Pilot Testing a Virtual Mindfulness-Based Intervention Aimed at Improving Reintegrating Veterans' Health Outcomes

IRB #15934

Principal Investigator

Sarah Shue, PhD, Research Scientist, Center for Health Information and Communication, Roudebush VA Medical Center, Indianapolis, IN

Co-investigators and study staff

Annie Do, BA, Project Manager/Research Assistant, Center for Health Information and Communication, Roudebush VA Medical Center, Indianapolis, IN

Marianne Matthias, PhD, Co-Investigator, Research Scientist, Center for Health Information and Communication, Roudebush VA Medical Center, Indianapolis, IN
a) Research Scientist, Regenstrief Institute, Indianapolis, IN
b) Indiana University School of Medicine

Matthew Bair, MD, Co-Investigator, Research Scientist, Center for Health Information and Communication, Roudebush VA Medical Center, Indianapolis, IN
a) Research Scientist, Regenstrief Institute, Indianapolis, IN
b) Indiana University School of Medicine

Jayme Brosmer, DPT, Consultant, Physical Therapist, Roudebush VA Medical Center, Indianapolis, IN

Stanley Taylor, Data Manager, Center for Health Information and Communication, Roudebush VA Medical Center, Indianapolis, IN

Stephanie Dickinson, Biostatistician/VA WOC appointment, Center for Health Information and Communication, Roudebush VA Medical Center, Indianapolis, IN
a) Executive Director, Biostatistics Consulting Center, Department of Epidemiology & Biostatistics, School of Public Health, Indiana University, Bloomington, IN

Lilian Golzarri Arroyo, Biostatistician/VA WOC appointment (pending), Center for Health Information and Communication, Roudebush VA Medical Center, Indianapolis, IN
a) Biostatistician, Biostatistics Consulting Center, Department of Epidemiology & Biostatistics, School of Public Health, Indiana University, Bloomington, IN

Funding

VA HSR&D Merit Review Award Pilot Project Program (I21), Office of Research & Development (ORD)

VA only / Non-Collaborative Research:
This project is not collaborative with another entity/institution/outside investigator. VA is the only institution, and all PIs/personnel are affiliated with and appointed by the VA. This is an RLR Indy VA Veteran participant only (identified via VA CDW), single VA personnel only, and VA HSRD salary supported study utilizing VA approved technology systems for/such as: VA encrypted Azure email, VA audio visual platform, VA approved recording devices, VA medical record access, with VA data collection tools and data analysis tools within the VA network and stored only on the VA network. All visits occur virtually.

1.0 Background

Community reintegration is a critical period of transition for post-9/11 Veterans that is rife with challenges.[1-3] Separating from military service and reintegrating into civilian life is often characterized by a range of psychosocial stressors and adjustment difficulties, such as social isolation and challenges establishing a new personal identity.[4,5] Reintegration

becomes further complicated if the Veteran is returning to civilian life with a service-related condition.[1,6] Of particular concern is depression, which is one of the most costly and common mental health diagnoses among the post-9/11 Veteran cohort.[7,8] Prior research has demonstrated that depression is strongly associated with poor psychosocial outcomes and reintegration challenges among Veterans.[6,8] Successful community reintegration requires programming that effectively promotes and addresses post-9/11 Veterans' mental health needs, particularly depression.[2]

2.0 Rationale and Specific Aims

If not properly addressed, Veterans' reintegration challenges can place a tremendous burden on Veterans, their families, communities, and healthcare systems.[9-11] Despite the well-documented needs of post-9/11 Veterans and numerous resources, Veterans continue to report inadequate support for the transition from military to civilian life.[4,10,12-16] Moreover, many Veterans do not use available services.[17,18] As such, reintegration services must address Veterans' mental health care needs using approaches that increase the likelihood of Veteran engagement. Mindfulness-based reintegration services are a promising approach for reducing post-9/11 Veterans' symptoms of depression and are supported by previous research that demonstrates (1) beneficial effects of mindfulness meditation in reducing depression;[19-22] (2) the potential of mindfulness to mitigate self-stigma, which is a key barrier to seeking mental health care among Veterans;[18,23] and (3) Veterans' interest in the use of mindfulness to help manage depression.[24-26] The appeal of mindfulness-based reintegration services may be further enhanced by virtual delivery.[24]

The overarching goal of the proposed project is to use mindfulness practices to reduce depression and improve community reintegration among post-9/11 Veterans. This proposal focuses on the REconnecting to Civilian Life using Activities that Improve Mindfulness (RECLAIM) intervention. RECLAIM is a virtual multi-component, mindfulness-based intervention developed by our study team in collaboration with VA clinicians, post-9/11 Veterans, and stakeholders and guided by the VA Whole Health framework.[27,28] The proposed project builds on preliminary pilot work and a Small Award Initiative for Impact (SWIFT) pilot project funded by our VA HSR&D Center of Innovation. In the SWIFT pilot, we refined the RECLAIM content and tested the feasibility of virtual delivery with a small sample (N=18) using a single arm pre/post-test design. The proposed pilot project builds on preliminary work by (1) testing the refined intervention in a randomized controlled design to assess feasibility of recruitment for a randomized trial, (2) randomization, (3) retention in both study arms, and (4) intervention acceptability. Findings from the proposed project will support a HSR&D Investigator Initiated Research Merit award application that will assess the effectiveness of RECLAIM while simultaneously planning for implementation in a Hybrid Type I trial.[29] The following are the specific aims for this pilot project.

Aim 1: Conduct a randomized controlled pilot study to assess feasibility of the RECLAIM intervention. We will conduct a two-arm randomized pilot study. Veterans (N=48) will be randomized to either the intervention arm (i.e., virtually delivered RECLAIM) or a control arm (i.e., psychoeducation materials). We will assess intervention feasibility, including recruitment, randomization, administration and completion of outcome assessments, treatment engagement, and retention in both the intervention and control study arms.

Aim 2: Conduct qualitative interviews to assess acceptability of RECLAIM. A purposefully sampled subgroup (i.e., based on attendance) of RECLAIM participants (i.e., Veterans from the intervention arm; N=16) will engage in a qualitative interview to explore experiences in RECLAIM, including perceived strengths and suggestions for future improvements.

Aim 3: Refine and finalize the RECLAIM intervention. As findings emerge from the Aim 1 pilot test and Aim 2 interviews with Veteran participants, we will iteratively update the RECLAIM protocol manual and testing procedures (i.e., randomization, control group materials). We will consult with the Patient Advisory Council of the Indianapolis VAMC to gather Veteran feedback on the revised RECLAIM protocol manual, as well as partners (e.g., Patient Centered Care and Cultural Transformation). These actions will help refine the study methods, design, and intervention in anticipation of a larger trial.

3.0 Study Plan, Experimental Design, and Methodology

Aim 1: We will conduct a two-arm randomized controlled pilot study to assess feasibility of (1) recruitment using VA electronic medical record data (in contrast to primarily networking and word of mouth in our preliminary pilot study), (2) the randomization strategy, (3) retention in both study arms, (4) participant engagement in the intervention, and (5) outcome assessment administration (e.g., time to complete, proportion completed, attrition).

Aim 2: We will conduct qualitative interviews with Aim 1 pilot study participants who were randomized to the RECLAIM arm. We will use principles of rapid analysis to analyze the qualitative data.[30,31]

Aim 3: Consistent with the intervention mapping approach[32] used to design RECLAIM, as findings emerge from this project - the Aim 1 pilot test and Aim 2 interviews with Veteran participants - we will iteratively update RECLAIM content in the protocol manual. Intervention protocol manuals are necessary to facilitate rigorous and systematic evaluation of interventions and are useful for translating effective intervention strategies across settings.[33] We will also refine the procedures for testing the RECLAIM intervention (e.g., recruitment strategies, control group materials).

4.0 Inclusion/Exclusion Criteria

To be eligible for this study, Veterans must be between the ages of 18 and 44. Majority of post-9/11 Veterans fall into this age range, as do the highest rates of depression in this Veteran cohort.[34,35] Veterans must have also served (a) active duty and/or (b) in the National Guard/Reserves after October 2001. Potential participants can still be in the National Guard or a Reservist. Veterans must be enrolled in VHA care. Veterans must also endorse at least a mild level of depression. We will use the Patient Health Questionnaire (PHQ-9)[36] to assess the presence and severity of depressive symptoms among potential Veteran participants. Mild depression is defined as a score of at least 5 on the PHQ-9. Finally, Veterans must also endorse at least a little difficulty adjusting to civilian life to be eligible for participation. Difficulty adjusting to civilian life will be assessed using the Military to Civilian Questionnaire (M2C-Q).[37] For this study, "a little" difficulty will be defined as a mean M2C-Q score of 1 (i.e., a 1 indicates "a little difficulty" on the M2C-Q).

Mental health screening: As previously mentioned, we will use the Patient Health Questionnaire[36] (PHQ-9) to screen participants for depressive symptoms. Veterans who present with a score of 20 or greater (i.e., severe depression) or endorse the 9th item (i.e., suicidal ideation) on the PHQ-9 will then complete the Columbia Suicide Severity Rating Scale (C-SSRS)[39] to determine if the Veteran is currently experiencing suicidal ideation and needs further evaluation by a VA provider. Veterans will not be immediately excluded from participation in the study; the study team will consult with the Roudebush Suicide Prevention Team and/or the Veterans' care provider to determine whether continued study participation is appropriate. If a Veteran is experiencing active suicidal ideation, the following steps, aligned with the Indianapolis VAMC policy (116-05), will be taken: Veterans who are experiencing active suicidal ideation will be immediately connected to the Veterans Crisis Line. If the warm transfer to the Veterans Crisis Line fails, the study team member will attempt to call the Veteran back immediately. If the Veteran cannot be located, then the study team member will call the Veterans Crisis Line to provide them with the Veteran's information and receive guidance on next steps. If the Veterans Crisis Line decides not to pursue follow up to locate a Veteran caller, the study team member will then contact the local suicide prevention team (i.e., the team located at the facility that the patient is receiving healthcare services). In either of these scenarios, the Suicide Prevention Team will initiate suicide risk management protocol, documentation, and follow up plans. The complete protocol for screening and referring Veterans needing additional care was developed in collaboration with the Roudebush Suicide Prevention Team). Screening measures will be collected prior to the baseline assessment and collected during each outcome assessment.

5.0 Recruitment/Enrollment/Randomization

Under an IRB approved HIPAA Authorization Waiver for recruitment, we will request a list of Veterans and their contact information based on the study inclusion criteria (e.g., age and service area) via CDW. Eligibility criteria included in this CDW request will also seek a depression diagnosis, but participation is not solely contingent upon any health conditions (i.e., potential participants may still present mild depression symptoms without a formal depression diagnosis). The research assistant will mail a recruitment brochure and letter to eligible Veterans. Study staff will then contact these eligible Veteran participants (who were initially contacted by mail) by phone and/or email to recruit them for the study. Veterans who enroll will be emailed using VA compliant methods (VA Azure encrypted email). Word-of-mouth and snowballing techniques will also be used to identify eligible Veteran participants.

Other methods of study referral: Preliminary work for the RECLAIM intervention established a network of VA staff and providers and VA stakeholders (e.g., Tricia Parker, M2VA Case Management program) who are willing to refer Veterans to the study. During recruitment, to ensure the representation of minoritized and women Veterans, we will contact the Minority Veterans Program and the Women's Clinic to discuss the proposed project and ask for staff and clinician assistance for study referral. Finally, participants will be recruited through word-of-mouth and snowballing techniques.

Recruitment and retention strategies: Based on findings in our preliminary studies,[27] the following strategies will be used to maximize recruitment and retention: (1) Use recruitment and program materials with clear and transparent messaging (based on preliminary findings from Veterans to avoid vague language); (2) Gather multiple forms of contact information; (3) Establish Veterans' preferred contact method (email or phone) and contact time preferences (e.g., morning or evening); (4) Offer incentives for outcome assessments and interviews; (5) Send recap emails following sessions that contain overviews of session topics and discussion, and a reminder for the upcoming session; (6) Reminder call day of RECLAIM session.

If target recruitment numbers are not being met, we will (1) consult with our operational and clinical partners (e.g., Office of Mental Health and Suicide Prevention; Tricia Parker, Military2VA Case Management program) for suggestions on identifying potential participants; (2) call and send letters to VA staff and providers and community-based Veteran service organizations to explain the study and ask for referrals; (3) present information about the study and preliminary findings to VA staff and providers and local organizations; (4) follow up with VA staff and providers and organizations who referred Veterans to the study to capitalize on good sources of referrals; and (5) use VA-approved social media to recruit Veterans.

6.0 Study Procedures

Aim 1 Procedures

Veterans who consent to participate in the pilot study will complete the eligibility screening over the phone or using VA-approved teleconferencing software. Eligible Veterans must (1) be between the ages of 18 and 44, (2) have served active duty and/or in the National Guard/Reserves after October 2001, (3) endorse a mild level of depression (i.e., at least a score of 10 on the PHQ-9, and (4) at least some difficulty with their community reintegration (i.e., a mean M2C-Q score of 2). Veterans will receive a copy of the consent form, which will include information such as potential risk and benefits and contact information if issues should arise. A request to VA ORD (Office Research Development) will be made and ORD permission provided, under VA's contracted use of DocuSign, to allow participants to sign the HIPAA Authorization electronically with DocuSign envelopes. Eligible Veterans will also complete baseline outcome assessments. These assessments will be completed again at the 2-month follow-up. Randomization: After completing the informed consent and baseline assessments, Veteran participants will be randomized to one of two study arms: (1) virtually delivered RECLAIM arm, or (2) the control arm. Randomization will occur using the block randomization method, which balances the number of participants in each study group across time.

Intervention arm: Veterans randomized to the intervention arm (n=24) will participate in the 8-week RECLAIM intervention after 12 Veterans (i.e., a cohort) have been randomized. Delivery of RECLAIM: The RECLAIM intervention is comprised of (1) four 60-minute sessions that are delivered bi-weekly in a virtual group setting and (2) four bi-weekly coaching calls. Participants will also be offered an introductory session (i.e., Session 0) that will serve as a technical assistance session to ensure that participants can access Microsoft Teams and to try and mitigate connection challenges prior to the start of the intervention. The bi-weekly coaching calls will happen in the weeks between the virtual intervention sessions. Delivery of the bi-weekly intervention virtual sessions will be led by Dr. Jayme Brosmer, who is a study consultant and an expert in mindfulness (e.g., certified as a Mindfulness Based Meditation for Pain Relief practitioner) and co-facilitated by Dr. Shue. Each RECLAIM session is structured with the following components to achieve this purpose: (1) an overview and discussion of the weekly topic, which is a domain of community reintegration; (2) a brief mindfulness practice (approximately 10 minutes); (3) reflection and discussion of the topic and mindfulness practice; (4) journal prompt and brief discussion; and (5) a discussion of ways to effectively engage in independent mindfulness practice(s). RECLAIM participants will be invited, but not required, to participate in optional check-in sessions which will occur between the regularly scheduled weekly RECLAIM sessions. The bi-weekly coaching calls will be conducted by the project manager (Annie Do) or Dr. Shue.

Control arm: The inclusion of a control group in the proposed pilot project will allow us to test aspects of and procedures for the control group in preparation for the larger scale study.[40] We will also assess feedback from the control arm participants to determine whether our approach is feasible for inclusion in a future fully powered randomized controlled trial (RCT). We will use an attention control group design. Participants in the control arm will not receive the RECLAIM intervention but will receive some similar RECLAIM activities. They will not be the same in intensity, time, and/or contacts as the intervention activities.[41] We will provide Veterans randomized to the control arm with psychoeducational materials (i.e., a list of suggested readings) that will also be received by the intervention arm. Control

arm participants will receive the psychoeducational materials in the same week that the intervention arm is scheduled to begin RECLAIM. Psychoeducational materials will be sent to the intervention and control arm using unencrypted email. Use of unencrypted emails for sending these materials has been approved by the Roudebush VAMC Privacy Office (see PO Request document).

Aim 2 Procedures:

A subset of participants from the intervention arm of the Aim 1 pilot study (n=16) will be invited to complete a single, individual qualitative semi-structured program experience and impact interview. Selection: Participants will be purposively sampled to take part in a qualitative interview based on their RECLAIM participation (i.e., participants who attended the most and fewest sessions). In each of the four cohorts, we will invite four participants to participate in a qualitative interview. This will provide a sample size of 16 interview participants. This sample size is consistent with published recommendations and our own experience to achieve saturation (i.e., when additional data do not provide new insights).[42-45]

Aim 3 Procedures:

At the conclusion of each study pilot cohort, the project team will review and refine the protocol manual. As we complete these iterative refinements, we will consult with the Patient Advisory Council of the Indianapolis VAMC (see letter of support) to gather Veteran feedback on the revised RECLAIM protocol manual. In addition, we will consult with partners from the VA Office of Patient Centered Care and Cultural Transformation and the Indianapolis Military 2VA Case Management Team (see letters of support). Refining the methods, design, and RECLAIM intervention will prepare us to submit a fully powered Hybrid Type I randomized controlled trial (RCT),[29] which we plan to submit as a HSR&D Investigator Initiated Research (IIR) Merit grant application.

7.0 Data Collection & Storage

Aim 1 Data Collection:

Data will be collected to assess feasibility of screening, recruitment, randomization, and retention. We will also assess intervention engagement, treatment fidelity, and administration and completion of the outcome measures. These are described in greater detail below.

Intervention engagement: We will measure three indicators of participants' engagement with the intervention: (1) attendance at RECLAIM sessions; (2) attendance at optional check-in sessions; and (3) amount of independent/at-home practice. To assess independent/at-home practice, all participants randomized to the RECLAIM intervention arm will be provided an electronic mindfulness practice log sheet at the start of the study to track their engagement. Specifically, between RECLAIM sessions, participants will be asked to record how many days in the past week and approximately how many minutes per day they practiced mindfulness. They will also be asked to document any successes or difficulties that occurred. Practice log sheets will also ask participants to indicate how often they access the VA-approved cloud-based file storage application (e.g., Box) to use intervention materials (e.g., scripts, recordings). [Note: The VA-approved cloud-based file storage application will allow participants do access and download materials. The application will not allow participants to revise materials, upload their own materials, or provide any personal information (i.e., this application will not be used for data collection).] The practice log sheet can be completed electronically, or participants can print their log sheets to be completed manually. Participants can submit their practice logs to a member of the study staff via email. Additionally, at the beginning of each RECLAIM session, we will provide an electronic survey within the teleconferencing software that will match the questions/prompts on the participants' practice logs. This will provide participants another opportunity to submit their mindfulness practice information if they have not done so by email. Practice feedback: At the start of each weekly session, we will engage in a discussion about participants' independent practice (e.g., successes and challenges) and engage in discussion on strategies to maximize facilitators and overcome barriers. We will do weekly reminder calls to make sure participants are completing their logs and this will be another opportunity to provide any additional information or feedback to assist participants' independent mindfulness practice.

Treatment fidelity: Intervention fidelity has been defined as the degree to which an intervention was delivered as conceived and planned.[46-50] Fidelity of the RECLAIM intervention will be evaluated by the Principal Investigator (PI), Dr. Shue, who will be co-facilitating the RECLAIM sessions, and the Project Manager, who will observe the eight RECLAIM sessions across all four cohorts. Fidelity will be assessed using a checklist, which will be iteratively refined throughout the Aim 1 pilot. The checklist will capture intervention content elements (e.g., presentation of reintegration challenges,

mindfulness practices), as well as unplanned components (e.g., discussion questions and participant responses). The fidelity checklist for RECLAIM will facilitate the larger prepare for the planned Hybrid Type I trial,[111] which will assess the effectiveness of RECLAIM while simultaneously planning for implementation.

Administration of outcome measures: Part of our feasibility assessment will be to determine the acceptability of measures administered, time for outcome measure completion, number of items missing, and follow-up rates. We will administer assessments after a Veteran has consented to study participation to measure (1) depression, (2) general difficulty adjusting to civilian life, (3) anxiety, (4) quality of life, (5) mindfulness, and (6) pain. Participants will complete outcome assessments at two timepoints: baseline and 2-month follow-up. Participants will receive a $25 gift card for each outcome assessment they complete, for a possible total of $50.

1. Depression severity: The Patient Health Questionnaire (PHQ-9) is a reliable and valid 9-item measure of depression severity used to screen, diagnose, monitor, and measure the severity of depression.[36] It is one of the most widely used, reliable, and validated measures of depressive symptoms.[36]
2. General difficulty adjusting to civilian life: The Military to Civilian Questionnaire (M2C-Q) is an empirically validated self-report scale that measures general difficulty in readjusting to civilian life by assessing important indicators of reintegration challenges over the past 30 days including social/health behaviors, specifically interpersonal relationships; productivity at school, work, or home; community participation; self-care; leisure; and perceived meaning in life.[37] Research supports the construct and factor validity of scale scores and indicates high internal consistency (Cronbach's alpha = .92).[37]
3. Anxiety: The Generalized Anxiety Disorder Scale (GAD-7) is a brief 7-item measure for assessing generalized anxiety disorder.[51] The GAD-7 uses some of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) diagnostic criteria to assess generalized anxiety disorder. Scores classify respondents as having minimal, mild, moderate, or severe anxiety. The GAD-7 has good reliability and validity.[51]
4. Quality of life: The Veterans RAND Health Survey (VR-12) is a brief, self-administered health survey primarily used to measure health related quality of life.[52-54] The VR-12 is one of the most widely used functional status measures and has been shown to be highly reliable and valid.[52]
5. Mindfulness: The Five Facet Mindfulness Questionnaire (FFMQ) is a 15-item scale to measure five factors of mindfulness: (1) Observing; (2) Describing; (3) Acting with awareness; (4) Non-judging of inner experience; and (5) Non-reactivity to inner experience.[55] The FFMQ has strong psychometric properties, including good reliability for all facets (i.e., aspects) of mindfulness.[37,56,57]
6. Pain: The PEG (pain intensity, interference with enjoyment of life, interference with general activity) is an ultra-brief measure that contains 3 items to assess pain levels on average, pain interference with enjoyment of life, and pain interference with general activity.[58] The PEG demonstrates strong reliability and validity.

Aim 2 Data Collection:

Interviews will take place using VA-approved teleconferencing software or over the phone. The Project Manager will conduct the interviews with pilot study participants. Purpose: Interviews will explore participants' experiences in the RECLAIM intervention. Interviews will also explore participants' perceived strengths of the intervention, suggestions for future improvements, and barriers and facilitators that impacted participation in RECLAIM. Interviews will take approximately 60 minutes to complete. Participants who engage in an interview will receive a $50 gift card.

Aim 3 Data Collection:

No new data collection will occur in Aim 3. We will use data from Aims 1 & 2 to inform RECLAIM revisions.

8.0 Data Analysis/Statistical Considerations

Aim 1 analyses. The feasibility assessments in Aim 1 will be determined by using raw count numbers and percentages. Descriptive statistics will be calculated for all baseline demographic data. Frequencies and percentages will be reported for categorical variables; means, standard deviations, medians, minimums, and maximums will be reported for continuous variables. We will explore the data collected from the outcome assessments (for feasibility purposes) to examine any trends on the outcomes of interest that could be informative for future trials. Study groups will be compared on baseline characteristics using standardized difference tests to understand their initial comparability.[59]

Aim 2 Qualitative analysis. Interview data will be analyzed using the principles of rapid qualitative inquiry (RQI), which is an "intensive, team-based qualitative inquiry using triangulation, iterative data analysis, and additional data to quickly

develop a preliminary understanding of a situation from the insider's perspective."[30] As outlined by Hamilton[31] we will conduct the following steps to rapidly analyze the qualitative data: (1) create a neutral domain that corresponds with each interview question; (2) create a summary template to capture the interview and observation data; (3) pilot test the template (i.e., assess usability, relevance) among a set of transcripts; (4) divide transcripts among the qualitative analysis team (Drs. Shue and Matthias, and the Project Manager, Ms. Do), who will code using the summary template; and (5) use a matrix to display summary points. This rapid assessment process will allow for a quick understanding of the major findings from the qualitative data in Aim 2 and will facilitate iterative refinement to the RECLAIM manual to be completed during the proposed project.

9.0 Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others

Due to the nature of this study, there are no anticipated adverse events. However, local IRB guidelines for reporting adverse events will be followed.

- The PI will determine if an event is an adverse event (AE) or a serious adverse event (SAE) by assessing if it is 1) unexpected, 2) related or possibility related to study participation, AND 3) suggests that the research places subjects or others at a greater risk of harm than was previously known. Serious adverse events must be determined by the PI as both unanticipated and related to the research study.
- Upon becoming aware of a serious adverse event, which was both unanticipated and related to the research, the study team will immediately (within 24 hours) notify the IRB via verbal notification. A written notice to the IRB will be submitted within 5 business days following the event.
- Data collection on AEs and SAEs will begin at the time participants have been provided the Study Information Sheet and will be kept on a tracking log by the program manager.

Additionally, this study will adhere to VA and university regulations in conducting studies with human subjects. Adverse psychosocial reactions by participants and risks to confidentiality and data security (detailed in section 12.0 below) will be minimized through: informing potential participants in advance of the nature of the project, the nature of the questions to be asked, and the individual's right to decline to answer any or all questions; providing full and proper training to research staff; never sharing research findings about one participant with another participant; keeping paper documents in locked cabinets in locked offices; and ensuring that compensation is non-coercive.

If there is a suspected or confirmed loss of information, the PI will ensure that the event is reported to the IRB according to IRB policy and to the VA Privacy Officer.

10.0 Study Withdrawal/Discontinuation

Participants will receive a copy of the Study Information Sheet form for their records and they will be reminded that participation is strictly voluntary and that they may withdraw at any time. Additionally, if at any time participants wish to skip a question or discontinue their participation study altogether, they will be permitted to do so.

11.0 Study Risks

There are no anticipated physical, social, or legal risks to participants in this study. Loss of confidentiality is a risk with protection measures described below.

12.0 Protection against Risks

The researcher will be responsible for the implementation of any and all reasonable steps to minimize disclosure of identifiable patient information. A study specific VA Information Security Officer (ISO) checklist has been provided to the VA information security officer and a VA Privacy Checklist form 10-250 provided to the VA privacy officer for review as requested by the local VA Research Administration office.

The following policies will be enforced to ensure that subject privacy and confidentiality is protected:

- All staff will be required to complete formal training regarding patient privacy and confidentiality of clinical information. Provisions for disciplinary action (including termination of employment) in case of unauthorized disclosure are included as policy and are covered in the formal training process.

- Access to identifiable information will be limited to people who require such access to perform the stated research. Any patient data held by research staff (whether identifiable or not) will be held in strictest confidence, with the need for confidentiality taking precedence over considerations of economy or convenience. Research staff will use, disclose, or request protected health information to the minimum amount necessary required to perform their specific job function and to accomplish the intended research purpose.
- The research team will participate in annual security awareness training which identifies the information security risks associated with their activities and their responsibilities in complying with policies and procedures designed to reduce those risks.

13.0 **Privacy/Confidentiality**

The study data will reside with the VA firewall to ensure appropriate protection. Primary data will be collected via outcome measures and interviews, which will be entered into and stored electronically in VA REDCap and within the secured research folder. Qualitative transcripts (i.e., interview data) will be uploaded into VA-approved computer assisted qualitative software for organization and analysis. All other computerized files will be protected by the electronic firewall at the Indianapolis VAMC, will be kept in locked areas accessible only by authorized persons (i.e. locked offices/filing cabinets), and will be password protected. All data will only be accessible to the PI and research staff. Procedures will be put in place which successfully minimize this risk:

- All stored electronic data will be de-identified and placed behind the VA firewall.
- All study assessments will be conducted in private locations.
- All audio video recordings will be conducted and saved in a secure study folder on a password-protected secure server.
- Participants' names will not appear on any of the data collected, including audio recordings. All participants' responses will be matched with a code number only. The key to this code number will be stored in a password protected computer file, separate from other data, locked behind closed office doors accessed by the research team for this study only.

14.0 VA Record Retention

This study will last for approximately 18 months. Data collected throughout the duration of the study will be stored on a password-protected secure server. Research records will be maintained per the VA Records Retention Policy and will be maintained by the investigator for 6 (six) years following the federal fiscal year end (September 30) after the study has been closed by the VA in accordance with the VHA Records Control Schedule or longer if required by other Federal regulations.

References

1. Department of Veterans Affairs Fiscal Years 2022-28 Strategic Plan (2022).
2. Derefinko KJ, Hallsell TA, Isaacs MB, Colvin LW, Garcia FIS, Bursac Z. Perceived needs of veterans transitioning from the military to civilian life. *The journal of behavioral health services & research*. 2019;46(3):384-398.
3. Olenick M, Flowers M, Diaz VJ. US veterans and their unique issues: enhancing health care professional awareness. *Advances in medical education and practice*. 2015;6:635.
4. Elnitsky CA, Blevins CL, Fisher MP, Magruder K. Military service member and veteran reintegration: A critical review and adapted ecological model. *American Journal of Orthopsychiatry*. 2017;87(2):114.
5. Ahern J, Worthen M, Masters J, Lippman SA, Ozer EJ, Moos R. The challenges of Afghanistan and Iraq veterans' transition from military to civilian life and approaches to reconnection. *PloS one*. 2015;10(7):e0128599.
6. Etchin AG, Fonda JR, Howard EP, et al. Childhood trauma differentially impacts depression and stress associations with reintegration challenges among post-9/11 US veterans. *Nursing outlook*. 2022;70(2):323-336.
7. Seal KH, Metzler TJ, Gima KS, Bertenthal D, Maguen S, Marmar CR. Trends and risk factors for mental health diagnoses among Iraq and Afghanistan veterans using Department of Veterans Affairs health care, 2002–2008. *American journal of public health*. 2009;99(9):1651-1658.
8. Vaughan CA, Schell TL, Tanielian T, Jaycox LH, Marshall GN. Prevalence of mental health problems among Iraq and Afghanistan veterans who have and have not received VA services. *Psychiatric Services*. 2014;65(6):833-835.
9. Sayer NA, Noorbaloochi S, Frazier P, Carlson K, Gravely A, Murdoch M. Reintegration problems and treatment interests among Iraq and Afghanistan combat veterans receiving VA medical care. *Psychiatric services*. 2010;61(6):589-597.
10. Morgan NR, Aronson KR, Perkins DF, et al. Reducing barriers to post-9/11 veterans' use of programs and services as they transition to civilian life. *BMC Health Services Research*. 2020;20(1):1-14.
11. Sayer NA, Carlson KF, Frazier PA. Reintegration challenges in US service members and veterans following combat deployment. *Social Issues and Policy Review*. 2014;8(1):33-73.
12. Demers A. When veterans return: The role of community in reintegration. *Journal of Loss and Trauma*. 2011;16(2):160-179.
13. Waszak DL, Holmes AM. The unique health needs of post-9/11 US veterans. *Workplace health & safety*. 2017;65(9):430-444.
14. Osinubi OY, McAndrew LM, De Candia V, et al. Organizational psychosocial factors and deployment-related exposure concerns in Afghanistan/Iraq war veterans. *Journal of occupational and environmental medicine*. 2012;54(6):670-676.
15. Aronson KR, Perkins DF, Morgan N, et al. Going it alone: Post-9/11 veteran nonuse of healthcare and social service programs during their early transition to civilian life. *Journal of Social Service Research*. 2019;45(5):634-647.
16. Perkins DF, Aronson KR, Morgan NR, et al. Veterans' use of programs and services as they transition to civilian life: Baseline assessment for the Veteran Metrics Initiative. *Journal of Social Service Research*. 2020;46(2):241-255.
17. Barr N, Davis JP, Diguiseppi G, Keeling M, Castro C. Direct and indirect effects of mindfulness, PTSD, and depression on self-stigma of mental illness in OEF/OIF veterans. *Psychological Trauma: Theory, Research, Practice, and Policy*. 2019;
18. Acosta JD, Becker A, Cerully JL, et al. *Mental health stigma in the military*. 2014.
19. Bohlmeijer E, Prenger R, Taal E, Cuijpers P. The effects of mindfulness-based stress reduction therapy on mental health of adults with a chronic medical disease: a meta-analysis. *Journal of psychosomatic research*. 2010;68(6):539-544.
20. Niazi AK, Niazi SK. Mindfulness-based stress reduction: a non-pharmacological approach for chronic illnesses. *North American journal of medical sciences*. 2011;3(1):20.
21. Jain S, Shapiro SL, Swanick S, et al. A randomized controlled trial of mindfulness meditation versus relaxation training: effects on distress, positive states of mind, rumination, and distraction. *Annals of behavioral medicine*. 2007;33(1):11-21.
22. Keng S-L, Smoski MJ, Robins CJ. Effects of mindfulness on psychological health: A review of empirical studies. *Clinical psychology review*. 2011;31(6):1041-1056.

23. DeViva JC, Sheerin CM, Southwick SM, Roy AM, Pietrzak RH, Harpaz-Rotem I. Correlates of VA mental health treatment utilization among OEF/OIF/OND veterans: Resilience, stigma, social support, personality, and beliefs about treatment. *Psychological trauma: theory, research, practice, and policy*. 2016;8(3):310.
24. Herrmann T, Marchand WR, Yabko B, Lackner R, Beckstrom J, Parker A. Veterans' interests, perceptions, and use of mindfulness. *SAGE open medicine*. 2020;8:2050312120938226.
25. Goldberg SB, Riordan KM, Sun S, Kearney DJ, Simpson TL. Efficacy and acceptability of mindfulness-based interventions for military veterans: A systematic review and meta-analysis. *Journal of psychosomatic research*. 2020;138:110232.
26. Goldberg SB, Zeliadt SB, Hoggatt KJ, Simpson TL, Fortney JC, Taylor SL. Utilization and perceived effectiveness of mindfulness meditation in veterans: Results from a national survey. *Mindfulness*. 2019;10(12):2596-2605.
27. Shue S, Brosmer J, Matthias MS. Reducing veterans' risk for suicidal behaviors: a qualitative study to inform development of the RECLAIM health promotion program. *BMC Health Services Research*. 2020/08/01 2020;20(1):707. doi:10.1186/s12913-020-05587-7
28. Krejci LP, Carter K, Gaudet T. Whole health: the vision and implementation of personalized, proactive, patient-driven health care for veterans. *Medical care*. 2014;52:S5-S8.
29. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*. 2012;50(3):217.
30. Beebe J. *Rapid assessment process: An introduction*. Rowman Altamira; 2001.
31. Hamilton A. Qualitative methods in rapid turn-around health services research. *Health Services Research & Development Cyberseminar*. 2013;
32. Eldredge LKB, Markham CM, Ruiter RA, Fernández ME, Kok G, Parcel GS. *Planning health promotion programs: an intervention mapping approach*. John Wiley & Sons; 2016.
33. Pyatak EA, Carandang K, Davis S. Developing a manualized occupational therapy diabetes management intervention: Resilient, Empowered, Active Living with Diabetes. *OTJR: occupation, participation and health*. 2015;35(3):187-194.
34. Profile of Post-9/11 Veterans: 2016 (2018).
35. Pemberton MR, Forman-Hoffman VL, Lipari RN, Ashley OS, Heller DC, Williams MR. Prevalence of past year substance use and mental illness by veteran status in a nationally representative sample. *SAMHSA Center for Behavioral Health Statistics and Quality, November*. 2016;
36. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine*. 2001;16(9):606-613.
37. Sayer NA, Frazier P, Orazem RJ, et al. Military to civilian questionnaire: A measure of postdeployment community reintegration difficulty among veterans using Department of Veterans Affairs medical care. *Journal of traumatic stress*. 2011;24(6):660-670.
38. Baird SO, Metts C, Conroy HE, Rosenfield D, Smits JA. Physical Activity and Community Engagement (PACE) to facilitate community reintegration among returning veterans: Study protocol for a randomized controlled trial. *Contemporary clinical trials communications*. 2018;11:136-141.
39. Posner K, Brown GK, Stanley B, et al. The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American journal of psychiatry*. 2011;168(12):1266-1277.
40. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *Journal of psychiatric research*. 2011;45(5):626-629.
41. Aycock DM, Hayat MJ, Helvig A, Dunbar SB, Clark PC. Essential considerations in developing attention control groups in behavioral research. *Research in nursing & health*. 2018;41(3):320-328.
42. Patton MQ. *Qualitative research & evaluation methods: Integrating theory and practice*. Sage publications; 2014.
43. Creswell JW, Poth CN. *Qualitative inquiry and research design: Choosing among five approaches*. Sage publications; 2016.

44. Morse JM. Designing funded qualitative research. *Handbook of qualitative research*. Sage Publications, Inc; 1994:220-235.
45. Kuzel AJ. Sampling in qualitative inquiry. In: Crabtree BF, Miller WL, eds. *Research Methods for Primary Care, Vol 3 Doing Qualitative Research*. Sage Publications, Inc.; 1992:31-44.
46. Moncher FJ, Prinz RJ. Treatment fidelity in outcome studies. *Clinical psychology review*. 1991;11(3):247-266.
47. Waltz J, Addis ME, Koerner K, Jacobson NS. Testing the integrity of a psychotherapy protocol: assessment of adherence and competence. *Journal of consulting and clinical psychology*. 1993;61(4):620.
48. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health psychology*. 2004;23(5):443.
49. Hawe P, Shiell A, Riley T. Complex interventions: how "out of control" can a randomised controlled trial be? *Bmj*. 2004;328(7455):1561-1563.
50. Harshbarger C, Simmons G, Coelho H, Sloop K, Collins C. An empirical assessment of implementation, adaptation, and tailoring: the evaluation of CDC's National Diffusion of VOICES/VOCES. *AIDS Education & Prevention*. 2006;18(supp):184-197.
51. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine*. 2006;166(10):1092-1097.
52. Jones D, Kazis L, Lee A, et al. Health status assessments using the Veterans SF-12 and SF-36: methods for evaluating outcomes in the Veterans Health Administration. *The Journal of ambulatory care management*. 2001;24(3):68-86.
53. Kazis LE, Miller DR, Clark J, et al. Health-related quality of life in patients served by the Department of Veterans Affairs: results from the Veterans Health Study. *Archives of internal medicine*. 1998;158(6):626-632.
54. Kazis LE, Miller DR, Skinner KM, et al. Applications of methodologies of the Veterans Health Study in the VA healthcare system: conclusions and summary. *The Journal of ambulatory care management*. 2006;29(2):182-188.
55. Baer RA, Smith GT, Hopkins J, Krietemeyer J, Toney L. Using self-report assessment methods to explore facets of mindfulness. *Assessment*. 2006;13(1):27-45.
56. Baer RA, Smith GT, Lykins E, et al. Construct validity of the five facet mindfulness questionnaire in meditating and nonmeditating samples. *Assessment*. 2008;15(3):329-342.
57. Bohlmeijer E, Ten Klooster PM, Fledderus M, Veehof M, Baer R. Psychometric properties of the five facet mindfulness questionnaire in depressed adults and development of a short form. *Assessment*. 2011;18(3):308-320.
58. Krebs EE, Lorenz KA, Bair MJ, et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. *Journal of general internal medicine*. 2009;24(6):733-738.
59. Austin PC. Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples. *Statistics in medicine*. 2009;28(25):3083-3107.