Informed Consent Form

Study Title: New Options for Treating Knee Osteoarthritis Pain

NCT Number: NCT05541718

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Consent and Authorization Document

You are being asked to participate in a research study. This document describes the procedures, risks, and benefits or your participation. Please read the information carefully as you determine if study participation is right for you. Participation in this study is voluntary, so it's up to you to decide if you want to join the study.

The purpose of this research study is to investigate new methods of treating knee osteoarthritis. Even after receiving traditional medical care, many people's knee pain persists. In this study, we are examining several new techniques for treating knee osteoarthritis, including mindfulness, supervised relaxation, and Reiki. The ultimate goal of this research is to identify new treatment options that can be offered to knee osteoarthritis patients in the future. The procedures for the study are described in detail in this document and include participation in four therapy sessions, monitoring your brain activity and heart rate during the therapy sessions, as well as surveys and pain threshold testing before and after treatment. Your participation will last about 3 months.

The risks of participation in this study are minimal. Learning and practicing the pain management techniques you will learn in this study are sometimes associated with sleepiness and may also increase awareness of anxiety. While there may be no direct benefit to you in participating, you could experience an improvement of symptoms of pain. Please read the section titled risks and benefits for more information.

You do not need to participate in this study to receive medical care. If you decide not to participate, you will receive the standard medical care offered by your physician/hospital. You may refuse to participate or discontinue participation without penalty or loss of benefits.

Study Procedures

Therapeutic Sessions

If you decide to participate in this study, you will be randomly assigned to one of four experimental conditions: 1) mindfulness meditation, 2) Reiki, 3) supervised relaxation, or 4) a waitlist condition in which you will receive the treatment of your choice after completing the study surveys. If you are randomized to mindfulness meditation, you will learn how to focus attention on your breath and body sensations while monitoring and accepting thoughts, negative emotions, and pain. If you are randomized to Reiki you will experience a healing technique designed to promote relaxation, reduces stress and anxiety through gentle touch. If you are randomized to supervised relaxation, you will spend time in a quiet, therapeutic room with a clinician. Neither you nor the study team will be able to choose which condition you are assigned to be in. A computer will decide which condition to put you in by random selection. Think of it like flipping a coin. Regardless of the experimental condition you are in, you will be offered four treatment sessions, each lasting 30 minutes.

During your four treatment sessions, you will have sensors attached to your body that will record information about your how fast your heart is beating. This device is safe and is similar to a cardiac monitor used in a doctor's office. Attaching these sensors is painless and harmless. Removing them is no more uncomfortable than removing a band-aid. We will also record your brain activity with a special cap and some sensors that may cause slight discomfort to the scalp. Wearing this cap may result in you getting some gel (used for recording brain activity) in your hair (which is harmless, but a little messy). If gel is needed, it will be applied with a gel applicator (which has a metal tip), which will be used to exfoliate dead skin from 6 small (1/2 inch) spots on your scalp.

Surveys and Interviews

As a part of your study participation, you will be asked to complete a brief survey before and after each treatment session. This survey will take no longer than 5 minutes. You will also be asked to complete a longer set of surveys before and after your full course of treatment. This longer set of surveys will take about 30 minutes to an hour to complete. We will collect the following information in these surveys:

- Information about your pain and other sensations in your body
- Information about your physical function, sleep, anxiety and depression
- Information about your substance use
- Information about your state of awareness and the effects of mindfulness practice

All of the information gathered in these surveys will be used for research purposes only. No study information (e.g., pain, mental health, substance use) will be added to your medical record or disclosed to your medical provider(s).

If you are in the mindfulness meditation, Reiki, or supervised relaxation condition you will complete:

1. A pre-survey before your four treatment sessions begin
2. A post-survey 1 week after your four treatment sessions end
3. A follow-up survey 1-month after your four treatment sessions end

If you are in the waitlist condition, you will complete:

1. A baseline survey when you first begin the study
2. A survey 1-month and 2-months after your baseline survey
3. Then, you will be offered the treatment of your choice
4. Treatment sessions visits will begin within two weeks after you complete the 2-month survey and will continue for four more weeks.

During the three visits when you complete the longer sets of surveys, you will go through several tests to measure your sensory responses. One type of sensory test will use a device that heats up on the skin of your arm. Another will use a blood pressure cuff that will be inflated on your lower leg. You will also put your hand into very cold water. The water temperature could range from 33° to 50° Fahrenheit. Other sensory tests will involve mechanical pressure applied to other parts of the body. You will tell the tester

when you feel pain from each of the tests, and you will rate the pain or other things you feel on a 0-100 rating scale. You can stop any of the tests at any time.

Costs and Compensation

By participating in this study, you will receive four, free, treatment sessions and you will be compensated $20 for each treatment session you attend (totaling $80 for attending all sessions). You will also be compensated $50 for each longer set of surveys you complete (totaling $150 for completing all surveys). Over the course of the study, you have an opportunity to be paid up to $230. In order to receive full payment, all four treatment sessions will need to be attended and all three surveys will need to be completed. There are no costs for you to be involved in this study.

Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. Accounts Payable will have limited access to the study information (e.g. the name of the study) for payment purposes. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however we will not be able to pay you as outlined in this consent form.

Risks

The relaxation experienced as part of mindfulness training may cause sleepiness. This usually lasts no more than a few hours. Participation in mindfulness meditation may also increase awareness of anxiety. If you experience these feelings, you should notify your therapist.

There is a slight chance of mild transient bruising associated with sensory testing. In our experience, this is quite rare (< 5% of cases). There is also reported to be a slight risk (< 1%) of skin puncture. Our team has tested over 500 participants and have not had a single skin puncture. There are no significant risks from immersion of a hand in cold water (i.e., from 33° to 50° Fahrenheit). We have previously used these sensory testing procedures in a number of previous studies with healthy adults and chronic pain patients. No serious adverse effects were ever reported. All of the personnel performing the sensory testing will be fully trained and supervised. The equipment is cleaned, calibrated, and disinfected regularly between study visits. You will be closely monitored by staff throughout the course of the study procedures. You may stop any of the procedures at any time, and the limits of sensory tests are set in order to prevent tissue damage.

You should continue your standard medical care as if they were not enrolled in a study. The study is not a substitute for your usual medical care.

Benefits

There may be not direct benefit to you from participating in this study but what we learn from the study may benefit others with chronic pain conditions.

Potential benefits include improvement of symptoms of chronic pain and a decreased level of stress as a result of being part of the study. You may gain insight from participation in mindfulness training that may be useful to improve your health. You may experience greater clinical improvement than you would otherwise experience with usual medical care alone.

Person to Contact

If you have questions, complaints or concerns about this study, or think you have been injured as a result of being in this study about this study, you can contact Adam Hanley, PhD at 801-213-4191.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

Authorization for Use of Your Protected Health Information

In order to conduct this study, we will need to collect and store health information about you. Signing this document means you allow the researchers in this study and others working with us to collect and use your protected health information. This is the information we will use:

- Demographic and identifying information like your name, address, telephone number, medical record number(s) and email address.
- Medical information about you including diagnoses, prescriptions, and past medical history.
- All tests and procedures that will be done in the study

How we protect and share your information

We will do everything we can to keep you information private, but we cannot guarantee this. The research records will be kept in a secured manner and computer records will be password protected. We may need to disclose information about you as required by law.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

- Members of the research team and University of Utah Health
- The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;

If we share your identifying information with groups outside of the University of Utah Health, the groups may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health **with no penalty**.

What if I Decide Not to Take Part After I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

Consent and Authorization

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____

Participant's Name

_____ _____

Participant's Signature Date

_____

Name of Person Obtaining Authorization and Consent

_____ _____

Signature of Person Obtaining Authorization and Consent Date