Consent to participate as a Research Subject in:

Investigating Methods of Pain Recovery with Outpatient Veteran Education ("IMPROVE")

SUMMARY OF STUDY: The purpose of the study is to compare two treatment groups to usual care treatment for chronic musculoskeletal pain. The two groups are mindfulness-based stress reduction (MBSR) and cognitive behavioral therapy for chronic pain (CBT-CP). To determine whether these groups are better than usual care, we will randomly assign Veterans to participate in one of the two groups or to continue with their treatment as usual. Veteran study participants will need to complete research questionnaires over an 8-month period to help us in measuring the symptoms related to chronic pain and in determining which treatment is the most effective.

Principal Investigators:
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Research Staff:
Lisa Glynn, PhD
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Study Title:
An Evaluation of MBSR and CBT for Veterans with Chronic Pain

For study-related questions, please call the study staff at (206) 277-3538.

We are inviting you to be in a research study. The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully.

You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

1. Who can I contact with questions while I am in this study?

During business hours (8:00 a.m. – 4:30 p.m.), please call the study staff at (206) 277-3538. After business hours (nights and weekends), please call 206-762-1010 and ask the operator to page the on-call psychiatrist.

The study researcher(s) listed above must be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues specifically related to the study.

You may also contact the Institutional Review Board (IRB) at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

2. What is the purpose of this research study?

The purpose of this study is to see if mindfulness-based stress reduction (MBSR) and cognitive behavioral therapy for chronic pain (CBT-CP) are each effective treatment options for Veterans with chronic musculoskeletal pain. We want to determine whether each of these treatments is more effective than the usual care offered to Veterans with chronic musculoskeletal pain.

To do this, we will be randomly assigning Veterans to take part in either 1) MBSR, 2) CBT-CP), or 3) treatment as usual. Both MBSR and CBT-CP will be held remotely using the VA's Video Connect platform. We will then compare chronic pain symptoms before and after 8 weeks of group sessions or at an equivalent time point for those who continue to receive usual care. Below is a brief outline of each group of the study:

- **MBSR** is the "mindfulness group," which teaches techniques for enhancing a person's capacity for mindfulness, such as the breathing meditation, the body scan, walking meditation, and some gentle yoga. These exercises are designed to help learn skills that can help work with chronic symptoms such as pain, fatigue, or memory lapses. The focus is on learning self-care practices that other studies have shown to be helpful for chronic symptoms.

- **CBT-CP** is the cognitive behavioral therapy group, which teaches Veterans to examine the relationship between their thoughts, feelings, and behaviors. Learning this is designed to help improve functioning and quality of life. The focus is on providing tools to cope with the challenges associated with chronic pain.

- **Treatment as usual** means that you would not participate in either research group but would continue to receive care from your regular health care providers. This can include continued use of your medications, specialty referrals, and other usual elements of care. If you are assigned to treatment as usual, you are still enrolled in the study even though you won't participate in either of the two group treatment options.

To be eligible for this study, you must have the following:

- Musculoskeletal pain of the low back, cervical spine, or extremities (hip, knee, or shoulder);
- Pain duration of at least 3 months; and
- Average pain severity of greater than or equal to 4 out of 10 in the past week (study coordinator will assess this during the screening process).

We plan to enroll up to 222 Veterans who received care at Veterans Affairs Puget Sound Health Care System (VA Puget Sound).

If you wish to join this study, you will need to complete phone screening and the consenting process. If you are eligible, you will then complete a Baseline appointment. In total, this should take 2½ to 3 hours.

We will ask you to have three 1-hour study phone appointments (completing questionnaires)—one appointment at baseline and two appointments after 8 weeks of attending weekly group sessions or 8 weeks of treatment as usual. In total, completing these study procedures will require commitment to this research study for a period of 8-9 months. All study visits will be held by phone.

3. What will I be asked to do in this research study?

If you are eligible to continue participating in the study, we will ask you to begin the baseline appointment immediately following the screening procedures (during the same phone appointment). This will take 1-2 more hours. The baseline assessment, as well as the remaining two assessments for this study, will include several questionnaires that measure your physical and mental health, including pain, anxiety, PTSD symptoms, depression, emotions, drug and alcohol use, and physical symptoms.

In this study, we will ask you to participate in two types of appointments—research appointments and group sessions:

- **Research appointments** will be scheduled with study staff at a mutually convenient time. At each study phone appointment, you will need to answer a series of questionnaires with a member of our study team; this is when the researcher collects information about your symptoms and health status. All participants will be asked to complete these research assessments.
- **Group sessions** are the MBSR and CBT-CP video appointments, which take place after the Baseline Visit.

For randomization purposes, we will use a computer-generated program to randomly assign each participant. “Randomization” means that you will be put into a group by chance, like the flip of a coin. The computer program will reveal which randomized group you will be in for the duration of the study. There will be an equal number of assignments for each group, so the odds of assignment to any group are one in three. Depending on which group you are randomized to, the following will be required:

If you are in the MBSR group, you will need to:
- Attend weekly video group sessions for 8 weeks. Each weekly group session will be for 2 hours.
- Complete two Follow-Up phone appointments.

If you are in the CBT-CP group, you will need to:
- Attend weekly video group sessions for 8 weeks. Each group session will be for 1½ hours.
- Complete two Follow-Up phone appointments.

If you are in the treatment-as-usual group, you will need to:

- Complete two Follow-Up phone appointments.

MBSR and CBT-CP only

Schedule of sessions. If you have been randomly assigned to MBSR or CBT-CP, we will provide you with a schedule for the video group sessions that you will need to attend. The group sessions will be intended as treatment; they may be entered into your medical record as clinical appointments.

Audio-recording. We will audio-record the MBSR and CBT-CP group sessions. These recordings may include the use of first names within the group. The purpose of these recordings is to ensure that the group leaders are adhering to the appropriate treatment curriculum as closely as possible.

Assessments for all groups

During the research appointments, assessments will be recorded from questionnaires that we will ask all groups to complete over the phone. Although health information will be created about you at this time, we will not include any of this information in your medical records.

Some of the assessment questions deal with sensitive topics. Examples of potentially uncomfortable questions include:

- *In the past month, did you think about suicide?*
- *Please indicate if you have experienced the following traumas* (which will include a checklist).

You may refuse to answer any question or item, but we reserve the right to exclude you from further participation if we are unable to get a complete picture of your health status and verify that you are eligible to participate.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

Medical reviews

We will be tracking the medications that you take and any other treatment you receive while you are enrolled in the study so that we are aware of whether factors—other than the study treatment—may contribute to fluctuations in the symptoms that we are measuring for this research. We will gather this medication and treatment information from your VA electronic medical record.

Drug use reviews

We will be tracking non-prescribed drug and opioid use while you are enrolled in the study so that we are aware of whether factors—other than the study treatment—may contribute to fluctuations in the symptoms that we are measuring for this research. We will gather this drug and opioid use information from you at all three study appointments (Baseline Visit and two Follow-up Appointments).

Below is a flowchart of the study procedures, including an estimated length of time each will take to complete:

Phone
consent appointment
(30 minutes)

Once signed consents received by study staff

Phone eligibility screening
(30 minutes)

If not eligible

Study participation ends here

If eligible

Phone Baseline Assessment
(2 hours)

Randomized to MBSR, CBT-CP,
or treatment as usual

Mindfulness-based
Stress Reduction
(8 weekly sessions)

Cognitive Behavioral Therapy
for Chronic Pain
(8 weekly sessions)

Treatment as usual
(NO GROUP SESSIONS)

First Phone Follow-up Assessment
(1 hour)

6-Months Later, Second Phone Follow-up
Assessment
(1 hour)

4. What are some risks of joining this research study?

The study procedures may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. If any of the risks included in this Consent Form become significantly updated during this study, we may ask you to sign an updated Consent Form to document that this new information has been explained to you. You will have the right to decide either to continue with the research study or to withdraw.

Below are study-related risks that are known at this time:

- **Confidentiality.** There will be a risk that a breach of confidentiality could occur; however, every effort will be made to prevent this from happening. Your personal information will be kept secure and only accessed by authorized study staff as needed to conduct this study.

- **Questionnaires.** Answering questions during the research appointments may result in emotional discomfort, since it can be unpleasant to think about different mental and physical health symptoms and their impact on your life. During the questionnaires, you may feel uncomfortable answering questions or focusing on past stressful or traumatic experiences. In addition, you may feel as if your privacy has been invaded. You should feel free to discuss any discomfort with the study procedures with any person on the study team.

Risks for MBSR and CBT-CP groups only

- **Group sessions.** Please be advised that although we take every precaution to maintain confidentiality of the data, the nature of group sessions prevents us from guaranteeing confidentiality. In addition, as this is a VA Video Connect group, there are some limitations in confidentiality that come with using an internet-based platform. We would like to remind you to respect the privacy of your fellow study participants and not repeat what is said in the group sessions to others. We take steps to positively identify all participants, and lock the video group to prevent intrusions.

- **Audio-recordings.** Although only your first name and no other identifying information will be mentioned during the recorded group sessions, there is a chance that the study staff listening to the group sessions could recognize your voice. However, please note that your voiceprint is considered a "personal identifier" according to the patient privacy rules. Therefore, even if you are identifiable by voice, your identity will never be disclosed without your authorization to anyone not listed outside the research team.

5. What are some benefits of joining this research study?

There may be no direct benefit to you by participating in this study. However, we will be monitoring you more closely and there is the possibility that you may receive more timely treatment of pain as a result of being enrolled in the study.

If you are randomized to either MBSR or CBT-CP, there is the possibility that your chronic pain symptoms may decrease—and your quality of life may increase—as a result of participating in this

study. It is also possible some of the strategies or methods involved in these programs may not be effective or could result in symptom worsening.

Regardless of whether you participate in the study or not, the results from this study may lead to new therapies for chronic musculoskeletal pain, which could help other individuals who also suffer from pain symptoms.

6. Are there other ways I could receive these benefits?

If you do not wish to participate in this research, you may continue your usual treatment for chronic musculoskeletal pain. If you are not currently receiving other treatment, we recommend that you speak to your primary care provider about the treatment options available to you.

If you would prefer to take MBSR or CBT-CP in a non-research setting, both are available clinically through VA Puget Sound. For Veterans randomized to treatment as usual and who would like the opportunity to participate in MBSR or CBT-CP, the study staff will provide information on how to access these groups at the time you complete the study.

7. Who will see my information and where will it be stored?

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members
- The Data Safety Monitor who will advise the Principal Investigator regarding the continuing safety of this study
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- The VA Puget Sound Fiscal Department and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

Medical Record

We will write a progress note in your medical record. The progress note will simply state when you joined the study and when your participation was complete. The progress note will also include the name of the study. We will not put any assessment results into your medical records. All approved users of the national VA medical records system can have access to your medical record. This record will be retained in accordance with the VA records retention policy.

Study Code

If you agree to participate in our study, we will assign you a study code number. We will not include your name or other identifiers (such as your name or social security number) on any of the information that we collect from you. Only your study code number will be used. We will keep a master list that links study participants' names to code numbers separate from the study data in a secure VA database with restricted access.

Safekeeping of Study Information

- **Study data (paper and electronic)**
  To protect the confidentiality of the information obtained about you during this research study, we take many preventative measures. Any paper study documents we have, received, or created will be secured in locked file cabinets accessible only to study staff. Any electronic study records will be kept in electronic folders on the secure VA network with access to the specific folders restricted to designated study staff. The data collected from the assessments will be saved directly to a database located in the password-protected VA computer system to which only VA study personnel have access.

- **Audio-files from MBSR and CBT-CP group sessions**
  The audio-files will be uploaded from the digital audio-recorder and saved to a password-protected VA network folder. Audio-files will be listened to by only members of the research staff. The audio-recorder will be stored in a locked cabinet when not in use and accessible only to authorized study staff.

Upon Study Completion

Once this study is completed, we will not use your data, including any recordings and transcriptions (or the study code linking it to you) for any additional research. We will keep your data and code in a secure database in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed).

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing. Neither you nor your family will gain financially from discoveries made in the future using the data you provide.

A description of this clinical trial will be available on 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.

Certificate of Confidentiality

We have been granted a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers will use the Certificate to resist any demands, even by a court of law, for information that would identify you. You may still share information about yourself or your part in this research as you see fit.

The Certificate of Confidentiality does not protect us from:

- Disclosing information to state or federal public health authorities to whom certain contagious diseases (tuberculosis, HIV, anthrax, syphilis) are reported (if we observe such diseases in any subjects).
- Disclosing information to law enforcement authorities if we get any information that suggests the occurrence of child abuse, elder abuse, or your intent to immediately and substantially harm yourself or others.
- Giving the VA Puget Sound office that manages payments to subjects your name, social security number, address, and the name of this study.
- Giving your name to state, federal, and institutional offices involved in auditing or compliance of research, risk management, patient safety, and financial controls.

8. What are some other things to think about before I decide to join this research study?

Research Assessments:
All study participants will be paid accordingly:

- Phone screening / Baseline Visit
  (even if you are not eligible) . . . . . $ 45

- First Follow-up Assessment . . . . . $ 60

- Second Follow-up Assessment . . . . . $ 75

  TOTAL for completing all study appointments. **$180**

You will receive a payment within approximately 8-10 weeks after you complete each research assessment. At this time all payments will be made electronically. If you do not have an electronic method established with the VA, or are unsure about the status of your electronic payment method, we can direct you to the information on how to set up your electronic payment. Should another method of payment become available we will update you.

To comply with Internal Revenue Service (IRS) guidelines, we will collect your social security number. You may receive an IRS Form 1099.

9. What will happen if I decide I don't want to be in this research study later?

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits. If you decide to withdraw from the study, no new information will be collected from you. Information already collected up to that point will continue to be used for the study.

Your participation in the study may be terminated without your consent if you become a threat to the safety of yourself, to others in your treatment group, or to the research team. In addition, your participation in the MBSR or CBT-CP group could be terminated if you do not follow the community agreements that the groups establish in session 1. Your termination can be initiated by any of the research team members, but the decision must be confirmed with the study's Principal Investigator before you are withdrawn from the study.

10. What will happen if I am hurt in this research study?

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this Consent Form.

11. What am I agreeing to by signing this form?

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are available to me.

My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this Consent Form.

I agree to participate in this research study as described in this document.

_____ _____

Subject Signature Date

_____

Print Name of Subject