Using surface neuromuscular electrical **stim**ulation for lower limb weakness early after **stroke**: A randomised controlled feasibility study **(STIM-STROKE)**

Clinician Participant Information Sheet

Lead Researcher: Dr Kathryn Collins

Physiotherapists Carrying Out the Research: [INSERT CONTACT DETAILS] Their role is to oversee the research at their trusts and to support participants and their families.

IRAS ID: **332116**
REC Ref:

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. **Part A** tells you about the purpose of this study, and what will happen if you take part. **Part B** gives you more detailed information about the conduct of the study. *Ask questions if anything is not clear, or if you would like more information. Take time, you may choose whether to take part or not.*

PART A:

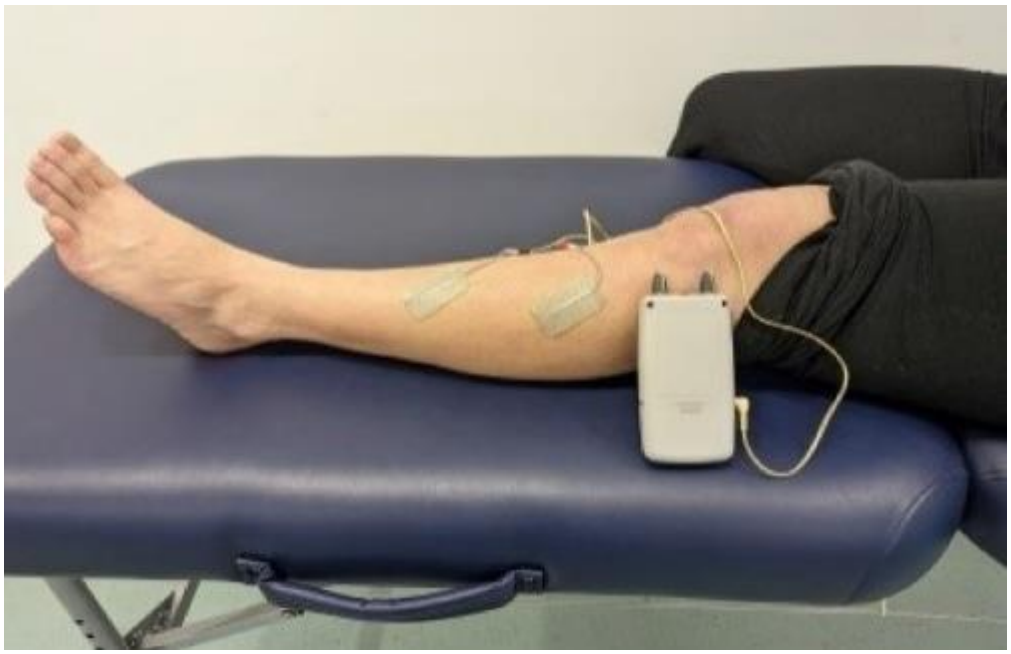
This part of the information sheet tells you about the study, and what would happen if you decide to be involved.

What is the purpose of the study?

We are looking at if treatment with electrical stimulation can help people get back to walking after stroke. Before we do a large study to find this out, we need to do a preliminary study to check that we are able to deliver the treatment in a way that is acceptable to patients and their carers.

Many patients are unable to walk after stroke because of leg weakness from the stroke. Some patients with weakness are not able to exercise and engage with the rehabilitation that will help them with their recovery.

Physiotherapists use electrical stimulation, a safe and painless treatment, to help people with different conditions. Electrical stimulation involves applying electrical currents (using sticky pads on the skin) to the weak muscles. See picture below.



The electrical stimulation helps the leg muscles to contract, exercising the muscle when the person can't do it on their own. This may make it easier for people to use their legs for standing and walking.

We are looking to see if electrical stimulation can be used to help patients with stroke that have leg weakness to exercise and if this will help get back to walking. We are also looking at patients, caregivers, and clinician's experience of taking part in the study and of using the electrical stimulation.

What we find in this study will help us to develop a larger study to see if this type of electrical stimulation for people with stroke helps to prevent their muscles from getting weaker and get back to walking faster.

Why have I been invited?
You have been invited to take part because you are a clinician working with patients after stroke and have supported patients with stroke to use the electrical stimulation for this study.

Do I have to take part?
No, it is up to you to decide. We will describe the study and go through the information sheet, which we will give to you. If you are happy to take part, we will ask you to sign a consent form to show you agreed to participate. You are free to withdraw at any time, without giving a reason. Not taking part in the study will have no impact on your work or continued support of this project.

What will happen to me if I take part?

If you decide to take part, you will be one of 10 clinicians who will take part in a focus group discussion. The focus group will be around 45 minutes to one hour and will be with four to five other clinicians and will be conducted by the study's Project Manager.

The focus group will explore your experience of this study such as supporting patients with stroke and their caregivers to use the electrical stimulation, how it fits within usual care, and what we could do differently in a larger study. We will also collect some additional information such as your age, sex, educational level, how long you have been working, and how long you have been working with patients with stroke.

The focus group will be in person or online, depending on the preference of the group. Focus group discussions will be recorded for transcription at a later date. During the focus group discussions, only your first name will be used to address you to protect your full identity in the audio recordings. Following the focus group the audio recording will be shared with a trusted third-party service for transcription. Before sharing, all identifiable personal details will be removed, and the third party will only have access to the anonymised audio for transcription purposes, ensuring confidentiality. Once the transcription is complete and verified, the original recording will be securely destroyed. The transcripts will be entirely anonymous.

Expenses and payments

There is no payment for taking part.

What are the possible disadvantages and risks of taking part?

There are no significant risks to taking part in this study. We are asking you to take some time in your day to join the focus group discussion.

What are the possible benefits of taking part?

The study will not help you personally, but the information we get from the study will help to better understand using electrical stimulation for muscle weakness after stroke. Furthermore, through the focus group, the team will understand clinician's perspective of the study and how we can improve the methodology and electrical stimulation intervention in future research. The findings from this study will be used to develop a larger study that will be able to see if electrical stimulation for the leg muscles can help to maintain the muscle size and ease return to walking.

PART B:

This part of the information sheet tells you more about the conduct of the study, how we will use your data, and what to do if there is a problem.

Who is organising or sponsoring the research?
This research is a collaboration between University Hospitals Dorset, Bournemouth University and the University of Plymouth. It is funded by the NHS National Institute of Health Research (NIHR), Research for Patient Benefit (RfPB) and has been approved by the XXXXX Research Ethics Committee (REC).

University Hospitals Dorest,based in England is the sponsor of this research.

The sponsor has relevant insurance in place which covers the study.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the lead researcher who will do their best to answer your questions.

Dr Kathryn Collins
telephone: 01202 961846
Email: kcollins@bournemouth.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting:

Research Team:
Clare Potter
email: Clare.Potter@uhd.nhs.uk
Telephone: 0300 019 4003

[INSERT LOCAL PATIENT EXPERIENCE TEAM DETAILS]

Alternatively, you can contact the Research and Development Department at ResearchOffice@uhd.nhs.uk or 0300 019 8500.

Will my taking part in the study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept confidential within the research team.

The audio recording of the focus group discussion will be shared with a trusted third-party service for transcription purposes. To ensure confidentiality, your full identify will be protected by only using your first name throughout the discussions. Once the transcription is complete and verified, the original recording will be securely destroyed.

How will we use information about you?

We will need to use information from you for this research project. The information will be held by the research site (Hospital Trust where you had your stroke) and members of the research team at Bournemouth University.

This information will include your:

- Name and initials
- Age
- Length of time being a health care professional
- Contact details
- Post code
- Education level

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.

University Hospitals Dorset is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- universities (e.g. Bournemouth University)

We will keep all information about you safe and secure by:

- Storing personal information separate to anonymised information collected during the study.
- Paper data will be stored in a locked filing cabinet in a locked room that only the research team have access to.
- Electronic data will be stored on a password protected, multi-factor authenticated computer that only the research team have access to.
- Anonymised data will be shared with Bournemouth University and University of Plymouth for data analysis.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

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.

We will keep your paper study data for a maximum of 10 years. Personal information will be destroyed at the end of the study. The study data will then be fully anonymised and securely archived for 10 years. The anonymised dataset will be stored on the Bournemouth University's- Bournemouth Online Research Data Repository, BORDaR.

What are your choices about how your information is being used

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. The anonymised dataset will be stored on the Bournemouth University's- Bournemouth Online Research Data Repository, BORDaR.

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

You can find out more about how we use your information:

- You can ask one of the research team
- Send an email to
    - Lead Researcher: Dr Kathryn Collins at: kcollins@bournemouth.ac.uk
    - Sponsor Research and Development Office at researchoffice@uhd.nhs.uk
- By ringing:
    - Lead Researcher: Dr Kathryn Collins at 01202 961846
    - Sponsor Research and Development Office at 0300 019 8500

What will happen to the results of the research study?

We will write to participants to let them know the results of the study.

In addition, The results of this study will be published in academic journals and presented at conferences. You will not be able to be identified in any report/publication.

Further information and contact details:

If you have any questions, you can speak to one of the research team.

Research Team:
Clare Potter
email: Clare.Potter@uhd.nhs.uk
Telephone: 0300 019 4003

[INSERT CONTACT DETAILS FOR LOCAL RESEARCH TEAM]

You are also welcome to contact the lead researcher directly.

Dr Kathryn Collins
Email: kcollins@bournemouth.ac.uk
Telephone 01202 961846

Alternatively, you can contact the Research and Development Department at
Email: ResearchOffice@uhd.nhs.uk
Telephone: 0300 019 8500

Thank you for taking the time to read this information.