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

NCT04664400

Study protocol – approved 04/02/2021

SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

CPHS template v. 04172017

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Important Note: The CPHS Department (Chair & Scientific) Review Form is required with this application. Find the form in the RAPPORT Library or on the CPHS Website.

- **Respond to each item, even if to indicate N/A or not applicable**
- **Attach and/or upload this form as your 'Investigator Protocol' in Rapport**
- **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

1. Introduction and Background

Pain perception has been shown to depend on many factors beside the sensory properties of the stimuli (e.g. temperature for heat stimuli), including expectations, past experience, social cues and context [1–8]. Previous studies have shown, for example, that pairing cues with low/high painful heat stimuli through symbolic learning (without actual pain delivery) induces higher pain expectations and pain responses (pain ratings, skin conductance responses (SCRs) and brain responses) to identical heat stimuli when it is preceded by the high versus the low cue in a subsequent test task [4,9]. Interestingly, this effect persisted although the cues were never predictive of pain intensity. The effect was shown to be driven by two processes: (1) a positive loop of modulated perception: pain responses are affected by cue-based expectations, which are in turn affected by previous pain responses; and (2) learning is affected by a confirmation bias, where expectations updating is stronger when the difference between the expected stimulus and the sensory information (the prediction error) matches the expected direction (i.e. when pain is higher than expected following high pain cues or lower than expected following low pain cues) [4]. Other studies have shown that cues that are paired with different heat intensities via classical conditioning, with no or minimal instructions, affect pain responses and also generalize to perceptually and conceptually similar cues, but only for some of the participants and via the modification of explicit expectations [5,6].

These studies demonstrate that, perhaps surprisingly, symbolic conditioning or suggestion-based manipulations affect pain perception more than experience-based conditioning. There are, however, a few properties that are common to the above described studies. In these previous studies: (1) there was only one session with a limited number of trials (for example, 10 test trials without extinction for the symbolic conditioned cues in Jepma et al., 2018 [4] and 24 conditioning trials per cue, out of which only half were in fact low/high in accordance with the preceding cue rather than an identical moderately intense stimulus, in Koban et al., 2016 [8]); (2) the difference between low and high pain stimuli was somewhat ambiguous, as the stimuli were relatively short (1 second at peak temperature) and the difference between low and high intensity was 1-2°C; and (3) in some of them, conditioned cues were combined with social cues. The social cues may have interfered learning of the cue-intensity pairing [5,8]. Overall, it is likely that the effect of conceptual conditioning and suggestions will eventually be extinct, and that experience-based conditioning will affect pain perception of all or most participants, across many trials or sessions, or when the low/high heat stimuli are more distinctive.

Another factor that has been shown to affect pain perception is the context. For example, an identical moderate heat stimulus was perceived as less painful (based on pain reports, SCRs and brain responses) when it was the better ("relative relief context", the other alternative was high heat) compared to the worst ("control context", the other alternative was low heat) option [7,10]. However, the results of these studies can be explained by the positive/negative affective response evoked by the visual representation of the outcome before heat onset, also presumably affecting expectations. Therefore, it is interesting to test whether the

counterfactual option affects pain perception when the outcome is not presented beforehand, and also when the alternatives are qualitatively, not just quantitatively, different.
Furthermore, since pain reports are not an objective measure of pain, it is important to test how additional measures are affected by the processes described above. While the above described studies have tested SCRs and brain responses, we plan to further test how the factors described above influence additional pain-related measures, such as facial expressions, the heat signature of the face/body (with thermal imaging) and heart rate, as well as participant's confidence in their expectations' ratings.
We plan to utilize an "N-of-few" approach, where comprehensive data are collected from a few participants across many sessions, in order to test how the effects of symbolic learning, conditioning and context unfold over time. In addition, since we recently established our lab at Dartmouth and purchased new equipment, we plan to test the "dose response" of various measures to heat stimuli of different intensities, without cues or manipulations: pain reports, expectations, physiological responses, facial expressions and heat signature of the face/body. Finally, the "N-of-few" design is also more feasible now during the COVID-19 pandemic, to minimize the number of participants and allow the participation of members of our department (Psychological and Brain Sciences).

2. Objectives and Hypotheses

1) Test the "dose response" curves of pain ratings, expectations, physiological responses (e.g. SCRs, heart rate, respiration), facial expressions and heat signature of the face/body (with thermal imaging) across heat intensities and multiple sessions. These curves will be used as baseline for the current as well as other studies in our lab with the same equipment.
2) Study how the effects of pure instructions or symbolic learning on expectations and pain perception, when cues are never in fact predictive of actual heat intensity, unfold over time. We hypothesize that biased perception and biased learning will support the effect as was shown before, but that it will decrease across sessions until complete extinction in our longitudinal design.
3) Study how expectations and pain perception unfold over time following conditioning without suggestion. We hypothesize that by substantially increasing the number of conditioning trials and sessions, as well as using more distinctive stimuli, we will induce stronger effects for all or most participants. We further hypothesize that such pure experience-based conditioning will strongly affect physiological responses, but heat evoked responses may decrease due to physiological preparatory or stress responses evoked by the cues.
4) Study how counterfactual monetary and pain-related outcomes affect pain responses. We hypothesize that heat stimuli will be more painful when the alternative option is better (e.g. lower heat or gaining money) compared to when the alternative option is worse (e.g. higher heat or losing money).

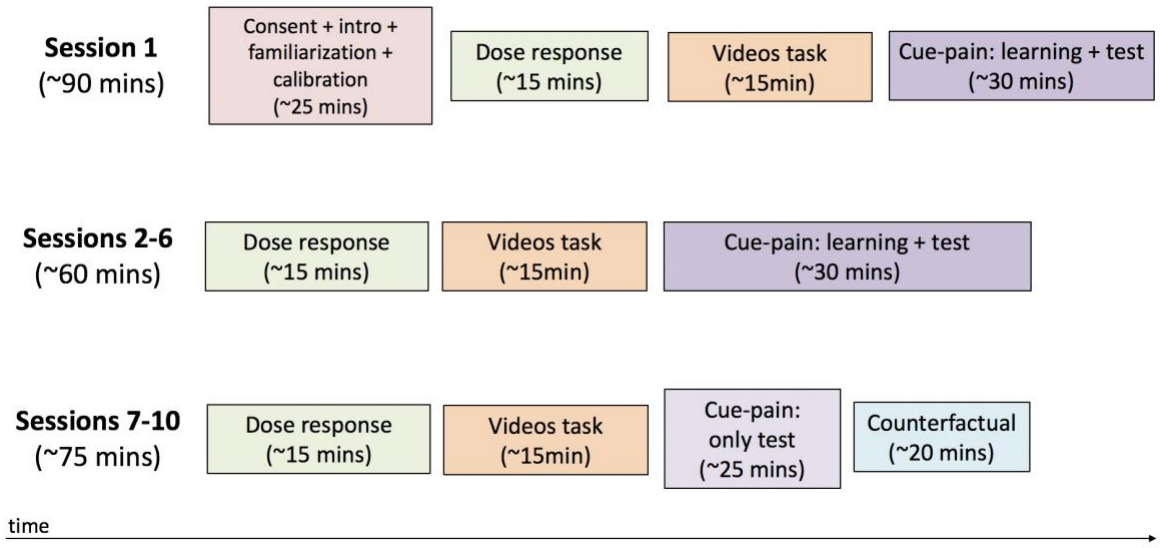
3. Study Design

Describe all study procedures, materials, and methods of data collection:

<u>General design and procedures</u>
This study is an "N-of-few" study, with a few participants completing 10 sessions each. The study includes four main components:
1) "Dose response".
2) Videos affective ratings task.
3) Cue-pain conditioning.
4) Counterfactual task.

The first part (~15 minutes) of each session will be dedicated to the "dose response" component. The second part of each session (~15 minutes) will be dedicated to the video watching task. The third part of each session (~30 minutes) will be dedicated to the cue-pain conditioning component. Finally, the last part of sessions 7-10 (~20 minutes) will be dedicated to the counterfactual task. The first session will also include a first part of consent, general instructions and demonstrations, to familiarize participants with the

experimental procedures and ensure that the heat stimuli we deliver to them during the experiment are tolerable. The four components will be described in detail below.



Across components 1, 3 and 4, participants will experience thermal pain stimuli delivered to different sites on their arms / legs. Pain stimuli will be delivered using a contact thermode (Medoc, Inc.; see details about the system below) that is placed against the skin. During and / or following stimuli, participants will be asked to rate how painful, intense and/or unpleasant was the stimulus they perceived. Prior to onset of some of the stimuli, participants will be asked to rate the expected intensity and their confidence in these expectations.

In addition to collecting behavioral ratings, we will collect all or some of the following measurements:

- **Facial video information and thermal infrared facial recordings:** Collection of these data will allow us to analyze facial responses to the pain stimuli. Thermal infrared facial recording is a non-invasive contact-free method to record the heat signature of the face, which is related to blood flow and indirectly to emotion. This method has been shown to provide information about the activity of the autonomic nervous system and psychophysiological states [11–13]. The facial recording data will be stored separately from any identifying information about participants and will only be coded using unidentifiable alphanumeric codes. These data will not be available on any website, or will not be downloadable by any computer user on or off campus. Participants will be asked to complete a separate video release form that allows them to specify how their video data can be used (within-lab research; scientific meetings and teaching events; included in future experiments; see Video Release Form).
- **Autonomic nervous system measurements** (e.g., heart rate, respiration and skin-conductance): We will passively record a number of physiological variables, which may include heart rate, skin conductance, and / or respiration. These recordings will be entirely passive and non-invasive, and will not require any additional effort on the part of the participants (except for having sensors attached to one's hand for physiological recording). Physiological data will be recorded using the BioPac Acquisition System.

As part of the screening process, before starting the main experiment, we will deliver one / a few pain stimuli similar to those used later during the main experiment to a different skin site/s on the participant's arm / leg. This will be used to (a) examine whether the participant is *hyper*-sensitive or *hypo*-sensitive to the painful heat stimuli; (b) familiarize the participant with the procedures and devices, and how to terminate the stimuli should they need to, before the main experiment; and (c) Calibrate the heat temperature if needed, to ensure all stimuli are tolerable to each individual. After each stimulus, we will ask participants to rate the intensity of painful experience. Inclusion based upon hyper- or hypo-sensitivity to painful stimuli will be done using the following criterion: We will include participants whose pain ratings fall between the levels of pain threshold and tolerance. At any point, if the participant indicate that pain is above the level that they are willing to tolerate, we will discontinue participation without cost to the participant.

Thermode System

A thermode is a device placed on the skin of an individual (e.g., their forearm), used to deliver heat or cold stimuli. This procedure is common in psychological research investigating the effects of pain in a safe manner. When utilized within operating guidelines, the procedure does not do any permanent damage to participants and does not provide stimulation beyond a level of reasonable discomfort. The thermode is actively heated and cooled by the hardware of the device. Temperature values are controlled to within 0.1 degrees Celsius by a computer, with a safety shutoff at a level tolerable to some participants, and nondamaging to skin.

A comprehensive list governing the maximum temperatures and durations that may be applied in any single experimental session or 24-hour period was approved for our lab by the CPHS as STUDY00031999 and will be strictly followed in the current study. We will use one of three systems: Pathway, TSA2 or Q-Sense models manufactured by Medoc LTD, with 30mm and / or 16mm thermodes. Medoc's systems are widely used in both experimental and clinical research laboratories, and are CE-marked, FDA approved / cleared.

Description of the four components

"Dose response"

Participants will experience different intensities of heat stimuli. Temperatures, duration and inter-stimulus intervals will be according to our lab's CPHS-approved stimulation guidelines (STUDY00031999). Participants will be asked to rate how painful each stimulus was. We will also collect physiological data and facial recordings as described above, and prior to some of the trials, participants will be asked to rate their expectations and their confidence in these expectations.

"Videos affective ratings task"

Participants will view a series of videos and will be asked to provide ratings about each video. The length and content of videos will vary between sessions. The videos were chosen to display a wide range of contexts, emotions and social relationships. These include but are not limited to amusement, contentment, surprise, fear, anger, sadness, tenderness, disgust, awe, serenity, sexiness, romance, family relationships, sporting events, nature landscapes, urban scenes, tools and machines, indoor and outdoor contrasts, vicarious pain, war, and animals. After each video participants will rate the content along 7 dimensions: self-relatedness, happiness, sadness, fear, disgust, warmth & tenderness, and engagement. The list of videos is attached (see Attachment6). The same videos and ratings are used in a different CPHS-approved study in our lab (Spatial Topology, study #31937). The inclusion of this task in the current study serves three aims: (1) Participants' facial recordings and physiological responses during the videos, considered along with their affective ratings, will be used to predict affective states based on facial recordings and physiological responses in the other components of the current study; (2) The videos task will be used to allow participants to rest between pain tasks and make the experiment more pleasant; (3) Anonymized physiological and facial data collected in this task will potentially be used in combination with data collected with the same task in other studies, in order to broaden the conclusions and relate physiological and facial measures to other measures, such as brain responses.

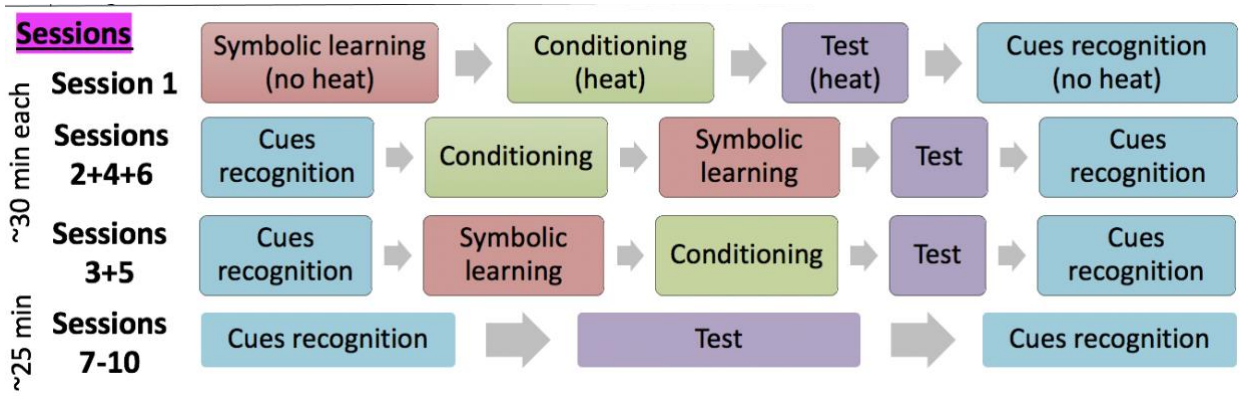
"Cue-pain conditioning"

For each participant, each cue will be paired with a distribution of low or a distribution of high heat stimuli in one of three ways: pure instructions, symbolic learning and/or experience-based conditioning. We will then test how each of these pairing methods affect anticipatory and pain responses across time following the different cues. We will also include an additional neutral cue that will not be paired with any intensity, to serve as a baseline condition. The "cue-pain conditioning" component will include the four following tasks:

1) *Symbolic learning*: This task will be similar to previous studies in our lab [4,9]. Low/high cues will be paired with pictures of thermometers showing low/high temperatures, respectively, without pain delivery. These cues will not be predictive of actual intensity in the following tasks that will include heat stimuli.

2) *Conditioning*: Low/high cues will be paired with heat stimuli taken from low/high intensity distributions, respectively, without suggestion. These cues will be predictive of actual intensity in the conditioning task, but not in the test task (see below).
3) *Test*: All cues will be presented in this task in a pseudo-random order and will be proceeded by heat stimuli with moderate intensity. This will allow us to compare the effect of the different cues on expectations and pain responses evoked by the same moderate stimuli. More than one moderate temperature will be used in the test task, to ensure that heat intensity affects pain responses, and pain reports are not driven by demand characteristic.
4) *Cues recognition*: In this task, all cues will be randomly presented one by one and participants will be asked to rate how hot they expect the stimulus paired with this cue to be. This task will be used to test explicit learning, in addition to the expectation ratings during the test task.

In the pure instructions condition, participants will be instructed for each cue whether it is paired with low or with high heat stimuli, without further conditioning. These cues will not be predictive of actual intensity in the following tasks.
In order to control for order effects between the symbolic learning and conditioning tasks, their order will be counter-balanced across sessions and participants (see below).
The structure of the tasks across the 10 sessions will be as follow (the order of the symbolic learning and conditioning tasks will change between participants):



The first session will include all tasks: first the conditioning tasks, then the test task and finally the cues recognition task. Sessions 2-6 will begin and end with the cues recognition task (to test for explicit learning between and within sessions), and include the learning tasks (symbolic learning and conditioning) as well as a test task. These sessions will be used to establish the pairing of cues and heat intensity, and to test the learning process. Sessions 7-10 will only include the cues recognition and test tasks, in order to test how the effects of previous learning unfold over time without further learning.

"Counterfactual"
In the counterfactual task, on each trial participants will be presented with one of the following binary alternatives:

- Low vs. moderate heat stimulus
- High vs. moderate heat stimulus
- Gaining money vs. moderate heat stimulus
- Losing money vs. moderate heat stimulus

Participants will be told that on each trial one of the two alternatives will be randomly chosen (50% chance each). Then, one of the alternatives will be pseudo-randomly chosen by the computer, and participants will either experience a low/moderate/high heat stimulus or will gain/lose money (+/- 3-6). Participants will not be asked to choose and will have no control on the outcome, but rather will be presented with the alternative option that was not chosen. This will allow us to test the pain responses to the same moderate

stimulus depending on the counterfactual- whether it was the better or the worse option, and whether the alternative option was a different intensity of heat or a monetary outcome.
To avoid a situation where participants randomly lose money during the experiment with no control from their side, we will make sure that while they may lose money in a given session (out of their compensation for this specific session), in total, across the four sessions with the counterfactual task, their gains and losses will sum to $0 or more.

Additional COVID-19-related procedures
The behavioral research procedures as described in the research plan will be carried out in the laboratory utilizing the 2020 re-opening plans and COVID-19 protection protocols as long as these are in place. We will strictly follow Dartmouth College's policies. We hope to enroll 10 voluntary participants, from the college / surrounding community or from subpopulations, as allowed by COVID-19-related policies at the time of recruitment and participation.. Equipment utilized for these behavioral interventions include, as described above, Thermode systems, the BioPac Acquisition System, cameras (GoPros and a Thermal camera) and computers. Cleaning procedures for these devices are in place as part of the lab's approved reopening plan and will be strictly followed (see Attachment2- CANlab phase 2A lab reopening worksheet_9.2.2020]).

4. Analysis

Describe any qualitative tests and measures as well as quantitative methods:

Data will be analyzed via univariate and multivariate regression models as well as statistical learning-based classification techniques and Bayesian analyses. All data will be processed, analyzed and visualized using a combination of Excel, R, JAGS, Python, Matlab and similar software.

5. Study Progress Monitoring

Note: appropriate monitoring may include periodic assessment of the following:
- data quality
- timelines
- recruitment and enrollment

Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:

Study progress will be periodically monitored. We will test the timeline and protocol of the study before recruiting participants. Following the collection of data from the first participants and sessions, we will visually observe the data and run preliminary analyses to ensure data quality. Those steps will allow us to make informed decisions about potential study alterations. Since we plan to collect extensive data from each participant, and taking into account the challenges and restrictions of participants' recruiting during these unpredictable times, we may change the planned compensation or the number and duration of sessions and amend this protocol accordingly. Those aspects will be monitored continuously by the research team.

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

Burn due to thermode malfunction: There is a very slight risk to the participant in case of thermode malfunction. Thousands of participants are tested using this equipment (Pathway, Q-Sense

and TSA2 systems, Medoc, Inc.) annually throughout the U.S. and the entire world, usually without adverse events. However, several reported cases of thermode malfunction have occurred in the past 5 years (four cases, to our knowledge), which have resulted in minor 1st or 2nd degree burns. The manufacturer (Medoc, Ltd.) has responded to these reports by building in enhanced hardware safety mechanisms; thus, we do not anticipate a substantial risk. The PI's lab has conducted experiments on more than 1,000 participants over the past 10 years with no adverse events. Although it is not possible to precisely determine the probability of a burn, we estimate based on our prior experience that it is considerably below 1%. We also note that the vast majority of potential burns that could potentially result from equipment malfunction would consist of minor blistering that would heal naturally without any treatment within several days. In addition, in the unlikely event that thermal heat becomes too intense for participants to tolerate, they will easily be able to stop the stimulus by releasing a strap to remove the thermode from their body. In conjunction with the software and hardware protocols built into the system by the manufacturer, we believe this procedure to be highly effective in ensuring minimal risk to participants.

Psychological discomfort: Studies involving administration of pain by definition require the induction of psychological discomfort, so this is an unavoidable risk of participation. However, as described above, the level of pain administered is calibrated to always be within participants' tolerable level, and participants are informed that they are free to discontinue the experiment at any time should they wish and can immediately stop any stimulus, if desired.

There are no known less risky alternatives to the use of any of the procedures proposed in these experiments that would provide comparable scientific information.

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:

Burn due to thermode malfunction: Given the proliferate use of this system in the psychological study of pain, the well documented safety guidelines, and the built-in software and hardware safety systems, we believe the risks to participants to be minimal.
Pain stimuli will always occur within well-tested and verified parameters (based on our lab's stimulation guidelines approved as part of STUDY00031999). The equipment used is widely available and includes several built-in safety mechanisms including an auto-shutoff as well as maximum temperature restrictions. Additionally, participants are given an emergency shut-off button that they can press at any time and instantly stops heat delivery. The equipment is regularly maintained and tested by our trained personnel. All personnel who use the equipment are trained on equipment procedures.

Psychological discomfort: Participants are clearly informed of this risk prior to participation during the instruction period. There is virtually no possibility of long-term psychological distress or unanticipated psychological discomfort that exceeds the proximal response to pain, as the amount of pain delivered is comparable to or less than that experienced in many day-to-day situations (e.g., holding a hot cup of coffee). However, they will be encouraged to inform the experimenter if they are uncomfortable with the nature of the stimuli. If participants experience any lasting negative effects related to this study, they will be encouraged to contact the Principal Investigator, Dr. Tor Wager, at Tor.D.Wager@Dartmouth.edu. He will discuss options for counseling referrals and provide a referral. The cost of any follow-up counseling, should any be required, would be borne by the participants and/or their insurance provider. The participant will be informed that neither the study team nor any of its individual members will be responsible for follow-up treatment.

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

Given the information collected from individuals, we will be able to make inferences about the human population at large without subjecting participants to anything more than minimal risk.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

Although we do not anticipate adverse events, we will follow reporting standards. In any case of thermodes malfunction/burn, we will stop the study and assess potential for harm to future participants. As this is a known, however very rare risk, we do not consider it as an adverse event under formal definition. Nonetheless, we will inform IRB on any such event and will investigate the incident to make sure all safety procedures are strictly followed. If necessary, we will change the protocol of the study to prevent future such incidents.
An experimenter will always be present a few feet away from the testing room in which the experiment will take place. In addition, Dick's House (on campus health services) is across the parking lot from Moore hall. Participants will be sent there should they report any symptoms of physical or mental discomfort. Any psychological, social or medical services required will be available through Dick's House and/or referral to Dartmouth Hitchcock Medical Center.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☒ **Yes** ☐ No

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

In the some of the tasks, we will lead participants to be believe that a cue is predictive of lower or higher heat intensities, where in fact some of the cues will not be predictive of actual heat intensities. This minimal deception is critical to test the effect of different types of suggestions/conditioning on pain perception, because the management of participants' expectations and beliefs is a one of the main focuses of the study. Participants will be debriefed about this procedure and the intended purpose of the study upon the study's conclusion (see debrief form).

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

5-10

b. Provide a justification of the proposed sample size

As described above, this study is designed as a "N-of-few" experiment to study effects on pain perception over time. This design is also in line with the current guidelines and required precautions

due to the covid-19 pandemic. If there will be an improvement of the situation, or we see that participants recruitment is less challenging than expected, we may increase the desired sample size.

c. Define the target population:

Participants will come from two primary sources:
1) Dartmouth undergraduate students
2) Non-student participants from either Dartmouth or the community recruited using the following.

Participants will be recruited using the online recruitment system (SONA) of the Department of Psychological and Brain Sciences at Dartmouth College (for undergraduate students), flyers posted online and offline, word of mouth, emails and online postings (see recruitment materials).

We will strictly follow the college's policies with regard to populations allowed to participate in studies on campus that are / will be in place during recruitment and participation. Non-undergraduate members of our department (Psychological and Brain Sciences) will be contacted mainly via email, Slack or similar methods (see Attachment4- recruitment template and Attachment5- "CPHS – EMPLOYEE and STUDENT FORM").

Participants less than 18 years old will be excluded because of population vulnerability issues. Participants over 55 years of age will be excluded based on a diminished sensitivity to pain that require special studies of older populations, which is outside the scope of this study. We will also exclude people who cannot tolerate heat pain (comparable to touching a hot mug of coffee), as determined by an initial introduction task before the beginning the main experiment.

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐ Pregnant Women, Fetuses and Neonates
☐ Children
☐ People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

Dartmouth's students and employees are likely to participate in this study. Participants will be informed and repeatedly reminded that they have the right to refuse to answer any question(s) or refuse to participate in any procedure for any reason, without any penalty or loss of benefits to which they are otherwise entitled, including no effect on their academic standing and / or employment. In addition, we will not collect private information that we usually collect in the lab, such as mental

health questionnaires. For more information see Attachment 4- recruitment template and Attachment 5- "CPHS –EMPLOYEE and STUDENT FORM".

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

- General recruitment: Participants will be recruited via online/offline advert.
- Students recruitment: Students will be able to see and choose to participate (or not) in laboratory experiments via the SONA online experiment system.
- Recruitment of non-undergraduate members of our department (the Department of Psychological and Brain Sciences): See Attachment 4- recruitment template and Attachment 5- "CPHS – EMPLOYEE and STUDENT FORM"

11. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. Please describe the consent and/or assent process, addressing the following:

- Who will obtain consent/assent from participants
- Where the consent/assent process will take place
- The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
- Any precautions taken to minimize the possibility of coercion or undue influence
- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured

Participants will be consented by one of the researchers or research assistants in Moore Hall at the beginning of the experiment. Researchers are authorized to obtain consent only after undergoing CPHS training. Prior to the beginning of the experiment, the experimenter will go over the consent form with the participant verbally, being available to answer any questions or address any concerns during the consenting procedure. Any participant that indicates that they do not understand the consent form will not be run in any experiment. The participant's voluntary participation is stressed in that they are informed, both verbally and in writing, that they can discontinue the study at any time. The consent procedure will take place over the course of several minutes (self-paced as participants read the consent form). Participants will sign the consent form with a physical or electronic signature. An electronic signature will be treated the same as a physical signature.
For studies that involve the collection of video/audio facial recordings, participants will be provided with a video release form.

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.
Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

- ☐ For the informed consent *process*
- ☐ For the *documentation* of informed consent
- ☐ For the HIPAA Authorization to use and/or disclose PHI
- ☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

For the first two sessions, participants will be paid $20 per hour. Hourly rates of compensation will increase across sessions, such that participants 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, participants who complete the entire study (all 10 sessions) will receive a completion bonus of $60. Participants may also loss/gain additional amounts of money during each of the four last sessions (7-10), but we will make sure the gains/losses sum up to $0 or more in total by the end of the experiment.
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. This will not affect payment amounts for the rest of their participation time and for the completion bonus.
Participants who discontinue participation will be paid a prorated rate for the time of participation based on the hourly rate established for each session.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

No activities or interactions will occur that could lead to a breach of a participant's privacy.

14. Confidentiality of Data

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☒ **No** ☐ Yes

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

N/A

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data

- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

Demographic and identifying information will be collected with a dedicated form (see Attachment 7 – participants details form). This information is collected in order to follow the guidelines of our funding agency, the National Institute of Mental Health (NIMH), with regard to data sharing and reporting. Identifying information, such as date and place of birth and full name in birth, is collected in order to get a GUID for data sharing in the NIMH Data Archive (NDA). GUID is a subject ID allowing researchers to share data specific to a study participant without exposing personally identifiable information and match participants across labs and research data repositories. This identifying information will not be publicly released.
To safeguard privacy, identifying information of participants will be stored in a password protected file on our secure servers and/or in locked filing cabinets in a locked room, 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. Participants' identifying information will not be directly connected to the data, and we will identify individual cases with alphanumeric codes. 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 publicly released, so the risk that anyone would be able to identify specific participants is minimal.

c. Describe the plan for storage or destruction of data upon study completion:

Physical consent forms will be stored in a locked room and will only be accessible to the PI and research staff who have passed CPHS certification. Data will contain only unique participant numbers and will be kept on password-protected/encrypted computers. It is now common practice in neuroscience and psychology research to store de-identified data and use them for future research. It is increasingly common for NIH-funded studies to require public sharing of de-identified data in a public NIH-sponsored or researcher-maintained data repository, as they are a valuable resource for large-scale scientific efforts, as well as to enhancing reproducibility and replicability of scientific findings. Our analysis plan includes sharing and reuse of de-identified data during the study and after the end of the study period. Upon the completion of the data and sharing of de-identified data, codes linking participants' data to identifying information will be removed and potential identifying information will not be included with the shared data.

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