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

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RICHARD L. ROUDEBUSH VETERANS AFFAIRS MEDICAL CENTER
INFORMED CONSENT STATEMENT FOR RESEARCH

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IRB #15934

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to pilot test a mindfulness-based intervention to reduce depressive symptoms and improve Veterans' community reintegration. We are testing this intervention to determine whether it is feasible and acceptable to Veterans.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of up to 48 Veteran participants taking part in this research. You will be in one of 8 groups of Veterans, each consisting of up to 6 Veteran participants.

WHAT WILL HAPPEN DURING THE STUDY?

After you sign this consent document, you will complete assessments to determine your eligibility for this study. To determine eligibility, we will assess your (1) demographic information, (2) depressive symptoms, and (3) community reintegration difficulty. If you are eligible for the study, you will complete additional baseline assessments to determine your anxiety severity, perceived quality of life, and mindfulness. After completing these baseline assessments, you will be randomized to one of two study groups: (1) the intervention group or (2) the control group.

If you are randomized to the intervention group, you will participate in the 8-week RECLAIM intervention. RECLAIM meets weekly for 60 minutes in a virtual setting. Sessions will include group discussions about reintegration challenges (e.g., relationships, self-care) and other topics of interest and will also include a facilitator-led mindfulness practice, such as deep breathing or chair yoga. Between weekly sessions, you will be encouraged to engage in mindfulness practices independently and asked to track your mindfulness engagement. Upon completion of the intervention, a sample of Veterans will be invited to participate in an interview to share their experience participating in RECLAIM.

If you are randomized to the control group, you will not receive the RECLAIM intervention. However, you will receive similar RECLAIM activities, such as list of suggested readings and mindfulness-based apps.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

You may be uncomfortable while answering questions during screening, completing the assessment measures, and responding to interview questions. While completing these tasks, you can skip any questions that make you uncomfortable or that you do not want to answer. There is a risk someone outside the study team could

get access to your research or medical information from this study. More information about how we will protect your information to reduce this risk is below.

If you have any health concerns during the study screening process (or at any point throughout the study), we will notify the Suicide Prevention Coordinator to contact you and document that appropriately.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?
The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees in accordance with applicable federal regulations. This does not apply to (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.

By signing this form, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?
There may be no direct benefits to you from engaging in this study. However, you may find that participating in studies that focus on improving resiliency and coping skills may have positive benefits on your overall health. We can communicate with your provider, using secured messages, to alert them to your interest in participating in other treatments or programs for potential referral, which could be of benefit to the Veteran.

WILL I BE PAID FOR PARTICIPATION?
You will be paid for taking part in this study. You will complete outcome assessments at two timepoints and will receive a $25 gift card for each set of outcome assessments you complete, for a possible total of $50. All Veteran participants, regardless of randomization assignment, can receive $50.

Intervention arm participants: If you are randomized to the intervention arm, you may have an opportunity to participate in a 60-minute one-on-one interview regarding your experience in RECLAIM. If you complete an interview, you will receive a $50 gift card. Therefore, you may receive $100 total in incentives throughout this project. Not all participants will be invited to participate in these interviews.

In order to receive payment, you may be required to provide your Social Security number or tax identification number. You may receive a 1099 tax form the following January and will need to report this payment as income on your federal and state tax returns. You are responsible for paying any state, federal, or Social Security taxes. If you have questions regarding how this impacts your tax return, please contact a tax professional to assist you.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

You will not be required to pay for medical care or services received as a subject in a VA research project except as follows:

Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are **not** part of this study.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study and databases in which results may be stored.

Audio/Video Recording

Your mental skills training sessions and interviews will be audio recorded for research purposes. At any time, you may tell the researcher that you feel uncomfortable or do not wish to continue. The audio files will be stored on a password-protected computer behind the VA firewall in a folder that is only accessible to the study team. If a recording device is used, no VA audio/video data can be stored on the device itself. All recordings will be uploaded to a secure server from the device. After the upload is complete the device recording will be erased.

Research records will be maintained by the investigator in accordance with the VHA Records Control Schedule.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the study sponsor, the Indiana University Institutional Review Board or its designees, the VA Research and Development Committee's designees, and federal agencies, including but not limited to the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), VA Office of the Inspector General (OIG).

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

Please direct questions about the consent process and the rights of research subjects to the VA Customer Service Office. For questions about your rights as a research subject or complaints about a research study, contact the Indiana University Human Research Protection Program. If you have any questions about the research study or want to check the validity, discuss problems, concerns or obtain information or offer input, please call the VA Research Personnel Office.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Roudebush VAMC.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please contact the Project Manager or the Principal Investigator.

PARTICIPANT'S CONSENT

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name: _____

Participant's Signature: _____Date: _____

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____Date: _____