University of Colorado Boulder

Permission to Take Part in a Human Research Study

Title of research study: Mind-body treatments for chronic back pain (NCT03294148)

Investigator: Tor D. Wager

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have not experienced any persistent back pain or other chronic pain conditions and meet all other inclusion criteria (e.g., fMRI safety criteria). You will serve as the control group for a group of back pain patients.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ***canlab@colorado.edu or tor.wager@colorado.edu***

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (303) 735-3702 or irbadmin@colorado.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

In this study, we want to understand the brain mechanisms of back pain and other forms of pain and unpleasant experiences. You will serve as the control group for another group of patients with chronic back pain completing the same tasks.

How long will the research last?

This study consists of a single visit lasting approximately 3 hours here at the Center for Innovation and Creativity (CINC) at the University of Colorado Boulder.

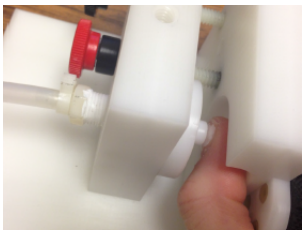
How many people will be studied?

We expect about 240 people will be in this research study.

What happens if I say yes, I want to be in this research?

First, we will test whether inflating and deflating a bladder under your back elicits back pain for you. This will feel similar to laying with a rolled-up towel placed under your low back. While the bladder is inflating and deflating, we will ask you to rate how much pain you are in. We also apply several painful pressure stimulations to your thumbnail, to confirm that these stimulations are painful but tolerable for you. We want to confirm this because later in the study we will apply more pressure stimulations to your thumbnail.

The pressure pain device uses a computer-controlled pressure regulator and compressed air to push a small soft piston into your thumbnail for a few seconds. This feels like someone squeezing your thumbnail. Depicted here is a picture of a thumb in the device.



We will then ask you to fill out an MRI safety questionnaire.

At this point, we will be able to determine whether you are eligible to continue in the study. If you are not eligible, we will pay you for your time today.

If you are eligible, you will complete some questionnaires about your mood and personality on a computer. One of these forms will be on a smartphone application that we will ask you to download on to your phone.

We will then prepare you for the MRI scan. During fMRI scanning we ask you to complete the following tasks:

1. Ratings of current back pain. We will inflate the bladder under your back in the scanner, and ask you to rate your back pain every 30 – 60 seconds.

2. Pressure and sound pain task. We will apply pressure stimulations to your fingernail of varying intensities, and play unpleasant sounds through earbuds that will be in your ears. These stimulations will be mildly to moderately painful or unpleasant but tolerable. Before each stimulation, we will also tell you how other people rated the stimulation. After each stimulation, we'll ask how painful it was for you.

Then you will be asked to complete a task in which you can earn small amounts of money (~$1-$3) for a number of button presses.

A blood sample will also be collected at this session. The blood sample will be collected with standard venipuncture (blood draw) technique of an upper extremity vein. You will have 8 ml of blood taken one time, which is about the amount of blood in 1 ½ teaspoons. If there is a contraindication to the blood draw, we will collect a blood spot instead. The blood spot uses a finger stick collection device. The device draws 2 -3 drops of blood from the fingertip, is mildly painful, and has minimal associated risks.

What happens if I do not want to be in this research?
You can leave the research at any time and it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. We will still use the data we have collected so far, unless you explicitly withdraw your consent in writing. However, it may not be possible to delete all your data because we de-identify them and may not be able to link you to all the data we have collected from you.

Is there any way being in this study could be bad for me?

The pressure stimulations: The pressure stimulations will cause you some physical discomfort, though the pain will always be kept within limits that are tolerable to you. Additionally, because some people respond differently to pressure, there is a slight risk of lingering tenderness or discomfort on the thumb. In addition, risks could also result from a malfunction of the pressure equipment used in this study. However, the probability of a machinery malfunction is extremely low: we extensively tested the equipment and carefully monitor it regularly to ensure its proper functioning. If at any point during the experiment the pressure is intolerable, please remove your thumb from the device immediately and alert the experimenter. If you experience severe tenderness or discomfort at any point during the experiment or after, please contact the experimenter immediately. Tenderness or discomfort normally disappears within 24 hours. In the event of injury, please seek medical attention immediately. Safety guidelines for the design and administration of this study are strictly followed in order to minimize any such risk.

Bladder inflation: The inflating bladder might be uncomfortable or painful but cannot damage your back. It may cause psychological discomfort by temporarily eliciting back pain. There is also the possibility of unforeseen risks with the bladder device, such as some lingering pain, even though the device cannot injure the back.

Blood sample: The risks of taking blood include pain, bruising, redness, swelling, or infection at the puncture site, and a rare risk of fainting. The risks will be minimized by using standard protocols for blood sampling, including techniques to minimize the risk of infection/adverse events.

Data: There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

MRI risks: MRI studies are among the safest of all non-invasive medical procedures, but certain hazards exist, including:

1) If a piece of metal, a device made of metal, or an electronic device were on or in your body, especially in the eye, heart, or brain, you could be injured by the magnetic field.

2) If you were to be pregnant, it is possible that this protocol could injure the fetus (there is no good data to predict a percentage), but many pregnant women have been safely studied with MRI without injury to the fetus. However, you will be screened prior to the procedure and specifically asked whether you could be pregnant. You will only be studied if you record "No."

3) If you were not to wear earplugs, the noise could potentially injure hearing. Earplugs will be offered prior to the examination.

4) You may have some discomfort due to lying in one position for a long time. The discomfort should subside once the scan is complete, but some participants may be sore for longer.

5) At sufficient exposure levels, peripheral nerve stimulation (PNS) is perceptible as "tingling" or "tapping" sensations. PNS symptoms will usually subside shortly after the scan is completed.

6) You may experience nervousness and/or feelings of claustrophobia. You will be screened for claustrophobia prior to entering the scanner, but should you feel any psychological discomfort upon entering the scanner, you will be able to communicate with the MRI technician and you may stop the scan at any time.

What are the possible benefits of the study?

You may not benefit directly by participating in this study. This study is designed for the researcher to learn more about the neurobiology of back pain and the effectiveness of back pain treatments. This study may contribute to developing better treatments for chronic back pain, and could influence how back pain is conceptualized and treated by the medical community.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research.

What happens to the information collected for the research?

Only the research team will have access to your personal information collected during this study. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also send blood samples to Dr. Michael Irwin, UCLA. Data sent to him will be completely de-identified (i.e., tagged only with a random ID, not with any identifying information). Only measures of immune system function will be extracted from these samples, and then they will be destroyed. The data about your mood and feelings that you enter into the smartphone application will also be shared with the application developers, Cliexa. This data will be also be completely de-identified (i.e., tagged only with a random ID, not with any identifying information).

The data, blood and specimens collected from you during this study are important to this study and to future research. Data will be de-identified and then maintained indefinitely, and blood samples will be destroyed after analyses are completed.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include MRI safety reasons or if the study doctor thinks that being in the study may cause you harm, you are not following study procedures, or any other reason.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the Foundation for the Study of the Therapeutic Encounter.

You may be able to serve as a scheduled back-up participant. Serving as a back-up is optional and has no bearing on any other aspects of their participation in the study. If you do this, you will be asked to arrive at the same time as another scheduled participant (the "primary" participant). If the primary participant fails to show, or is unable to be scanned for an unexpected reason, then you will be scanned

instead. If the primary participant does show and is able to be scanned as expected, you will be paid $25 and sent home. This determination will be made approximately 1 hour and 10 minutes after the you are asked to arrive, once the scan for the primary participant is successfully underway. If you are a back-up, you may also have a "primary" scan scheduled at a future date (after which you can no longer serve as back-ups), or, you may continue serving as a back-up indefinitely and have your primary scan scheduled only when enrollment nears its end.

We do not expect any harm to you as part of this study, but if you feel you need medical care because of taking part in this research study, seek medical attention immediately (if it is a medical emergency, first call 911). Generally, this care will be billed to you, your insurance, or another third party. The University of Colorado has no program to pay for medical care for research-related injury.

It is important that you tell the Principal Investigator Tor Wager if you think you have been injured as a result of taking part in this study. You can call him at *303-492-7487* or contact him via email at Tor.Wager@Colorado.edu.

How much will I be paid for participating in this study?

You will be paid $75, or instead can choose to receive a 3D print-out of your brain. The market cost of a 3D brain print-out is over $250. If you leave the study early, or if we need to take you out of the study, you will be paid only for the portions of the session you have completed at a prorated hourly rate. If you are ineligible, we will pay you $25. You can also earn several dollars during the assessment session from the progressive ratio button pressing task. The exact amount will vary depending on your choices, but is estimated to be $0 - $15. If you are a back-up participant, you will be paid $25 for each visit. Payments for participation in a study is taxable income.

May we have permission to contact you in the future regarding other studies?
____ Yes, you my you may contact me regarding future studies.
____ No, you may not contact me regarding future studies.

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	07.23.2018 IRB Approval Date