

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

<b>Submission date</b> 07/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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 addition 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?
<a href="#">Protocol article</a>	protocol	11/04/2008		Yes	No
<a href="#">Results article</a>	results	01/03/2013		Yes	No