N-of-few Study of Pain Perception (NOF)

NCT04664400

Consent form – approved 04/09/2021

Dartmouth College

Study title: "N-of-few" pain perception study

Principal Investigator: Tor Wager

What is the purpose of this study?

The purpose of the study is to test how different factors affect various measures of pain perception.

Voluntary participation and withdrawal

Whether or not you take part in this research is your choice. You can leave the research at any time and it will not be held against you. If you are a student, your decision whether or not to take part will have no effect on your academic standing.

You have the right to refuse to answer any question(s) or refuse to participate in any procedure for any reason. Refusing to participate in this study will not result in any penalty or loss of benefits to which you are otherwise entitled. If you choose to discontinue the study early, you will be paid a prorated rate based upon the amount of time you participated in the study, with no penalty for discontinuing.

Will you benefit from taking part in this study?

There is no direct benefit to you should you decide to participate in this study. The data collected in this study are purely for the purposes of research.

What does this study involve?

Your participation in this study will include 10 sessions. The first session is expected to take up to 90 minutes, and the rest of the sessions are expected to last about 60-75 minutes each.

Thermal heat stimuli. During the experiment, you will receive safe, non-damaging thermal heat stimuli from a computer-controlled device. The machine will heat a small metal plate and cool down very quickly. Each stimulus period will last for a few seconds, and will be painful in some cases, but it will not damage your skin. The heat is similar to holding a hot cup of coffee. The metal plate and heat sensation will be applied to your arms and/or legs. At the beginning of the experiment, we will deliver a few stimuli and will ask you to rate the amount of pain you feel, so that we can always keep them within a tolerable level for you. Then we will perform the main experiment. During the experiment, you will sometimes be asked to rate if and how much pain you expect and/or experience. You will be given detailed instructions on how to perform the task, and there will be time for you to ask questions regarding the instructions. All stimuli will be delivered at a level tolerable to you, and you will always have control and have the option to stop immediately if you need to. Please remember that you can discontinue your participation at any time if it becomes too uncomfortable.

Additional data recordings. During the experiment, we will noninvasively record physiological measurements (heart rate, skin-conductance and / or respiration). We will do so by using non-invasive sensors, which are not associated with any uncomfortable, harmful or painful sensations. In addition, we will record your face with a video camera (including voice) and with infrared thermal imaging. These recordings will be entirely passive and noninvasive and will not

require any additional effort on your part (except for having sensors attached to you for physiological recording). We will collect your facial data and will only use it for the purposes you consent to in a separate form (video release form). We may also ask you to complete short cognitive behavioral tasks (e.g., a series of perceptual and emotional judgments, performed on the computer) and/or to watch videos and rate how they made you feel.

What are the risks involved with being enrolled in this study?

There are some potential risks if you take part in this study. These may include:

Thermal heat stimuli. You will be exposed to experimental pain induced by applying heat to your skin. This is likely to 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 thermal stimuli, there is a slight risk (less than 1%) of irritation and/or blistering to the stimulated skin site. Several factors, including dryness of skin, dehydration, and possibly skin pigmentation, may influence a person's response to thermal pain stimuli. Skin irritation and/or blistering could also result from a malfunction of the equipment used in this study. However, the probability of a machinery malfunction is extremely low, as thousands of individuals are safely tested each year on this equipment, and we carefully monitor the equipment regularly to ensure its proper functioning. Over 1,000 participants have undergone thermal stimulation in the Principal Investigator's lab over the past 10 years with no adverse events reported.

If at any point during the experiment, the thermode temperature becomes intolerable to you, manually remove the thermode from your arm immediately and alert the experimenter.

Should you experience any skin irritation or blistering at any point during the experiment or shortly after, please contact the experimenter immediately. In the event of a burn, run the affected skin site under cool water for several minutes and seek medical attention if the site continues to burn. Safety guidelines for the design and administration of this study are strictly followed in order to minimize any such risk. Stimuli will be administered with a widely used commercial product, and the risk to human subjects is rated as low.

Psychological Discomfort. You will be exposed to pain, videos, and audio narratives which may cause psychological discomfort. However, as described above, the level of pain is calibrated to always be within your tolerable level. We do not expect the videos or audio content of this experiment to cause any lasting psychological discomfort. In addition, you may discontinue the experiment at any time should they wish.

To be clear: you may immediately end your participation if any aspect of the research procedure makes you too uncomfortable to continue. However, we do not expect this to happen, as the vast majority of participants experience no undue discomfort.

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*** **(603)-646-2196.**

Payment for research related injury If 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. Dartmouth College is not responsible for the costs of medical care for research-related injury. Please contact

the investigator as soon as possible to report any adverse events associated with participation in the study.

How will your privacy be protected?

Strict standards of confidentiality are maintained. Identifying information (such as your name, birth date and contact information) will be stored in a password protected file on our secure servers and/or in locked filing cabinets, to which only the Principal Investigator and members of the research team have access. Study data will be stored in separate files from those with identifying information and will be collected and stored indefinitely on our secure servers. Your identifying information will not be directly connected to the data, and we will identify individual cases with alphanumeric codes.

This study also involves video recordings of your face, which is a source of potentially identifying information. Video data will be stored in a password-protected area on our secure servers, with access only to the research team. Non-identifiable features will be extracted and coded for analysis, and then combined with other study data.

De-identified data may be published and shared in public repositories for scientific purposes, as required by our funding agencies and scientific journals; however, no identifying information will be released, so the risk that anyone would be able to identify you or link your data to you personally is minimal.

Will I be paid to take part in this study?

If you agree to take part in this research study, you will be paid for each session. For the first two sessions you will be paid $20 per hour. Hourly rates of compensation will increase during the study, such that you will be paid $25/hour for sessions 3-4, $30 per hour for sessions 5-6, $35/hour for sessions 7-8 and $40 per hour for sessions 9-10. In addition, if you complete the entire study (all 10 sessions), you will receive a completion bonus of $60. Note that you may also lose/gain additional random amounts of money during each of the four last sessions (7-10). If you decide to withdraw before completion of the experiment, you will be paid a prorated time to the nearest half hour, based on your time of participation and the hourly rate established for each session. Payment for participation is taxable income. Eligible Dartmouth students may choose to receive T-points (at a rate of 1 T-point / hour) instead of money for some of their participation hours. Payment amounts for the rest of participation hours, as well as the completion bonus, will not be affected by such a choice.

Whom should you call with questions about this study?

If you have questions about this study or concerns about a research related injury, you can contact Dr. Tor Wager (the Principal Investigator) at tor.d.wager@Dartmouth.edu, or Dr. Rotem Botvinik-Nezer at rotem.botvinik.nezer@dartmouth.edu, during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-6482 during normal business hours.

Participation in follow-up assessments or future studies

I understand I may be re-contacted for follow-up assessments or future studies. I understand that if contacted, I can freely choose to participate in future research or not.

Consent

I have read the above information and have been given time to ask questions.

I agree to take part in this study.

Signature of participant	Date	Printed name of participant

Signature of person obtaining consent	Date	Printed name of person obtaining consent