Royal National Orthopaedic Hospital NHS
NHS Trust

PARTICIPANT INFORMATION SHEET

A study using sound feedback for enhancing bodily feelings and emotional state in patients with Complex Regional Pain Syndrome Type 1.

You are being invited to take part in a study. Before you decide if you want to take part, it is important for you to understand why the study is being done and what it will involve. Please take the time to read the following information carefully. Talk to others about the study if you wish. Ask us there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of this research study is to see if we could develop a new method for enhancing the perceptions of one's body and the emotional state of those with Complex Regional Pain Syndrome Type 1 (CRPS). This method has been found to lead to these enhancements in healthy people. In this study we wish to find out whether the use of this new device changes how you perceive sensations to your limb. We are also interested to know what effect our current treatment has on your emotional state and your physical activity.

Why have I been invited?
We are asking people with CRPS Type 1 to volunteer for this study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care you receive.

What will happen to me if I take part?
If you decide that you do want to take part in the study we will ask you to sign a consent form. We will ask you to attend the Royal National Orthopaedic Hospital at Stanmore for a session lasting a maximum of 2 hours. During this time you will be introduced to the technology used in this new method. The Chief Investigator, Dr Helen Cohen or the Principal Investigator Dr Ana Tajadura-Jiménez will ask you to:

- Try the technology by wearing it while walking (on a treadmill or on the floor) for a maximum duration of 2 minutes at a time.
- Wear some motion sensors that will capture your walking patterns. These sensors will not do any harm and are often used in therapy.
- Wear a pair of headphones.
- Complete some questionnaires on perceived pain and emotional state.
- Have your body weight and height measured.
- Answer some questions about how you perceive your affected limb.
- Undergo some simple assessments that tell us how you perceive your limb in terms of size and shape. We will do these assessments by asking you to indicate with your hands the size of your limb(s) as well as to indicate the size of objects displayed in a screen that corresponds to the size of your limb(s), and by adjusting an avatar limb(s) to represent your perceived limb dimensions and shape.

If at any stage of the activity you feel uncomfortable, you can withdraw from the study. You may also find that a session of 120 minutes is too long for you, and we will adjust the timings as you find tolerable. You will be video recorded during the activity session if you agree for us to do so. We will seek your agreement for the video recording to be used for this research study. You can refuse to consent to be filmed and still take part in the study. Videos are not a critical part of data collection although are useful during analysis to get information about the particular events occurring during the study. We will also seek your agreement for the videotape to be used by the researchers for teaching or conference presentations. Videos used in teaching or conference presentations will not be lodged online with public access. Videos will not be used in publications at any stage and/or end up online. If you consent for the video to be used for the research study only, it will only be the investigators in this research study who will have access to the video data. All data will be held in accordance with the data protection act.

Expenses and payments
We do not anticipate that you will incur any costs participating in this study. There are no parking costs at the Royal National Orthopaedic Hospital. However, we will reimburse the expenses of you travelling for participating in this study.

What is the device that is being tested?
The device is called an 'auditory stimulation device' and it aims to enhance the perceptions and feelings about your body. The device consists of a pair of sandals with microphones, a small backpack containing some small pieces of equipment and some small sensors attached to the sandals and to your skin. You will also be required to wear a pair of headphones.

What are the possible risks or side effects of taking part?
We do not anticipate any risks or side-effects from undertaking the assessments. However you may feel a temporary exacerbation of pain and if at any time point you feel uncomfortable then we will discontinue the study immediately. The auditory device carries no particular risk in itself and it delivers sound through headphones at a level that cannot harm you. Likewise, the sensors used carry no particular risk in itself. However, people with your condition often dislike having their painful limb touched or find that sensory tasks increase their symptoms in the short term. You may find the sensors uncomfortable when they are first put on your skin and when performing physical activity. If at any time you feel you cannot tolerate this sensation, and would like the device or the sensors removed, then you should inform the researcher and they will remove them immediately. Likewise, if over time, you feel that the device is increasing your pain or other sensations and you do not wish to continue with the trial then you should inform the researcher and you may withdraw at any time without this affecting your ongoing care.

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get from this study may help improve the treatment of people with Complex Regional Pain Syndrome.

How will Information be kept?
If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept strictly confidential and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised. A unique research ID number will be assigned to the information we collect from you, and any personal identifiable information, such as your name and data of birth, will be in a separate file and not linked directly with the rest of the information.
Paper records will be stored in locked filing cabinets. Digital information (e.g. your movement data and the video recording which will be encrypted) will be stored in password protected and secure computers to be used by researchers involved in the project.

What if there is a problem?
Every care will be taken in the course of this study. However, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study, the normal National Health Service complaints mechanisms are available to you. The Patient Advice and Liaison Service via [redacted] or telephone: [redacted] can advise you about this process. Please ask a member of the research team if you would like more information on this

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the Royal National Orthopaedic Hospital but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of the research study?
We would hope to publish and disseminate the results, or to present them at conferences, during and after the project. During the dissemination process no patients' names will be disclosed either in publications or in conferences. If you would like us to send you a summary of our findings, please give us a mailing or e-mail address so that we can do so.

Who is organising and funding the research?
The research is funded by an Economic and Social Research Council (ESRC) grant to Dr Tajadura-Jimenez at UCL.

Withdrawal from the project
Your participation in this study is entirely voluntary. You are free to decline to enter or to withdraw from the study any time without having to give a reason. If you choose not to enter the trial, or to withdraw once entered, this will in no way affect your future medical care. All information provided will be treated as strictly confidential and will only be used for medical purposes. Participation in this study will in no way affect your legal rights.

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Cambridge South Research Ethics Committee.

Contact for further general research information
You can contact the Research and Development office at the Royal National Orthopaedic Hospital via [redacted] or [redacted].

Who do I contact for specific information about this research project:
If you want any further information about the study, please contact:
Dr Helen Cohen [redacted]
Dr Ana Tajadura-Jimenez [redacted]

Or visit the project website: http://www.ucl.ac.uk/uclic/research/project-pages/hearing-body

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