**Participant Information Sheet (A)**

**Study title**: Investigating the processes of an EEG-based neurofeedback device in people with central neuropathic pain after a spinal cord injury

**Researcher**: Krithika Anil

**NHS Ethics Reference:** 234857 **University of Southampton Ethics Reference**: 29852

**Please read this information carefully before deciding to take part in this research. If you are happy to participate, you may be asked to sign a consent form.**

**What is this research about?**

This research will evaluate a neurofeedback system. Neurofeedback is where your brain activity (here we will use electrical brain activity: EEG) is visualised for you with the aim of helping you to control it. The purpose of our neurofeedback system is to provide pain relief for people with central neuropathic pain (pain caused by damaged nerves) after a spinal cord injury. A part of this study is on people without pain (control group), which may help in understanding how this EEG activity is controlled, and how physiology (heart and respiratory rate, and galvanic skin response) and physical sensations may change during the neurofeedback. Understanding these topics will help us to develop the effectiveness of the neurofeedback, which will greatly help those with central neuropathic pain who seek pain relief. This study is a student project for the completion of a PhD, and has been reviewed and approved by the Berkshire REC committee.

**Why have I been asked to take part?**

You have been asked to participate in this study because you are between 18 and 69 years old (inclusive) and do not have, or ever had, any chronic pain conditions, brain injury, or any other neurological condition. This study focuses on people who do not have central neuropathic pain, so that we can make comparisons to people who do have this pain.

**Do I have to take part?**

No. Your participation is voluntary. There are no consequences if you decide not to take part; your legal and medical rights will not be affected.

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

If you let us know that you are interested in taking part, we will send you this information sheet and ask you some simple questions to ensure you are suitable for taking part in the study. If you are, we will then invite you to come to the allocated study site. At this site, you will have the opportunity to ask further questions about taking part and be asked to give your written informed consent. Taking part in the study will require you to attend the study site on four occasions, at least once a week. Each visit will last between and 1 and 2 hours. During each visit, the following will happen:

1. We will ask you to give us some background information about yourself and your beliefs about control over responsibilities in daily life. We will be recording galvanic skin response, breathing and heart rate during the study. To do this, we will put a band around your chest (over your clothes) to record your breathing rate, and we will put sensors on your fingers, wrists, and feet to record your skin response and heart rate. We will also ask you about any physical sensations you are experiencing at the time of the study.
2. You will then be asked to wear a headset, which will translate your EEG activity into a video on a tablet screen. The video will present your EEG as three moving bars, and you will be asked to try to control the movement of these bars through mental strategies of your choice.
3. After using the headset for about 30 to 45 minutes, we will again ask you about your control beliefs and any physical sensations you are experiencing. The headset will then be removed and we will interview you about how you controlled the bars. This interview will last about 10-15 minutes and will be audio recorded. You may take breaks at any time during the study if you wish.

If you are uncomfortable with permitting us to put the equipment on you to record your physiological responses (band and sensors), you may bring a friend along with you to attend the study while the equipment is being set up. Otherwise, you may ask the researcher to provide someone else to attend the study during the equipment set up. If you prefer not to have the equipment set up at all, you may still take part in the study without this equipment. Please let the researcher know if this equipment causes you any discomfort.

**Will my personal details be confidential?**

Yes. The researcher carrying out the study will maintain a record of your details in a secure location. All recorded data for further analysis will be pseudo-anonymised, where a participant identification number will be linked with personal information to arrange your study sessions. In accordance with the University of Southampton Research Data Management Policy, all significant research data will be held for a minimum of ten years after the end of the study. Informed consents forms and any other personal information will be kept in a secure and locked office and not be stored digitally. The University of Glasgow (main collaborator), Stoke Mandeville Hospital (main collaborator), and The University of West of England are collaborating institutions of this study. University of Southampton, and Defence Science and Technology Laboratory (DSTL) jointly funds this study with the aim of identifying ways to improve recovery after injury. Any data that are shared by the research team of the University of Southampton with these organisations, DSTL or future third parties will be anonymised. This means the data will only be shared after removing all the links to the participant identification number and personal information. If you would prefer that your anonymised data are not accessible to third parties at any time during or after the study, please inform the researcher. Please see the end of this document for further details about how your data will be handled.

**What are the risks involved in taking part?**

The simple purpose of the device is to show you your EEG activity so that you can learn to control it, and therefore, nothing will be done to you. You might be concerned that this neurofeedback method may cause you pain. Current research does not indicate that this is a risk, so it is very unlikely that the neurofeedback will cause pain. However, if you feel any painful sensations during the neurofeedback, please let the researcher know and the study will be halted. Other sensations (non-painful) may be induced by the neurofeedback. While these sensations are not painful, the study can be halted if these sensations causes you any discomfort. When the study is halted, the researcher will remove all research equipment from your person.

The questions we ask you about your control beliefs may make you feel uncomfortable. If this is the case, you do not have to answer any questions that you do not want to, and you may also ask to stop the study and are free to withdraw from it without giving any reason. You may also request that any data we have collected from you are destroyed.

Electronic equipment will be used throughout the study to gather physiological data from you (EEG, heart rate, breathing rate, and skin sweat response). These equipment have been assessed and tested to ensure equipment safety for use in this study. However, in the unlikely case of equipment failure causing distress, the study will be halted immediately and you will be attended to by the researcher and a clinical staff member.

A headset will be used to gather EEG data, which may cause mild discomfort. If the headset is uncomfortable, the researcher will adjust the headset so that it sits comfortably. If the headset continues to cause discomfort for you, the study can be halted.

Medical tape and liquid for sensors will be used in this study. These items may cause some discomfort, e.g., skin irritation. Both items are made to be sensitive for skin; however, a small sample of each will be put on your hands and neck at the start of the study. These samples will be checked several minutes later for any signs of irritation. The study will continue if there are no signs of irritation. If there are signs of irritation, the study will be halted. Additionally, the medical tape may cause some discomfort, as it may pull on hair when taken off. The researcher will take care when removing the tape.

During the neurofeedback, you will be asked to stay as still as possible. This may cause some mild discomfort. There are multiple opportunities to take breaks throughout the study, during which you may move your body to relieve any tension from staying still.

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

Your participation is voluntary and you may withdraw from the study at any time. You do not have to give a reason for withdrawal and it will not affect your legal and medical rights.

**What happens if something goes wrong?**

In the case of concern or complaint, you should contact the Head of Research Governance (02380 595058, rgoinfo@soton.ac.uk). You may also contact the Stoke Mandeville PALS (Patient Advice and Liaison Service; 01296 316042, pals.office@buckshealthcare.nhs.uk). Please note that the researchers, supervisors or any other persons involved in the study will not deal with any complaints. If you experience any persisting emotional or physical discomfort after the study, we advice you to consult your GP.

**Any further questions?**

Should you require any further information regarding this study, please contact:

Krithika Anil (project researcher)

k.anil@soton.ac.uk

**Further Details About Your Data**

University of Southampton is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Southampton will keep identifiable information about you until the study is completed, and will only use it for the purposes of carrying out our research. 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.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

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>). If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

The only people in University of Southampton who will have access to information that identifies you will be people who need to contact you to arrange your study sessions or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. Buckinghamshire Healthcare Trust will keep identifiable information about you from this study until the completion of the study.

For further information on the University of Southampton’s privacy notice for research participants, please go to:

<https://www.southampton.ac.uk/about/governance/regulations-policies-guidelines.page>