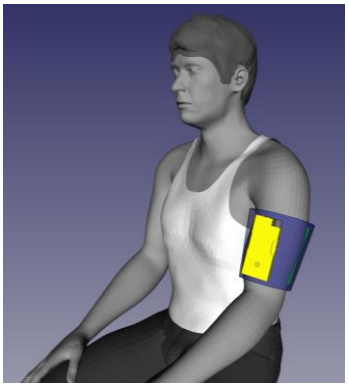
Participant information leaflet for SHAPES Research Study (Easy Read)

Study Title: A new therapy for post-stroke arm spasticity: **Sh**effield **A**daptive **P**atterned **E**lectrical **S**timulation (**SHAPES**)



Introduction

Hello, you are being invited to take part in a research study.

Before you decide it is important for you to understand why the research is being done and what it will involve.

Please take the time to read this information carefully and discuss it with friends, family and your GP if you wish to do so. There is a more detailed information sheet available also.

Ask the research staff if there is anything that is not clear or if you would like more information

Chief Investigator:

Dr KPS Nair, Consultant Neurologist;

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What is the purpose of the study?

Following a stroke people often experience stiffness (spasticity) in their arm.

We have developed a small device that is worn on the arm which stimulates sensory nerves using gentle electrical pulses.

It can give 2 forms of stimulation: Transcutaneous Electrical Nerve Stimulation (TENS) and Sheffield Adaptive Patterned Electrical Stimulation (SHAPES).

These techniques may be able to reduce muscle spasticity.

Do I have to take part?

No. It is up to you to decide whether or not to take part.

If you do, you will be asked to sign a consent form. If a carer will be helping you, they will also be asked to sign a consent form.

You (and your carer) are free to withdraw the consent at any time and without giving a reason. This would not affect your treatment or care.

What will taking part involve?

If you agree to participate in this trial, you will receive one of three types of treatment for six weeks. People are allocated to groups randomly

- Group-1 will receive the SHAPES stimulation with usual care,
- Group-2 will receive TENS stimulation with usual care
- Group-3 will receive usual care without electrical stimulation.

All groups will have their arm movement assessed by a therapist and be asked to complete some questionnaires about how your arm spasticity affects you.

After the 6 weeks of treatment, we will invite you for follow up assessment with a therapist:

- at 6 weeks
- at 3 months
- then at 6 months

You will be asked to meet the researcher 6 times. Most of these appointments will be at a community clinic in Sheffield. You may wish to have a carer come with you to these visits.

Taking part = 7 extra visits in 8 months

What will happen on each of the 7 visits?

Visit 1 (Week-1) will last around 2 hours

- The researcher will explain the study and what you will need to do
- You can decide if you want to take part
- A doctor will assess you to check that you meet the entry requirements for the study and it is safe for you to take part
- You (and your carer) will be shown how to assess the severity of your arm stiffness (spasticity) and how to record it in a 'spasticity diary'. This will only take a few minutes but needs to be done every day at a consistent time, for 10 weeks during the trial.

Visit 2 (Week-2) will last around 2 and half hours

- The researcher will do a series of assessments looking at the tightness and muscle strength in your arm and how this affects you.

If you are in Group 1 or 2

- You will receive your usual therapy

- The researcher will show you or your carer how to use the electrical stimulation equipment to deliver treatment to your arm
- The researcher will do a treatment with you
- You will need to do the stimulation treatment for **1 hour a day for a total of 6 weeks**.
  You will need to record your arm spasticity every day

If you are in Group 3

- You will receive your usual therapy
- You will need to record your arm spasticity every day

Visit 3 (Week 3 or 4) call will last around 30 minutes

- The researcher will contact you to find out how you are doing with the treatments and with keeping the 'spasticity diary'.

Visit 4 (Week-8) will last around 1 hour
At the end of the 6 week treatment period

- The researcher will collect back the stimulation device (if you have been given one)

The researcher will do a series of assessments looking at the tightness and muscle strength in your arm and how this affects you. We will use the data that the device will record.

Optional Interview (Between weeks 9 and 14), around 30-60 minutes

- If you agree, a researcher will ask about your experiences of the study therapies. This may be by telephone or video to suit you.
- The interview may be recorded to aid note taking. You (and your carer) will be asked whether you agree or not. Recording could be audio only, video only, both or none to suit you.

Visits 5, 6 and 7 (weeks 14, 20 and 32) each will last around 1 hour)

- At each of these 3 visits the research therapist will check you have completed the 'spasticity diary' over the week before the visit.
- They will then do a series of assessments looking at the tightness and muscle strength in your arm and how this affects you.

We will reimburse the travel expenses for coming to the visits.

Will my taking part in the study be kept confidential?

With your permission, your research doctor will contact your GP to inform him/her that you are participating in this research assessment.

All the information about your participation in this study will be kept confidential.

Personal information collected during the study will be stored confidentially for 12 months following the end of the study.

What will happen to the results?

In this research study we will use information from you, your medical records and your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it.

Short direct quotations may be used in publications but would not be attributed to an individual or be identifiable.

We will make sure no-one can work out who you are from the reports we write.

We will share the results of the study with everyone who takes part.

We will share learning from the study in a medical journal, at conferences and on professional websites.

Thank you for reading this information.

If you have any questions, please contact:

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