ISRCTN12548377 https://doi.org/10.1186/ISRCTN12548377

Re-education of arm and hand function following stroke

Submission date	Recruitment status	[ ] Prospectively registered
14/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/05/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/04/2017	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Taylor

Contact details
The National Clinical FES Centre
Salisbury District Hospital
Salisbury
United Kingdom
SP2 8BJ
+44 (0)1722 429119
p.taylor@salisburyfes.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at http://www.salisburyfes.com/pdfs/pat%20info%20SA%20ReACH%20salisbury%20v1.pdf

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 measure
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).

Secondary outcome measures
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).

Overall study start date
01/04/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
England

United Kingdom

Study participating centre
The National Clinical FES Centre
Salisbury
United Kingdom
SP2 8BJ

Sponsor information

Organisation
Salisbury NHS Foundation Trust (UK)

Sponsor details
Salisbury District Hospital
Odstock Road
Salisbury
England
United Kingdom
SP2 8BJ
+44 (0)1722 336262
Stef.Scott@salisbury.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.salisbury.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration