

Re-education of arm and hand function following stroke

Submission date 14/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/05/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/04/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
TSA 2008/2

Study information

Scientific Title
A randomised controlled trial of an accelerometer-triggered functional electrical stimulation (FES) device for recovery of upper limb function in chronic stroke patients

Acronym

REAcH

Study objectives

That accelerometer-triggered functional electrical stimulation (FES) to the finger, thumb, wrist and elbow extensors may be a useful treatment to assist upper limb recovery of function following stroke and is more effective than conventional physiotherapy methods.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wiltshire Research Ethics Committee, 16/03/2009, ref: 09/H0104/9

Study design

Interventional randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stroke more than 6 months post-cerebrovascular accident (CVA)

Interventions

Intervention group:

Functional electrical stimulation of the wrist, finger, thumb and elbow extensors, triggered using a movement sensor (an accelerometer) detecting an attempt to reach forward to grasp an object. Stimulation is delivered through self-adhesive skin electrodes placed over the extensor muscles. A stimulator/controller is carried on the arm. The stimulation helps complete the reaching function by extending the elbow and wrist and opening the hand.

Comparator group:

Conventional physiotherapy exercises mimicking the action of the device but without the assistance of FES.

Both groups use the treatment for 12 weeks. Outcomes are assessed then and 12 weeks later.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Action Research Arm Test (ARAT). The ARAT was chosen as it includes elements of both shoulder, arm and hand function.

Assessments are made at the beginning of the baseline period (-6 weeks) at the end of the baseline (week 0), at the end of the treatment period (week 12) and 12 weeks after the intervention is removed (week 24).

Key secondary outcome(s)

Impairment:

1. Fugl-Meyer Test (FM): a measure of impairment commonly reported in similar studies in the literature, so enabling comparison with other trials
2. Modified Ashworth Scale (MAS): to measure elbow, wrist and finger spasticity. Spasticity is a major inhibition to the use of the hand and high tone levels can be distressing. Increased tone would be an indication of an adverse response to treatment.

Function:

3. Box and Block Test (B&B): a measure of dexterity. This functional test has been added as it has fewer elements of subjectivity than the ARAT.

Activities of daily living:

4. Canadian Occupational Performance Measure (COPM): to assess patient perception of their performance and their satisfaction with activities of daily living

Quality of life:

5. Stroke Impact Scale (SIS): a measure of the impact of stroke on quality of life

Cost analysis:

6. Cost effectiveness and cost utility: for the cost-effectiveness analyses an appropriate clinical measure will be chosen from the above outcome measures. For the cost-utility study health outcomes will be measured by the health states reported by patients using the EQ-5D questionnaire. These health profiles will be converted to utility values using the published population utility tariffs for the EQ-5D. Costs related to service use incurred by the research volunteers will be recorded using a purpose designed Client Service Receipt Inventory (CSRI) form. Treatment cost will be recorded using case report forms (TCRF) to be completed by the clinical staff throughout the project.

Research Volunteer perspective of treatment:

7. Use of Device Questionnaire (UDQ): this custom questionnaire will be used to systematically record the research volunteers' experiences and opinions about their treatment

Compliance:

8. Each subject will be asked to complete a compliance diary

Safety:

9. Safety will be assessed by recording adverse incidents

Assessments are made at the beginning of the baseline period (-6 weeks), at the end of the baseline (week 0), at the end of the treatment period (week 12) and 12 weeks after the intervention is removed (week 24).

Completion date

31/03/2012

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

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

Date of first enrolment

01/04/2009

Date of final enrolment

31/03/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
The National Clinical FES Centre
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Sponsor information

Organisation
Salisbury NHS Foundation Trust (UK)

ROR
<https://ror.org/00ja2ye75>

Funder(s)

Funder type
Research organisation

Funder Name
The Stroke Association (UK) (ref: TSA 2008/2)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes