Mental Practice embedded in Stroke Rehabilitation: a randomised controlled, multi-centre trial

Published: 23-04-2007
Last updated: 30-11-2024

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30722

Source
ToetsingOnline

Brief title
Mental Practice in stroke Rehabilitation

Condition

- Other condition
- Vascular injuries

Synonym
Cerbrovascular Accident (CVA), stroke

Health condition

cerebrovasculair accident (beroerte)

Research involving
Human

Sponsors and support

Primary sponsor: HsZuyd
Source(s) of monetary or material Support: SKO

Intervention

Keyword: mental practice, rct, rehabilitation, stroke

Outcome measures

Primary outcome

The primary outcome measure is perceived effect on performance of *drinking from a cup and walking* as assessed by an 11-point Likert Scale.

Secondary outcome

Secondary outcomes are on a functional status: Motricity Index, Nine Hole Peg Test, Barthel ADL scale, Timed up and Go, 10 metres walking test, Rivermead Index. A quantitative electro-encephalogram (QEEG) is performed at T0. Results might have a prognostic value. Because of the additional load in assessment time, re-measurements with the QEEG at T1 and T2 are optional. A sample size (n=10) of the patients and all therapists involved in the study will be interviewed on their opinion of the MP rehabilitation program to assess the feasibility of the program and patients are asked to keep a log in order to determine unguided training intensity.

Study description

Background summary

Mental practice as an embedded or additional therapy form is getting increased attention in stroke rehabilitation around the world, especially in Europe and America. A systematic review of the studies undertaken so far in stroke shows

that although there may be some evidence to suggest that the technique might be effective, at present it is not certain whether it is effective. Little is known about the short- and long-term effect (>6 months) of mental practice interventions. This trial investigates whether mental practice can contribute to a quick or better recovery of stroke patients in every day practice. The trial will be conducted in the Klevarie Nursing Home of the Vivre Foundation (Maastricht) and Nursing Home St. Camillus, Land van Gelre and Gulick (Roermond), The Netherlands, over a period of 2 years (mid 2007- mid 2009).

Study objective

The overall aim of the proposed research project is to investigate systematically the therapeutic potential of mental practice embedded in daily therapy on the improvement of daily activities of adult stroke patients compared to therapy as usual alone. The first additional research question is which prognostic variables or patient* characteristics are associated with a positive outcome in the experimental subgroup. The second additional research question investigates the feasibility of the mental practice-based therapy as judged by the patients and therapists.

Study design

The study design is a multi-centre randomised controlled trial.

Intervention

Patients will be followed over a 6 weeks intervention period (T0 and T1). The control group will receive multi professional approach therapy as usual. The experimental group will receive multi professional approach therapy in which mental practice is embedded in every physical, occupation and speech therapy session. Patients will be instructed how to perform MP training for improving 'drinking from a cup' and *walking*. The instruction for use, training and evaluation of MP takes place in 4 phases during 6 weeks A follow up measure will take place after 6 months (T2).

Study burden and risks

As there are no invasive interventions, nor any untested experimental measurement instruments used, there is no additional risk to the assessment or therapy of the patient.
As the experimental intervention is embedded in therapy as usual the additional time spend seeing professionals to learn the mental practice technique and assess the cognitive structure of movements is limited to2 hours per subject over a 6 weeks period.
The extra load due to additional testing of patients in the experimental as well as control group, is approximately 35-45 minutes at each assessment point

if the patient agrees to quantitative electro-encephalogram measures (QEEG) at T1 and T2 (demographics, prognostic and outcome measures). Otherwise, the additional time will increase with 20 minutes at T1 and T2. Patients that agree to being interviewed will add another 20 to 30 minutes to the assessment time needed for data collection (n=10 per site).
A small sample of the participants will be interviewed by the researcher on experiences and beliefs during MP in the experimental group and on content of therapy as usual in the control group (n=10 per site).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- clinically diagnosed adult stroke patients

- sufficient cognitive level and communication skills to engage in mental practice

Exclusion criteria

- severe additional impairments prior to stroke

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:	Completed
Start date (anticipated):	08-10-2007
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2007
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL16266.096.07