**Participant Information Sheet**

**Study Title**: Pain-related interpretation bias

**Researcher**: Philippa Broadbent

**ERGO number:** 54360

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

My name is Philippa Broadbent and this study forms part of my PhD research. I am researching the existence of cognitive biases and their effects on somatosensory processing in healthy individuals. This research is investigating whether different interpretations of ambiguous information can influence perceptions of hot and cold sensations.

This research is funded by the Economic and Social Research Council (ESRC) through the South Coast Doctoral Training Partnership.

**Why have I been asked to participate?**

You are eligible to take part in this research if you meet all of the following criteria:

1. You are aged 18-50.
2. You have normal or corrected to normal vision.
3. You are fluent in the English language.
4. You do not have any type of chronic pain or psychiatric condition.
5. You are not currently experiencing pain.
6. You do not have any known reading difficulties.

You are **not** eligible to participate if you are showing symptoms of COVID-19, shielding, or clinically vulnerable.

We aim to recruit 134 participants. In most cases participants will have contacted the researcher after seeing a poster or advertisement in a newspaper or social media, seeing the study on ‘efolio’, or hearing about the study through word-of-mouth.

**What will happen to me if I take part?**

You will be asked to complete a health questionnaire remotely either via the internet or phone before travelling to the Pain Research Laboratory. Those classified as high risk for COVID 19 infectious status or other infectious disease will not be recruited to participate in our research.

Your forehead temperature will be tested using a digital thermometer upon arrival at building 44. If you have a fever (> 37.8C), you will not be permitted entry into the building and will be advised to self-isolate and take a COVID-19 test. Both you and the researcher will sanitise your hands at entrance to building 44 and the lab (on both entry and exit) to minimise risk from having touched a contaminated surface. You will be required to wear a face covering while in the University, although you may take this off when alone in the Pain Research Laboratory.

This study will last for approximately 2 hours.

First you will be asked to complete questionnaires related to your perceptions and experiences of pain, as well as questionnaires about anxiety and depression. You will also be asked to provide demographic information about yourself including your date of age, gender, occupation, level of education, which hand you write with, and whether any of your close family have chronic pain.

The researcher will measure your cold and hot pain thresholds. A thermode (a cuboid with contact surface area 3cm x 3cm) will be attached to your hand with a Velcro strap and will cool down or heat up gradually. You will be asked to press a button at the very first moment you feel that the temperature is painful. When you press the button the thermode will return to the baseline temperature.

You will then complete the first computer task. In this task you will be asked to read a description of a scenario and complete the final word of the description from a word fragment. You will also be asked some comprehension questions about the scenarios. For this task you will be randomly assigned to one of two groups. One group will complete the task with pain-related scenarios, the other group will complete the task with neutral scenarios.

In the second computer based task, you will be asked to respond as quickly as you can to the location of a target. In a third task you will be asked to type a sentence featuring a specific word.

After that, the thermode will be attached to your hand again and you will be feel a series of hot and cold sensations. Following each sensation you will be asked to rate the intensity and unpleasantness of the sensation on scales from 0 to 100. If at any point you want to stop the hot or cold sensation say ‘stop’ and the researcher will return the thermode to baseline temperature.

In the next computer task you will be asked to read a description of a scenario and complete the final word of the description from a word fragment.

Finally, you will be thanked, debriefed, and you will have the opportunity to ask any questions about the study.

**Are there any benefits in my taking part?**

If you are an undergraduate Psychology student at the University of Southampton, you will be awarded 24 research credits (1 credit per 5 minutes). If you are not an undergraduate psychology student you will be reimbursed £12 for your time (£6 per hour). The results of this study will improve understanding of pain-related cognitive biases, which might contribute to improvements in future treatments for chronic pain.

**Are there any risks involved?**

Use of the computer may cause tiredness. Please inform the researcher if using a computer typically makes you feel unwell. Pain-related words and/or scenarios may be included in the tasks, which may produce some emotional distress, although this is unlikely. You can stop the experiment at any time if you find these words distressing. The hot and cold sensations may be mildly painful but will not cause any pain or harm beyond the duration of the study. You can stop the cold or hot sensation at any time if you find it too painful or distressing by saying ‘stop’. The questionnaires address personal issues including your emotions. Some participants may find these questionnaires upsetting, although they are commonly used in research such as this.

There are support services available, which you can contact if you feel distressed following your involvement in the study.

The Student Life Team provide wellbeing support for students at the University of Southampton. Phone: 023 8059 8180; Email: studentlife@soton.ac.uk

The Samaritans provide confidential support for people experiencing feelings of distress or despair. Phone: 116 123 (free 24-hour helpline).

**What data will be collected?**

You will be asked to complete a short demographic questionnaire that will ask you for your age, gender, occupation, education level, which hand you write with, and whether any of your close family have chronic pain. Information about which hand you write with will be used to determine the hand on which you will experience the hot and cold sensations. The other information will be used to evaluate whether any of these factors influence interpretation bias. You will be asked to complete some questionnaires about your experience of anxiety and depression as well as pain related emotions and thoughts. Your responses to the computer-based tasks will also be collected. Data will be pseudonymised at the point of consent. This will be done by associating your data with an ID number rather than your name.

A record of your name and email address will be kept on a password-protected computer for the duration of the study. This will be stored in a password protected file, separate from the rest of the data. This will only be used for the purpose of contacting you if anyone in the School of Psychology tests positive for COVID-19.

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential. Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Data will be pseudonymised at the point of consent. This will be done by associating your data with an ID number rather than your name.Your contact details will not be stored beyond the duration of the study. Non-electronic data will be stored in a locked filing cabinet, separate from consent forms. Electronic data will be stored in a file on a password protected computer. Only the research team will have access to electronic and non-electronic data (Philippa Broadbent, Prof. Christina Liossi, Dr. Daniel Schoth). No identifying information will be used in reports or publications.

For students and staff at the University of Southampton, if we are concerned for your health or wellbeing we may share relevant data with the University's Enabling Services, who may then contact you. For participants who are not students or staff at the University of Southampton, if we are concerned for your health or wellbeing we may contact you on the details you provided to raise our concerns and recommend you speak to your GP.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. If you withdraw before completing the entire study you will be reimbursed in proportion to the time you spent completing the study. For example, if you withdraw after spending 30 minutes participating you will be reimbursed 6 credits/£3.

You can withdraw at any point during the study by verbally informing the researcher. If you withdraw from the study all of your data will be destroyed. You can withdraw from the study until the end of July 2021 by contacting the researcher, Philippa Broadbent.

Email: pkb1g14@soton.ac.uk

Phone: 023 8059 6652

**What will happen to the results of the research?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

This study will be written up as part of the PhD thesis for Philippa Broadbent at the University of Southampton. This study may also be published in a scientific journal.

Data will be pseudonymised; participants will be identified by ID numbers rather than names. The data will be deposited in the repository controlled by The University of Southampton for 10 years as per the university’s data management policy. This data may be shared for use in future studies. This will contribute further to this area of research and may prevent the same data from having to be collected again.

If you would like to contact the researcher about the use of your data please do so using the contact details above. If you have a complaint about the use of your data, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)).

**Where can I get more information?**

Primary researcher: Philippa Broadbent, pkb1g14@soton.ac.uk, 023 8059 6652

Supervisors: Prof. Christina Liossi, C.Liossi@soton.ac.uk; Dr Daniel Schoth, D.E.Schoth@soton.ac.uk.

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

Primary researcher: Philippa Broadbent, pkb1g14@soton.ac.uk, 023 8059 6652

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)).

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).

Data will be pseudonymised and access to the codes associated with the pseudonymisation will only be accessible by the researcher.

**Thank you.**

Thank you for taking the time to read the information sheet and considering taking part in the research.