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

Person with Stroke Participant Information Sheet

Chief Investigator:	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:

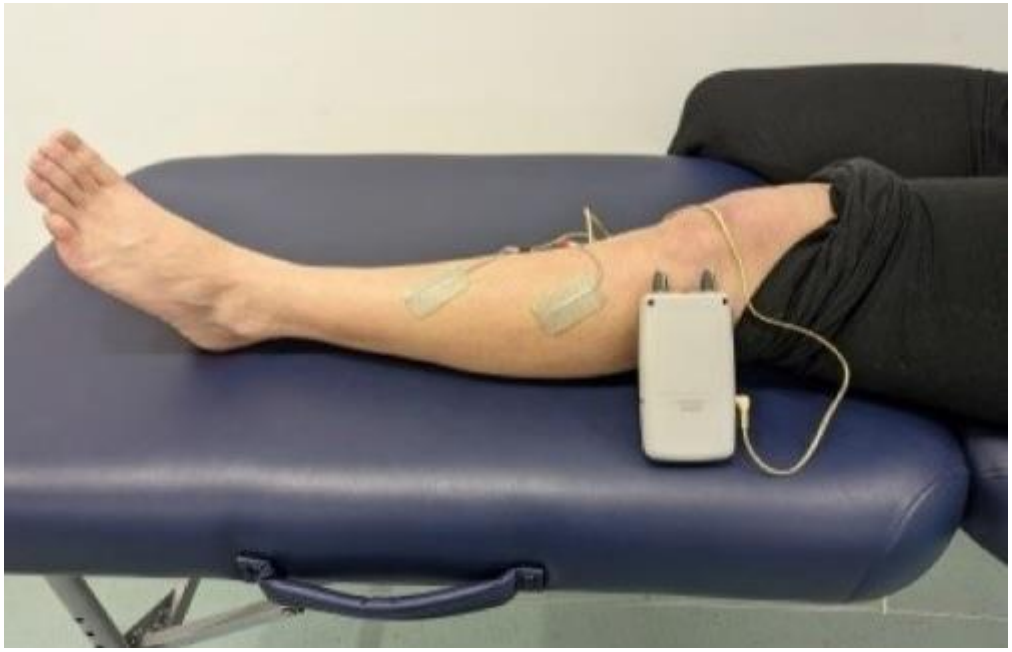
This part of the information sheet tells you about the study, and what would happen if you decide to be involved.

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 resulting 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.

We are aiming for 60 patients with stroke to join our study.

We are exploring:

- How patients and therapists get on with the electrical stimulation
- Is electrical stimulation acceptable to the patients?

Why have I been invited?

You have been invited to take part because you have had a stroke and have weak leg muscles making it difficult for you to walk.

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 agree . You are free to withdraw at any time, without giving a reason. Withdrawing from the study will have no impact on your health care or rehabilitation.

What will happen to me if I take part?

If you decide to take part, you will be one of 60 patients randomly put into one of two groups.

1) Usual care rehabilitation – what you normally do after a stroke
2) Usual care rehabilitation and electrical stimulation, using the electrical stimulation 3 times a week for 12 weeks

The research team and research nurses will collect information from you at different times throughout the study. You will be in the study for 3 months.

Visit 1

- This is the first visit that will take place, it will be done at the hospital. The research team will collect information about you and your stroke. Some of the information will be gathered from your medical chart.

- The research team will help you to complete questionnaires about how you are feeling, if you have any pain, how you are able to get on with doing everyday activities such as dressing, eating, and getting up from a chair.

- The research team will take a few measurements of your leg strength, the size of your leg muscles, and how many times you are able to stand from a chair in 30 seconds.

- You will be given rest breaks as you need to complete the questionnaires and measurements.

- After all the information has been collected you will be **randomised** to either the **usual care** group or the **usual care group with electrical stimulation**.
    - **Randomisation** means there is an **equal chance** that you will be put into one of the two groups. This process helps to ensure that the study is fair.
    - If you are in the **usual care group** you will continue to receive your usual rehabilitation as you normally would and we will continue to collect information from you.
    - If you are in the **usual care and electrical stimulation group** you will continue to receive your usual rehabilitation as you normally would as well as use the electrical stimulation.
        - Electrical stimulation will be used **3 times a week for 12 weeks**.
        - The electrical stimulation will be used on **the muscles in your weak leg** from the stroke on **your thigh (front and back) and calf (front and back).**
        - The electrical stimulation takes around 30 minutes to complete all muscles.
        - The team will show you and your caregivers/family how to use the electrical stimulation.
        - You will take the electrical stimulation unit with you when you are discharged and continue to use it for 12 weeks.

If you are in the group using the electrical stimulation, we will ask you to keep a diary to keep track of when you are using the electrical stimulation, how you felt after, and reasons for not using it. The stimulator will also record when it is being used for the team to track the number of sessions of stimulation.

The research team will follow up with people in both groups to collect data during the study.

Visit 2 (6 weeks after the first visit)

- This is the second visit that will take place this will happen 6 weeks after your first visit. This visit will most likely take place at the hospital. If you have been discharged you will be invited back to the hospital for the visit.

- The research team will help you to complete questionnaires about how you are feeling, if you have any pain, how you are able to get on with doing everyday activities such as dressing, eating, and getting up from a chair.

- The research team will take a few measurements of your leg strength, the size of your leg muscles, and how many times you are able to stand from a chair in 30 seconds.

- The research team will also collect information about the rehabilitation you have been doing and the different health care professionals that you have been working with.

Visit 3 (12 weeks after the first visit)

This is the third visit that will take place, this is 12 weeks after your first visit when you joined the study.

This visit will take place either at the hospital or if you have been discharged you will be invited to come back to the hospital.

- The research team will help you to complete questionnaires about how you are feeling, if you have any pain, how you are able to get on with doing everyday activities such as dressing, eating, and getting up from a chair.

- The research team will take a few measurements of your leg strength, the size of your leg muscles, how many times you are able to stand from a chair in 30 seconds, and how you do walking 10 metres.

- The research team will also collect information about the rehabilitation you have been doing and the different health care professionals that you have been working with.

- If you were in the group that received the electrical stimulation the team will ask you to return the electrical stimulation unit and any sticky pads that you have not yet opened.

Interview

- Some participants (from both groups) will be invited to take part in an interview with the study Project Manager.
- The interview will be around 30-40 minutes.
- The interview can take place online, over the telephone, or at your home.
- During the interview we will ask you about your experience of taking part in the study, how it was to do the questionnaires and measurements, if you used the electrical stimulation we want to know how it was for you and what we could do differently.

Visit 4 (final visit and end of study, 6 months after first visit)

This is the fourth and final visit in the study. This visit will take place 6 months after your first visit when you joined the study.

You will be in invited to come back to the hospital for this visit.

- The research team will help you to complete questionnaires about how you are feeling, if you have any pain, how you are able to get on with doing everyday activities such as dressing, eating, and getting up from a chair.

- The research team will take a few measurements of your leg strength, the size of your leg muscles, how many times you are able to stand from a chair in 30 seconds, and how you do walking 10 metres.

- The research team will also collect information about the rehabilitation you have been doing and the different health care professionals that you have been working with.

All information collected will be treated confidentially. It will be fully anonymised meaning that no one will be able to know which data belongs to you and will only be accessed by the researchers.

Expenses and payments

You will not be paid for taking part. When you are discharged, we will invite you to come back to the hospital for the tests. The study will cover all expenses involved with travelling to the hospital, and can organise a taxi or other transport, if needed.

What are the possible disadvantages and risks of taking part?

There are no significant risks to taking part in this study. Some people can have skin irritation from the sticky pads used for electrical stimulation, this is rare. You may find the tests tiring, we will do our best to accommodate your needs. You will have opportunity to rest if needed, and can ask to stop at any time.

What are the possible benefits of taking part?

We cannot promise the study will help you personally. However, the information we gather will increase the understanding of how best to treat leg muscle weakness after stroke.

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 chief 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:

[INSERT LOCAL PATIENT EXPERIENCE TEAM DETAILS]

Alternatively, you can contact the research team at the UHD at:
email:
Telephone:

[INSERT LOCAL RESEARCH TEAM DETAILS]

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..

Information about you, such as details taken from your medical record, will be anonymous and given a unique research code, known only to the researcher. A master list identifying participants to the research codes data will be held on a password protected computer accessed only by the researcher which is separate to the information collected during the study.

If you agree to participate in the interview, your 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.

How will we use information about you?

We will need to use information from you, your medical records, and healthcare team 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
- NHS number
- Age
- Contact details
- Past medical history
- Medication history
- Stroke (date it happened, locations of the stroke, and type of stroke
- 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 toLead ResearcherDr Kathryn Collins at: kcollin@bournemouth.ac.ukSponsor 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:

[INSERT CONTACT DETAILS FOR LOCAL RESEARCH TEAM]

You are also welcome to contact the chief researcher directly at

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

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.