Informed Consent Form

Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function

Document Date: 1/26/23

NCT03800654

Title of Study:
Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function (Phase 2)

Principal Investigator:	**VAMC:**
Matthew Herbert, PhD	VA San Diego Healthcare System

Subject Name:	**Date:**

1) Purpose of this research study

Matthew Herbert, PhD is conducting a research study to find out more about how mindfulness meditation works for Veterans who have chronic pain, called Mindful Action for Pain, or MAP. In MAP, you will learn mindfulness meditation, a secular type of meditation used to develop greater awareness of moment-to-moment experience, as well as other techniques that can help manage chronic pain. MAP is being compared to cognitive behavioral therapy (CBT), which teaches you about the relationship between thoughts, emotions, and behaviors, and other techniques that can also help manage chronic pain. You have been asked to participate because either you or your healthcare provider believes you may qualify for the study. There will be approximately 86 participants at this VA site.

2) How long the study will take

Your participation will take approximately 2 hours each time you come to the VA hospital, and you will be expected to come to the hospital 10 times over a 10 – 14 week period. If your participation coincides with COVID-19 restrictions on in-person research visits, these visits may occur remotely via telehealth methods such as Veteran Video Connect (VVC) or VA-approved Cisco Webex.

Overall, the entire study will take about 5 years.

3) What will happen to you in this study

If you agree to be in the study, the following will happen to you:

1. You will be interviewed and asked to fill out some questionnaires about your experience living with pain, other symptoms, and beliefs. It takes about 45 minutes to complete the questionnaires and about 30 minutes to complete the interview. If you are not eligible for the study after completing this process your participation will end. You will be paid $40 for this meeting. During COVID-19 restrictions, interviews may occur via telehealth (as noted above) or by telephone. The questionnaires will be collected by various approved methods: 1) through a link to a Qualtrics survey by study staff that you can complete on any internet-connected device with an internet browser, 2) by phone with research staff who will record your responses, 3) by encrypted email correspondence with password-protected documents, 3) by the LifeData application (app). The interview at 6-months post-treatment will be conducted via the Microsoft Teams video platform.

2. If you qualify and agree to participate, you will be randomly (by chance, as if by the toss of a coin) assigned to one of two study groups: MAP or CBT. You will meet with your

Title of Study:
Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function (Phase 2)

Principal Investigator:	**VAMC:**
Matthew Herbert, PhD	VA San Diego Healthcare System

group for eight 2-hour sessions over 8-weeks. Treatment sessions will be audio recorded so that they may be reviewed to ensure the treatment is being administered properly. These recordings will be saved in a secure data file and destroyed when your participation ends. You will be asked to complete questionnaires between group meetings. These questionnaires will ask about your pain symptoms.

3. You also will be asked to practice what you have learned at home (homework). This will take 10-20 minutes per day. You will log this homework on a daily basis through the LifeData app which will take 1-2 minutes, and be compensated $1 for each day (a total of 50 days for up to $50) you practice and log in your homework through the app.

4. You will wear a small wrist-watch device on your wrist, called an actigraph, for a 1-week duration prior to starting treatment and after completing treatment. The purpose of wearing the actigraph is to record your physical activity levels.

5. After completing the treatment you fill out questionnaires about your symptoms. This will take about 1 hour. You will be paid $40 for this meeting.

6. Three months after completing treatment you will fill out the same questionnaires about your symptoms one final time. This will again take about 1 hour and you will be paid $40 for this assessment.

7. Six months after completing treatment you will be contacted to complete a 10-20 minute interview where we will ask you questions to obtain feedback on the impact of treatment and your current level of pain and daily functioning.

4) Which procedure(s) or treatment(s) are done for research only
Procedures for this study are done for research purposes only.

5) RISKS <u>reasonably</u> to be expected
Participation in this study may involve some added discomforts. The procedures used are likely to cause:

a. The interview questions and/or questionnaires may produce discomfort or anxiety from the discussion of personal or emotional topics.
b. It is possible that the intervention will produce some discomfort including feelings of anxiety, frustration or restlessness.
c. Your confidentiality will be protected to the extent permitted by law; however, there is always a risk of breach of confidentiality.

Title of Study:
Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function (Phase 2)

Principal Investigator:	**VAMC:**
Matthew Herbert, PhD	VA San Diego Healthcare System

Unforeseeable RISKS
Because this is an investigational study there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you.

6) BENEFITS reasonably to be expected.
There may or may not be a direct benefit to you from these procedures. The investigator, however, may learn more about the best way to treat chronic pain.

7) Voluntary nature of participation and right to withdraw without penalty.
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

8) Alternatives to the research procedure or treatment
If you choose not to take part in the study, you can seek care through the VA or in the local community.

9) Procedure for the orderly termination of a volunteer's participation
If you decide that you no longer wish to participate in this study please call or contact in person Dr. Herbert at (858) 642-1411.

You should come in for a final visit if you decide to stop your participation in this study so that the investigator can determine how to best meet your future treatment needs.

Your participation in this study may be stopped if the investigator decides that stopping is in your best interest, you do not comply with study procedures (not completing questionnaires, diaries, interviews, not attending treatment sessions), or if the study is stopped.

10) Information learned from the study will be shared with you
While you are a participant in this study you will be told if any important new information is found that may affect your wanting to continue.

If the results of this research might influence your medical care after you have completed your participation, the investigators will contact you to let you know these results.

11) Care provided if you are injured as a result of this study

Title of Study:
Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function (Phase 2)

Principal Investigator:	**VAMC:**
Matthew Herbert, PhD	VA San Diego Healthcare System

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

12) Privacy and confidentiality
Participation in this study may involve a loss of privacy, but information about you will be handled as confidential as possible. Notes about the treatment you receive will be entered in the VA Computerized Patient Record System.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall. Any presentations or publications from this information will not identify you.

Information transmitted over the internet may be intercepted by third parties; because of this we will not ask you to disclose any personally identifiable information in the app and we will use current industry best practices for security measures to safeguard your de-identified online information.

In addition, audio recordings of your treatment sessions will be stored as digital files behind the secure VASDHS firewall. All recordings will be made using digital recorders, stored securely on the VA computer system behind the VA firewall, and destroyed in compliance with the current VA Records Control Schedule.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, and federal compliance officers may look at or copy portions of records that identify you.

Any presentations or publications from this information will not identify you.

13) Payment
Costs to you or your insurance

Title of Study:
Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function (Phase 2)

Principal Investigator:	**VAMC:**
Matthew Herbert, PhD	VA San Diego Healthcare System

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact the Principal Investigator.

Payment for participating
As described above, you will be compensated $40 for the baseline interview and questionnaires, $40 for the posttreatment questionnaires, $40 for the 3-month questionnaires, and up to $50 for fully completing the homework assignments.

Note that you will not be financially compensated for participation in the treatment phase of the study. Therefore, total compensation for completion of all parts of the study will be $170. Payments will be made directly to your bank account using electronic funds transfer. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

14) Additional Information
Funding: The VA San Diego Healthcare System provides oversight and resources for this study. Financial support for this study is provided by VA Rehabilitation Research and Development Service.

Clinical Trial: A description of this clinical trial will be available on http:\\www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Future Use of Data: Future Use of Data: Your data will be retained after the study and put into a data repository upon completion of this project for future research. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall. Only Dr. Herbert, his designated staff, or qualified investigators that complete a Data Use Agreement contract will have access to this data. The purpose of this repository is to access the study data after completion of this project for additional data analyses and/or to share the data with other qualified investigators interested in a similar research area and/or validation of study results.

Re-contact: The research team may wish to contact you in the future to invite you to participate in other studies. Therefore, we ask your permission to contact you in the future by telephone.

Title of Study:
Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function (Phase 2)

Principal Investigator:	**VAMC:**
Matthew Herbert, PhD	VA San Diego Healthcare System

Giving your permission for the research team to contact you does not obligate you to participate in future research – you always have the right to decline.

The research team may contact me in the future by phone for possible participation in future research studies. □Yes □No _____ (initials)

15) RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. **You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.**

In the event of illness or injury that you believe to be related to the study, or have questions about this research, you can call Dr. Herbert at (858) 642-1411. If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at (858) 642-3817, VA Research Service at (858) 642-3657, VA Regional Counsel at (858) 642-1540, or the VASDHS Human Research Protection Program at (858) 642-6320.

_____ has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You will receive a copy of this consent form and a copy of the Health Insurance Portability and Accountability Act (HIPAA) Authorization that you signed. You will also receive a copy of the California Experimental Subject's Bill of Rights.

By signing this form you indicate that you have been informed of your rights as a research subject, and that you voluntarily consent to participate in this study. You have been informed what the study is about and how and why it is being done.

_____ _____
Subject's Signature Date

_____ _____ _____
Signature of Researcher obtaining consent Name (print) Date