Effect of Pain Catastrophizing on Prescription Opioid Craving

Informed Consent Form
NCT04097743
October 21, 2024

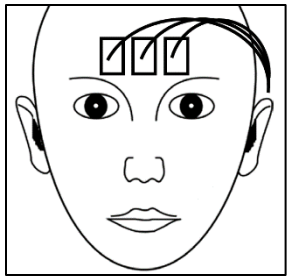
IRB Use Only
Approval Date: October 21, 2024
Expiration Date: **(Does Not Expire)**

Are you participating in any other research studies? ☐ Yes ☐ No

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Emma Raney, Study Coordinator at Stanford Systems Neuroscience and Pain Laboratory, 1070 Arastradero, Suite 200, MC 5596, Palo Alto, CA 94304. Phone number is (650) 313-9562. Email is eraney@stanford.edu.

DESCRIPTION: The purpose of this research is to better understand potential factors affect pain medication use such as stress, thoughts, and emotions. You will be asked to come to a laboratory experiment (Part 1) and answer daily online questions for 14 days (Part 2). For Part 1, you will participate in a 2.5-hour laboratory experiment, complete several questionnaires, donate a blood sample and five salivary samples, undergo a cold water sensory testing, and may read coping statements. For Part 2, you will complete a short daily survey for 14 days, collect three salivary samples (immediately after waking up, 30 minutes after waking up, and 9pm) on day 1, 7, and 14, and may read daily coping statements for 7 days. We ask that you refrain from pain psychology classes or therapy during the 15-day study period.

Part 1 (up to 2.5 hours, Laboratory, 2:30pm-5:00pm): Participants will undergo the following procedures. Firstly, experimenter will review consent, ask final eligibility question, and immediately inform you if you can continue with the study. Second, an experimenter will do vital sign check, blood draw (1/2 tablespoon), and salivary sample collection. If you take certain medications (steroid or benzodiazepines) within 3 days of a saliva sample collection, saliva samples will not be collected. Thirdly, the experimenter will apply physiological sensors [heart rate, respiration, skin conductance, skin temperature, and facial electromyography (EMG)] to you and ask you to complete questionnaires. For facial EMG, three sensors will be applied to the forehead to assess your facial expression during the experiment (see figure). Then, you will be randomly assigned to one of the three conditions below. You will have an equal chance (33%) of being assigned to any of the three study condition.



1. Condition 1 and 2: Participants will be asked to think about their own pain experience and read different statements for 10 minutes.
2. Condition 3: Participants will be asked to write down any thoughts coming into the mind for 10 minutes.

Then, all participants will donate salivary cortisol and undergo cold water pressor test. Then, participants will be asked to donate salivary sample 10, 20, and 30 minutes after the pain testing.

The cold water pressor test involves having you place your non-dominant hand in a tank of cold water (about 39.2°F) and keeping it in the tank until you were asked to remove it. You may remove your hand at any time, but will be encouraged to keep it submerged until you can no longer tolerate it, or until the researcher instructs you to remove it. This will not exceed five

minutes. We will use a circulating pump to ensure that the water remains a consistent temperature (PolyScience Performance Digital 15L Recirculating Bath, Model PD15R-30A11B).

Baseline	Condition	Survey	Sensory Testing	Survey
Blood sample Survey	1	survey	Cold Water	survey
	2			
	3			
Saliva		Saliva		Saliva 10, 20, & 30 min
Heart rate, skin conductance, respiration, skin temperature, and facial EMG				

Part 2 (2-5 min, daily home survey): All participants will be asked to complete daily questionnaire about pain, mood, thoughts and medication use for 14 days. Additionally, all participants will be asked to collect 3 salivary samples at the time of wake-up, 30 minutes after wake-up, and 9pm on day 1, 7, and 14. You will keep the samples in the freezer until being shipped. After the last saliva samples are collected on day 14, you will put all of the samples and ice pack in the provided FedEx envelope for overnight shipping. You can ship the sample only on Monday, Tuesday, or Wednesday and you will need to email or call a study coordinator so we can receive and handle the sample properly. You will be randomly assigned to one of the two conditions below. You will have a fifty percent chance of being assigned to each study condition.

1. Condition 1: Participants will be asked to complete a daily survey, read coping statements, and donate salivary samples.
2. Condition 2: Participants will be asked to complete a daily survey and donate salivary samples.

Day	1	2	3	4	5	6	7	8 - 13	14
Survey	X	X	X	X	X	X	X	X	X
Salivary Cortisol	X						X		X
Reading statements	X	X	X	X	X	X	X		

Specimen Sampling for Research: Research using specimen is an important way to try to understand human disease. You have been given this information because the investigators want to include your specimen in a research project and because they want to save the specimens for future research. There are several things you should know before allowing your specimen to be studied.

Your blood samples will be stored in a secure location and labeled with a unique study number. Only the research staff will be able to associate your study number with your identity. Your name or other public identifiers will not be included with any data shared with other investigators. The samples will be stored for analysis in the future. Once all research on the samples has been completed, the samples will be destroyed. You have the right to refuse to allow your specimen to be studied now or saved for future study. You may withdraw from this study at any time. Because the results of the study of your specimens will be used for research purposes only, you will not be told the results of the tests. Your samples may be sent outside of Stanford for analysis.

RISKS AND BENEFITS: The risks associated with this study are:

- There is a risk you may feel uncomfortable answering some of the questions on the questionnaires. You have the right to refuse to answer particular questions.
- Participants may experience physical discomfort in undergoing cold water pressor test.
- There risks from the blood draw include bleeding, soreness, bruising and stinging at the site of the blood draw. To minimize this risk, we will check your vital signs before the blood draw.
- There is a small risk that people outside our research lab could learn this information, but we do our best to keep all your information confidential. We also obtained a ***certificate of confidentiality***, which allows us not to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other legal actions, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. You should 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 researchers to release it.

The possible benefits associated with this study are:

- The benefits which may reasonably be expected to result from this study are that we may have better understand challenges that patients face in taking pain medications. Subsequently, your information may help us to develop a better strategy for pain medication management.
- We cannot and do not guarantee or promise that you will receive any benefits from this study.

Your decision whether or not to participate in this study will not affect your medical care.

TIME INVOLVEMENT: Your total participation in this experiment will take 15 days.

PAYMENTS: You may receive up to $[redacted] as payment for your participation in the study, which includes completing Part 1 ($[redacted]) and Part 2, including completion of the daily questionnaires ($[redacted]) and three saliva samples at three time points ($[redacted]). You will also be paid for $[redacted] for the completion of all study requirements.

We will compensate your travel cost: $[redacted] for people living within 60 miles and $[redacted] for people living beyond 60 miles.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

The National Institutes for Health (NIH) is providing financial support and/or material for this study.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed. You have the right to refuse to answer particular questions.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

It is possible that, based on information gained from this study, the researchers may have serious concerns (e.g., severe depression, etc.) about your health and/or safety; in such a case, the researchers may contact you and provide a referral for your care. It is also possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, etc.) to the appropriate authorities.

CERTIFICATE OF CONFIDENTIALITY: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The 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, for example, if there is a court subpoena, 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 except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if 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 the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project. You should 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 researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse or harm to self or others.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this research study is to examine factors affecting prescription pain medication use in patients with chronic pain conditions. Information we collect from you will be used to evaluate the relationship between factors like thoughts, emotions, and stress levels and medication use, and may be used in publications as well.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dokyoung Sophia You, PhD at [redacted], Palo Alto, CA 94304.

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your name,

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contact information (email, telephone number, home address), date of birth, demographics, medical and pain history (diagnoses, medical treatments, medications), psychological history, pain intensity, pain catastrophizing scale scores, and medication use. We may also collect responses to questionnaires and a blood and saliva samples.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dokyoung Sophia You, PhD.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- The University of Oklahoma at Tulsa Lab – EDTA samples only
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health (NIH)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31st, 2060, or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

WITHDRAWAL FROM STUDY: The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Endorsement of any of the ineligibility criteria
- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant, you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form;
- and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

CONTACT INFORMATION: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dokyoung Sophia You, PhD at (650) 724-9320. You should also contact them at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

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May we contact you about future studies that may be of interest to you? We may also send you a participant newsletter with updates on this study and other studies in our lab in appreciation of you participation. You may choose to be removed from our contact list at any time.

☐ Yes ☐ No

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent