Upper limb retraining in stroke

Submission date	Recruitment status	Prospectively registered
28/05/2010	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/05/2010	Completed	Results
Last Edited	Condition category	Individual participant data
11/05/2017	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7511

Study information

Scientific Title

A feasibility study of use of a cheap, portable, robotic aid for delivering repetitive practice of reach, supination and manipulation in acute stroke

Study objectives

The aim of this study is to conduct a feasibility study of use of a cheap, portable, robotic aid for delivering repetitive practice of reach, supination and manipulation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Hospital for Neurology and Neurosurgery & Institute of Neurology Joint REC, April 2008, ref: 08/H0716/13

Study design

Single-centre randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Device used

Interventions

The study is recruiting the first 100 stroke patients admitted to UCLH trusts. Subjects following consent to participate are to have baseline outcome measures taken. If participants have arm impairments these measures are retaken at 6 weeks or on discharge if earlier. Subjects with arm impairments are also assessed weekly to see if they can interface with a mock up of a robotic device.

Patients will be assessed by a physiotherapist seven days after admission and weekly for the first six weeks or until they are discharged, whichever is the earlier. A final assessment will take place for all patients at six weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured seven days after admission, then weekly until 6 weeks:

- 1. Action Research Arm Test (ARAT)
- 2. Disabilities of Arm, Shoulder, Hand (DASH)
- 3. Chedoke Arm and Hand Inventory
- 4. Measure of manual ability for adults with upper limb impairments (ABILHAND)
- 5. Stroke Rehabilitation Assessment of Movement (STREAM)

Secondary outcome measures

Measured seven days after admission, then weekly until 6 weeks:

- 1. Barthel Index
- 2. European Quality of Life Questionnaire (EQ-5D)
- 3. 36-item Short Form Health Survey (SF36)
- 4. National Institutes of Health Stroke Scale (NIHSS)

Overall study start date

16/06/2009

Completion date

01/06/2011

Eligibility

Key inclusion criteria

- 1. Confirmed stroke
- 2. Capable of giving informed consent
- 3. One hundred consecutive stroke patients (all ages, either sex)

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

Planned sample size: 100; UK sample size: 100

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

16/06/2009

Date of final enrolment

01/06/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Multiple Sclerosis and NMR London United Kingdom WC1N 3BG

Sponsor information

Organisation

National Hospital for Neurology and Neurosurgery (UK)

Sponsor details

Institute of Neurology Queen Square London England United Kingdom WC1N 3BG

Sponsor type

Hospital/treatment centre

Website

http://www.uclh.nhs.uk/Our+hospitals/National+Hospital+for+Neurology+and+Neurosurgery.htm

ROR

https://ror.org/048b34d51

Funder(s)

Funder type

Charity

Funder Name

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration