University of California, San Diego

Consent to Act as a Research Subject

Mechanisms of Affective Touch in Chronic Pain

Introduction

Dr. Laura Case and associates are conducting this research and asking for your consent to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family, friends, or another physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or mention concerns before, during or after the research.

The purpose of this study is to compare how different types of touch do or do not effect pain perception, and whether this differs in people with chronic pain. We will also examine what risk factors might explain differences in touch perception between individuals with and without chronic pain. This research will improve our understanding of how touch can interact with pain and health, and whether this differs in people who suffer from chronic pain. Participation in the study will not benefit you directly, but may result in new knowledge that may help others.

A member of the study team will email you a link to REDCap (online survey software) to complete a series of study questionnaires at home (up to 1 hour) prior to coming into the laboratory. You will then participate in two study sessions on the UC San Diego campus. During these sessions, we will first administer a urine test for opiates (drugs like morphine, opium, vicodin, oxycontin, hydrocodone, codeine, heroin) and pregnancy (if applicable). If you test positive for either, you will be dismissed from the study. These test sessions will involve making ratings of a variety of painful or non-painful touch stimuli. Each session will last about 1-2 hours. Up to 20 participants will also be invited to an additional, optional magnetic resonance imaging (MRI) session, with similar touch stimuli.

The most commonly expected risks of the study are discomfort from the heat and cold water pain that is administered, and becoming bored or upset with the questionnaires.

The most serious risks of the study may include skin burns, which have not been observed at the temperatures and time durations used in the study, or serious injury if you receive an MRI and were not properly screened for metal or medical implants in your body. These risks are

extremely unlikely since we conduct careful screening and you may stop study procedures at any time.

Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

Why have you been asked to participate, how you were selected, and what is the approximate number of participants in the study?
You have been asked to participate in this study because you have a diagnosis of Fibromyalgia, or you are a healthy control volunteer. There will be approximately 100 participants at this site.

What will happen to you in this study and which procedures are standard of care and which are experimental?
In addition to the information at the beginning of this form, here are some additional details about what will happen to you if you agree to be in this study:

In Session 1, you will provide a sample of your urine so that we can test if you are pregnant (if applicable) and if you are taking any opiate medications. A respiratory transducer belt will be affixed around your abdomen in order for us to record your respiration rate. You will then receive several types of touch on your arms or legs, including light brushing, deeper pressure, tapping, heat pain, and pain from submerging your hand in cold water. You will be asked to make ratings about how intense or painful and how pleasant or unpleasant they feel. A training and practice period will be included. If you are not able to follow instructions or rate your sensations on our scales you may be dismissed from the study and compensated only for Session 1. In Session 2, you will provide a urine sample to test for pregnancy (if applicable) and opiates. A respiratory transducer belt will be affixed around your abdomen. You will receive the same types of touch from Session 1 in several different combinations, repeated many times, and you will again be asked to make ratings. In the optional MRI session, you will provide a urine sample to test for pregnancy (if applicable) and have a MRI scan while receiving these types of touch. All of these procedures are experimental and not for treatment purposes.

How much time will each study procedure take and how long will the study last?
Each block of sensory testing will take about 5 minutes. In Session 1, there will be approximately 3 blocks of testing. In Session 2, there will be approximately 6 blocks of testing. Each Session will last approximately 1-2 hours.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. In addition to the risks described at the beginning of this form,

1) Heat Pain Stimuli

Reddening/darkening of the skin may occur with thermal stimulation. This is temporary and will not damage the skin.

2) Cold Water Bath

It is possible (although rare) that participants may experience increased heart rate in response to immersing their hand in the cold water. In extremely rare instances, fainting might occur. It is also possible that discomfort and numbness of the hand may occur during and after submerging the hand into the cold water. This is temporary and will not damage the skin. Participants can remove their hand from the cold water in the event they find it intolerable or do not wish to continue.

3) Brushing and Pressure

Repeated skin compression could theoretically dislodge any active blood clots in the participant's limb, so all participants will be screened to ensure they do not have any signs of clots present.

4) MRI

The MRI scan is not associated with any known risks to your health, but you may be uncomfortable because you will be lying in a small space. If you cannot tolerate this, the scan will be stopped immediately. In the MRI scanner, we will provide you with a "squeezeball" that you can squeeze which will subsequently end the scan. During scanning, the MRI machine produces loud noises, so your ears will be protected by plugs or specialized headphones. Persons with any electronic objects or certain metal objects in their head or body such as cochlear implants, pacemakers, or aneurysm clips may not participate. A checklist of excluded metal objects will be presented to you by the MRI technician or study staff prior to the MRI scan. <u>There is no radiation associated with this type of scan.</u>

Reproductive Risks: Due to unknown risks and potential harm to the unborn fetus from MRI, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

Due to unknown risks to the fetus, pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a urine pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential and not using reliable birth control. We will administer a urine based pregnancy assessment for all females at the beginning of the first and second study session and (if you participate in MRI) at the beginning of the fMRI session.

5) Confidentiality

There is a risk that information collected in our study could become known to individuals not involved in our study. Breaches in confidentiality could impact future insurability or employability. However, in our experience, this has not occurred with this type of research.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Are there risks to the reproductive system or a developing fetus?
Due to unknown risks and potential harm to the unborn fetus from MRI, sexually active women of childbearing potential must use a reliable method of birth control if participating in the MRI portion of this study. Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a urine pregnancy test will be required during the MRI Session, if you are a sexually active woman of childbearing potential and not using reliable birth control.

After you have been enrolled in this study and during the research, pregnancy testing will be performed. If you have a positive pregnancy test, we will withdraw you from the study. If you (or your partner) become pregnant or if there is any chance of pregnancy (e.g., late menstrual period), please contact the study personnel immediately so that we may provide medical assistance and counseling.

What are the alternatives to participating in this study?
You do not have to participate in this study. This is not a treatment study. The alternative to not participating in this study is to not participate.

What benefits can be reasonably expected?
In addition to the benefits listed at the beginning of this form, the investigator(s) may also learn more about touch and pain processing and how these may differ in chronic pain.

What happens if you change your mind about participating?
If you decide that you no longer wish to continue in this study, you will be requested to inform the investigators and tell us why you are leaving the study.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons: your eligibility information changes, or the study physicians Dr. Mark Wallace or Dr. Krishnan Chakravarthy believes that it is in your best medical interest to leave the study. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?
In compensation for your time and travel, you will receive $60 for intake/Session 1 and $60 for Session 2 for a total of $120. The subset of subjects participating in the MRI session will receive $120 for the MRI session.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?

All data will be processed in a HIPPA-compliant fashion to ensure confidentiality. Data are assigned a unique identification number and stored separately from your name and other identifying information. Digital data will be stored on both physically and software protected computers and will only be accessed by study personnel from within the medical center. Any reference to individual participants in reports of this work will be encoded to preserve confidentiality.

Research records will be kept confidential to the extent allowed by law. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), UCSD Institutional Review Board, and NIH, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

If you choose to participate in this study, your medical record at the University of California, San Diego will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at UCSD, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

This research is covered by a Certificate of Confidentiality from NCCIH. Researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research *unless* there is a federal, state, or local law that requires disclosure (such as to report child abuse, elder abuse, intent to hurt self or others, or communicable diseases), you have consented to the disclosure, including for your medical treatment; or it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of federal or state government agency sponsoring the project that is needed for auditing or program evaluation

by NCCIH which is funding the project or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). You should also understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the research to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, such as research data entered into your medical record.

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.

Will you receive any results from participating in this study?
You will not receive any individual research results from this study. However, if important health information is uncovered such as an unexpected finding on your brain scan, you will be notified.

Who can you call if you have questions?
This study has been explained to you and your questions have been answered. If you have other questions or research-related problems, you may reach Dr. Laura Case at 858-246-4968.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

By clicking "You agree" below you are indicating that you are at least 18 years old, have read this consent form, and agree to participate in this research study. Please print a copy of this page for your records.

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Signature of the person conducting the informed consent discussion (hard copy only) | Date

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