Salisbury Foundation Trust

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PATIENT INFORMATION SHEET

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You are being invited to take part in a research project. 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?

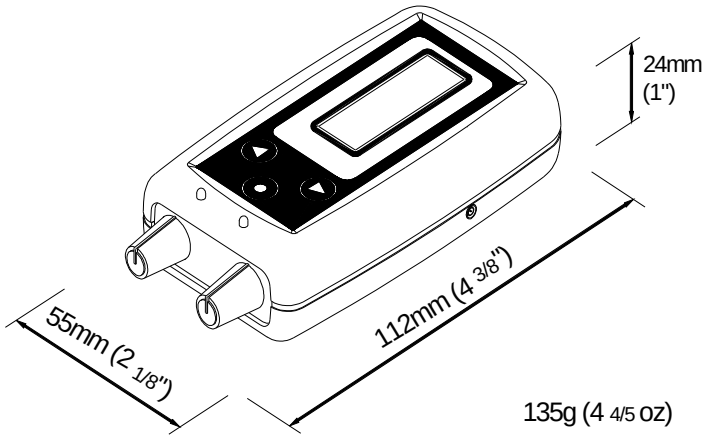
The purpose of the study is to investigate clinical use of a device intended to improve hand and arm function following a stroke. The Reach Stimulator was tested in a pilot study that showed promising improvements in hand function, activities of daily living, quality of life and spasticity of the hand 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 and a control group who receive physiotherapy exercises.

What is Functional Electrical Stimulation (FES)?

It is using 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?

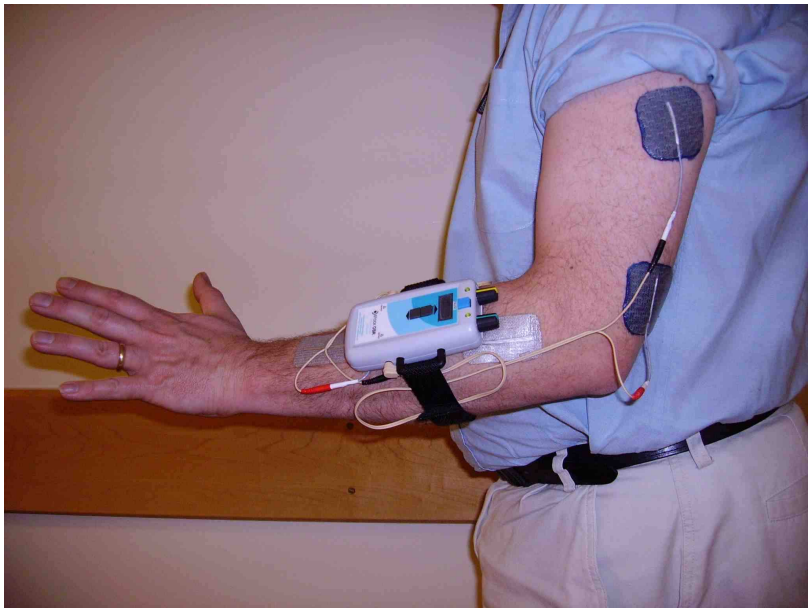
The Reach Stimulator is a two channel programmable stimulator that can be used either for exercise or as a device to assist function. The stimulator can be programmed to produce sequences of stimulation appropriate for different activities of daily living. The device detects movements produced by the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



Dimensions are approximate

How does the Reach Stimulator work?

Surface self-adhesive electrodes will be placed on your arm below the elbow over the muscles that cause your hand to open. 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 chosen?

You have been referred to the National Clinical FES Centre for an assessment for FES treatment. If you fit the criteria for the trial you will be offered the opportunity to take part.

Inclusion criteria

- First stroke leading to hemiplegia
- Aged 18 years and above (no upper age limit)
- Reduced hand and arm function, limiting voluntary elbow extension and hand opening
- Medically stable
- Able to understand and comply with assessment procedures
- Able to give informed consent
- Minimum 45 degrees active shoulder flexion
- Able to initiate elbow extension
- Enough active wrist and finger extension to pick up and release a 2.5cm cube (easiest task in grasp section of Action Research Arm Test)
- Responds to stimulation to open the hand

Exclusion criteria

- An ARAT score of greater than 40 (out of 57) at initial assessment.
- Any existing orthopaedic condition affecting the upper limb
- Cardiac pacemaker
- Painful shoulder
- Fixed contractures at elbow, wrist or fingers
- Pregnancy
- Malignancy in the area of the electrodes
- A history of poorly controlled epilepsy

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. During the project, you are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from Salisbury District Hospital.

How long will I be involved with the project if I take part?

The study lasts 30 weeks in total of which 12 weeks is spent using the treatment at home.

What will happen to me if I take part?

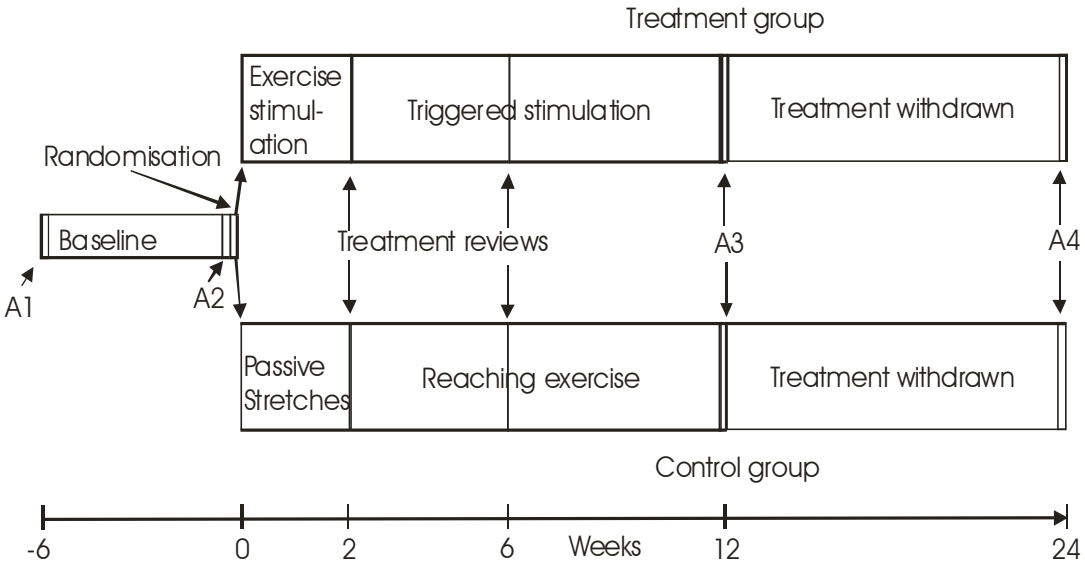
You will first be given an appointment for an assessment. At this appointment the trial will be explained to you and your suitability assessed by a physiotherapist. If you are a suitable candidate for the research you will given one week to make a decision whether you wish to be involved with the project or not. If you require further information you will be able to speak to the research team at any time by telephone during this period.

If I am a suitable candidate and decide to be involved, what happens next?
Convenient dates will be arranged with you to attend the National Clinical FES Centre, Salisbury District Hospital for 6 clinic sessions. It is important that you are able to attend the clinic at the correct time.

What clothes should I wear?
Wear what you feel comfortable in; we will need to put electrodes on your arm so a loose, sleeveless or short sleeved garment would be ideal.

What facilities does your department have?
There are disabled parking facilities outside the department. Within the department there is a toilet suitable for wheelchair users and we have facilities to enable privacy when changing, placing electrodes or measuring equipment. Chaperones will be provided as necessary.

What will happen in the clinic sessions?



Session 1: At the first session you will be asked to complete several questionnaires about your hand function and ability to perform activities of daily living as base line assessments. The physiotherapist will assess how easy it is to move your affected arm. (A1)

Several assessments will be made

- The Action Research Test (ARAT). This is a practical test of how you use your hand an arm.
- Box and Block Test. This is a second practical test of hand and arm function
- Modified Ashworth Scale. This is a physiotherapy assessment of the spasticity and stiffness in your hand and arm

- Fugl-Meyer test. (FM) This is a measure of impairment commonly reported in similar studies in the literature, so enabling comparison with other trials
- Stroke Impact Scale (SIS) this is a measure of the impact of stroke on quality of life
- Cost questionnaires. These questionnaires are designed to record all the costs associated with receiving the treatments. This information will be used to assess the cost effectiveness of the treatment.

Most of the outcome measures will be performed by a clinician who is "blinded" to which trial group each Volunteer is in. This is so they can not be biased in the way they make the assessments. It is **very important** that you do not tell the clinician which group you are in.

There is no treatment at the first session.

Session 2: The assessments are repeated at session 2, six weeks later. At this session you will also be asked to complete a questionnaire about how you perform tasks of daily living called the Canadian Occupational Performance Measure (COPM). (A2)

Randomisation.
Once all the assessments have been made, you will be asked to pick an envelope from a box. In the envelope will be your group allocation. These envelopes are prepared by an independent medical Statistician. The members of the research team have no influence over group allocation.

Control Group
Volunteers allocated to the control group will then be instructed in performing self-administered stretching exercises of the hand, arm and shoulder. The exercises will be performed for 10 minutes twice a day building to 20 minutes twice a day.

Session 3: The volunteer will return to the clinic 2 weeks later at which point the exercises will be changed to voluntary reaching exercises. Exercises will consist of shoulder flexion with elbow, wrist and finger extension. Volunteers will be asked to attempt a variety of every day tasks involving reaching and grasp, both in sitting and standing. The exercises will be performed for 20 minutes, twice a day, building to 30 minutes twice a day over the intervention period. Additionally, the volunteer will be encouraged to use their hand and arm as much as possible in daily life by discussing strategies for its inclusion in every day tasks.

Session 4: The volunteer will return to clinic at 6 weeks for review and progression of the exercises.

Session 5: At week 12 the volunteer will be instructed to discontinue the formal exercises but will still be encouraged to us their affected arm in activities of daily living. Outcome measures are repeated. (A3)

Session 6: The outcome measures are repeated 12 weeks after treatment is stopped. (A4)

Treatment Group
Volunteers allocated to the treatment group will be instructed in the use of the Reach Stimulator. The device will be set up for exercise only, producing cyclic contractions to exercise the muscles of the forearm, upper arm and shoulder. The exercises will be performed twice daily for 10 minutes building to 20 minutes twice a day.

Session 3: The volunteer will return to the clinic at 2 weeks for progression to triggered electrical stimulation. Reaching exercises based on typical daily tasks will be practised in the same way as the control group but with the assistance of the device. The exercises will be performed for 20 minutes, twice a day, building to 30 minutes twice a day over the intervention period. Unrestricted use of the device will then be allowed for assistance of tasks throughout the day.

Session 4: The volunteer will return to clinic at 6 weeks for review and progression of the exercises.

Session 5: At week 12 the volunteer will return the Reach Stimulator but will still be encouraged to use their affected arm in activities of daily living as much as possible. Outcome measures are repeated. (A3)

Session 6: The outcome measures are repeated again, 12 weeks after the treatment has stopped. (A4)

How long will the clinic sessions be?
Each session will be approximately 90 minutes long.

What are the possible disadvantages and risks of taking part?
There are no known side effects from using FES, but there are some minor risks.

The stimulation feels like pins and needles. Most people quickly become used to it, but it is possible that you may find the sensation too uncomfortable and may decide too not to use the stimulator. Similarly, turning the stimulation up too high may be uncomfortable, but not dangerous.

In some cases skin irritation can occur. If this happens, then you are asked to contact us. We will provide advice on how to solve the problem.

Always remember to turn off the stimulator before you remove the electrodes to avoid the small possibility of minor discomfort.

Some people who have epilepsy can have an increase in symptoms in response to electrical stimulation.

There are no known serious side effects to physiotherapy exercises. Over exercise may cause some discomfort and possible over stretching of tendons and joints.

What are the possible benefits of taking part?
Although it has not yet been scientifically proved it is believed that the Reach Stimulator may help to improve hand and arm function for people who have had a stroke. The project may lead to a new treatment within the NHS.

What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, we will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

With your permission, we will contact your doctor and, where appropriate, your medical consultant before you start on the trial. If you do start the trial and there is any new information from your doctor, consultant or one of the researchers that could affect you continuing on the project, we may ask you to withdraw from the project. In reaching any decision we will discuss it fully with you and consider your best interests at all times.

What happens when the research project stops?
You will be asked to return the equipment to the department. If appropriate you will be followed up in the FES clinic.

What if something goes wrong?
If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this project, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this project be kept confidential?
All information collected about you during the course of the research will be kept strictly confidential. Each patient on the project will be given a unique code that does not contain any personal details. All data collected will be anonymised and confidentiality will be maintained at all times.

In the consent form, we will ask for your permission to allow restricted access to your medical records. This access will only be by the named researchers who are members of NHS staff within this department.

What will happen to the results of the research project?
A report will be submitted to the Stroke Association who is funding this work. The results will be used for planning the next stage of research. Findings may also be published in scientific and medical journals, at conferences and at

training days for clinicians. Confidentiality and patient anonymity will always be maintained. If you are interested, we would be pleased to discuss the results and conclusions from the project with you.

Who is organising and funding the research?
The project is funded by the Stroke Association. The money is to cover research expenses associated with the project, including part of the salaries of the named research staff. No payment is made to your referring doctor.

Who has reviewed the project?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Wiltshire Research Ethics Committee.

Contact for further information
If you need further information about the project, please contact:

- **Paul Taylor.** Consultant Clinical Engineer
- **Geraldine Mann.** Consultant Physiotherapist
- **Julie Esnouf.** Occupational Therapist
- **Rod Lane.** Clinical engineer

All four are staff in the Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ.
Telephone. 01722 429065.
E-mail enquiries@salisburyfes.com
Web page. www.salisburyfes.com

Thank you for reading this information sheet.
If you wish to participate in this project, please either telephone or write to us at the above address.

Salisbury Foundation Trust NHS

CONSENT FORM

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

Please initial box

1. *I confirm that I have read and understand the information sheet dated October 2008 for the above study and have had the opportunity to ask questions.* ☐
2. *I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.* ☐
3. *I understand that at the end of the study data collected from me will be stored at the National Clinical FES Centre, Salisbury District Hospital in line with the institutional guidelines for good clinical practice in research and in line with the policies for postgraduate research.* ☐
4. *I give permission to the research team to contact my GP informing them that I am taking part in this study.* ☐
5. *I am/am not participating in another study at this time (delete as appropriate)* ☐
6. *I agree that I will be videoed in the study and I agree that the video will be used for teaching and scientific conferences.* ☐
7. *I agree to take part in the above study.* ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**
_____	_____	_____
Researcher	**Date**	**Signature**

Participants copy

Salisbury Foundation Trust NHS

CONSENT FORM

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

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10. *I am/am not participating in another study at this time (delete as appropriate)* ☐

11. *I agree that I will be videoed in the study and I agree that the video will be used for teaching and scientific conferences.* ☐

12. *I agree to take part in the above study.* ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**
_____	_____	_____
Researcher	**Date**	**Signature**

Researchers copy

Salisbury Foundation Trust NHS

CONSENT FORM

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

Please initial box

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14. *I give permission to the research team to contact my GP informing them that I am taking part in this study.* ☐

15. *I am/am not participating in another study at this time (delete as appropriate)* ☐

16. *I agree that I will be videoed in the study and I agree that the video will be used for teaching and scientific conferences.* ☐

17. *I agree to take part in the above study.* ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**
_____	_____	_____
Researcher	**Date**	**Signature**

Copy for medical notes