Mental practice based rehabilitation training aimed at improving arm function and performance of daily activities in stroke: a randomised clinical trial

Submission date	Recruitment status No longer recruiting	Prospectively registered	
07/12/2007		[X] Protocol	
Registration date 14/01/2008	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 06/11/2013	Condition category Circulatory System	[] Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

(Cost)effectiveness of a mental practice based rehabilitation training in patients with an unilateral stroke: a randomised controlled trial

Acronym

IMAGE

Study objectives

A mental practice based rehabilitation training aimed at the improvement of arm hand function in patients with upper extremity paresis in the sub-acute phase of stroke is (cost)effective in improving arm function and the performance of daily activities as compared to therapy as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the medical ethical board of SRL METC (Rehabilitation Foundation Limburg Medical Board) on the 21st February 2008 (ref: METC-08-0001).

Study design

A multi-centre, single-blinded, placebo-controlled randomised trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stroke/neurorehabilitation

Interventions

Intervention:

Mental practice training: training programme three times a day (10 - 15 minutes) during 10 weeks in additional to therapy as usual. The training is guided by CD-rom. Different training tasks are available depending on the functional level of the patient. Patients can practice at home, in the hospital or in a rehabilitation centre. A occupational therapist will coach during the programme.

Control group:

Patients will be instructed to practice additional bimanual upper extremity techniques based on conservative neurodevelopmental (NDT) principles. Training intensity is three times a day during 10 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Upper extremity functioning assessed on activity level:

- 1. Wolf Motor Function test
- 2. Motor Activity Log

Both primary and secondary outcome measures will be assessed at baseline, after 10 weeks and 6 and 12 months.

Key secondary outcome(s))

Upper extremity functioning assessed on impairment and participation level:

- 1. Impairment: Brunnstrom-Fugl-Meyer test
- 2. Participation:
- 2.1. Impact on Participation and Autonomy questionnaire
- 2.2. Quality of life: EuroQol (EQ-6D)

Both primary and secondary outcome measures will be assessed at baseline, after 10 weeks and 6 and 12 months.

Completion date

01/01/2011

Eligibility

Key inclusion criteria

- 1. First ever stroke
- 2. Post-stroke time of 2 6 weeks
- 3. Clinically diagnosed central paresis of the arm/hand with strength Medical Research Council (MRC) grade 1 to 3 of the elbow flexors at entry into the study
- 4. Age between 18 and 85 years, male and female
- 5. Fair cognitive level (Mini Mental State Examination [MMSE] score above 23)
- 6. No severe additional neurological, orthopaedic, rheumatoid or cardiac impairments prior to stroke
- 7. No severely impaired communication as to comprehension

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not comply with the above inclusion criteria.

Date of first enrolment

01/01/2008

Date of final enrolment

01/01/2011

Locations

Countries of recruitment

Netherlands

Study participating centre Rehabilitation Foundation Limburg Hoensbroek

Netherlands 6432 CC

Sponsor information

Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

ROR

https://ror.org/01yaj9a77

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

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	01/03/2013	Yes	No
Protocol article	protocol	11/04/2008	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes