Participant Information Sheet

Study Title: Efficacy of transcutaneous nerve stimulation in patients with knee pain due to osteoarthritis: a pilot randomised controlled trial
Researchers: Professor Elaine Dennison, Professor Kai Yang, Stefanos Christodoulou, Gillian Lake-Thompson, Meijing Liu, Lynn Reeves, Professor Isabel Reading, Professor David Scott
ERGO number: 97608
IRAS number: 335669
REC number: 24/SC/0358

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?

Osteoarthritis (OA) is the most common musculoskeletal condition and affects about a fifth of adults over the age of 45 years. Currently there is no single treatment, with most patients being advised to control their weight, take regular exercise and use painkillers as necessary.

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive stimulation technique that applies mild current through electrodes that are in contact with your skin. We have developed a wearable garment with TENS electrodes built in, shown in the figure to the right. TENS can be used to help to manage knee pain. Therefore, this research study funded by the Medical Research Council will assess how effective this treatment is at controlling knee pain. The device is a functional prototype that has been previously tested in volunteers in a one-week home usability test.

This study is sponsored by the University Hospital Southampton [RHM RHE0001] and has been reviewed and approved by The Medicines and Healthcare products Regulatory Agency & Research Ethics Committee [IRAS Project ID: 335669 – LREC: 24/SC/0358]

Why have I been asked to participate?

We want to recruit 80 people who have been diagnosed with knee osteoarthritis. You have been approached because you may have knee osteoarthritis.

What will happen to me if I take part?

If you decide that you would like to take part in the study, a member of the research team will answer any questions you may have about it. You will be asked some initial screening questions and if you are eligible for this study, you will be asked to sign a consent form of which you will receive a copy. We will take body measurements and you will be asked to try one of our standard size prototype garments which is closest to your measured size. This will allow the garment developer to assess if any changes need to be made to make sure the garment is a good fit for you.

Approximately 1 week later we will ask you to attend to collect the wearable garment and a control device and a diary to record when you use the prototype device. A member of the research team will explain how to use the wearable garment, and the electronic control unit. You will be asked to use the garment for 12 consecutive weeks. Each week, we ask that you use the garment 5 out of 7 days.

The daily treatment will involve using TENS in either one session lasting 60 minutes or two separate sessions, each lasting 30 minutes. We will ask you to keep a diary reporting how long you use the device for each time, and at what level of stimulation. You will be randomly allocated to one of two groups, with different levels of exposure to TENS stimulation. A statistician has provided guidance on how to randomise into each group.

After 12 weeks using the garment, we will arrange a third study visit to return the garment and to complete a final questionnaire. Unfortunately you will not be able to keep the garment as this is a study to test the prototype's effectiveness before it is widely available.

We will phone you one week after you start using the garment at home to check if you have any questions. We will supply you with paper questionnaires which should be completed at 1, 4, 8 and 12 weeks to be returned in the pre-paid envelopes provided. We will remind you by phone/text/email according to your preference.

The in-person sessions will last about one hour and will take place at facilities of the University of Southampton, at the MRC Lifecourse Epidemiology Unit (SO16 6YD) or Winchester School of Art (SO23 8DL).

Are there any benefits in my taking part?
You will be able to use a TENS garment for 12 weeks which may reduce or alleviate knee pain. The information collected in this study will help the research team to evaluate the efficacy of TENS on knee pain management, and the findings will contribute to scientific evidence that can lead to make recommendations. We will reimburse you via voucher (e.g. Amazon; Love2Shop) at £20 per in person session plus additional vouchers to cover all travel expenses incurred attending the in-person visits. You will not be out of pocket for any travel expenses you incur.

Are there any risks involved?
The knee sleeve is made of fabric used for everyday clothing, and the electrode material has passed the biocompatibility tests. The electronics used in the TENS device has been designed following standard safety guidance. You can choose the level of current you are comfortable with, and the maximum current is set within the safe limit. It is possible that you may experience muscle soreness similar to that experience after undertaking exercise at a level beyond normal levels. You may experience minor skin irritation which may develop over time. Please contact us immediately if this should occur.

What data will be collected?
You will be asked to provide personal information such as your e-mail address (if you have one), phone/mobile number and address to allow us to stay in contact with you over the course of the study. We will measure your height and weight, with other measurements to allow us to provide the best fit of wearable garment for you. We ask you to complete several questionnaires that ask about the level of knee pain you experience, how this affects your function and use of health care resources. This information will be collected on paper questionnaires, which will be securely stored in lockable cabinets or using password secured computers for digital data.

Will my participation be confidential?
Your participation and the information we collect about you during the research will be kept strictly confidential.

Only members of the research team and responsible members of the University Hospital Southampton NHS Foundation Trust, PHARMexcel, or 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.

Personal data that can be sensitive (e.g. name, date of birth) will be collected but only for research purposes in connection with this study. Your name will not appear on any of the research documents, and they will be coded and identified by unique subject number. All personnel involved in the processing of the data will take all appropriate measures to protect the data and treat the information as strictly confidential. The data recorded, for the purpose of the research project, will be kept on a password protected computer or as paper records kept in a locked filing cabinet in a secure office within the University of Southampton.

Hard copies of linked data (e.g., consent forms) will be kept separately from the anonymised research data in a lockable filing cabinet.

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. If you would like to take part in the study please contact Stefanos Christodoulou at etex@soton.ac.uk or by telephone on 07767 701701.

What happens if I change my mind?
Your participation is voluntary and you are free to withdraw from this study at any time without giving a reason, and without your medical care being affected. If you withdraw from the study, it may not be possible to remove your data once your personal information is no longer linked to the study data. You can withdraw your data from use in this study within two weeks following your participation.

If you lose the capacity to consent to take part, we will withdraw you from the study. If this happens within two weeks following your participation your data can be withdrawn, however, it may not be possible to remove your data once your personal information is no longer linked to the study data.

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only. If you choose to withdraw from the study, please contact Stefanos Christodoulou at etex@soton.ac.uk

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.

Where can I get more information?
If you would like further information, please contact Stefanos Christodoulou by email at etex@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 Elaine Dennison (emd@mrc.soton.ac.uk, Telephone: 02380 777624) or Professor Kai Yang (E-mail: ky2e09@soton.ac.uk, Tel: 023 8059 1654) who will do their best to answer your questions.

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

Data Protection Privacy Notice

How will we use information about you?
For the purposes of data protection law, University Hospital Southampton NHS Foundation Trust is the 'Data Controller' for this study, we will need to use information from you for this research project to assess your eligibility for the study.

This information will include your name/ contact details and email address. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep all identifiable information that we already have about you
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you

Where can you find out more about how your information is used?

You can find out more about how we use your information in the following ways:

- The Health Research Authority (HRA) protects and promotes the interests of patients and the public in health and social care research, More information can be found at www.hra.nhs.uk/information-about-patients/
- A leaflet is available from [www.hra.nhs.uk/patientdataandresearch]
- by sending an email to Hospital's Data Protection Officer (dataprotection@uhs.nhs.uk)
- by asking one of the research team or from our general privacy policy.
- by sending an email to Stefanos Christodoulou at etex@soton.ac.uk or by ringing us on 07767 701701.

The University Hospital Southampton NHS Foundation Trust and University of Southampton will keep identifiable information about you for 3 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 Hospital and University will not do anything with your personal data that you would not reasonably expect.

Professional Indemnity and Clinical Trials Insurance – University of Southampton
Project Title: Wearable Textile with Integrated Electrotherapy for Joint Pain Management
ERGO Ref: 97608
This project will be covered under the terms and conditions of the above policy, subject to informed consent being obtained from participants.

Thank you very much for taking the time to read the participant information sheet and considering taking part in the research. If you would like to participate in this study, please contact Stefanos Christodoulou at etex@soton.ac.uk or by telephone on 07767 701701.