focus on transitioning Veterans—due to their elevated risk for suicide—and their close supports (selective prevention). However, gatekeeper training may also be relevant at a broader population level to support "upstream" suicide prevention (universal prevention).

Gatekeeper training is promising but understudied. Positive outcomes from gatekeeper training include improvements in knowledge, self-efficacy, and behavioral intentions related to suicide prevention.[11] Intervention studies also have shown improvements in attitudes such as stigma and social norms towards mental health treatment, which thereby lead to increased help-seeking behaviors.[12,13] Studies also support these improvements in diverse community-based populations,[14] over long-term follow-up (up to two years),[15] and using brief ($\leq$ 2 hours) gatekeeper training.[14,16] Some large studies—including a multi-site randomized controlled trial (RCT) and large-scale observational studies—have found preliminary evidence of reduction in suicide attempts[17] and suicide mortality rates.[18] Nonetheless, multiple systematic reviews have called for additional research on gatekeeper training.[19–22] A primary reason is the lack of studies demonstrating that gatekeeper training directly decreases suicide rate. This is likely due to the constraints of adequately powering a study to show change in suicide mortality which has a low base rate (a limitation common to many suicide prevention interventions), as well as historically suboptimal interactions between

healthcare systems and suicide prevention programs (a limitation unique to community-based interventions such as gatekeeper training).[23]

Two additional areas of research needed on gatekeeper training are:

1) **Feasibility and potential efficacy of *online*-based gatekeeper training.** While online gatekeeper training is appealing due to its practicality and accessibility, research into it has been lacking,[24] and no studies have been conducted in the U.S. or targeted Veteran populations.[25,26] One non-comparative study examined the feasibility of using an online gatekeeper to direct individuals searching for suicide-related keywords to a website encouraging use of an e-mail consultation service. While the strength of evidence was low, modest levels of treatment engagement and improvement in mood were seen.[27]
2) **Outcomes for the recipient of the training.** While the primary goal of training is to equip a close support to help another individual, there is preliminary evidence of an ancillary benefit to the trainee. In post-hoc analyses from a recent RCT, researchers found that recipients of gatekeeper training increased their own mental health care utilization at three months post-intervention.[12] Because close supports for Veterans are often Veterans themselves, exploring the potential benefit of gatekeeper training for the trainee is especially important in a VHA context.

PsychArmor S.A.V.E. is an accessible, engaging, brief online gatekeeper training tailored to the Veteran community. As with all gatekeeper trainings, it teaches practical skills in how to assist a person at risk of suicide and increase formal help-seeking.[5,12,18] Unlike other gatekeeper trainings (e.g., QPR, Mental Health First Aid, ASIST), though, it is both free and online, which increases its accessibility to Veterans and their close supports.[28] PsychArmor S.A.V.E. is also intentionally brief (24 minutes), has a video format, and includes three scripted role plays; these features may help engage individuals who might otherwise be reluctant.[25] Finally, it was developed in partnership between VA and the non-for-profit PsychArmor Institute; it is culturally tailored to needs and circumstances of the Veteran community. Cultural tailoring an intervention may improve treatment outcomes, particularly when the population has unique vulnerabilities, and/or when there is a reduced responsiveness to other interventions.[29]

Social media is an innovative way to reach transitioning Veterans and their close supports, and promote participation in PsychArmor S.A.V.E. Recruitment of participants via social media offers the potential for immediate delivery of an online intervention such as PsychArmor S.A.V.E. Among social media platforms, Facebook is used by most Veterans and has the largest and most active base of users: 76% log on daily and spend on average 50 minutes on the site.[30–32] Ads on social media platforms such as Facebook have the added benefit of being able to presented to narrowly targeted populations (i.e., "micro-targeting") based on demographics, location, interests, and behaviors.[33]

VA-SPECIFIC REQUIREMENT (relevance to VA mission):

This project is highly responsive to multiple top VHA priorities. This project focuses on VA's topic clinical priority, suicide prevention. The 2019 VA and Department of Defense Clinical Practice Guidelines also identified gatekeeper training as an important research gap and priority for future research.[23] Finally, our research design addresses three separate goals and objectives in VA's National Strategy for Preventing Veteran Suicide: 1) use a "comprehensive public health approach to reduce Veteran suicide rates, one that looks beyond the individual to involve peers, family members, and the community"; 2) "Develop and promote educational materials about the warning signs for Veteran suicide and how to connect individuals in crisis with assistance and care"; and 3) "Provide training on suicide prevention to community groups."[1]

Preliminary Studies

1. Feasibility of a social media ad campaign to recruit a high-risk Veteran population. In our previous work, we used a similar recruitment strategy to target younger Veterans (Iraq/Afghanistan service era, average age 40 years old) to participate in an online, cross-sectional study. Ads from this campaign were seen over 800,000 times (a metric called "impressions"), 85% of eligible individuals enrolled, and we recruited 587 participants eligible for data analysis in six weeks (~100 participants/week recruited).[34] In the same study, we found high rates of screening positive for current suicidal ideation (23%), posttraumatic stress disorder (45%), problematic drinking (42%), and major depression (28%). In addition, while 67% of respondents reported being enrolled in VHA care, 55% denied using VHA care in the prior year. Together, these data indicate our ability to successfully reach Veterans at risk of suicide and support our hypothesis that gatekeeper training may be of benefit to trainees themselves.

2. Acceptability of online suicide prevention training. As part of the same project above,[34] we analyzed survey responses from the 587 participants and found over 40% were very to extremely interested in learning how to help a peer who was having suicidal thoughts, 30% very to extremely interested in learning how to spot warning signs of suicide, and 30% very to extremely interested in learning where to find mental health services or treatment options (unpublished data).

3. Efficacy of in-person gatekeeper training. Dr. Cross (Co-I) is a distinguished expert in the area of gatekeeper training, including the original development of S.A.V.E. (the precursor to PsychArmor S.A.V.E.). She has also led numerous clinical trials of gatekeeper training, which demonstrate improvements in knowledge, self-efficacy, and intentions to use and disseminate training information among participants.[35–39] Dr. Teo (PI) has also led a trial of a culturally-tailored, brief format in-person gatekeeper training for lay community members (n = 106). Results showed significant increases in behavioral intentions and attitudes related to gatekeeping, compared to an attention control.[14]

4. Collaboration and partnership among the investigative team. Members of the research team have worked together since 2014 on multiple projects related to suicide prevention in Veterans, including suicide risk factors[40,41] (Teo/Dobscha/ Cross/Gamble), an ongoing training program on discussing lethal means safety (Dobscha/Karras-Pilato), and depression (Teo/Dobscha).[42] The PI has also built and maintained robust partnerships with PsychArmor Institute and OMHSP.

5. Research experience and technical expertise in the proposed data collection and analytic methods. In the area of social media, Dr. Teo (PI) has significant experience with recruitment via social media and analyzing data obtained from social media platforms including Facebook and Twitter.[34,43] He has also collaborated with the Oregon Health & Science (OHSU) Strategic Communications social media team who will partner on this project and possess broad expertise in marketing across an array of social media platforms. In terms of experience with web-based suicide prevention training, the team includes Dr. Rodgers (Consultant; oversight in the development and management of PsychArmor S.A.V.E.)., Dr. Gamble (Consultant; collaborates with education leaders across VHA to develop and disseminate suicide prevention trainings through web-based modalities), and Dr. Dobscha (Consultant; led a team that systematically developed and evaluated web-based training programs for clinicians and patients related to OpenNotes in mental health).[44] Finally, the research team is experienced with longitudinal data collection and analysis, mixed methods research, and intervention studies and human subjects research with individuals at risk of suicide.[42,45–48]

Research Design and Methods

Recruitment via social media. We will recruit participants through a targeted social media advertisement campaign. Recruitment through social media offers the advantage of being able to reach veterans outside the VA system and immediately deliver an online intervention.

We will use Facebook as our primary platform for recruitment; however, in consultation with our partners including the Oregon Health and Science University (OHSU) Strategic Communications social media team, we may include advertisements on other platforms for which they have extensive experience running campaigns (e.g., Instagram). Following a procedure developed in our previous research,[36] we will set ads to be presented to Facebook users likely to fit our eligibility criteria. Examples of characteristics we will use include: age, military-related interests or behaviors (e.g., making a charitable donation to a Veteran service organization, listing the military as their industry or employer), and "liking" Facebook pages related to Veterans, suicide prevention, or related topics. Ads will be placed in users' "News Feeds" and optimized for computer and mobile devices. To assure that sensitive information is not sent in an unencrypted email, these ads will not invite communication from participants. From these feeds, participants will click on the ad and be taken to screening and consent in OHSU REDCap to enter the survey. Ad performance will be monitored in real-time, allowing the potential to retain only the most cost-effective ads in the campaign. The research team will collaborate closely with the OHSU Strategic Communications Social Media team to host ads, and monitor, audit and report on interval progress of the communication campaign. OHSU REDCap captures and stores the number of screened and consented participants and stores this information; we will be able to view and monitor recruitment progress by logging into REDCap and checking these numbers.

Based on our preliminary work recruiting Iraq/Afghanistan-era veterans, budget for recruitment, and empirical data on the slower pace of recruitment for web-based intervention studies that include close supports as participants,[34,49] we estimate a 10-week recruitment period to meet our target enrollment of 200 participants (20 participants/week).

A subset of approximately 15 participants from the intervention group will be invited to participate in an interview. These participants may be veterans or their close supports. For this, a research staff member will contact potential participants to determine interest and conduct the interview in a format (telephone, video call, or in-person) that is best suited to each research participant.

Intervention Description. We will use PsychArmor S.A.V.E. (see description above in Scientific Rationale and Significance section). In brief, the online training is tailored to Veterans and their close supports, is free, brief (24 minutes), and includes three scripted role plays. It closely follows the S.A.V.E. model employed by the VA by teaching four skills: learning **S**igns of suicide, **A**sking about suicidal thoughts, **V**alidating feelings, **E**ncouraging help and **E**xpediting treatment.[50]

Control Group Description. Consistent with best practices for behavioral interventions, our control group accounts for the benefits seen with the passage of time and attention received in the intervention group.[51] The control group will consist of a "sham" training – a different online, video-based training course developed by PsychArmor Institute designed for transitioning military service members and their family. Topics in this training include information on preparing finances, networking, searching for a job, and using educational benefits. The length of the training will be matched to the intervention (24 minutes), and the "sham" training also contains other design features similar to the intervention (e.g., motion graphics). By using another PsychArmor training, we are able to isolate the difference seen in the control group to be the educational content related to S.A.V.E.

Sources of Data. We will use three data sources (website administrative data, survey responses, and qualitative interviews) to obtain a mixed methods evaluation of PsychArmor S.A.V.E.

1. **Website administrative data**. These include measures of engagement with the web-based training in the current study: number of log-ins, enrollments, and completed trainings, as well as time spent on the website. These data will only be obtained from participants who are enrolled in the study.
2. **Surveys**. Participants will complete surveys online at baseline (before and after the training) and at monthly follow-up (1, 2, 3, 4, 5, and 6 months). Surveys contain standard items and scales to collect self-reported information and attitudes. This includes sociodemographic characteristics, knowledge,

self-efficacy, social norms, stigma, behavioral intentions, use of gatekeeper behaviors, suicidal ideation, and help-seeking. See **Appendix B** for baseline survey. Follow-up surveys will contain a subset of baseline survey measures—see **Table 2** below for a timeline of measures.

3. **Interviews**. A small subgroup of study participants (n = 15) who were assigned to the intervention group will be invited to participate in an interview to take place approximately one-month post-intervention. Interviews will include questions on feasibility and acceptability of the social media ad campaign and on PsychArmor S.A.V.E. See Qualitative Data Collection section below for a more detailed description and **Appendix C** for the interview guide. Interviews will be audio-recorded and written notes will be recorded by the interviewer.

Potential Difficulties, Limitations, and Alternatives. A potential difficulty is struggling to recruit enough interested and eligible participants online. We will monitor recruitment progress on a weekly basis using a module in our data management software (OHSU instance of REDCap), which allows real-time monitoring of progress against targets. If we do not meet a minimum recruitment milestone of 50 participants in three weeks, the research team may consult with a recruitment specialist at the Oregon Clinical and Translation Research Institute and OHSU's Strategic Communications social media team about adding recruitment strategies in accordance with NIH guidelines,[52] and/or placing advertising on additional social media platforms.

Given the 6-month length of follow-up, another potential difficulty is sample retention. To promote sample retention we will employ methods with empirical validation in increasing online study response and retention rates: 1) minimizing survey burden, 2) specifying survey time estimates, and 4) sending reminder emails, texts, and small messages of appreciation to study participants.[53] Of note, prior research among military personnel suggests that survey retention is higher in web-based surveys than paper-based surveys.[54] We will also employ modest financial incentives. In the case of incomplete follow-up, reminders will be sent with use of email and additional modalities (e.g., text message) as consented to by the participant.

Timetable for study. The project timeline is presented in the **Table 1**. Special consideration was made for the time required to: develop the social media ad campaign (3 months), setup study infrastructure including REDCap data collection and management system and a study website containing integration of the two study arms (4 months), and conduct recruitment (2.5 months) and participant follow-up (6 months). During the dissemination and next steps phase, we will prepare a grant application for the larger-scale RCT and prepare the study products noted above.

Table 1

	Year 1				Year 2	
	Quarter					
Activity	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2
Start-up, IRB, and hiring	X					
Social media ad development		X				
Study infrastructure setup		X	X			
Online recruitment			X			
Baseline & follow-up assessments				X	X	
Interview training			X			
Interview conduct				X		
Qualitative data analyses					X	X
Quantitative data analyses					X	X
Dissemination/Next steps						X

Measures. A timeline of measures is presented in **Table 2** and described further below.

Table 2: Summary of Study Measures

Timepoint(s)	Measure	Main Function	Aim(s)
0	Numbers screened, eligible, and enrolled per week; proportion eligible who enroll	Feasibility	1

PT, 1, 2, 3, 4, 5, 6	Retention rate; survey completion rate; exposure	Feasibility	1
PT	Completion of training; satisfaction; usability	Acceptability	2
0	Background characteristics	Descriptive data	1, 2
0, PT, 2, 4, 6	Intention to use of gatekeeper behaviors	Mechanisms of action	2
0, PT, 2, 4, 6	Knowledge; stigma; self-efficacy; social norms	Mechanisms of action	2
0, PT, 1, 2, 3, 4, 5, 6	Gatekeeper behaviors; suicidal ideation; help-seeking, social support	Measurement characteristics	2
1	Semi-structured interview about social media ads and PsychArmor S.A.V.E.	Feasibility and acceptability	1, 2

0=pre-training (baseline); PT=post-training (immediately after); 1=1-month follow-up, 2=2-month follow-up, etc.

Feasibility: We have selected feasibility measures most appropriate for a pilot intervention and previously used to assess online interventions.[55,56] These measures address each stage of the project including screening (number screened/eligible per week), recruitment (number enrolled per week), randomization (proportion of eligible who enroll), cross-contamination (number of control group participants who report taking PsychArmor S.A.V.E. training), retention (i.e., loss to follow-up), and assessment process (survey completion rates).

Acceptability: For acceptability, we will use a combination of three measures: completion of the training, satisfaction (measured using the validated eight-item Client Satisfaction Questionnaire (CSQ-8),[57] and the System Usability Scale (SUS) along with a single item usability rating that is highly correlated (r=0.82) with the SUS.[58,59]

Background Characteristics: This will include standard items on age, gender, race/ethnicity, education, marital status, zip code (rurality), occupation, military experiences, social media platform use, frequency of social contact with Veterans, social network size, and VA and other health service use.

Intentions to Use Gatekeeper Behaviors: Suicide prevention training research has shown that behavioral intention has a direct effect on actual behavior and also mediates the relationship between attitudes and actual behaviors.[60] Thus, we have chosen a three-item scale to assess behavioral intentions to use core skills learned in gatekeeper training (recognizing gatekeeper opportunities, inquiring about suicidal ideation, and making a professional referral). In research conducted by our research team and others, scales of intentions to use gatekeeper behaviors have shown adequate internal reliability.[14,60]

Knowledge: The 12-item short form of the Literacy of Suicide Scale (LOSS) measures knowledge about suicide. A total literacy score can be calculated as the percent of all correct items.[61]

Stigma: The 16-item short form of the Stigma of Suicide Scale (SOSS) measures public stigma towards individuals who die by suicide. It shows reliability and validity in community-based samples.[62]

Self-Efficacy: A four-item scale we have previously used to assess confidence to use gatekeeper skills. This scale has shown adequate internal reliability in our prior trial of gatekeeper training.[15]

Social Norms: A two-item scale we have previously used that assesses the degree to which one believes that most people do seek (descriptive norm) or should seek (injunctive norm) professional care if having suicidal thoughts. Items show adequate internal reliability.[14,48]

Gatekeeper Behaviors: Three items that assess actual self-reported frequency of: 1) recognizing gatekeeper opportunities ("In the last month, how many people have you encountered that you suspected were in an emotional crisis?"); 2) inquiring about suicidal ideation ("…how many times did you directly ask such a person if they were having suicidal thoughts?"); and 3) making a professional referral ("…how many times did you directly refer such a person to mental health or other professional treatment?"). Items are derived from outcome measures in prior gatekeeper training trials.[63]

Suicidal Ideation: The Depression Symptom Index Suicidality Subscale (DSI-SS) is a four-item measure of suicidal ideation over the past two weeks with strong psychometric properties.[64,65]

Help-Seeking: The Actual Help-Seeking Questionnaire (AHSQ) consists of four dichotomous items asking whether in the last month the respondent has sought help for a mental health problem.[66]

Social Support: The Patient-Reported Outcomes Measurement Information System (PROMIS) short form – Emotional Support 4a is a four-item measure of emotional support.[67]

Sample Size Considerations. We first consider whether our proposed sample size (n=200) is sufficient to meet our proposed benchmarks for the proportion of individuals who enroll in the study and loss to follow-up. For the primary analyses in Aim 1, we calculate CI's for a single proportion to determine whether the target benchmarks are within or beyond the CI's. Correspondingly, we used a confidence approach to determine whether our proposed sample size is sufficient to meet our proposed benchmarks.[68] **Hypothesis 1.2** is that at least 50% of eligible individuals will enroll in the study. Assuming that 357 people are eligible for the study, and 56% enroll (resulting in a sample size of 200 participants), this will give a 95% binomial exact confidence interval of 50.7% to 61.2%. The lower bound of this CI does not overlap with our threshold for an enrollment rate > 50%. For numbers as low as 300 people eligible for the study, a study enrollment rate of at least 56% would be adequate, and with 400 people eligible we would only need 55% to enroll. The **Hypothesis 1.3** benchmark for loss to follow-up at end of study is < 50%. Assuming that the study loss to follow-up rate is 42%, a sample size of 200 gives a 95% binomial exact confidence interval of 35.1% to 49.2%. The upper bound of this CI does not overlap with our 50% threshold for loss to follow-up. For a sample size as low as 150, we would also need a loss to follow-up rate of at most 40%, and with 250 we would need the rate to be at most 42%.

Aim 2's hypothesis is that participants will complete on average at least 70% of the PsychArmor S.A.V.E. training. Since this hypothesis is restricted to the treatment arm, our proposed sample size is 100. Assuming that the mean percentage of time spent on the training is 73% with a standard deviation (SD) of 15%, a sample size of 100 gives a 95% t-distribution confidence interval of 70.02% to 75.98%. The lower bound of this CI does not overlap with our minimum threshold of 70% completion of the training. For a sample size as low as 75, we would need a mean of at least 74% with SD = 15% and at least 76% with SD = 25%.

Randomization and Blinding. Block-randomization schemes using random block sizes to assign the two study arms will be created in R using the blockrand package (Version 1.3) before study start and pre-loaded into REDCap. Following recommendations for blinding in behavioral interventions, participants will be blinded by limiting details about the study hypotheses and differences between the study arms.[69] Blinding will also be achieved because no study personnel are involved in intervention delivery, and the biostatistician will be blinded for analyses involving study group comparisons.

Statistical Analyses. We will examine descriptive statistics and distributions for variables at each of their timepoints. Variables will be summarized both with the arms combined and stratified. Differences in baseline values between study arms will be tested using t-tests or chi-squared tests. For variables measured with multiple items, Cronbach's alpha will be conducted to examine internal reliability, and, when necessary, measurement modifications will be made to improve reliability. If missing data meet minimal missing data assumptions (i.e., at least missing at random), then multiple imputation or full maximum likelihood estimation can be used to improve standard errors compared with analyses based on listwise deletion.[77] All statistical analyses will be done in R.

Qualitative Interview Sample Considerations. A small subgroup of study participants (n = 15) who were assigned to the intervention group will be invited to participate in an interview to take place approximately one-month post-intervention. We will use maximum variation sampling, a purposive sampling strategy which increases depth of understanding by selecting a diverse group of individuals who are expected to communicate different perspectives.[70] Characteristics considered in sampling will be use of gatekeeper behaviors, transitioning Veteran vs. close support, rurality, and VHA service use.

Qualitative Data Collection. Research staff will set up a time to speak with the participant over an agreed upon and VA-approved remote video modality. This includes VA Video Connect, although in specified circumstances other video conferencing applications such as Apple Facetime, Facebook Messenger, Skype, Zoom, Cisco WebEx, or Google Hangouts may be used. Public facing applications will not be used. Participants will be informed that certain third-party video applications may introduce additional privacy risks. Research staff will use all available encryption and privacy modes.

Semi-structured qualitative interviews will be used with the goal of providing the qualitative component to mixed methods evaluations of the social media ad campaign and PsychArmor S.A.V.E. In the first section of the interview, questions will focus on feasibility and acceptability of the social media ad campaign. We will probe ad reactions/responses (e.g., "What went through your mind when you saw this Facebook ad?"), ad features (e.g., "Who do you think these messages should come from?"), and facilitators and barriers to recruitment via social media (e.g., "What can be done with these ads to motivate a person to learn how to help Veterans having a crisis?"). In the second section of the interview, questions will focus on PsychArmor S.A.V.E. This includes inquiry about its acceptability, usefulness, suggestions for improvement, potential modifications to the content (e.g., addition of booster sessions),[71] and facilitators and barriers to further implementation. A list of interview questions is included in **Appendix C**. Interviews will last approximately one hour and be audio recorded using a handheld VA audio recorder. Audio recordings may also be sent to the VHA Salt Lake City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services.

Qualitative Data Analysis: We will employ qualitative content analysis with a directed grounded theory approach.[71] We have chosen this approach because it will allow us to identify tacit and implicit content in transcripts and use our conceptual framework and theory to guide our initial codebook.[72] The investigative team (Drs. Teo, Karras-Pilato, and Cross) will review the first transcript, discuss general impressions and insights, and develop a preliminary codebook. Full coding of the transcripts will then begin with each transcript being double coded by team members with at least two years' experience analyzing qualitative data. We will use open coding to add relevant, unexpected, and emergent themes. Conceptual memos to track developing themes and parent/child nodes showing the interrelationship among codes will be created as necessary. Supervised by the investigative team, the coders will review areas of disagreement in coding, develop a consensus, and iteratively refine the codebook as needed. For data management we will use the software program Atlas.ti and use an audit trail to document creation and modification of codes.

Study Endpoints. The study will conclude with an assessment of feasibility and acceptability based on a mixed methods analysis of the quantitative (200 surveys, measures in **Table 2**) and qualitative data (15 interviews) collected. This will contribute towards the design of a larger RCT and may contribute to submission of journal articles for dissemination of findings.

Study Population

Eligibility Criteria. All potential participants will be identified through the targeted social media advertising campaign. After a potential participant clicks on an ad, they will complete a screening that will take place prior to consent. Half of the participants will be randomized to the intervention and half to the control condition. The eligibility criteria are presented in **Table 3** below. Through the targeted social media advertisement campaign, we will recruit recently transitioned veterans (active duty within past 12 months) who have at least weekly social contact with another veteran, and we will recruit friends or family of veterans who have at least weekly social contact with a veteran. Potential participants will be excluded for lacking necessary means of contact for follow-up, lacking fluency in English needed because the

intervention is delivered in English, having already been exposed to the intervention, or misrepresenting their Veteran status.

Table 3: Eligibility Criteria	
Inclusion Criteria	**Exclusion Criteria**
1a) Veteran who has served on active duty in the U.S. Armed Forces within the prior 12 months, or 1b) family member or friend of a Veteran	1) lack a U.S. phone number, email, or computer access 2) not fluent in English 3) have previously taken or intend to take PsychArmor S.A.V.E. training (to minimize contamination of the control group) 4) duplicate study entry or misrepresentation of Veteran status.[73]
2) social contact with a Veteran at least weekly	

Number of Participants. In order to obtain a final study sample of 200 participants (half randomized to the intervention and half to the control condition), we anticipate consenting and enrolling a higher number of participants as shown below:

Number of intervention group participants consented: 400
Number of participants enrolled (assumes 50% enroll): 200
Number of participants analyzed (assumes 50% lost to follow-up): 100

Number of control group participants consented: 400
Number of participants enrolled (assumes 50% enroll): 200
Number of participants analyzed (assumes 50% lost to follow-up): 100

Number of total participants consented: 800
Number of total participants enrolled (assumes 50% enroll): 400
Number of total participants analyzed (assumes 50% lost to follow-up): 200

Exclusion of Children. In addition to the above exclusion criteria, we will also exclude children under age 18 years. Children would not qualify as Veterans and would typically not be considered a close support to Veterans due to their young age. The primary focus of this study is looking at the outreach and uptake of online training in an adult population that can be difficult to reach though other means (for example, Veterans that don't use VHA services for their health care) and are at risk of depression and suicide. Although children can suffer from depression and suicide, the proposed methods of this study (an online platform) may not adequately address the sensitive nature of working with children under 18 that are at risk for suicide. Additionally, the military-focused gatekeeper training contained in this study has not been studied or tailored to a younger audience.

Inclusion of Women and Minorities. People of any gender, race, or ethnicity are invited to participate in our study. Based on the demographic characteristics of participants in a preliminary study in which we used similar recruitment strategies as will be employed in the current project, we anticipate a higher proportion of minority and women participants, compared to the national Veteran population. Our communication campaign messages and recruitment materials will be developed with readability and low literacy principles in mind. However, study materials will only be available in English, which may lead to an under-representation of some ethnic groups. The resources needed to adequately translate and validate study materials into other languages are outside of the scope of this developmental grant. We anticipate that we will have approximately the same proportion of minority participants in the study as there are in the populations they are drawn from. If we find that we are falling below recruitment targets for minority participants, we will make special efforts to increase minority recruitment, which is relatively easy to

accomplish through advertisement targeting features available through our recruitment modality (social media advertisements).

For our qualitative interviews, we anticipate that the proportion of minority participants in the study will be similar to the local environment surrounding the primary study site, Portland, Oregon. In the state of Oregon, 9% of Veterans are ethnic minorities and 8% are women. Demographic characteristics of Veterans' close supports is not well known. We anticipate that the proportion of minorities among close supports will match that among Veterans, while the proportion of women is expected to be significantly higher given that Veterans' spouses are usually of the opposite gender.

VA-SPECIFIC REQUIREMENT (inclusion of non-Veterans):

Inclusion of non-Veterans. PsychArmor S.A.V.E. is a gatekeeper training geared towards suicide prevention in a veteran population. The intended audience for this intervention includes not only Veterans but also their close supports, who may be non-Veteran friends or family members. To understand the effectiveness of this intervention, when delivered to non-Veteran close supports of Veterans, it will be necessary to include non-Veterans in the study.

Subject Identification/Recruitment

Recruitment via Social Media. We will recruit participants through a targeted social media advertisement campaign. We will use Facebook as our primary platform for recruitment; however, in consultation with our partners including the OHSU Strategic Communications social media team, we may include advertisements on other platforms for which they have extensive experience running campaigns (e.g., Instagram).

Following a procedure developed in our previous research,[36] we will set ads to be presented to Facebook users likely to fit our eligibility criteria. Examples of characteristics we will use include: age, military-related interests or behaviors (e.g., making a charitable donation to a Veteran service organization, listing the military as their industry or employer), and "liking" Facebook pages related to Veterans, suicide prevention, or related topics. Ads will be placed in users' "News Feeds" and optimized for computer and mobile devices. Ad performance will be monitored in real-time, allowing the potential to retain only the most cost-effective ads in the campaign. The research team will collaborate closely with the OHSU Strategic Communications Social Media team to host ads, and monitor, audit and report on interval progress. We will monitor recruitment progress on a weekly basis using a module in our data management software (OHSU instance of REDCap), which allows real-time monitoring of progress against targets.

Based on our preliminary work recruiting Iraq/Afghanistan-era veterans, budget for recruitment, and empirical data on the slower pace of recruitment for web-based intervention studies that include close supports as participants,[34,49] we estimate a 10-week recruitment period to meet our target enrollment of 200 participants (20 participants/week). We will monitor recruitment progress on a weekly basis using a module in our data management software (OHSU instance of REDCap), which allows real-time monitoring of progress against targets. If we do meet a minimum recruitment milestone of 50 participants in three weeks, the research team may consult with the Oregon Clinical and Translation Research Institute and OHSU's Strategic Communications social media team about adding recruitment strategies in accordance with NIH guidelines[52] and/or placing advertising on additional social media platforms.

After interested individuals click on an ad, they will be brought to a study website landing page. This website will be hosted and managed through OHSU REDCap, which allows study participants to access materials from any computer and stores data on a server at OHSU, separate, secure and independent of Facebook. Prior to consent, they will complete a brief screener to determine study eligibility (see Appendix B, submitted

for review). No identifying information will be collected as a part of the screener. If they are eligible, they will then complete an online informed consent process before being randomized into one of the two conditions.

Materials for Recruitment via Social Media. As Aim 1 of our study includes determining the feasibility of recruiting participants via social media advertisements, a part of the study will involve the development and evaluation of the social media advertisements we will use for recruitment. We are planning three months for the development of our social media ads as seen in the timeline presented in **Table 1** in the Research Design and Methods section. In **Appendix E** we have included a pool of potential text and images that we will use in creating our social media ads for recruitment.

Informed Consent & HIPAA Authorization

VAPORHCS-SPECIFIC REQUIREMENT (inclusion of those with impaired decision-making capacity):

☑ N/A. The study does not include those with impaired decision-making capacity

We will conduct an informed consent process electronically using OHSU's instance of REDCap. Potential participants who click on a social media-based study advertisement will be redirected to the study website where they will complete a brief screener. No identifying information until after participants complete study screening. If they are eligible to participate, they will be provided with a study information sheet explaining the purpose of the study, procedures, risks, benefits, and alternatives (**Appendix A**). If they wish to participate, the participant will then click on a box to indicate consent to the study. Documentation of electronic consent will be captured and stored in the secure REDCap database. No study procedures will occur prior to obtaining consent from the participants.

As both study recruitment and delivery of the intervention occurs online, conducting written informed consent would not be practical to achieve the study aims. In addition, sending and receiving a written informed consent document containing participants' names would add risk to study participation. Given the online nature of the study and that it involves no more than minimal risk to participants, we are submitting a request for waiver of informed consent documentation and waiver of authorization. This waiver or alteration will not adversely affect the rights and welfare of the participants as the study will yield only generalizable results and will not impact individual welfare.
For the qualitative interviews, before the interview begins, we will obtain and record a verbal consent for recording.

Risks and Side Effects:

Potential Risk. As the intervention in this study does not include direct contact with participants, this study is highly unlikely to involve risks to participants. Nonetheless, it will be the responsibility of the project manager to monitor the progress of individual participants and report any concerns to the PI during regular study meetings. Interviewers and anyone else who has contact with study participants during study activities have the responsibility to monitor for any potential safety issues and report any concerns to the PI. The balance of risk and benefit will be continuously monitored by the PI, and the study may be modified or terminated if risks begin to outweigh benefits.

Participation includes completion of an online training followed by intermittent longitudinal observations (surveys and, for a subgroup of participants, an interview). The risks associated with participation in this study are minimal. The primary risk is breach of confidentiality via inadvertent disclosure of personal health

information (PHI). For study activities involving direct contact with participants (qualitative interviews), the risk is also minimal due to the nature of the interaction. The primary risk is discomfort during the interview.

Participants may experience discomfort during interviews or surveys while discussing sensitive topics such as emotional problems, suicidal ideation, and training in suicide prevention skills. Numerous studies have established that inquiring about suicide does not induce suicidal ideation, whether in adults or adolescents, or in general or at-risk populations. On the contrary, research suggests that asking study participants about suicidal thoughts may in fact reduce suicidal ideation, and lead to improvements in mental health in treatment-seeking.

Protection Against Risk. Participant confidentiality will be maintained in accordance with HIPAA regulations. Numerous efforts will be made to minimize the likelihood of the risk of a breach of confidentiality. The project manager will conduct a review of study files every six months to assure compliance with approved procedures. The research team will work closely with the VAPORHCS Information Security Officer and Privacy Officer to ensure that any data transfer, storage, and handling by non-VA entities adhere to VA security policies.

The confidentiality of participants will be protected in the following ways:

- Unique identifiers will be assigned to all participants at the time of electronic consent and kept consistent for the duration of the study.
- Surveys, administrative data, and all other measures related to individual participants will contain the ID number instead of names or other PHI.
- A master list linking names and ID numbers will be stored in a password-protected electronic file, located behind the VA firewall on a secure server or in locked file cabinets, separate from other study data and accessible only to IRB-approved research personnel.
- With the exception of zip codes needed to assess rurality, all identifiable information will be removed from datasets prior to statistical analyses. We will analyze and report participant data in aggregate form only, and no PHI will be reported for any participant.
- Access to study data will be limited to IRB-approved study personnel and those with regulatory oversight responsibilities, and all study staff will complete the required research ethics, data security, and HIPAA training within the prior 12 months.
- Any hard copies of data will be stored in locked file cabinets in locked rooms.
- No study data will be stored on laptops unless they meet data security policies.
- The study data will be managed and stored in OHSU's instance of REDCap, a highly secure and robust web-based research and data collection and management system, and in a password and firewall protected network drive on the secure (Veterans Health Administration) VHA network accessible only to study staff.

Access to the REDCap database will be limited to IRB-approved study staff. REDCap is a secure, customizable, web-based application for building and managing HIPAA compliant databases. REDCap resides on a server housed in ITG's Advanced Computing Center (ACC), providing locked physical security. The servers are maintained by ITG Database Administrators and Systems Administrators in accordance with all relevant OHSU policies and guidelines. REDCap is hosted on ACC servers and maintained by developers in the Oregon Clinical and Translational Research Institute (OCTRI) in accordance with all relevant OHSU policies and guidelines. Additionally, ACC employs a second firewall within the OHSU network to attain a high level of security and access control. All web-based data transmissions are encrypted with industry-standard SSL methods. The ACC's architecture has been reviewed by the OHSU Office of Integrity and undergoes periodic internal security audits.

REDCap employs a robust multi-level security system that enables researchers to easily implement "minimum necessary" data access for their research staff, including specification of data fields that are identifiers. This feature includes “single click” ability to provide completely deidentified (removing all identified data fields and shifting dates) for analysis or other purposes. User activities are logged to enable auditing of all data access. Access is integrated with OHSU's network such that users who are also OHSU employees are authenticated against their OHSU network credentials.

REDCap is jointly managed in accordance with OHSU Information Security Directives by ACC staff and members of OCTRI's Biomedical Informatics Program, ensuring fidelity of database configuration and back-ups. User activities are logged to enable auditing of all data changes.

With the exception of ZIP Codes needed to assess rurality, all other identifiers will be removed from the dataset prior to export from REDCap. Data containing the ZIP Code identifiers may be stored on OHSU Box (OHSU.box.com), an institution supported, cloud-based file sharing and storage option with added protections in place for OHSU confidential and restricted data or protected health information. Box.com adheres to the highest industry standards for security and is compliant with HIPAA requirements as well as federal government agency requirements such as the Department of Defense. All files uploaded to Box are encrypted at rest using 256-bit AES encryption, and further protected by an encryption key-wrapping strategy. The company also offers customer-managed encryption keys. Box provides you with in-depth, unchangeable audit logs, user permission options and restrictions, and organization-wide controls and permissions. OHSU and Box have entered into a Business Associate Agreement, including a data use agreement, that meets all OHSU privacy, confidentiality, and information technology policy compliance requirements. This includes requirements for software applications to use specific login IDs, passwords, OHSU-approved encryption, audit software, and reporting requirements to privacy officers when becoming aware of any users not in compliance.

Communications with participants will include invitations and reminders for follow-up surveys, reminders and notifications about incentive payments, and for a subset of participants, invitations to participate in an interview and the interview itself (**Appendix D**). Study invitations and reminders will be sent by email or SMS text message to study participants. For these communications, we will take special precautions to preserve privacy, confidentiality, and data security. These communications will not contain PII/PHI. Any email communication that does contain PII/PHI will be encrypted and sent via Azure Rights Management Services (RMS).

For the qualitative interviews, individual interviews will be digitally audio-recorded using a handheld VA audio recorder. After the interviews, digital recordings will be uploaded on a password secured server behind the VA firewall. Recordings will then be deleted from the audio recorder. Audio recordings will not be destroyed since they will contain the verbal consent for the recorded interviews. Filenames of digital recordings will not include participant names; only a unique study ID number will be listed in filenames. Transcriptions will be de-identified during the transcription process by personnel who have training and experience in transcription. Audio recordings may be sent to the VHA Salt Lake City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services. Only study personnel will have access to de-identified transcripts. Any hardcopies made of transcripts will be kept in locked files in investigators’ offices. We will ensure that any quotations used in manuscripts or reports do not contain identifying information. Upon completion of the study, all audio files and documents containing participants’ names and other identifying information will be destroyed.

Additional Participant Safeguards:

☑ N/A. The study does not include vulnerable populations and/or those with impaired decision-making capacity.

VAPORHCS-SPECIFIC REQUIREMENT (inclusion of those with impaired decision-making capacity):

☑ N/A. The study does not include those with impaired decision-making capacity

Suicidality*:*

We expect some participants to indicate symptoms of active suicidal ideation on our self-report survey instrument that assesses for suicidal ideation, the Depressive Symptom Inventory – Suicidal Subscale (DSI-SS). Due to the online format of this study, it is not feasible for the PI or research staff to locate and respond in "real-time" to positive responses to survey items related to suicidality, or provide individualized follow-up if concerns are raised by survey responses. Suicidal ideation and suicide risk are by their very nature, fluid.

Because of this, we have opted to provide resources at multiple time points in the study, including the time of consent, and any time in which we would become aware of a subject's positive suicide screen, i.e., when the person is completing the survey instrument (**Appendix B**). Providing resources at that time, rather than conducting risk assessment hours if not days later, is preferable in the context of the current study design. Resources will include information on online, phone, and text messaging-based mental health treatment resources. They will include options for crisis situations, non-urgent treatment referral, and—as we will not be fully aware of the location of respondents—ways to locate local support and treatment resources. Our study team will not provide therapy to directly treat depression or other mental health symptoms for participants who experience distress over the course of the study. We are not limiting participants' engagement with mental health providers in any way.

If a participant indicates they are suicidal during an interview, a warm transfer will be initiated. The interviewer will ascertain that the participant will be available by phone while calling the warm transfer number for the VA National Suicide Hotline (503-393-7938). They will provide the participant's name and telephone number to the VA National Suicide Prevention Hotline.

Benefits:

Potential benefits to the individual include the possible acquisition of gatekeeper training skills in suicide prevention for those in the intervention condition. All individuals will also receive information on mental health resources.

This study includes two key potentially important impacts to knowledge of suicide prevention in Veterans. The first impact is the feasibility of the use of social media to provide outreach to Veterans, particularly those who are not VHA connected, and their family and friends. The second impact is the knowledge on the feasibility and acceptability of online training that provides the trainee with the skills to help individuals at risk of suicide. We believe that the knowledge to be gained and the potential benefits from the proposed study outweigh the associated risks.

Protected Health Information:

In terms of the identifiers included, these are the minimum necessary in order to maintain contact with consented research participants during the course of the study; identifiers will be exported and removed from REDCap once study activities are complete Contact information including names, phone numbers, and email addresses is necessary to send them follow-up survey invitations, reminders, and information about the study. We will also collect zip codes as a variable of interest reflecting rurality. Because participation is remote, we may need additional identifying information to be able to provide payment for participation. Depending on the mode of payment preferred by the participant, we may additionally need to collect mailing addresses, social security numbers, and/or banking account information in order to provide payment. This information will not be recorded as part of the study record or stored with any health information. Participants will be informed of the risk of providing this information and that it would be optional but that we may not be able to pay them without it.

Health information collected directly corresponds to our research aims. As this study is related to suicide risk, suicide prevention, and seeking help for mental health issues, data collected from participants may relate to these topics (see **Appendix B** for survey measures and **Appendix C** for the interview guide).

Collaborative Research

All research work will be conducted at VAPORHCS by VA staff on VA time using VA equipment, with the following exceptions related to data collection software and collaborators located outside VAPORHCS.

- **OHSU's instance of REDCap**, housed on secure servers at OHSU, will be used to collect data, store data, and communicate with participants for follow-up. While we will consult with the Oregon Clinical and Translational Research Institute (OCTRI) for assistance in building the survey in REDCap, all recruitment, data collection, and communication done through REDCap will be accessed by VA staff on VA time using VA equipment. OHSU will have ownership of research data for this research study.
- **Wendi Cross, PhD, Co-Investigator.** Dr. Cross is the Director of Clinical Psychology Training and a Researcher at the VA's VISN 2 Center of Excellence for Suicide Prevention. She will attend research team meetings, provide input and oversight on evaluation of PsychArmor S.A.V.E. in our randomized pilot study, and participate in manuscript-writing and other dissemination activities. She will be paid as an IPA.
- **Elizabeth Karras-Pilato, PhD, Co-Investigator**. Dr. Karras-Pilato is the Co-Director for Research with the Center of Excellence for Suicide Prevention at the Canandaigua VA Medical Center. She will travel to Portland, OR for a workshop to develop messages for the social media ad campaign (or do so remotely if travel is not feasible). She will also attend research team meetings, provide input and oversight on development of messages for use in the social media advertisement campaign, and participate in manuscript-writing and other dissemination activities. Effort is limited to Year 1 when the social media ad campaign will occur.
- **Carie Rodgers, PhD, Consultant.** Dr. Rodgers is the Education Director at the PsychArmor Institute and is a Clinical Professor of Psychiatry at the University of California San Diego School of Medicine. She will act as liaison between PsychArmor Institute and the primary VA site. She will be involved with and provide consultation for the development of a reusable web-based interface and clone of PsychArmor S.A.V.E. for use in this project. She will provide consultations for the project without compensation.
- **Stephanie Gamble, PhD, Consultant.** Dr. Gamble is the Deputy Director for the Center of Excellence for Suicide Prevention at the Canandaigua VA Medical Center and an Associate Professor in the Department of Psychiatry at the University of Rochester Medical Center. She will

provide input regarding the development, preparation, and evaluations of the trainings used in the intervention and control arms.

VA Canandaigua will be notified of the research through the JIT process since they will receive funding. The PI will notify the local directors of other sites if engagement of their site is no longer required.

Resources Available
VA-SPECIFIC REQUIREMENT:

The study will take place at the VA Portland Health Care System (VAPORHCS) in Portland, Oregon. OHSU will be the coordinating center for the study. The VAPORHCS HSR&D Center of Innovation is the Center to Improve Veteran Involvement in Care (CIVIC) is where the science of this research study will take place, in collaboration with other CIVIC investigators, staff, and the CIVIC Veteran Engagement Group.

Most project personnel will be located at the Center to Improve Veteran Involvement in Care (CIVIC). CIVIC will provide office space, equipment, and administrative research support to project staff. Dr. Teo and his research staff retain private office space in CIVIC. CIVIC has approximately 4,500 square feet of office space, which includes the second and third floors of VAPORHCS Building 6. This contiguous space allows extraordinary opportunities for collaboration and synergy. All necessary equipment including computers, printers, copiers, and scanners are available to the research team. Dr. Teo will devote 2/8 time to this study, and his study coordinator will be devoting 8/8 time to this study.

Subject Compensation/Payment:

Participants will receive compensation because they are taking time out of their day to complete the surveys, intervention training, and interviews. All participants who complete their follow-up surveys will receive compensation valued at $20 and an additional $20 at the completion of the study. The subset of 15 participants who complete an interview will also receive compensation valued at $25 as a thank you for their time. Participants may be paid according to their preferences via cash (in the case of any local participants of interviews who may choose to come in), Electronic Funds Transfer, mailed check, ClinCard, gift card, or other allowable VA payment method suitable for paying participants remotely. These compensation terms are included in the information sheet provided during consent. Additional identifiers may be collected for payment purposes; depending on payment method, identifiers may be stored in REDCap, VA server only accessible to the study team, or on a secure payment site (such as ClinCard).

The compensation offered is a fair amount for the time and effort involved for each section of study participation. It is enough to encourage completion and is not so large as to constitute undue pressure or influence. Compensation will not be prorated for participants who do not complete the study because the cost is low and our sample large, thus making prorated payments difficult to manage for a pilot project.

Privacy and Confidentiality:

Privacy and confidentiality will be maintained in accordance with HIPAA regulations. Numerous efforts will be made to minimize the likelihood of the risk of a breach of confidentiality. The project manager will conduct a review of study files every six months to assure compliance with approved procedures. The research team will work closely with the VAPORHCS Information Security Officer and Privacy Officer to ensure that any data transfer, storage, and handling by non-VA entities adhere to VA security policies.

The confidentiality of participants will be protected in the following ways:

- Unique identifiers will be assigned to all participants at the time of electronic consent and kept consistent for the duration of the study.
- Surveys, administrative data, and all other measures related to individual participants will contain the ID number instead of names or other PHI.
- A master list linking names and ID numbers will be stored in a password-protected electronic file, located behind the VA firewall on a secure server or in locked file cabinets, separate from other study data and accessible only to IRB-approved research personnel.
- With the exception of zip codes needed to assess rurality, all identifiable information will be removed from datasets prior to statistical analyses. We will analyze and report participant data in aggregate form only, and no PHI will be reported for any participant.
- Access to study data will be limited to IRB-approved study personnel and those with regulatory oversight responsibilities, and all study staff will complete the required research ethics, data security, and HIPAA training within the prior 12 months.
- Any hard copies of data will be stored in locked file cabinets in locked rooms.
- No study data will be stored on laptops unless they meet data security policies.
- The study data will be managed and stored in OHSU's instance of REDCap, a highly secure and robust web-based research and data collection and management system, and in a password and firewall protected network drive on the secure (Veterans Health Administration) VHA network accessible only to study staff.
- Access to the REDCap database will be limited to IRB-approved study staff. See Protection of Risk subsection of Risk and Side Effects section for a description of REDCap's security features.

With the exception of ZIP Codes needed to assess rurality, all other identifiers will be removed from the dataset prior to export from REDCap. Data containing the ZIP Code identifiers may be stored on OHSU Box, an institution supported, cloud-based file sharing and storage option with added protections in place for OHSU confidential and restricted data or protected health information. Box.com adheres to the highest industry standards for security and is compliant with HIPAA requirements as well as federal government agency requirements such as the Department of Defense. All files uploaded to Box are encrypted at rest using 256-bit AES encryption, and further protected by an encryption key-wrapping strategy. The company also offers customer-managed encryption keys. Box provides you with in-depth, unchangeable audit logs, user permission options and restrictions, and organization-wide controls and permissions. OHSU and Box have entered into a Business Associate Agreement, including a data use agreement, that meets all OHSU privacy, confidentiality, and information technology policy compliance requirements. This includes requirements for software applications to use specific login IDs, passwords, OHSU-approved encryption, audit software, and reporting requirements to privacy officers when becoming aware of any users not in compliance. Only study personnel with VAPORHCS appointments will work with identifiable data.

Any transfer of data containing identifiable information between the VA network and Box.com will utilize encrypted email or encrypted flash drives.

For communication with participants, we will take special precautions to preserve privacy, confidentiality, and data security. Personal email accounts will not be used for research communications with participants. These communications will not contain PII/PHI. Any email communication that does contain PII/PHI will be encrypted and sent via Azure Rights Management Services (RMS).

For the qualitative interviews, individual interviews will be digitally audio-recorded using a handheld VA audio recorder. After the interviews, digital recordings will be uploaded on a password secured server behind the VA firewall. Recordings will then be deleted from the audio recorder. Audio recordings will not be destroyed since they will contain the verbal consent for the recorded interviews. Filenames of digital recordings will not include participant names; only a unique study ID number will be listed in filenames.

Transcriptions will be de-identified during the transcription process by personnel who have training and experience in transcription. Audio recordings may be sent to the VHA Salt Lake City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services. Only study personnel will have access to de-identified transcripts. Any hardcopies made of transcripts will be kept in locked files in investigators' offices. We will ensure that any quotations used in manuscripts or reports do not contain identifying information. Upon completion of the study, all audio files and documents containing participants' names and other identifying information will be destroyed.

Certificate of Confidentiality

☑ N/A. The study does not include a Certificate of Confidentiality.

Information and/or Specimen Management

Unique identifiers will be assigned to all participants at the time of electronic consent and kept consistent for the duration of the study. Surveys, administrative data, and all other measures related to individual participants will contain the ID number instead of names or other PHI. A master list linking names and ID numbers will be stored in a password-protected electronic file, located behind the VA firewall on a secure server or in locked file cabinets, separate from other study data and accessible only to IRB-approved research personnel.

Survey data will be captured and stored in REDCap, which employs a robust multi-level security system that enables researchers to easily implement "minimum necessary" data access for their research staff, including specification of data fields that are identifiers. This feature includes a "single click" ability to provide completely deidentified (removing all identified data fields and shifting dates) for analysis or other purposes. All HIPAA identifiers contained in our dataset except for ZIP Code, used to assess rurality, will be removed prior to data analysis. Other identifiable information that was collected, such as names and email addresses will only be accessed, separate from any health data, to send out invitations and reminders for follow-up surveys and interviews.

For the qualitative interviews, individual interviews will be digitally audio-recorded using a handheld VA audio recorder. After the interviews, digital recordings will be uploaded on a password secured server behind the VA firewall. Recordings will then be deleted from the audio recorder. Audio recordings will not be destroyed since they will contain the verbal consent for the recorded interviews. Filenames of digital recordings will not include participant names; only a unique study ID number will be listed in filenames. Transcriptions will be de-identified during the transcription process by personnel who have training and experience in transcription. Audio recordings may be sent to the VHA Salt Lake City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services. Only study personnel will have access to de-identified transcripts. Any hardcopies made of transcripts will be kept in locked files in investigators' offices. We will ensure that any quotations used in manuscripts or reports do not contain identifying information. Upon completion of the study, all audio files and documents containing participants' names and other identifying information will be destroyed.

All information linking study data to PHI will be kept within VAPORHCS electronically in secure computer files stored behind firewalls requiring password access, or in hardcopy form in locked file cabinets in locked offices. Except for ZIP Codes, all patient identifiers will be removed prior to analysis. All investigators and team members who will have access to the data will have received appropriate background checks as part of hiring and/or credentialing, and will have completed Data Security Training within the prior 12 months.

Disclosure/Sharing:

☑ N/A. The study does not include disclosure/sharing outside the IRB-approved VAPORHCS study personnel.

Transfer of Data Ownership

☑ OHSU will have ownership of research data for this research study.

Web Application(s), Mobile Device(s) and/or Mobile Application(s):

Facebook ads will be used for study recruitment. On Facebook advertising, all consumer data is automatically “hashed,” meaning their unique identifiers are stripped before we (the advertisers) gain access to the information. The only info we see is basic demographics, geographic info and performance data.

After interested individuals click on an ad, they will be brought to a study website landing page. This website will be hosted and managed through OHSU’s instance of REDCap,[74] a highly secure, web-based application that allows study participants to access materials from any computer and stores data on a server at OHSU, separate, secure and independent of Facebook. Eligibility questions, consent, questionnaires, and presentation of intervention will all be done through REDCap.

REDCap employs a robust multi-level security system that enables researchers to easily implement "minimum necessary" data access for their research staff, including specification of data fields that are identifiers. User activities are logged to enable auditing of all data access. Access is integrated with OHSU's network such that users who are also OHSU employees are authenticated against their OHSU network credentials.

For communication with participants, we will take special precautions to preserve privacy, confidentiality, and data security. Personal email accounts will not be used for research communications with participants. VA email, email generated through OHSU REDCap, and SMS text messages sent through REDCap may be used to provide reminders about survey completion or related general communication about the study. REDCap uses a third party web service, Twilio Inc., to send automated SMS text messages. No PII/PHI besides the participant’s phone number will be shared with Twilio and participants will be informed in the information sheet that their phone number may be shared with Twilio for this purpose. These communications will not contain PII/PHI. Any email communication that does contain PII/PHI will be encrypted and sent via Azure Rights Management Services (RMS).

Some data containing PHI may be stored on OHSU Box, an institution supported, cloud-based file sharing and storage option with added protections in place for OHSU confidential and restricted data or protected health information. Box.com adheres to the highest industry standards for security and is compliant with HIPAA requirements as well as federal government agency requirements such as the Department of Defense. All files uploaded to Box are encrypted at rest using 256-bit AES encryption, and further protected by an encryption key-wrapping strategy. The company also offers customer-managed encryption keys. Box provides you with in-depth, unchangeable audit logs, user permission options and restrictions, and organization-wide controls and permissions. OHSU and Box have entered into a Business Associate Agreement, including a data use agreement, that meets all OHSU privacy, confidentiality, and information technology policy compliance requirements. This includes requirements for software applications to use

specific login IDs, passwords, OHSU-approved encryption, audit software, and reporting requirements to privacy officers when becoming aware of any users not in compliance.

For the qualitative interviews with the subset of 15 participants, research staff will set up a time to speak with the participant over an agreed upon and VA-approved remote video modality (i.e. VA Video Connect, although in specified circumstances other video conferencing applications such as Apple Facetime, Facebook Messenger, Skype, Zoom, Cisco WebEx, or Google Hangouts may be used. Public facing applications will not be used). Participants will be informed that certain third-party video applications may introduce additional privacy risks. Research staff will use all available encryption and privacy modes.

Data and Safety Monitoring Plan (DSMP)

This study does not involve pharmaceuticals or medical devices. Data collection relies on self-report online surveys and interviews; no invasive testing or procedures are involved, and the intervention involves no direct contact with participants. The risks related to participation are likely much lower than those of a trial involving pharmaceuticals, medical devices, or somatic interventions or procedures. Nonetheless, we will very carefully monitor the progress of the study and any potential risks or adverse events.

Because the primary risk is a breach in confidentiality, no statistical analysis of safety data is planned. The study coordinator will monitor for breaches in confidentiality and problems will be addressed and reported according to regulations. Other safety information collected will include self-report information participants may tell us while filling out online surveys or, for a subset of 15 participants, through interviews. This data will be collected at the time of participation when participants enroll in the study and once a month for six months of follow-up surveys. The interviews will occur approximately one month post-intervention. PI Dr. Teo holds weekly meetings with his study personnel where they will discuss adverse events and protocol deviations associated with this project and ways to reduce repeat occurrences. Research staff will examine all cumulative adverse events quarterly to determine if there are any systematic problems and to implement protocol corrections as needed after receiving IRB approval.

Monitoring for any potential adverse events and protocol deviations will be performed by research staff that oversees data collection activities, including the interviewers or anyone else who has contact with study participants during study activities. Dr. Teo will be responsible for ensuring the absence of conflicts of interest within the research staff and training them in the responsible conduct of research and reporting adverse events. Any adverse event will be reported immediately to PI Dr. Teo, who will contact the participant and determine if additional intervention is needed to ensure participant safety. Protocol deviations will also be immediately reported to Dr. Teo who will ensure that adverse events deemed to be unanticipated problems and protocol deviations are properly reported to the IRB in a timely manner. Detailed written documentation will be kept for all adverse events that occur over the course of the study. The balance of risk to benefit will be continuously monitored by the PI, and the study may be modified or terminated if risks begin to outweigh benefits.

Our data and safety monitoring plan includes adverse event (AE) and serious adverse event (SAE) monitoring by all staff working on the project. AEs will be identified by spontaneous reports to any study staff member, and all staff will be trained to be receptive to participant complaints and concerns about the study. Any breach of confidentiality will be considered an AE.

We will classify an AE as:
0 - No AE

1 - Mild - no treatment needed
2 - Moderate - resolved with treatment
3 - Severe - inability to carry on normal activities, required professional medical attention
4 - Life-threatening or disabling
5 - Fatal

The PI will review all adverse events to determine if they meet the definition of an Unanticipated Problem (UP). All Unanticipated Problems, including AEs that meet the definition of a UP as determined by Dr. Teo, including breaches of confidentiality and participant complaints, will be reported to the IRB as soon as possible and within the following time frames:

- Deaths and potentially life-threatening events within 7 days of the PI learning of the event days.
- All other unanticipated problems will be reported within 15 days of the PI learning of the event.

If any AEs or UPs require a change to the protocol or consent form (as determined by the PI or IRB) the PI will submit the revised protocol for review and approval by the Joint IRB promptly. A brief summary of UPs and all adverse events will be submitted to the IRB at the time of annual continuing review. Adverse events, enrollment, and data collection problems will be reviewed quarterly by the PI. In addition, dropouts and AEs will be reviewed for patterns indicating problems with the study procedures. Any protocol deviation identified during the quarterly reviews will be reported per IRB policy.

Step-by-Step Guidance on Conducting the Study

1. Project Setup
   - 1.1. Social media campaign (**Appendix E**) development
     - 1.1.1. Dr. Karras-Pilato to deliver workshop to develop messages for ad campaign
     - 1.1.2. Consultation with OHSU Strategic Communications social media team and a Veteran engagement representative
     - 1.1.3. Submit finalized social media ads to IRB for approval
   - 1.2. REDCap setup
     - 1.2.1. Build survey (**Appendix B**) in REDCap with consultation from Oregon Clinical and Translational Research Institute (OCTRI)
     - 1.2.2. Submit any substantive changes to survey to IRB for approval (if applicable)
2. Recruitment
   - 2.1. Implement social media ad campaign on Facebook
     - 2.1.1. Monitor recruitment pacing through REDCap
   - 2.2. Interested participants click on a link to connect to the study website on OHSU's REDCap
   - 2.3. Interested participants complete electronic eligibility screening
   - 2.4. Eligible participants will be directed to an information sheet (**Appendix A**) for electronic informed consent
   - 2.5. Consented participants provide contact information (name, phone number, email address) needed for follow-up (if participants choose to withdraw, they will be given the option to stop receiving communications of any format from the study team).
   - 2.6. Participants will be randomly assigned to either the intervention or control group trainings
3. Intervention
   - 3.1. Participants will complete the baseline survey (see table 2, reproduced below, for included measures)
   - 3.2. Participants will view either intervention gatekeeper training or control "sham" training
     - 3.2.1. Data collected on training completion rates

3.3. Participants will immediately complete a follow-up survey (see table 2 for included measures)
4. Longitudinal survey follow-up
   4.1. Participants will receive a communication (**Appendix D**) via email and or SMS text messages automated through REDCap from the study team 1-2 weeks prior to the time points indicated in table 2 to complete the survey responses noted
   4.2. Participants will have the option for compensation to be sent to them via an approved VA modality at the conclusion of all surveys
5. Qualitative interviews
   5.1. Study staff will use maximum variation sampling to select a subset of participants to invite for qualitative interview
   5.2. Research staff will set up a time to speak with the participant either in person at VAPORHCS, or over an agreed upon and VA-approved remote video modality (i.e. VA Video Connect, although in specified circumstances other video conferencing applications such as Apple Facetime, Facebook Messenger, Skype, Zoom, Cisco WebEx, or Google Hangouts may be used. Public facing applications will not be used).
      5.2.1. Participants will be informed that certain third-party video applications may introduce additional privacy risks.
      5.2.2. Research staff will use all available encryption and privacy modes.
   5.3. Informed consent from interview participants will be collected verbally and will be audio recorded
   5.4. Interviews will be audio recorded and will last between 45-60 minutes using the interview guide (**Appendix C)**
   5.5. Participants interviewed in-person will receive compensation at the conclusion of the interview at the hospital agent cashier.
   5.6. Participants interviewed remotely will receive compensation at the conclusion of the interview via an approved VA modality.
6. Data analysis
   6.1. Conduct quantitative data analysis of survey data to examine descriptive statistics and distributions for variables at each of their timepoints.
   6.2. Conduct qualitative content analysis with a directed grounded theory approach with interview data.
7. Dissemination Activities
   7.1. Review quantitative and qualitative analysis and develop publications
   7.2. Review data and use to develop future larger RCT

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Appendix – Supporting Documents List

Appendix A: Information Sheet
Appendix B: Survey
Appendix C: Interview Guide

Appendix D: Communications with participants
Appendix E: Recruitment materials