UNIVERSITY OF CALIFORNIA, SAN FRANCISCO SAN FRANCISCO VA HEALTH CARE SYSTEM CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Feasibility Clinical Trial of Integrated Mind-Body Therapy for Chronic Low Back Pain

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This is a research study about investigating an 8-week MBPR (Mindfulness-Based Pain Reduction) program, to optimize a mindfulness-based intervention for chronic low back pain. The study researchers, Wolf Mehling, MD and Kirsten Rogers from the UCSF Osher Center for Integrative Medicine, will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Wolf Mehling, MD and colleagues at the University of California (UCSF) Osher Center for Integrative Medicine, and Irina Strigo, PhD and colleagues at the San Francisco VA Medical Center, the VA Advanced Imaging Research Center (VAARC).

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this study is to develop a mindfulness pain reduction program for chronic low back pain.

You are being asked to participate because you have chronic low back pain.

Study Procedures: If you choose to be in this study you choose to be in this study, you will first undergo an eligibility assessment. If eligible, you may then answer a series of questionnaires by mail or online and—only if you are eligible for the MRI, for example if you are not older than 65 years of age—undergo MRI brain imaging at the Veterans Affairs Medical Center.

After the initial assessment, you will be assigned either to the proven evidence based MBSR program or the new MBPR program.
You will be in this study for 8-10 weeks total with a follow-up on-line visit at 6 months, and you may be asked to visit the research site at the San Francisco Veterans Affairs Medical Center two times for the MRI. All other activities are online or by Zoom video-call.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- General distress, such as fatigue, restlessness, anxiety
- MRI-related: claustrophobia, muscle aches, fatigue, mild pain

There are no serious risks of participation.

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we do not know about.

Possible Benefits: There will be no direct benefit to you from participating in this study.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Taking part in another study.
- Not taking part in this study

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have chronic low back pain.

Why is this study being done?

The purpose of this study is to find out whether it is possible to improve the proven evidence based MBSR program for chronic pain management and how attention and attitudes affect pain and brain function. This study will be performed at the University of California San Francisco and the San Francisco VA Medical Center and VA Advanced Imaging Research Center (VAARC). This study is being funded by the National Institutes of Health.

How many people will take part in this study?

About 50 people will take part in this study.

What will happen if I take part in this research study?

If you agree and chose to enroll in this study, the following procedures will occur:

- **Questionnaires:** You will be provided a set of questionnaires to fill out. These questionnaires will ask you a variety of questions about topics such as your physical and psychological health, substance use, your thoughts, believes, and feelings, etc. You will answer these questionnaires at the beginning of the study, at the end of the 8-week classes, and 6 months after the classes.
- **Magnetic Resonance Imaging (MRI):** MRI is an electronic picture of your brain created using a strong magnet instead of x-ray energy. You will be asked questions about MRI safety during screening and again at the time of the MRI by staff at the clinic. The MRI scan will be performed at the VA Advanced Imaging Research Center (VAARC) at the San Francisco VA Medical Center. **Pregnancy Assessment (females only):** If you are a female and capable of childbearing, you will be asked a number of questions regarding your use of reliable contraceptive methods (e.g. abstinence, diaphragm, condom, or intrauterine device) in order to be as sure as possible that you are not pregnant. You will not undergo MRI if you are older than 65 years of age, because age-related brain changes would make it difficult to analyze the data.
- **Pain Attention Task in the MRI**: neutral stimuli and individually determined, moderately painful (~115 degree) heat stimuli of 20 seconds duration will be delivered at the forearm. Before scanning you will be instructed and trained in different attention styles towards pain, such as thinking about it versus sensing or reflecting about it. The task will be administered in four 7-min sequences. The task has been used in prior studies, is adapted to your individual sensitivity, and is safe.

  Exclusions from MRI*:* People with pacemakers, aneurysm clips, cochlear implants, or certain other metal/foreign objects in the body are not permitted to do MRI studies. There are no known biological risks from MRI. Even though there are no known risks to an unborn child associated with MRI, women of childbearing potential who are not using reliable contraceptive methods (i.e., a medical device or medication designed and taken to reduce the chance of pregnancy) will be excluded from this study.

  MRI Procedure: A picture of your brain and spine will be obtained while basic physiological information (e.g. breathing and heart rate) may be recorded. This part of the visit will last approximately 1-2 hours.

  If there are any potentially abnormal results from the MRI scan requiring additional medical attention, the study team will consult a radiologist. If the radiologist confirms an abnormal result your medical provider will be informed.

Depending entirely by chance, you will be assigned to either the MBSR or the MBPR program:

- **Mindfulness Based Stress Reduction (MBSR) Program:** You will participate in an 8-week program, delivered once a week in 2½-hour group sessions and a daylong retreat. This program trains individuals in several mindfulness practices, e.g. focus on breath and

bodily sensations, mindful walking and yoga poses. You will be asked to listen to audio-recordings and review written materials for home practice. Yoga poses at home are supported with video recordings. This is the guideline-recommended evidence based standard mindfulness program already used world-wide in countless medical settings

- **Mindfulness Based Pain Reduction (MBPR) Program:** You will participate in an 8-week program, delivered once a week in 2½-hour group sessions and a daylong retreat. This program trains individuals in several mindfulness practices, e.g. focus on breath and bodily sensations, and yoga. You will be asked to listen to audio-recordings and review written materials for home practice. The yoga practices are supported with video recordings. You will also download and use the free InsightTimer app on your phone using a new private e-mail account with a unique pseudonym set up only for you and only for this study. The app will connect to the research team, record the time you spent with meditation practice and link to guided meditation audios. The MBPR program is patterned after the MBSR program with a few changes. We do not know whether these changes influence the program's effect.
- **In-detail exit interview:** The researcher may interview you with a 2 hour long Zoom video call. The researcher will ask you to describe your personal experiences with the attention task and your low back pain. The researcher will make a sound recording of your conversation. After the interview, someone will type into a computer a transcription of what's on the tape and will remove any mention of names. The sound recordings will be obtained by UCSF personnel at the Osher Center for research purpose only and used for transcription and subsequent analysis by the research team. The sound recordings will not be listened to by anybody outside the UCSF research team. The sound recording will then be destroyed.
- **Recordings:** Phone and video conferences will not be recorded except for the program classes and the exit interviews. These recordings are for research purposes only and will only be accessible by research staff. These will be saved on a secure UCSF server for 1 year after study completion or until final publications of the study results, whatever comes first, and then destroyed.

Study location: the MRI scan will be performed at the VA Advanced Imaging Research Center (VAARC) at the San Francisco VA Medical Center, all other study procedures will be carried out remotely via phone call and video conferencing.

How long will I be in the study?

Participation in the study will take a total of about 35 to 42 hours over a period of 8-10 weeks plus a 6-month questionnaire assessment, depending on the scheduling and length of the weekly phone calls and the exit interview.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- **Questionnaires:** The questionnaires may be distressing to some participants, and you may experience restlessness, anxiety, or fatigue when filling out questionnaires. You are free to decline to answer any questions or to stop the questionnaires at any time. The study staff will be available to immediately assist with any problems that arise in the interview and will make a referral, if required. However, it is very likely that these feelings of upset or distress will be temporary.
- **MRI:** If at any time you experience distress or discomfort you may stop the study by pressing a button that will immediately notify the study staff you would like to exit the scanner.
    a. Before the scan, the research team will determine if you are appropriate for the MRI based on the absence of the following conditions: cardiac pacemaker, metal fragments in eye, skin, body; heart valve replacement, brain clips, venous umbrella, being a sheet-metal worker or welder, aneurysm surgery, intracranial bypass, renal, aortic clips; prosthetic devices such as middle ear, eye, joint, or penile implants, joint replacements; hearing aid, neurostimulator, insulin pump; I.U.D; being pregnant or trying to become pregnant; shunts/stents; metal mesh/coil implants; metal plate/pin/ screws/wires, or any other metal implants; permanent eyeliner, eyebrows, and some tattoos. If for any of these reasons you are not appropriate for the MRI you can still take part in study; but you will not have any MRIs done.
    b. Tasks completed in the scanner may be emotional in nature. For this reason, practice version of all tasks will be completed before the scan, and you may terminate the scan if you become overly emotionally affected.
    c. Some people undergoing this procedure become anxious because of the closed space. If this happens to you, you can stop this procedure at any time.
    d. Muscular aches from lying on your back for a total amount of up to 1 hour in the scanner.
    e. Banging noises that the machine makes while taking pictures. You will be asked to wear ear plugs and headphones to minimize the risks of these loud noises to your hearing.
    f. Potential muscle twitches or tingling during the magnetic resonance imaging procedure.
    g. As the risks of scanning during pregnancy is unknown, if you cannot confirm that you are not pregnant then – for your safety – we will not continue with the study.
    h. In the MRI, (~115 degree) heat stimuli of 20 seconds duration will be slightly painful at the forearm and may cause some redness. There have never been lasting injuries from these stimuli.

- **Mindfulness Based Pain Reduction and Mindfulness Bases Stress Reduction:** It is possible that you will become more aware of your pain. However, this task will not aggravate your chronic pain condition. As the InsightTimer phone app will not use your usual personal e-mail but rather a newly set up email with a unique pseudonym, your privacy will be secure.

  Although every reasonable effort has been made, confidentiality during internet communication procedures cannot be guaranteed, and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with the study. Participation in the research may impact your mobile device's Data Usage Plan. You may incur expenses for which you are responsible.

For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand the relationship between physical and mental health conditions.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Study staff may use text messaging with links to questions about your pain. Your phone company may charge you for message and data services when you receive or send a text.

Will I be paid for taking part in this study?

If you are able to undergo the MRI, in return for your time, effort, and travel expenses, you will be paid $100 per visit at the San Francisco VA Medical Center, plus $15 travel reimbursement,

in the form of a check or a gift card. You will receive $1.00 for each smart phone response during weeks 1 and 8 of the classes (up to $40). You will receive $50 each time you complete the questionnaires at 8 weeks and 6 months (up to $100). If you take part in the exit interview you will be paid $100. The total payment amount will be up to $440 plus up to $30 for travel expenses. This is the total amount and includes the amount for the study activities at the VA.

Treatment and Compensation for SFVA Research Injury: If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable), or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided.

What happens if I am injured because I took part in this study?

It is important that you tell the study investigators, Dr. Wolf Mehling and Dr. Irina Strigo, if you feel that you have been injured because of taking part in this study. You can tell Dr. Mehling and Dr. Strigo in person or call them at 415-353-9506 (Dr. Mehling).

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may

give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researchers Kirsten Rogers at 415-476-7464 *or* Emily Murphy at 415-221-4810 ext. 23324.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent