



University of Salford
A Greater Manchester University

Salisbury



NHS Foundation Trust

PATIENT INFORMATION SHEET

April 2009 V1.1

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 time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Project title: A Randomised Controlled Trial of an Accelerometer Triggered Functional Electrical Stimulation Device For Recovery of Upper Limb Function in Chronic Stroke Patients.

A short title for the project is: REACH - Re-Education of Arm and Hand function following stroke

What is the purpose of the project?

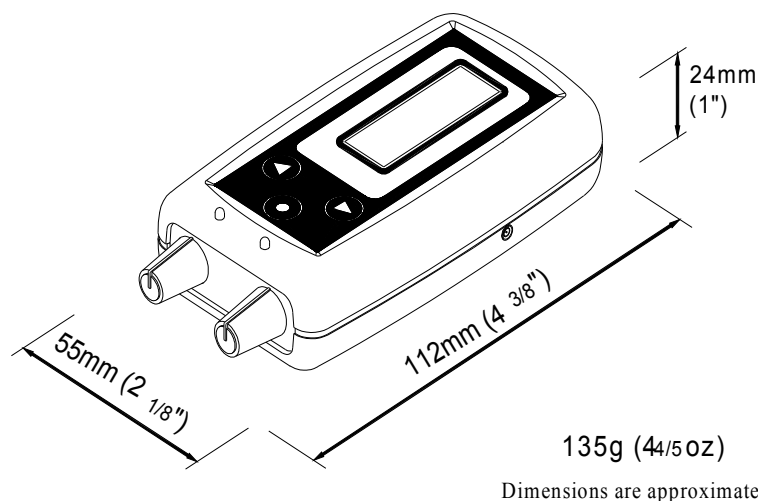
The purpose of the study is to investigate clinical use of a device intended to improve hand and arm function following a stroke. The Reach Stimulator was tested in a pilot study that showed promising improvements in hand function, activities of daily living, quality of life and spasticity of the hand and arm. This second study is required to scientifically demonstrate these benefits. The study is a randomised controlled trial meaning that volunteers will be randomly assigned to treatment group who use the Reach Stimulator or a control group who receive physiotherapy exercises.

What is Functional Electrical Stimulation (FES)?

It is the use of small electrical impulses to activate paralysed muscles and so produce useful movement. The electrical impulses work by exciting the nerves leading to the muscles. Self-adhesive patches (electrodes) are placed on the skin close to the nerve supplying the muscle. Leads connect the electrodes to a stimulator (Reach Stimulator) that produces the impulses. Electrical stimulation feels like pins and needles; most people quickly become used to the sensation.

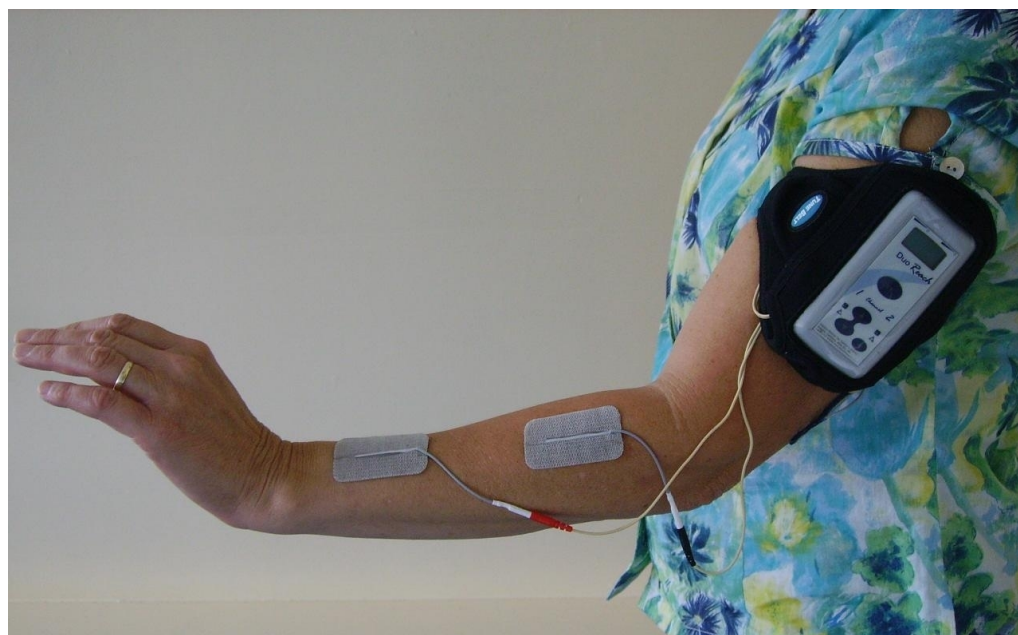
What is the Reach Stimulator?

The Reach Stimulator is a two channel programmable stimulator that can be used either for exercise, or as a device to assist function. The stimulator can be programmed to produce sequences of stimulation appropriate for different activities of daily living. The device detects movements produced by the wearer and uses these to control the output from the stimulator.



How does the Reach Stimulator work?

Surface self-adhesive electrodes will be placed on your arm. The Reach Stimulator will be worn on the back of your upper arm or forearm. A member of the research team will programme the device to suit your needs. You will have the ability to turn the device on and off, pause at any time and adjust the level of stimulation.



Why have I been sent this information?

You have been sent this information sheet as you have recently expressed an interest in our study. If you fit the criteria for the trial you will be offered the opportunity to take part. There are a number of criteria on which we will judge whether or not potential participants can join the study, but some of the more detailed aspects can only be assessed in our laboratory.

Below, is a **summary** list of the main criteria that for inclusion in the study that will allow you to work out whether or not you may be able to join the study.

If you believe that you meet these criteria we would be very interested to meet you at our laboratory for further screening with a view to inclusion in the study.

If you:

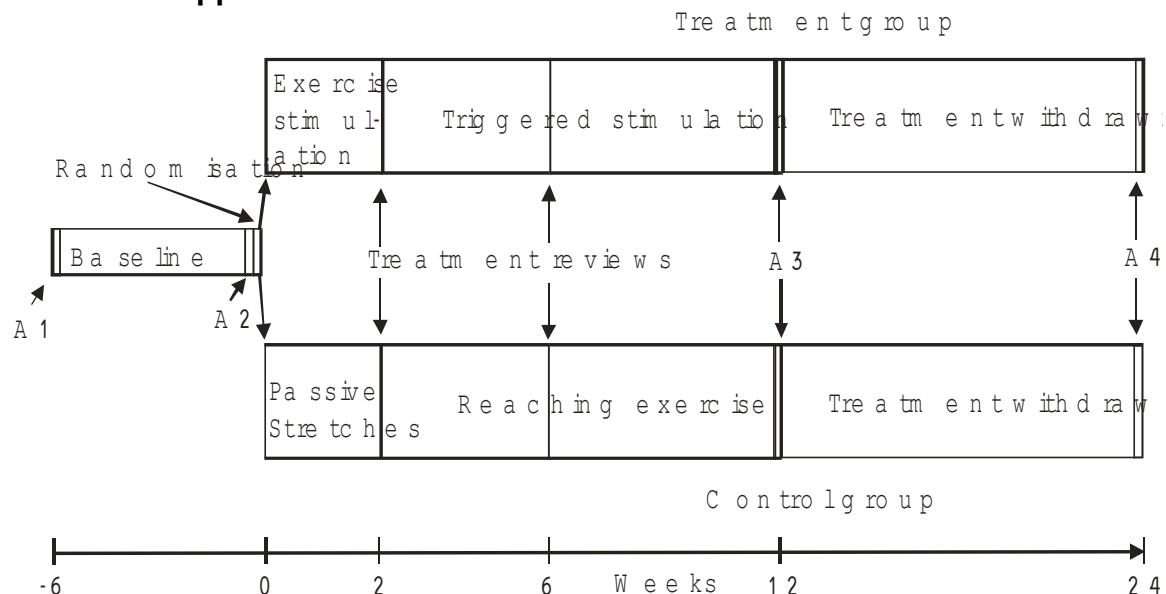
- **Are aged over 18**
- **Have had a first stroke**
- **Have reduced hand and arm function on your affected side, limiting your ability to straighten your arm and open your hand, but can reach forward to a limited extent**
- **Have sufficient function in your affected wrist and fingers to allow you to pick up and release a 2.5cm (1") cube**

And you:

- **Do not have a cardiac pacemaker**
- **Do not have a painful shoulder**
- **Do not have a history of poorly controlled epilepsy**
- **Do not have a high degree of stiffness in your elbow, wrist or fingers (i.e. you cannot straighten these joints by using your other unaffected hand)**
- **Are not pregnant**

If you think that you fit the criteria above and, after having read the rest of the information leaflet you are interested in taking part, please contact us using the contact details at the end of this information sheet. A final decision on whether or not you may be able to participate in the study will be made on the first visit to our laboratory.

What will happen in the clinical sessions?



The figure above illustrates the trial, lasting a total of 30 weeks. It shows all participants following the same procedures for the first 6 weeks (week -6 to week 0). At week 0, participants will be randomly assigned to either the Control Group or the Treatment Group. Participants in the control group will receive standard stretching exercises, while the participants in the Treatment group will receive the new stimulation device. At week 12 both groups will have their treatment withdrawn and measurements will continue for a further 12 weeks. The trial is explained in more detail below.

shoulder. The exercises will be performed twice daily for 10 minutes building to 20 minutes twice a day.

Contact for further information

The study is taking place at two separate sites, one in Salisbury and one in Salford. For further information about the project and participating, please contact your nearest site, either:

Salisbury, Wiltshire

Paul Taylor 01722 439542 or p.taylor@salisburyfes.com

Or

Salford, Greater Manchester

Helen Luckie / Karen Waring 07791 444669 or h.m.luckie@salford.ac.uk

Thank you for reading this information sheet.