Participant Information Sheet

Project title: Reliability of Pressure Pain Threshold (PPT) and Conditioned Pain Modulation (CPM) with Neck and Shoulder Pain

Invitation paragraph

Thank you for your interest in this study. Before you decide whether to take part, you need to understand why the research is being done and what it will involve. Please take the time to read the following information carefully before you consent to take part. Your participation is completely voluntary and will not affect any access to treatment or services that you may be currently receiving. There is information at the end of the leaflet on how to contact us if you have any questions or concerns.

What is the purpose of the study?

Neck-shoulder pain is a widespread condition. Currently, the most common method of measuring pain is to ask a person to rate their pain intensity on a number scale (e.g., 0-10). This lacks objectivity and prevents us from understanding the different qualities of pain. This study aims to investigate the consistency of two objective pain measures across different examiners and sessions. Using pressure to create pain.

Why have I been invited to participate?

You have been invited because you are aged 18-65 years, currently experiencing an episode of neck-shoulder pain with an intensity greater than 2/10 (0 is no pain, 10 is maximum pain). To participate, you should have no history of neck trauma or recent neck trauma, recent neck and shoulder surgery, or any medical conditions that could affect normal sensation.

Do I have to take part?

It is up to you to decide whether or not you wish to take part in this study. If you do decide to take part, you will be asked to provide written consent. You are free to withdraw at any time, without giving a reason. Any collected data will continue to be used. However, no more data will be collected from you after you withdraw. Your records will be kept strictly confidential at all times.

What will happen to me if I take part?

If you are interested in participating in this study, we will verify your eligibility. This will happen either in person or via email. If you meet the inclusion criteria, we will arrange suitable dates for you to come to the University for testing.

The following procedures will be conducted in the University:

1. Full briefing of the entire data collection process, answering any questions, and signing of the informed consent (~10 mins).
2. Complete a questionnaire and neck pain assessment to collect characteristic data (e.g., age, height, weight, gender) (~15 mins)
3. Pressure pain testing on your neck and arms, like in the picture below (figure 1), across two 40-minute sessions. (~120 mins)

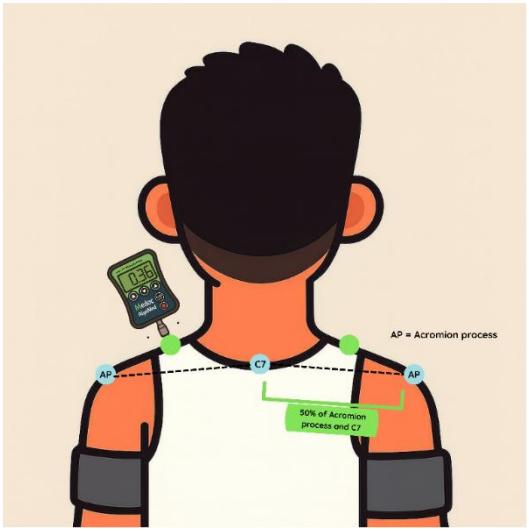

Figure 1 Pressure point and measurement tools

4. After the session, receive a therapeutic massage to the neck-shoulder region (~10 mins).

What information will be collected?

We will ask for your name, age, email address, and telephone number. We will also record personal characteristics such as age, height, body mass, gender, education level, and ethnicity, information surrounding your neck pain, and measure your pain sensitivity to both pressure and mechanical stimuli.

What are the possible benefits of taking part?

There will be no direct personal benefit to you by participating in this study. However, the information from this project will contribute to a better understanding of pain and how best to measure it objectively.

Will I receive payment for my participation?

You will not receive any payment for your participation. However, the test will be inducing pain using PPT and CPM equipment on the shoulder muscle. After the test, the participant will receive a 10-minute massage (optional). The estimated value of a 10-minute massage is £10.

What are the possible disadvantages and risks of taking part?

There is a very minor risk that this study will occur after the session. Your neck pain may worsen after the session, as we will be exerting pressure on your neck-shoulder region. The increase in pain is temporary and will return to your baseline within 24 hours. To further reduce the risk of increased pain after the session, the researcher (Supawan Chaiprakaiwan) will provide a 10-minute therapeutic massage to the neck and shoulder regions.

How will my data be stored, and who will have access to it?

Table 1. Data storage and access

Type of data	How will it be stored	Who will have access
Hardcopy data (consent form, data collection sheet) - non-anonymised	Digitised and uploaded to Box within one month of your testing session. Identifiable information, such as your name, age, and email address, will be transferred to a password-protected folder on the Box during this time. All non-anonymised data. Hardcopy forms will be stored in a locked cupboard in the primary supervisor's (Dr Bernard Liew) locked room. All hardcopy data will be securely destroyed using a shredding process at the School of Sport, Rehabilitation, and Exercise Sciences (University of Essex) upon project completion.	All investigators listed in this project.

Questionnaire data in Qualtrics (anonymised)	Stored in a secure cloud system called Box and Qualtrics. Qualtrics data, after finishing the data collection, the data will be downloaded to Box and anonymised. The raw Qualtrics data will be deleted after 3 years, whereas the anonymised data will be stored indefinitely. Only the investigators listed on this sheet will be able to access it.	
Objective pain measurement data (anonymised)	Stored in a secure cloud system called Box. only the investigators listed on this sheet will be able to access it.	

The purpose of storing anonymised data indefinitely and sharing it in public repositories is to contribute to future research projects in movement analysis.

How long will my data be stored for?

Table 2 details how long each data type will be stored.

Table 2. Duration of data storage

Type of data	Duration of data storage
Hardcopy data (consent form, data collection sheet) - non-anonymised	Hardcopy data will be destroyed after project completion using a shredding process at the School of Sport, Rehabilitation, and Exercise Sciences (University of Essex). The digitised version of the hardcopy data will be destroyed after three years. Personal information, including your name and email address, is stored in an Excel file • If consent for name and email to be retained, kept indefinitely. This information will be used solely to contact

	participants regarding their interest in future research that may emerge from this project. • If not consenting for name and email to be retained, they will be deleted after three years.
Questionnaire data in Qualtrics (anonymised)	Indefinitely on Box. The raw Qualtrics data will be deleted after 3 years.
Objective pain measurement data (anonymised)	Indefinitely on Box.

Will my participation be kept confidential?

All data will be kept confidential, and unique participant numbers (e.g., “subj_01”) will be allocated instead of using your name on any electronic and hardcopy files. Your identifiable data will be stored on the University of Essex cloud service (Box), and only the investigators listed on this sheet will be able to access it. As a result, people who do not need to know who you are will not be able to see your name or contact details. All your data will have a code number instead. We will keep all information about you safe and secure. The only hardcopy (paper) data that will be collected are the signed informed consent sheet and the physical data collection checklist. This hardcopy data will be safely stored in a locked cupboard within a locked room in the Supervisor’s office. The cupboard can only be assessed by the principal investigator listed on this sheet. All hardcopy data will be securely destroyed using a shredding process at the School of Sport, Rehabilitation, and Exercise Sciences (University of Essex) upon project completion. The Qualtrics data will be stored anonymously on Box indefinitely. The raw Qualtrics data will be deleted after 3 years. Only the investigators listed on this sheet will be able to access the Qualtrics data in both systems.

How will my data be used, and in what form will it be shared further?

We will need to use information collected from you for this research project—Table **3** details how we will use each data type and how we will share it.

Table 3. Information on data usage and sharing.

Type of data	Usage	Form of sharing
Name and email	Use this information to conduct the research or to check your records to ensure that the research is being done properly.	Not shared
Questionnaire in Qualtrics (anonymised)	Used to describe the study cohort when presenting the results emerging from this project.	Publications, presentations, seminars, and workshops. Stored on Box, University of Essex Research Data Repository, and shared on public scientific repositories.
Objective pain measurement data (anonymised)	Used as results for reporting in publications, presentations, seminars and workshops.	Stored on Box, University of Essex Research Data Repository, and shared on public scientific repositories.

We will need to use information from you for this research project. This information will include your name and email address when you are testing in our laboratory. The research team will use this information to conduct the research or to check your records to ensure it is being done properly.

Once we have finished the project, we will keep the data so we can check the results. We will write our reports so that no one can determine how you participated in the study. The results from this project will be used for scientific conference presentations, published scientific journal articles, and as part of teaching materials. We may share the fully anonymised data and results with other researchers for future projects. In addition, we may publish the entire fully anonymised (i.e., no names, emails) data onto the University of Essex's Research Data Repository (https://researchdata.essex.ac.uk/) and also the public reposition (e.g., https://figshare.com/).

Withdrawing my data

You can stop being part of the study at any time without giving a reason. You will be given an option in the Informed Consent whether you give us permission to retain and use the data collected for research purposes. If permission is not granted to retain and use the data after you withdraw, all data collected from you will be deleted. Your rights to access, change, or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. This means that we won't be able to let you see or change the data we hold about you. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information by contacting the Information Assurance Manager (dpo@essex.ac.uk).

What is the legal basis for using personal data, and who is the Data Controller?

The legal basis for using the data is your informed consent to the study. The Data Controller is the University of Essex, and the specific contact is the University Information Assurance Manager (dpo@essex.ac.uk). We will be using information from you to undertake this research. This means that we are responsible for looking after your information and using it properly. All information and data you give us will be kept safe and secure.

The University processes personal data for the primary purpose of research under the lawful basis of processing set out in Article 6 (1)(e) of the UK GDPR, 'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller'. The University's lawful basis for processing Special Category data is Article 9 (2), (j) 'processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1)'. Using this lawful basis requires the University to also meet a substantial public interest condition as set out in Schedule 1, Part 1 of the Data Protection Act 2018. The condition that the University will use is 4. Research, etc. Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University's research. For more information on data protection legislation and your rights, visit the University's Data Protection and Research Activity webpage. For any queries, email: dpo@essex.ac.uk.

Who has reviewed the study?

This study has been granted a favourable ethical opinion by the University Ethics Committee under the reference ETH2526-0271.

Concerns and Complaints

If you have any concerns about any aspect of the study or you have a complaint, in the first instance, please contact the principal investigator of the project (Supawan Chaiprakaiwan) using the contact details provided. If you are still concerned, and you think your complaint has not been addressed to your satisfaction or you feel that you cannot approach the principal investigator, please contact the departmental Director of Research in the department responsible for this project (Dr Jamie Tallent, E-mail: Jamie.Tallent@essex.ac.uk). If you are still not satisfied, please contact the University of Essex REO Research Integrity Manager (reo-integrity@essex.ac.uk). All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. Please include the ERAMS reference which can be found at the footer of this page so that the study can be identified, details of the name or description of the study, the researcher(s) involved, and the details of the complaint you wish to make.

Contact details

Principal investigator: Miss Supawan Chaiprakaiwan, PhD student,
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