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

	Submission date 27/02/2006	Recruitment status	Prospectively reg	
		No longer recruiting	[_] Protocol	
	Registration date 22/03/2006	Overall study status Completed	[] Statistical analysi	
			[X] Results	
	Last Edited	Condition category	[] Individual partici	
	26/06/2009	Nervous System Diseases		

Plain English summary of protocol

Not provided at time of registration

Study website http://www.spiegeltraining.de

Contact information

Type(s) Scientific

Contact name Dr Christian Dohle

Contact details

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Additional identifiers

EudraCT/CTIS number

gistered

is plan

pant data

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

Аде дгоир

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 Bad Neuenahr-Ahrweiler Germany D-53445 +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

Refonet (Germany) (ref: 3015)

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?
<u>Results article</u>	results	01/03/2009		Yes	No