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

Submission date
07/12/2007

Recruitment status
No longer recruiting

Registration date
14/01/2008

Overall study status
Completed

Last Edited
06/11/2013

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

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)

Sponsor details

P.O. Box 93245
Den Haag
Netherlands
2509 AE

Sponsor type
Research organisation

Website
http://www.zonmw.nl

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

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?
Protocol article	protocol	11/04/2008		Yes	No
Results article	results	01/03/2013		Yes	No