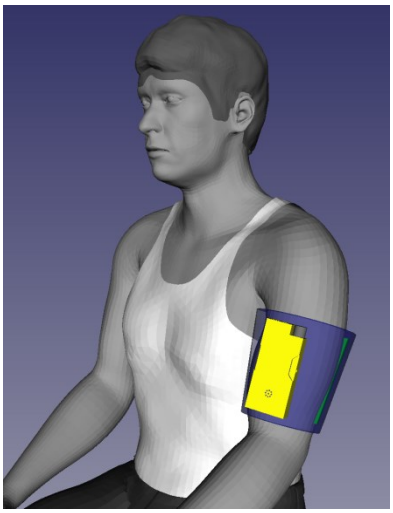
Summary Participant Information Sheet

A new therapy for post-stroke arm spasticity: Sheffield Adaptive Patterned Electrical Stimulation (SHAPES) – a co-designed system improvement followed by a powered multi-arm randomised control trial

Introduction

Following a stroke people often experience muscle stiffness (spasticity) in their arm. This study is comparing different ways to potentially help reduce spasticity at the elbow.

We have developed a small device that is worn on the arm (ShefStim APS). It 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. The purpose of this study is to compare the effect of SHAPES and TENS on spasticity at the elbow alongside usual treatment.



What will taking part in the trial involve?

Your participation in the study will last for **32 weeks <u>in total</u>**, but you will only need to do study activities for **10 weeks.**

Visit 1 (in week 1, duration: 2 hours): If you agree to participate in this trial, you will first be assessed by one of the study doctors to check that you meet the entry requirements for the study.

You (and, if appropriate, your carer) will be shown how to assess the severity of your spasticity and record it in a 'spasticity diary'. This will only take a few minutes. It needs to be done every day at a consistent time, ideally between 6pm and 9pm, for a total of 10 weeks during the trial.

Visit 2 (in week 2, duration: 2:30 hours): At your next visit a therapist will check you have completed the 'spasticity diary'. They will then do a series of assessments looking at the tightness and muscle strength in your arm and how this affects you. They will use this information to assess how much your ability to use your arm changes over time with the different treatments.

You will be randomly allocated to be in one of three groups:

- Group-1 will receive the SHAPES stimulation plus usual care
- Group-2 will receive TENS stimulation plus usual care
- Group-3 will receive usual care without any stimulation

If you are in groups 1 or 2, you (and, if appropriate, your carer) will be trained to apply the device and deliver the intervention to your arm for **1 hour a day for a total of 6 weeks**. This is in addition to completing the 'spasticity diary' every day.

Visit 3 (in week 3 or 4, duration: 1/2 hour): After approximately 2 weeks, a researcher will contact you by phone or arrange a video call. They will check how you are getting on with completing the 'spasticity diary' and with any equipment that you have been provided. A visit will be offered if additional help is required.

Visit 4 (in week 8, duration: 2 hours): A study researcher (not the therapist) will collect the study equipment from you. We will use the data recorded in the device about its usage and function. The research therapist will then check you have completed the 'spasticity diary'. They will do a series of assessments looking at the tightness and muscle strength in your arm and how this affects you.

Between visits 4 and 5, you will be offered a telephone or video interview about your experience of the arm therapies. This will be optional. If you wish a carer to be present, they will be welcome. If you (and, if appropriate, your carer) agree it may be recorded to aid the researcher.

Visits 5, 6 and 7 (in weeks 14, 20 and 32, duration: 2 hours each): At each of these 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.

Do I have to take part?

No. It is up to you to decide whether to take part. If you do agree, you will be asked to sign a consent form. A decision not to take part or to withdraw at any time, will not affect your treatment or care.

What should I do if I am interested in taking part in this study?

Please read the full Participant Information Sheet, which contains a detailed explanation of the study. If you have any questions, concerns or need further information about the study please discuss these with the research staff.