Efficacy of Mind-Body Approaches for the Treatment of Chronic Pain with Psychological Comorbidity

NCT04651296

September 20, 2022

Study Title: Efficacy of Mind-Body Approaches for the Treatment of Chronic Pain with Psychological Comorbidity

Principal Investigator:

VA Facility: San Diego Healthcare System

Participant Name:	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is about mind-body approaches, which refers to a large and diverse group of procedures that are administered or taught by a trained practitioner or teacher and include techniques designed to enhance the mind's positive impact on the body. We want to compare two different mind-body groups among Veterans who have concerns with chronic physical pain and mental health symptoms (posttraumatic stress disorder (PTSD) and/or depression symptoms). We are comparing a compassion meditation training group to a health and wellness education group. This study is being funded by the Department of Veterans Affairs. By doing this study, we hope to understand the effectiveness of these approaches for reducing pain-related functional problems and improving mental health among Veterans.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

The purpose of this research is to gather information on the effectiveness of mind-body approaches for reducing pain-related functional problems and improving mental health among Veterans.

During your initial visit today, you will be interviewed and fill out some questionnaires about your feelings, symptoms, health, and beliefs. We will also ask some questions about any other treatments that you have been using for pain problems and/or mental health symptoms, including your current or past experiences with talk therapies, medication therapies, other pain interventions, and other mind-body practices. It takes about 60 minutes to complete the questionnaires and about 45-60 minutes to complete the interview. If you are not eligible for the study, your participation will end. If you are eligible, you will also complete the following steps. You will be paid $50 at the end of this meeting. If you are eligible and you choose to enroll in the study, we will ask you to maintain your current regimen of medications and other treatments (e.g., pain injections) during the course of the study. We will also ask you to refrain from engaging in other talk therapies or mind-body practices outside of the study interventions.

After your initial visit, you will attend the Therapy Expectations Session. The goals of this session are to 1) identify reasons for coming into treatment at this time, 2) identify goals of engaging in treatment, 3) learn about expectations of the treatment and overview of the treatment process, 4) identify and discuss any barriers to treatment, and 5) assess for appropriateness of moving forward within the study.

If you decide to continue, you will be randomized to one of two mind-body groups. Randomization simply means that you will have an equal chance (one out of two) of receiving either of the two treatments, kind of like a coin toss. You cannot choose your study group. Depending on which condition you are randomized to, this will involve either 10 compassion meditation group training sessions or 10 educational sessions about health and well-being. You will begin the mind-body group in person. You will participate in ten 90-minute group meetings over 10 weeks. You will be asked to complete questionnaires during and between group meetings. These questionnaires will ask about your symptoms and your reactions to the group and will take about 10 minutes per week. You also will be asked to practice what you have learned daily at home and keep a diary of your meditation practices to provide impressions and feedback. This should take 15-30 minutes per day.

At the midpoint of your treatment, you will fill out some questionnaires about your feelings, symptoms, health, and beliefs; this will take about 30 minutes. After you complete your treatment and at 3-month and 6-month follow-up, you will complete some questionnaires and be interviewed about your feelings, symptoms, health, and beliefs, this will take 60-90 minutes. You will be paid $50 at the end of each of these meetings.

Your participation in this research will last about 9 months. In order to participate, you must plan to attend the 4 individual study visits and the 10 group sessions.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
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 with mental health symptoms.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
We will ask you to maintain a stable regimen of medications and other treatments that target pain and/or mental health symptoms so that we can make sure that any treatment response is related to the study treatment, rather that changes in your other treatments. It is possible that your PTSD and/or depressive symptoms may either not change or may worsen in the absence of a standard psychotherapy treatment. It is likewise possible that your chronic-pain related functioning may either not change or may worsen in the absence of a standard psychotherapy treatment. It is also possible that your that your chronic pain, PTSD and/or depressive symptoms may either not change or worsen while maintaining stable regimen of medications.

As with any study involving human participants, a risk of disclosure of personal material also exists. The compassion meditation and psychoeducational health and wellness groups will be conducted in a group format, and thus a further risk of loss of confidentiality exists because other participants will be privy to information you may reveal during the group sessions. Participants will be reminded of the importance of keeping information about others in the group confidential. The assessment meetings (interviews only) and group training sessions will also be audio recorded and may be reviewed by a member of the study team as part of the assessor and/or therapist's supervision. Group participants will be heard in the audio recordings.

The alternative to participation is to receive treatment for chronic pain, PTSD, and/or depression through VA clinical (nonresearch) mental health services. You may also talk with your physician about other options for treating chronic pain, PTSD and/or depression symptoms.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact information is: XXX-XXX-XXXX.

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

This study is being sponsored by the Department of Veterans Affairs.

Members of the research team have certified that they do not have a significant financial interest and/or a conflict of interest related to the research.

The purpose of the research is to compare two different mind-body groups among Veterans who have concerns with chronic physical pain and mental health symptoms (PTSD and/or depression symptoms). We are comparing a compassion meditation training group to a health and wellness education group.

You are being asked to participate because you have had chronic physical pain most days for the past 6 months of more, and this pain interferes with important areas of your functioning, and you have some mental health symptoms related to PTSD and/or depression. Approximately 168 Veterans will take part in this research at this facility.

Many Veterans experience chronic pain with mental health symptoms (PTSD and/or depression), but there are few existing treatments available to address both chronic pain-related functional problems and psychological concerns. Prior research, including one study of Veterans with PTSD, suggests that group training in compassion meditation may be effective in reducing mental health symptoms and improving pain-related functioning. negative emotions and increasing positive emotions and well-being. We are conducting this larger and more definitive study comparing compassion meditation to a health and wellness educational group.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take approximately 9 months. The overall study will last approximately 5 years. The study will involve 14 visits:

- 1 initial individual study visit lasting 2-3 hours,
- 1 individual therapy expectations meeting lasting 30 minutes,

- 10 weekly group sessions of 90 minutes each,
- Mid-treatment questionnaires (30 minutes), posttreatment, 3-month follow-up, and 6-month follow-up individual study visits lasting 60-90 minutes.

After the final study visit, your participation will be complete.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you decided to participate, the following will happen:

All study procedures will take place at the VA San Diego Medical Center in La Jolla, at one of the VA community-based outpatient clinics (such as Mission Valley or Chula Vista), or you will participate from home, via teleconferencing/telephone (remote visits). Before you decide to participate, you will be told where your study procedures will occur.

All remote visits will take place virtually through programs called Veteran Video Connect (VVC) and Cisco WebEx, which will allow you to see, hear, and speak with study staff/group instructors and the other group participants using your computer, tablet, or smartphone. Both VVC and Cisco WebEx meet VA privacy and security standards.

Visit 1 (2-3 hours): You will meet individually with one or more of the study staff to be interviewed and complete questionnaires regarding psychological symptoms, physical health (including chronic physical pain), well-being/quality of life, and current and previous experiences with chronic pain and/or mental health treatments, as well as your thoughts, beliefs, and psychological characteristics. Portions of this visit (clinical interviews) will be audio recorded and potentially reviewed by authorized study staff for the purposes of training and quality control.

We will also ask you questions about your age, education, gender, relationship status, medical conditions, and active medications, and may review your VA electronic medical records to confirm details about your medical conditions and medications.

Visit 2 (may be combined with visit one; 30 minutes): You will meet individually with one of the study staff to identify your goals and expectations, identify any anticipated barriers to treatment engagement, and confirm that you would like to continue to next step (randomization to treatment group). This visit will be audio recorded and potentially reviewed by authorized study staff for the purposes of training and quality control.

Visits 3 through 13: Next, you will be randomized to participate in either of the following groups. This means that you will be put into a study group by chance (like a coin toss/like drawing straws). You have a 1 out of 2 chance of being placed in each group. You cannot choose your study group.

A. Compassion Meditation Training: The compassion meditation training involves 10 weekly 90-minute group sessions (our goal is to have up to 10 Veterans in each group). Sessions 1 - 4 assist

participants in basic, foundational meditation; sessions 5 - 8 focus on personal analysis of factors underlying difficulties with compassion for self or others; the final two sessions (9 and 10) review content and assist with relapse prevention; if you prefer, we can mail an audio disc that contains the recordings to guide your at-home practice (for example, if you prefer to use a CD player/stereo for practice or you have difficulty accessing digital audio files).

B: Psychoeducational Healthy and Wellness group: This will involve 10 weekly 90-minute group sessions involving informational presentations and group discussions/activities about various health and wellness-related topics including nutrition/healthy eating, sleep, relaxation, physical activity, stress, mood, communication, and social support.

For both groups, on a weekly basis, a team-member will review these at-home practices and questionnaires with you virtually (VVC or WebEx) or by telephone; we can also provide necessary technical support to participate in remote procedures during these weekly check-ins or as needed.

The amount of time between Visit 1 (and 2) and starting the groups may also vary depending on how quickly the groups are filled, but we will give you our best estimate before you decide whether or not to participate.

At the midpoint of treatment (before visit 5; 30 minutes) you will complete several brief questionnaires regarding psychological symptoms, physical health (including chronic physical pain), well-being/quality of life, as well as your thoughts, beliefs, and psychological characteristics.

Regardless of which group you are randomized to, we will ask you to complete several brief questionnaires before each group session to check in on your symptoms and functioning. You will also be asked to complete at-home questionnaires and structured practice sessions that will help reinforce the concepts you learned in the group sessions. Appointment reminders will be emailed to you from a VA-secure email program or texted from a VA phone.

The group training sessions will be audio recorded and reviewed by a member of the study team as part of the therapist's supervision.

Visits 14-16: Within 1 to 2 weeks after the final group session, and again at 3- and 6-month follow-up, you will again meet individually with one of the study staff to repeat the measures that were collected at Visit 1. The purpose of re-collecting this information is to determine if there are any changes following group participation. Visits 14-16 are expected to take about 60 to 120 minutes.

For all questionnaires, you can skip any question that makes you uncomfortable and you can stop at any time.

Although compassion meditation has been found useful in in other settings (including non-Veterans), it has not been evaluated in Veterans with chronic pain and mental health symptoms, so is considered experimental for this purpose.

As part of your participation, you are expected to:

- Complete the questionnaires and interviews,
- Participate in the groups and ask questions as you think of them,
- Complete between-session assignments and complete weekly diaries to record these activities,
- Be polite and cooperative with the study staff and other participants,
- Keep the identify of other group participants confidential,
- Inform the research staff, group leader, and/or study investigators if you have concerns or if you choose to stop participating.

If you choose to stop attending the groups, we will ask you if you are willing to complete the posttreatment and follow-up visits, but whether you do so is voluntary.

You are also expected to keep your study appointments. If you miss an appointment, please contact us to reschedule as soon as you know you will miss the appointment.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

All of the procedures and measures described above are for research purposes only. They not part of standard care for your chronic pain, PTSD, and/or or depressive symptoms.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any study procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- The study procedures and assessments require time and concentration. You may become bored, fatigued, or distressed while undergoing these assessments and/or while participating in the study group sessions. If, for any reason, you wish to not answer specific questions or you wish to terminate the session, you will be able to do so.
- It is possible that your chronic pain, symptoms of PTSD, and/or depression may either not change or may worsen in the absence of starting standard psychotherapy during study participation or making changes to your current medication regimen during study participation.
- As with any study involving human participants, a risk of disclosure of personal material also exists. The compassion meditation and psychoeducational health and wellness groups will be conducted in a group format, and thus a further risk of loss of confidentiality exists because other participants will become aware of information that you reveal during the group sessions. You can choose not to reveal any personal or confidential information during the group sessions.

In addition to the risks described above, you may experience a previously unknown risk or side effect. You will be

informed if the researchers learn of any change in the amount of risk to you. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this facility or loss of benefits to which you are entitled.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. If you participate in the health and wellness educational group you may learn information that you might find useful or interesting such as information about things like exercise, diet, stress management, or sleep. If you participate in the compassion meditation group, you may learn meditation methods that you might find helpful in reducing pain-related functional problem and/or PTSD and/or depressive symptoms.

The investigators may learn if group trainings are helpful for Veterans with chronic pain and PTSD and/or depressive symptoms. This could ultimately help future Veterans.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS RESEARCH STUDY?

If you choose not to take part in the study, you can seek care through the VA or in the local community.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

While you are a participant in this study, you will be notified if any important new information is found that may affect your willingness to continue.

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

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

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.

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled. If you decide to discontinue participating, please inform a member of the research staff or investigators. The investigators may continue to review the data already collected for the study but will not collect further information without your permission, except from public records, such as survival data.

If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. You may discontinue taking part at any time without any penalty or loss of benefits.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The group leaders, research staff, and/or investigators may also withdraw you from the study if they believe your participation is contraindicated (e.g., if you symptoms are getting noticeably worse, or if you are non-cooperative or disruptive in the group sessions or study visits), of if they believe it is in your best interest to discontinue participation.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

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 us so they can check into and correct the situation.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will receive $50 payment for participation at each of the five assessment visits. You are also eligible to receive a one-time bonus payment of $50 for completing all five assessments, for a total of $300 for complete participation. Payments will be made directly to your bank account using electronic funds transfer or by certified check. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

ADDITIONAL INFORMATION:

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by study staff while you are participating in this study. The said voice recording is intended for the following purposes: training and quality assurance.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded, and you may rescind your consent for up to a reasonable time before the voice recording is used.

VASDHS provides oversight and resources for this study. Financial support for this study is provided by the Department of Veterans Affairs.

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.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, or concerns about the research or other related matters, you may contact us so they can check into and correct the situation.

Study Title: Efficacy of Mind-Body Approaches for the Treatment of Chronic Pain with Psychological Comorbidity

Principal Investigator:

VA Facility: San Diego Healthcare System

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 XXX-XXX-XXXX, VA Research Service at XXX-XXX-XXXX, VA Regional Counsel at XXX-XXX-XXXX, or the VASDHS Institutional Review Board at XXX-XXX-XXXX. This is the Board that is responsible for overseeing the safety of human participants in this study.

FUTURE USE OF DATA AND RE-CONTACT

We may wish to contact you in the future about participating in future studies for which you might qualify. Only people within the VA would be contacting you if this were to occur. You can agree to or decline this option, by checking the appropriate box below.

☐ **Yes, I may be contacted for future research opportunities as described**. _____ (initial)

☐ **No, I do not wish to be contacted for future research opportunities as described**. _____ (initial)

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. Because the study involves a group treatment, a note in your VA medical record describing participation is required following each study visit.

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.

In addition, audio recordings of your training sessions may be reviewed by a study investigator who are experts in compassion meditation and health and wellness training. These recordings will be stored as digital files behind the secure VASDHS firewall and may be reviewed here to be sure that treatment is being delivered as planned. All recordings will be made using digital recorders, securely transported to the VA La Jolla Medical Center (if applicable), stored securely on the VA computer system, 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.

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

While this study is being conducted, you will not have access to your research related health records. This will not

affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

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

Your private information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

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.

_____ has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.

_____ _____

Participant's Signature Date

_____ _____ _____

Signature of Researcher obtaining consent Name (print) Date

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Principal Investigator:

VA Facility: San Diego Healthcare System

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, mental health treatment, etc. Information about alcohol or substance use disorders and treatment will be collected. In addition, the last four digits of your Social Security number will be collected for accessing your medical record and for payment purposes.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. Other VA entities may include the Human Research Committee (HRC) and the VA Office of Research Oversight (ORO), Institutional Review Board (IRB), Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address:

X

If you revoke this authorization, PI and the research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

While this study is being conducted, you will not have access to your research-related health records.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study; any study information that has been placed into the investigators' database may be used by the investigators for future research and will not expire.

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AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records.

_____	_____	_____
Participant's Signature	Last 4 of SSN	Date

A copy of this document will be provided to the research participant.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at XXX-XXX-XXXX. You may leave an anonymous comment at the VASDHS research compliance hotline at XXX-XXX-XXXX

REF: California HSC 24170-24179.5

A copy of this document will be provided to the research participant.