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Mirror Arm Exercises for STROke

Submission date	Recruitment status	[X] Prospectively registered
18/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2015	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
9353

Study information

Scientific Title
Mirror Arm Exercises for STROke

Acronym
MAESTRO

Study objectives
A new technique, called mirror therapy, may improve the recovery of the upper limb. With this method, a mirror is placed alongside the 'good' arm so that the reflection looks as if the weak arm is moving. The patient moves both arms, as much as they can, while looking in the mirror. The appearance of both arms moving normally seems to strengthen the brain's attempts to 'rewire' the connections to produce movements of the weak limb. Ultimately we want to investigate whether mirror therapy works if used during stroke rehabilitation in a manner that is suitable for the NHS. Initially we want to test whether mirror therapy:
1. Is acceptable to patients and the clinical team
2. How much it is used by patients
3. Is practical to use in the NHS
4. Causes any side effects
5. Improves different types of problems such as weakness, numbness, awareness of the affected side, grips and grasps and use of the arm and hands

The results will also tell us how many patients we can recruit, how much therapy they are able to do and how variable their outcomes are; information that we will use in future studies.

Participants who are in a rehabilitation unit will be recruited at least 1 week after their stroke. They will be randomly divided to receive mirror or control therapy. The control treatment is exercises to the legs delivered in the same way as the mirror therapy (but with no mirror). Both groups will also receive usual treatment. Participants will aim to exercise for up to 30 minutes a day (in several sessions according to their ability and tolerance) for 4 weeks. We will assess how well the patient can move and use their weak arm and hand before and after the trial and again one month later. At the end of the treatment we will also assess how acceptable the patients and the clinical team found the therapy, how much the patients used the treatment and whether there were any side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised interventional phase II 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: In hospital study

Interventions
Participants in a rehabilitation unit are recruited at least 1 week after their stroke and are randomly divided to receive mirror or control therapy. The control treatment is exercises to the legs delivered in the same way as the mirror therapy (but with no mirror). Both groups will also receive usual treatment. Participants will aim to exercise for up to 30 minutes a day (in several sessions according to their ability and tolerance) for 4 weeks.

Intervention Type
Behavioural

Primary outcome measure
How well the patient can move and use their weak arm and hand, measured at baseline, immediately after the trial, and one month after the trial

Secondary outcome measures
Measured at end of treatment:
1. Acceptability of therapy to patients and clinical team
2. How much the patients used the treatment
3. Side effects

Overall study start date
03/01/2011

Completion date
02/07/2012

Eligibility

Key inclusion criteria
1. First time stroke at least 1 week previously and inpatient in a stroke rehabilitation unit
2. No premorbid conditions limiting upper limb function
3. Sufficient cognitive and communication skills to give consent (as judged by the clinical team)
4. Medically stable and able to participate in rehabilitation (as judged by the clinical team)
5. Upper limb weakness which limits activity (Motricity Index Upper Limb score less than 99)

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
Planned sample size: 83

Key exclusion criteria
1. Unable to consent
2. Not a first time stroke
3. Previous condition limiting upper limb function
4. Unable to participate in rehabilitation
5. No upper limb weakness

Date of first enrolment
03/01/2011

Date of final enrolment
02/07/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Salford
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Sponsor information

Organisation
University of Salford (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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	07/04/2015		Yes	No