

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

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Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON32124

Source

ToetsingOnline

Brief title

IMAGE

Condition

- Central nervous system vascular disorders

Synonym

stroke

Research involving

Human

Sponsors and support

Primary sponsor: Hoensbroek Revalidatiecentrum (HRC)

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: mental practice, randomized clinical trial, stroke, upper extremity function

Outcome measures

Primary outcome

Primary outcome measures for the effect evaluation are upper extremity

functioning on the activity level scored based on:

the Wolf motor Function test (WMFT); Frenchay Arm test (FAT) and based on accelerometry(ACC).

Secondary outcome

Secondary outcome measures are focussed on both the impairment:

arm section of the Fugl Mayer test (FM)

and the participation level of the ICF:

Impact on participation and Autonomy questionnaire (IPA), the stroke specific quality of life (SS-Qol) and the EuroQol 6D (EQ-6D).

Study description

Background summary

In the Netherlands, in the year 2000 the incidence of stroke appeared to be 2.2/1000. Over 50 % of patients with an upper limb paresis as a result of stroke, is confronted with long term impaired arm function and a resulting disability in daily life performance. Although currently early rehabilitation treatment in the first phase of stroke is advised in clinical guidelines on stroke, only little evidence is available on effective rehabilitation treatment for improving arm hand function in the early phase of stroke. More recently, mental practice and movement imagery have emerged, specifically targeting cognitive processes associated with enhancement of motor performance and specific skilled movement in healthy persons. Training and applying movement

imagery on a regular basis in training and competition is called 'mental practice'. In sport psychology several studies show that mental practice can be effective in optimizing the execution of movements in athletes and help acquisition of new skilled behaviours. Combining mental practice training principles with active movement training seems beneficial as compared to mental practice training alone. Mental practice might be used in addition to physical rehabilitation in patients with neurological disorders and will probably be most effective in the early stage of recovery, the stage in which the reorganizing of brain patterns is most prominent.

At this moment, possible benefits of movement imagery as to motor performance in acute and chronic stroke patients have been investigated in several studies. In 2006, Braun et al presented a systematic review specifically focussing on effectiveness of mental practice training in improving upper extremity functioning and concluded that, based on the included studies, no definite conclusions could be drawn except that further research, using clear definitions of the content of mental practice and standardized measurement of outcome, are needed.

Study objective

The aim of the current study is to evaluate a new therapy based on theories regarding mental practice and functional task-oriented training focussing on improvement in arm function outcome in sub acute stroke patients and to study predictors for a positive treatment result.

It is hypothesized that a 6 weeks mental practice-based training (additional to 'therapy-as-usual'), targeting specific upper extremity skills, important to the individual patient, will significantly improve both arm function and the performance of daily activities and will be cost-effective.

Study design

A multi-centre, single-blinded, placebo-controlled randomized controlled multi center trial will be conducted to evaluate the effects of a 6 weeks mental practice based treatment on improvement of arm function in patients with an unilateral stroke. Evaluation of functioning will cover the first year post-stroke.

Intervention

Patients in the intervention group will receive 'therapy as usual' (in accordance with the Dutch guidelines for stroke rehabilitation) and additional mental practice-based arm function training. The mental practice training is supervised by the occupational therapist of the rehabilitation team. After baseline measurements are performed, patients in the intervention group will be

familiarised with the mental practice-based therapy. For every patient a training task tailored to the functional level of the patient, is selected by the occupational therapist. Five different mental practice training tasks, derived from the Frenchay Activities Index, are available, with a gradual increase in complexity. For all tasks a training CDrom containing video-training material is available to guide the patient during training. Patients are asked to mentally practice the movement. In case they are able to actually perform a part of the task, they are allowed to do so, concurrently with the imagination of the movement. Patients have to practice at least three times a day during a session of 10 minutes. During the intervention period, functional progress of the arm/hand is evaluated by the occupational therapist every two weeks. In case the functional level is improved, a new task will be chosen and CDroms will be changed. The total intervention takes six weeks.

Patients in the control group receive therapy as usual. In addition, they will be instructed to practice additional bimanual upper extremity techniques based on conservative neurodevelopmental (NDT) principles. These exercises are a part of the usual trainings programme. In clinical practice, training according NDT principles has been accepted as a conventional therapy. However, recent studies questioned the additional value of NDT above care as usual in patients with a stroke. Patients receive a booklet with all tasks presented and are instructed to practice during 10 minutes at least three times a day. Every two weeks, the home based training sessions are evaluated by the occupational therapist of the team.

Total contact-time with the occupational therapist in the intervention and control group will be equal.

Study burden and risks

There will be no increased risk as compared to the risk of care as usual in rehabilitation treatment.

Contacts

Public

Hoensbroek Revalidatiecentrum (HRC)

zandbergsweg 111 Hoensbroek

6432 CC

NL

Scientific

Hoensbroek Revalidatiecentrum (HRC)

zandbergsweg 111 Hoensbroek
6432 CC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

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 MRC grade 1 to 3 of the elbow flexors at entry into the study
4. age between 18 and 85

Exclusion criteria

1. severely impaired cognition
2. severe additional neurological, orthopaedic, rheumatoid impairments prior to stroke
3. severely impaired communication as to comprehension

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL21365.022.08