ISRCTN40128145 https://doi.org/10.1186/ISRCTN40128145

The effects of a mirror therapy based action observation protocol to improve motor learning of the affected upper arm in patients in the chronic stage after stroke

Submission date
22/08/2014

Recruitment status
No longer recruiting

Registration date
15/09/2014

Overall study status
Completed

Last Edited
22/03/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims.
More than half of people surviving after stroke suffer from impaired motor function in the arm. The affected limb typically is weak, slow, lacks coordination and has difficulty with movements, and spasticity (tightness of muscle) may be present. Mirror therapy is an example of a treatment for improving movement of the affected arm after stroke. The mirror reflection creates the illusion that the affected side moves as normal. The effects of mirror therapy are due to the activation of mirror neurons (nerve cells) in the brain. Mirror neurons activate during both action execution and action observation (AO) of corresponding movements. Therefore, the beneficial effects of mirror therapy may, at least partly, be explained by similar working mechanisms as in action observation. This study aims to look at whether a mirror therapy-based AO protocol improves movement in 6 months or more after stroke by studying a simple upper-arm motor task.

Who can participate?
Patients who were affected by stroke at least 6 months ago with difficulty in moving their affected arm.

What does the study involve?
First, the ability to move the upper limb will be assessed in all participants. Hereafter, participants will be randomly allocated to one of two conditions - Action Observation (AO) or Control Observation (CO). Participants will train a simple upper-arm reaching task by performing 7 sets of 10 reaching movements alternated with periods of observation (AO or CO). Measurements are not invasive to the participants and take place on one single day. Measurements will take about 90 minutes.

What are the possible benefits and risks of participating?
Our participants will possibly improve the performance of the simple upper-arm reaching task. The limited duration and type of motor task that was selected for the study will make overuse injuries very unlikely.

Where is the study run from?
The study is run from Erasmus MC, Dept. Rehabilitation Medicine in collaboration with Rijndan Rehabilitation Center, Netherlands.

When is the study starting and how long is it expected to run for?
Recruitment started in October 2012 and ended in June 2013.

Who is funding the study?
Adriaan Children's Foundation (KinderFonds Adriaanstichting), Netherlands.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The effects of a mirror therapy based action observation protocol to improve motor learning of the affected upper arm in patients in the chronic stage after stroke: a randomized controlled experiment

Study objectives
Whether the beneficial effects of mirror therapy on motor learning after stroke could be explained by similar working mechanisms as in action observation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical ethical board Erasmus MC, 08/07/2010, ref. mec 2010-192

Study design
Randomized controlled experiment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Upper limb motor problems after stroke

Interventions
Participants were randomly allocated to the action observation (AO) or control observation (CO) group. To minimize possible confounding effects of age and motor ability, participants were stratified into four groups based on age (younger than 55 years of age or 55 years and older) and motor function (assessed with the Fugle Meyers Assessment (FMA), FMA score < 50 or a FMA score > 50). The randomization procedure was concealed; participants had to pick a sealed envelope before training. Participants had to train a simple upper limb reaching movement. The training contained 7 sets of 10 affected arm reaching movements, alternated with periods of observation (AO or CO).

Participants enrolled to the AO group observed video tapes with upper-arm reaching movements that were offered in such a way the AO is almost similar to the mirror reflection during mirror therapy. To provide participant-specific videos, reaching movements from the non-affected arm were video-taped and mirrored to create maximal postural familiarity and the

illusion that the affected arm performed the reaching movements in a normal movement pattern.

Participants enrolled into the control observation (CO) group will observe a slideshow with static photographs of landscapes as control stimuli. The photographs contained no images of humans or animals and are selected not to trigger the mirror neuron system and therefore not likely to interfere with the goal in this study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The beneficial effects of AO will be assessed by analysing the performance of the simple upper arm reaching task. Primary outcome measure is movement time (s) of the reaching task

As this study is an experimental study, patients only train for 30-45 minutes, so outcome will be measured before the start of the single training session (baseline) and after training (follow-up).

Secondary outcome measures
No secondary outcome parameters

Overall study start date
01/10/2012

Completion date
01/06/2013

Eligibility

Key inclusion criteria
1. At least 6 months after stroke
2. Brunnstrom score for upper-extremity function between III and VI
3. Home dwelling status

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria

1. Participants with neglect (indicated by the star cancellation test and/or reported by the occupational therapist or psychologist),
2. Co-morbidities that influence voluntary upper-extremity function
3. Participants who suffered from multiple strokes

Date of first enrolment
01/10/2012

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Postbus 2040
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Center (Netherlands)

Sponsor details
P.O. Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
Adriaan Children's Foundation (KinderFonds Adriaanstichting) (Netherlands) grant number 2010 /0098

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	01/07/2015		Yes	No