Information about the LAMP Study: Learning to Apply Mindfulness to Pain

VA Central IRB
VA Institutional Review Board for Multisite Studies

You are being asked to participate in a research study conducted by Dr. Diana Burgess at the Minneapolis VA Healthcare System. This is a study to see if a mindfulness program will help reduce pain and improve quality of life among Veterans with chronic pain. In this program, you will learn "mindfulness practices" – techniques aimed at helping people become aware of their body and work with their thoughts and emotions, to better manage their pain. These techniques have been shown to improve people's chronic pain and overall well-being. You are being asked to participate because your name was selected from a list of patients at the Minneapolis, Durham, Indianapolis, or Los Angeles VA Healthcare Systems with a chronic pain diagnosis. Your participation in this research study is voluntary. You may choose not to participate at all, and you can leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?

We are conducting this study to find out whether our mindfulness program will improve pain and well-being among Veterans with chronic pain.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you agree to participate, you will:

- Be asked to complete a short survey to see if you are eligible for the study. For example, you will need to have access to a smart phone.
    - The study staff will also review your medical record to see if there is any reason it is not in your best interest to participate in the study.
- Complete 4 surveys during a 12-month period:
    - A survey at the beginning of the study completed online
    - 3 surveys completed about 10 weeks, 6 months, and 12 months after the first survey, completed online, on paper via mail, or over the phone.
    - Each survey takes about 20 to 30 minutes. You may skip any question(s) you feel uncomfortable answering or discontinue the study at any time.
- Have a 1/3 chance you will be selected to participate in the online "Group Mindfulness" program using online video conferencing, consisting of 9 weekly group sessions that are about 1½ hours long. You will also be asked to do daily "practice" of up to 20 minutes using a

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mobile app on your phone. The group sessions will randomly be observed by additional study staff, to make sure we are doing a good job. You will be asked to download a mobile application (app) onto your phone and accept the permissions requirements.

- Have a 1/3 chance you will be selected to participate in the "Mobile Mindfulness"program, consisting of 8 sessions, of about 45-60 minutes each. You will access the online program using the mobile app on your phone. A facilitator will give you a call at the beginning, middle , and end of the program to check in and help guide you. You will also be asked to do daily "practice" of up to 20 minutes using the app. There are 8 sessions on the app, but they are not delivered to the app in real time, so you can do them at your convenience. You will be asked to download a mobile application (app) onto your phone and accept the permissions requirements.
- Have a 1/3 chance you will be selected to participate in the "Normal Activity group" in which you will not participate in a mindfulness program. After the study is over you will be given the mobile mindfulness program to do on your own if you choose.

NUMBER OF PARTICPANTS

Our goal is to enroll up to 950 Veterans at the Minneapolis, Durham, Indianapolis, and Los Angeles VAs to be in this study.

DURATION OF RESEARCH

This research study is expected to take approximately 4 years. Your individual participation in the project will take 20-30 minutes for each of the 4 surveys (occurring at the start and at about 10 weeks, 6 months, and 12 months after the start). If you are selected to participate in the "Group Mindfulness" program, you will be participating in 9 video conference sessions, about 1½ hours long, as well up to 20 minutes of daily practice over 8 weeks. If you are selected to participate in the "Mobile Mindfulness" program, you will be participating in 3 phone calls and 8 sessions, 45-60 minutes long, as well as about up to 20 minutes of daily practice over 8 weeks. If you are selected to participate in the "Normal Activity" group, you will only be asked to complete the surveys. Regardless of which group you're in, your total participation will last about 14 months.

SPONSOR

This project is funded by the Department of Defense.

RIGHT OF INVESTIGATOR TO TERMINATE

We may have to end your participation in this study for the following reasons:

1. You display abusive behavior toward other participants and/or the study staff.
2. The study staff believe it is not in your best interest to stay in the study.
3. You become ineligible to participate.

4. You do not following instructions from the researchers.
5. The study is suspended or canceled.
6. You choose to withdraw consent.

ARE THERE ANY RISKS OR DISCOMFORTS?

There is the possibility that you may be uncomfortable answering some of the questions.

You may withdraw from the study at any time by calling the Study Coordinator at 877-467-5079.

As with any study, there is a risk of loss of privacy. We will make every effort to protect your privacy, and we will not contact your providers at your facility regarding your participation. We will only break confidentiality if you express an intent to harm yourself or others, at which point we would disclose only the information necessary to protect you or others. We will communicate with you directly whenever possible. If we are concerned for your immediate safety, we may try calling and/or emailing you, contacting your emergency contact person, and escalate further (for example, asking the Veteran Crisis Line staff to contact you, asking the Suicide Prevention team at your VA site to contact you, or asking your local police to do a wellness check) as it seems necessary to protect you or others.

Risks associated with this type of mindfulness program are considered minimal and rare.

- Some people may experience minor discomfort while performing mindfulness practices in certain positions (e.g., sitting, walking, gentle movements).
- Some people experience difficult feelings (e.g., sadness, anxiousness) or other mental symptoms while engaging in a mindfulness or meditation practice or when participating in group activities.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to you not following the study procedures.

You do not give up any of your legal rights and you do not release the VA from any liability by agreeing to participate in this study.

ARE THERE ANY BENEFITS?

There are many benefits of mindfulness practice. Mindfulness practice has been shown to improve chronic pain and conditions that often co-occur with pain, like depression and insomnia. Mindfulness practice has also been shown to reduce stress and improve people's general health. Your participation may benefit others in the future by guiding the development of strategies to improve healthcare within the VA, particularly for Veterans with chronic pain.

WHO WILL SEE MY INFORMATION?

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us permission to use your information, including health information in your medical records that can identify you. If all identifiers are removed from your private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional agreement.

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. The Department of Defense (DoD) may access your records as part of its human subjects protection oversight activities.

If we discover that you are experiencing worsening depression or suicidal thoughts, we will share this with your VA primary physician and, if you have one, with your mental health provider immediately. If you express an imminent intent to harm yourself or others, we will break confidentiality, disclosing only the information necessary to protect you or others.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

As a thank you for your time, you will receive $25 for each of the four surveys you complete for a total of $100. Once we receive your completed survey, you will receive a $25 check in about 4 business weeks.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, please immediately contact Dr. Diana Burgess at 612-467-1591. If you have any questions, comments or concerns about the research, please contact the study staff at 877-467-5079 or vhaminLAMP@va.gov.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.