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Effect of combined somatosensory stimulation and task specific training on upper limb function in chronic stroke patients

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 08/05/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7835

Study information

Scientific Title
Effect of combined somatosensory stimulation and task specific training on upper limb function in chronic stroke patients: a double blind randomised controlled trial

Acronym
Sensory Stimulation

Study objectives
Background:
After rehabilitation following a stroke many people recover the ability to walk without assistance, but are very limited in the activities of daily life because of poor recovery in their arm and hand. This loss of function may affect them and their carers and increase their dependency on health and social services. Recent research in both healthy and stroke subjects has indicated that low intensity electrical stimulation of the nerves in the arm, just strong enough to be felt, can lead to changes in the brain and its connection to the stimulated muscles with a resultant improvement in functional performance.

Aims:
We want to investigate whether this type of stimulation in combination with specific exercise training is better than exercises alone (the current clinical practice) for improving arm function and usage in stroke patients who have stopped improving with rehabilitation.

Subjects and methods:
We will carry out a double blind randomised controlled trial. We will recruit people aged 65 years and above who have had a stroke at least three months previously, and are not currently receiving rehabilitation, able to understand instructions and give consent for the study. Subjects will be randomly allocated to two groups to receive either of two packaged interventions. The intervention will take place three times weekly for four weeks at our laboratory located near London Bridge. We will also explore how the stimulation works using techniques which explore brain and movement function.

Outcome measures:
Several arm function tests such as task performance, strength etc in addition to brain function measurements will be assessed at the beginning, immediately after the training and for 6 months after the training at 3-monthly intervals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guy's Research Ethics Committee approved on the 27th October 2009 (ref: 09/H0804/87)

Study design
Single centre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Therapy type

Interventions
Somatosensory stimulation will be delivered to three arm nerves (ulnar at the medial epicondylar groove of the elbow, median in front of the elbow joint and radial nerve above the lateral epicondyle) in the upper arm using three pairs of self adhesive electrodes (2.5 cm by 2.5 cm). It will be delivered in the laboratory for 2 hours, 3 times each week for 4 weeks using the following dose: 1 ms pulses at 10 Hz, 500 ms on and off. The amplitude will be approximately 3 times feeling threshold.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in functional ability of the upper limb arm. Outcome measures will be assessed at beginning and end of the intervention (duration: 4 weeks) and then at 3 and 6 months follow up. A retest will be made within a week of the initial assessment and before the first treatment session in order to establish the stability of the baseline.

Secondary outcome measures
1. Level of dependence in basic activities of daily living (Barthel Index)
2. Hand dexterity by the Block and Block test
3. Real life use of upper limb (Motor Activity Log)
4. Assessment of motor function by the upper limb motor function (FuglMeyer Motor Assessment)
5. Health related quality of life (36-item Short Form [SF36])
6. Changes in upper limb movement trajectory by 3D motion analysis of upper limb funtion
7. Upper limb spasticity by the Modified Ashworth Scale and Tardieu Scale

Outcome measures will be assessed at beginning and end of the intervention (duration: 4 weeks) and then at 3 and 6 months follow up. A retest will be made within a week of the initial assessment and before the first treatment session in order to establish the stability of the baseline.

Overall study start date

01/10/2009

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. At least 65 years of age, either sex
2. History of a single ischaemic stroke at least 3 months duration
3. Abbreviated Mental Test Score (AMT) greater than 7
4. Ambulant and able to attend the laboratory
5. Active range of shoulder elevation at least 60 degrees and 10 degrees of wrist extension
6. Passive pain free range of movement (ROM) of at least 75 % of normal in shoulder, elbow, wrist and hand
7.Presence of motor evoked potential (MEPs) in the hand muscles in response to TMS

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned sample size: 52; UK sample size: 52

Key exclusion criteria
1. Currently undergoing a stroke rehabilitation programme
2. Neurologic disorders or infarcts in the vertebrobasilar territory
3. Severe heart or lung disease
4. Severe aphasia (normal score on the Frenchay Aphasia Screening Test)
5. Visuospatial disorders (as screened by the Star cancellation test)
6. Metal in the head, seizures, auditory or cardiac implants, severe spasticity (defined as a score of greater than 3 on the Modified Ashworth Scale [MAS])

Date of first enrolment
01/10/2009

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kings College London
London
United Kingdom
WC2R 2LS

Sponsor information

Organisation
Kings College London (UK)

Sponsor details
School of Social Sciences and Public Policy
London
England
United Kingdom
WC2R 2LS

Sponsor type
University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust (UK)

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No