Feasibility and Acceptability of Mobile Mantram Repetition Program for Veterans With PTSD (IVI 22-115)

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SPECIFIC AIMS

Easily accessible interventions to address post-traumatic stress disorder (PTSD) can play critical role in reducing PTSD and associated symptoms in Veterans, especially for those who remain symptomatic after treatment with other evidence-based interventions, those who prefer complimentary and integrative therapies, or those who have difficulty accessing traditional face-to-face mental health services. The value of these programs is their ability to provide Veterans with more options in their recovery journey and to reach a broad range of Veterans across multiple settings, including remote rural contexts.

The Mantram Repetition Program (MRP) is a meditation-based practice that consists of the repetition of a spiritual word, one-pointed attention, and slowing down. MRP has been shown to reduce stress in several high-risk populations, and two large randomized, controlled studies show that MRP reduces PTSD symptoms among Veterans. A brief, web-based, self-directed version of MRP has been developed to increase the accessibility of evidence-based PTSD treatment. This version of MRP was tested in a pilot study with undergraduate students, demonstrating its ease of use and success in getting students to engage with the practice. The proposed mixed method study will use the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework to evaluate the mobile MRP in Veterans with PTSD in two conditions: self-directed and with text/phone support. Data from this pilot study will inform the refinement of the MRP delivery strategy and the development of a full-scale trial to test its effectiveness and implementation outcomes, as well as barriers and facilitators, and other contextual factors.

Aim 1. To assess the reach and implementation of the mobile Mantram Repetition Program using a mixed methods approach focusing on feasibility, acceptability, appropriateness, and facilitators of and barriers to program implementation.

Aim 2. To compare Veterans who are self-directed users of mobile MRP versus Veterans who receive text and phone support in terms of engagement with the intervention and change in PTSD and associated symptoms.

BACKGROUND AND SIGNIFICANCE

Posttraumatic stress disorder (PTSD) is common among US military Veterans (Gradus, 2007). Untreated, PTSD is chronic and highly impairing (Santiago et al., 2013) thus it is a high priority for the VA. Current evidence-based treatments can be highly effective; nonetheless, many Veterans remain symptomatic even after successful treatment (Steenkamp et al., 2020). Further, many Veterans express a preference for alternative approaches or complements to other treatment strategies (Whitehead & Kligler, 2020). Consistent with the Hannon Act, both meditation and spiritually-based approaches are potentially important avenues for restoring Whole Health for Veterans.

The Mantram Repetition Program (MRP) is a meditation-based approach that involves silent repetition of a spiritual word in combination with development of one-pointed attention and slowing down (Bormann et al., 2014). The MRP is a transdiagnostic intervention, with documented positive effects on a range of outcomes, including improved stress management among healthcare workers (e.g., Leary et al, 2018) and caregivers (e.g., Bormann et al., 2009) and better coping among individuals with HIV (e.g., Bormann et al., 2006). Importantly, **two large randomized controlled trials with Veterans have demonstrated that MRP was associated with large effect size reduction symptoms of PTSD** as well as increased spiritual well-being and reduced insomnia (Bormann et al., 2012, 2018). The MRP can be taught in person or remotely, including by use of pre-recorded videos or by clinicians, paraprofessional or lay people. For example, the MRP was recently applied to increase patient-centered care and decrease burnout in nurses via internet-based learning (Kostovich et al., 2021). Recent work in our lab demonstrated that MRP can be taught in a self-directed manner through a series of brief videos delivered via Qualtrics. This brief, self-guided, web-based version of MRP was implemented with an undergraduate student sample and showed good retention in the program (88% completed the full intervention and 87% completed the follow-up assessment). Mantram repetition was regularly utilized by 80% of the group, and 96% endorsed applying the concept of slowing down. On average, participants were practicing 4-5 days/week (Vannini, et al, 2021). These initial data on the feasibility and acceptability of this MRP implementation strategy show promise for use in Veterans, given the demand for a wide range of easily-accessible and complementary and integrative treatment options.

eScreening is a web-based, patient-facing screening and information-provision system developed with Veteran and staff feedback that allows for the rapid capture of self-report data and has been shown to improve the quality of documentation and access to care (Pittman et al., 2019). Across multiple VHA facilities, eScreening has been utilized over 34,000 times with Veterans in Transition Care Management, primary care, and mental health settings; eScreening supports both screening and measurement-based deployment of evidence-based psychotherapy. In 2016, the eScreening program was named a Gold Standard Practice for diffusion throughout VHA by the Under-Secretary for Health (Elnahal et al., 2017). eScreening is available nationwide and is a promising platform for the delivery of MRP to Veterans.

The goals of this study are to (1) better understand mobile MRP by measuring reach, feasibility, acceptability, appropriateness, barriers and facilitators; and (2) compare effectiveness (i.e., mantram use, PTSD and associated symptoms) of self-directed MRP (i.e., used without support from a facilitator) to supported MRP (i.e., text/phone support provided by a facilitator) in Veterans with PTSD using the existing VA eScreening platform for delivery of the program.

This project is responsive to several HSR&D priorities. If successful, this program would enhance access to care, thereby increasing health equity through the utilization of virtual care. This project also targets PTSD and associated symptoms, including insomnia, important mental health issues prioritized by HSR&D. This project features meditation, which is of interest to an increasing number of Veterans and a potential component of the Whole Health approach, whereby Veterans may focus on overall wellness, including spirituality. Finally, this study uses eScreening, an electronic, self-report screening system, developed by our research group for data collection and access to the intervention videos. Consistent with the aims of the SWIFT-IVI program, we will pilot an implementation strategy in preparation for a future fully-powered implementation trial with the aim of rapidly deploying the MRP into routine practice.

METHODS

Study Design

This study is a prospective, randomized trial assessing implementation and effectiveness outcomes of a brief, self-directed, web-based meditation training. We will employ a mixed-method convergent approach to collect and analyze data to inform future implementation of the MRP (Palinkas et al., 2019).

Participants

Participants will be 40 Veterans with PTSD residing in San Diego County, CA. These individuals will be recruited from VA clinics (self- and provider-referral) and through community outreach (e.g., advertisements). Eligibility is intentionally broad to approximate future real-world users of MRP.

Inclusion: Veteran, 18 or older, primary clinical complaint of PTSD, ability to access internet-enabled smart phone, tablet, or computer.

Exclusion: Cognitive impairment or mental health concerns that necessitate a higher level of care or interfere with the ability to consent or engage in study activities (serious mental illness, untreated alcohol or substance use disorder, serious suicidality or homicidality, marked cognitive impairment).

Interventions

MRP consists of four online training modules that were developed for a Veteran audience by Dr. Jill Bormann, the developer of the intervention. They cover the basic intervention components: choosing a mantram, slowing down, attentional control and habit formation. These videos were created in conjunction with PsychArmor, Inc., a non-profit organization that provides training to multiple sectors who support Veterans and are available via internet (refer to Letter of Support from Dr. Carie Rodgers). In the **self-directed condition**, enrolled Veterans will not be contacted unless they reach out using contact information in the weekly module. In the **supported condition**, Veterans will receive a daily text reminder to practice their mantram (e.g., "Did you find a moment to practice your mantram today? Please respond YES, NO or HELP if you would like to talk to one of our staff."). Those who answer in the affirmative will receive praise and an offer of support (e.g., "Great job! A regular practice happens one day at a time!"). Those who answer in the negative will receive brief encouragement and an offer of assistance (e.g., "You can repeat your mantram at any spare moment. Would you like to speak with a trainer about working it into your day?"). A request for help will be followed by a personal text and call by study staff.

Procedures

Following provision of written informed consent and HIPAA authorization using a telehealth-based informed consent process, Veterans will confirm access to a study-compatible device (Internet-enabled smart phone, tablet or computer) and be administered a semi-structured interview (MINI) and brief cognitive screen (blind MoCA) via telephone by a trained Research Assistant (RA) to confirm eligibility. If deemed eligible, the Veteran will be randomly assigned to one of two conditions: self-directed MRP or supported MRP. Veteran involvement then proceeds as follows:

1. Veterans complete a brief assessment battery (see **Measures**) including demographics and mental health symptoms using eScreening.
2. Veterans access the training videos via eScreening.
    a. Day 1: All complete a brief symptom screener (see **Measures**), watch a ~15-minute instructional video (#1) and answer comprehension and credibility questions about the video.
    b. Days 2-7: *Supported condition only*: They are prompted daily to engage in meditation practice and may receive support toward that end (see **Interventions**).
    c. Day 8: All complete a brief symptom screener and questions about meditation practice, watch a ~15-minute instructional video (#2), and answer comprehension questions about the video.
    d. Days 9-14: *Supported condition only*: Daily prompts/support.
    e. Day 15: All complete a brief symptom screener and questions about meditation practice, watch a ~15-minute instructional video (#3), and answer comprehension questions about the video.
    f. Days 16-21: *Supported condition only*: Daily prompts/support.
    g. Day 22: All complete a brief symptom screener and questions about meditation practice, watch a ~15-minute instructional video (#4), and answer comprehension questions about the video.
    h. Days 23-28: *Supported condition only:* Daily prompts/support.

3. Veterans complete a brief assessment battery about mental health symptoms and answer questions about the feasibility, acceptability, and appropriateness of mobile MRP (Weiner et al., 2017).

Data Collection and Measures

We will collect data for the reach, implementation, and effectiveness outcomes of RE-AIM (Glasgow et al., 2019) as depicted in Table 1. In this study, we will not be focusing on the last two dimensions of RE-AIM (i.e., adoption and maintenance). The advantage of this mechanism for delivering MRP is that it is self-directed, requiring little or no support from providers, and utilized similarly to other VA apps (e.g., PTSD Coach); consequently, factors related to the providers' adoption of mobile MRP are minimal. Collection of data pertaining to maintenance is beyond the scope if this one-year study, but it will be an important factor to measure in the full-scale trial of this self-directed adaptation of the delivery of MRP with or without support in Veterans with PTSD.

Table 1. Select RE-AIM Implementation Outcomes and their Assessment

RE-AIM	**Definition**	**Measure/Instrument**	**Data source**
Reach	The absolute number, proportion, and representativeness of participants	Number of screenings Percent eligible/ineligible Refusal rate Characteristics of participants	Study recruitment logs eScreening platform surveys
Implementation	How much and how well the MRP is implemented and how it is received by Veterans	Acceptability of Intervention Measure (AIM) Intervention Appropriateness Measure (IAM) Feasibility of Intervention Measure (FIM) Credibility of MRP % of videos completed with comprehension Satisfaction with MRP Mantram use	eScreening platform surveys Qualitative interview
Effectiveness	The impact of an intervention on Veteran outcomes	Brief Symptom Screen PCL-5 PHQ-9 ISI Brief PHI	eScreening platform surveys

Screening

The Mini International Neuropsychiatric Interview (**MINI 7.0**) (Sheehan et al., 1998) will be used to assess suicidality, substance dependence, and serious mental illness. **Blind MoCA** (Wittich, et al., 2010)**,** which is a version of the Montreal Cognitive Assessment that can be used to assess for cognitive impairment via videoconferening, will assess cognitive readiness to participate. **Demographic characteristics** include age, gender, race/ethnicity, relationship status, years of education, SES/income/living situation, residential ZIP code, occupation/work status, branch of service/highest rank, service connection/disability status.

Reach Measures

The **number of screenings***,* **percent eligible/ineligible**, and **refusal rate** will be calculated, and **characteristics** of participating Veterans with PTSD will be compared those who refuse or are ineligible and to clinical eScreening data from the facility to assess generalizability.

Implementation Measures

The Acceptability of Intervention Measure (**AIM**), Intervention Appropriateness Measure (**IAM**), and Feasibility of Intervention Measure (**FIM**) developed by Weiner et al, 2017) will be used to calculate mean ratings of acceptability, appropriateness, and feasibility. A **Qualitative Interview** will be used to collect additional qualitative data on the AIM, IAM, FIM using the interview guides that we have previously modified for use in our other studies (McCreight et al., 2019; Pittman et al., 2021). We will also explore barriers and facilitators of the implementation of MRP. **Credibility ratings** of the intervention will be assessed with three items adapted from Borkovec & Nau (1972). Ratings that are comparable to previous studies using mantram suggest that acceptability is retained in this format. **Comprehension Questions** will be module-specific and test the participants' knowledge and understanding of each video. Using a conservative approach, we will not consider a video completed unless the comprehension question is answered successfully. The questions were developed for the Vannini et al. (2021) pilot of mobile MRP. **Satisfaction** will be assessed using a set of five-point Likert scale (1 =very dissatisfied; 5=very satisfied) items rating the module narrator, learning outcomes, overall course, and module content. The **Mantram Use Scale**, which has been used in several MRP efficacy studies, queries aspects of mantram use (frequency, practice/coping, sleep).

Effectiveness Measures

A **brief symptom screen** (items 9-11 of the SF-12, Ware et al., 1996, anchored to the past week) will be used as a weekly indicator of mental state. The PTSD Checklist for DSM-5 version (**PCL-5**, Bovin et al., 2016) will be used to quantify PTSD symptoms over the past week. PCL-5 scores demonstrated good internal consistency (α = .96), test-retest reliability (r = .84), and convergent and discriminant validity (Blevins et al., 2015). The Patient Health Questionnaire depression items (**PHQ-9**; Kroenke et al., 2001) will be used to quantify depression severity. The PHQ-9 has strong internal consistency (0.74-0.81), validity, and demonstrated responsiveness to change (Titov et al., 2011). The Insomnia Severity Index (**ISI**; Bastien et al., 2001), a 7-item instrument that assesses the consequences of and distress related to insomnia, which is a common and impairing problem associated with PTSD. Research compared insomnia *symptoms* assessed with the ISI to weekly sleep diaries and overnight polysomnography for insomnia *disorder* and found a total score of ≥10 on the ISI indicates insomnia *disorder* in community samples with excellent internal consistency (Morin et al., 2011). The 21-item Brief Personal Health Inventory (**Brief PHI**; Department of Veterans Affairs, 2019) is a self-reflection tool that assesses all aspects of Whole Health corresponding to the Circle of Health (Department of Veterans Affairs, 2019). It consists of a series of closed and open-ended questions that encourage Veterans to reflect on the multiple facets of health outlined in the Circle of Health and Well-Being. Veterans are asked to rate their overall general physical well-being, mental/emotional well-being and daily life on a 1-5 scale, in which 1 = miserable and 5 = great. Current state (now) and ideal state (goal) functioning for each of the nine areas of the Circle of Health are rated. The Brief PHI has been recently used Almklov and colleagues (submitted) to characterize Veterans' needs and preferences for services.

Data Analysis

Quantitative Analysis. Quantitative data from surveys and study databases will be summarized using descriptive statistics including frequencies, proportions, measures of central tendency (mean and median), and variability (standard deviation and interquartile range) along with data visualization methods, such as frequency tables, bar charts, line graphs, and scatter plots to understand implementation and effectiveness outcomes. 95% confidence intervals will be calculated when estimating proportions and means. Change from baseline to each post-intervention on effectiveness measures and mantram use will be calculated overall and by group (self-directed vs supported). Wilcoxon signed rank test and rank sum test will be used to examine the change in each group and compare the change between two groups. Linear mixed effects model will be used to examine the trajectory of change from baseline to post-intervention.

Qualitative analysis. Interviews will be recorded and transcribed. All qualitative data will be coded using a rapid qualitative data analytic approach. Unique and common themes across the two groups will be compared. Data analysis will be led by Drs. Rabin and Lindamer and will also include qualitatively-trained members of the research team.

A matrix approach will be used to triangulate data from quantitative and qualitative sources. We will use a joint display analysis to support the integration of different data sources and types. Unique and common themes emerging across the two groups (self-directed and supported) will be identified and described.

Sample size. As a feasibility study, the sample size was not projected to ensure enough study power for hypothesis testing. We assessed the effect size of the effectiveness measures (e.g., PCL-5) that can be detected with the planned sample size and 80% power. The effect size for change in outcome from baseline to post treatment in each intervention group and for overall was estimated based on a paired t-test. With a sample size of 20 per group and 40 in total, we could detect an effect size of 0.66 and 0.45, which are moderate effect sizes. To compare the outcome change between the self-directed and supported groups, we could detect a large effect size of 0.91 for the difference with 20 subjects per group. This effect size would be clinically meaningful thus signaling the need for additional study. The sample size assessment was also conducted for assessing feasibility measures (e.g., initiation rate). First, we assessed the precision of estimates based on projected sample size. We considered a range of target rate from 0.60 to 0.90 and estimated the width of the 95% exact binomial confidence interval for overall and for each intervention group. If an estimated intervention initiation rate is 0.80, a sample size of 40 (total) and 20 (per intervention group) will produce a two-sided 95% confidence interval with a width of 0.243 and 0.335, respectively. If an estimated intervention initiation rate is 0.90, the width of the 95% CI is reduced (becomes more precise) with the same sample size projected above.

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