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Promotion of cerebral plasticity by mirror therapy - evaluation of a new therapy approach for neurological rehabilitation

Submission date
27/02/2006

Registration date
22/03/2006

Last Edited
26/06/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.spiegeltraining.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0315

Study information

Scientific Title
Effect of mirror therapy early after stroke: a randomised, single-blinded, placebo-controlled trial

Study objectives
Patients after a first-ever, single stroke in the middle cerebral artery (MCA) area show a significantly better outcome when treated for six weeks with additional mirror training compared to six weeks of additional training with a direct view of their affected hand.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Physicians Chamber North Rhein (Arztekammer Nordrhein) (General Medical Council) approved on the 14th July 2004 (ref: 2004189)

Study design
Randomised single-blinded placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Can be found at http://www.refonet.de/projekte/documents/Pat-Information-080924.pdf

Health condition(s) or problem(s) studied
First-ever, single stroke in the MCA territory not more than eight weeks prior to study inclusion

Interventions
Additional occupational therapy for six weeks (30 minutes a day, 5 days a week) - mirror training versus training with a direct view of the affected hand

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Fugl Meyer (FM) score after six weeks of intervention

Secondary outcome measures
1. Action research arm test (ARAT) score after six weeks of intervention
2. Functional independence measure (FIM) score after six weeks of intervention

Overall study start date
01/07/2004

Completion date
31/08/2006

Eligibility

Key inclusion criteria
1. First ever, single stroke in the MCA territory not more than eight weeks prior to study inclusion
2. Aged 30 to 80 years
3. Severe hemiparesis
4. Cardiovascular stability for participation at several therapy units a day
5. Communication level allowing obedience to therapy protocol
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Multiple strokes
2. Significant hemorrhagic imbibition
3. Prior hemicranectomy
4. Restricted mobility of the upper extremity by orthopedic, rheumatologic or other concomitant disease

Date of first enrolment
01/07/2004

Date of final enrolment
31/08/2006

Locations

Countries of recruitment
Germany

Study participating centre
MEDIAN Klinik Berlin
Berlin
Germany
D-14089

Sponsor information

Organisation
Refonet (Germany)

Sponsor details
Burgweg 3
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+49 (0)264 190 620
service@refonet.de

Sponsor type
Industry

Website
http://www.refonet.de

ROR
https://ror.org/04yeh2x21

Funder(s)

Funder type
Industry

Funder Name

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	01/03/2009		Yes	No