Mental practice in stroke rehabilitation

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
16/07/2007		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/07/2007 Last Edited	Completed Condition category	Results		
		☐ Individual participant data		
14/11/2022	Circulatory System	Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Mental practice in stroke rehabilitation: a randomised controlled trial

Acronym

MIND (Moving In a New Direction)

Study objectives

It is hypothesised, that mental practice embedded in daily multi-approach therapy in Nursing Homes will improve daily activities of adult stroke patients more and/or faster compared to therapy as usual alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the medical ethical committee of the Atrium Medical Centre and the Maasland Hospital (de medisch ethische toetsingscommissie Atrium MC - Maaslandziekenhuis) on the 23rd April 2007 (ref: 07-T-17).

Study design

Multicentre, randomised, single blinded, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Autonomy, Rehabilitation, Mental training, Stroke

Interventions

All patients included in the study will receive six weeks of multi-professional approach interventions. The control group will receive therapy as usual. The experimental group will receive therapy as usual, in which MP-techniques and principles are embedded in every paramedical therapy session. Six paramedical therapists working at the Klevarie Nursing Home and six paramedical therapists working at Nursing Home St. Camillus will be instructed on how to treat the patients in the experimental group (two occupational, two physical and two speech therapists). Patients allocated to the control group can be treated by any of the therapists. To prevent/limit contamination in therapy of the instructed therapists, an expert (also the trainer

of MP for the participating therapists) will monitor the contrast between the experimental and control therapy.

Experimental intervention:

The experimental group will receive therapy in which mental practice is embedded in every occupational, speech or physical therapy. We choose embedded MP for several reasons. There is some evidence that mental rehearsal should be combined regularly with the overt movement to increase imagery vividness. Second, improving skills seems to depend on continuous practice. In addition, we believe that a higher training intensity will not only increase skills but also consolidate the MP technique, making the patient more confident that he/she is practicing correctly and thereby increasing compliance and motivating patients to practice unguided. The experimental intervention period is divided into four phases.

Patients will first be familiarised with MP-based therapy and educated by an expert as to basic imagery principles and the importance of imagery training on a regular basis (phase 1). The expert will therefore instruct all the patients in the experimental group in phase 1. There is some evidence that patients educated on and familiarised with the technique are more likely to practice in general and to practice correctly.

In phase 2 they will be taught by their 'own' treating therapist how to use the MP technique to improve 'drinking from a cup' and 'walking'. We choose these two activities for several reasons. The main reason is that patients in both sites report these activities the most frequently as being activities they want to improve. Second, we wanted two common activities all patients practiced. We can standardise the learning process by using the same activities and we will be able to compare results at the end of the study. Third, 'drinking from a cup' and 'walking' are different kind of tasks involving different amounts of cortical information. We would like to assess if arm-hand-functions are more suitable to practice for they need more cortical involvement (attention) for a successful performance than walking. The vividness of imagery will be enhanced using videos of the tasks, results from the Structural Dimensional Analysis of Motor Memory (SDA-M) program and external cues.

The SDA-M is used to determine the basic architecture of specific goal-directed movements. It is for example used to identify weak spots in the sequence of events that should lead to a certain motor performance in sports. In a preliminary study, we investigated the reproducibility and feasibility of the SDA-M in the Klevarie stroke population for the motor action 'drinking out of a cup'. The measuring protocol was successfully adjusted to the ability of the stroke population to process information. The measure instrument seems useful in rehabilitation. The SDA-M outcome will be used to tailor the MP intervention of individual patients in the experimental group.

During the four week training period (phase 3) patients will receive guided MP-based therapy and will be motivated to practice unguided as much as they want. Three refreshment sessions will be held in which the task is shown. Only if the patient benefits from the information, the SDA-M is repeated and results used to adjust the content of the mental practice intervention. Apart from optimizing the mental practice of drinking from a cup and walking the aim of the refreshment session is to add additional tasks in case the patient is fully able to perform the drinking and the walking task.

In the fourth phase, a general evaluation will take place to see whether any adaptations, advice or alterations are necessary in order for the patient to continue MP at home.

Control intervention:

The control group will receive therapy as usual in accordance with the Dutch Guidelines for Stroke Rehabilitation.

The patients in the control group will be assessed with the same testing battery at baseline and follow up (T1 and T2). To compensate for the unguided imagery training, patients in the control group will be motivated to do homework as well (physical training). As the experimental group will receive more attention due to keeping a log and being interviewed, patients in the control group will be instructed to use logs as well and will be interviewed on their opinion on therapy as usual.

Just as in the experimental group, the rehabilitation program (therapy as usual) will be evaluated and patients motivated to practice at home (phase 4).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

It is hypothesised that MP has the most effects on the movement that is actually mentally rehearsed. Improvement of these activities should therefore be assessed. To measure if MP improves the performance of activities in the experimental group more than in the control group an 11-point Likert scale will be used; the 11-point Likert scale assesses changes in the performance of the activities 'drinking' and 'walking' ranging from 10 ('excellent') to 0 ('poor') as perceived by the patient and the therapist.

Secondary outcome measures

- 1. Motricity Index (MI function [impairment] level): the Motricity Index evaluates voluntary movement activity and the maximum muscle strength with a 6-point Likert Scale. Reliability and Validity are sufficient in stroke populations. This is a staff-completed index of limb movement aiming to measure general motor impairment. Three movements for each limb are assessed based on the MRC strength grades and weighted; 0 for no movement, 9 for palpable movement, 14 for movement seen, 19 for full range against gravity, 25 for movement against resistance and 33 for normal movement. The side score is the sum of the arm and leg score, divided by two. The minimum score is 0 and the maximum score is 100. The higher the score the less motor impaired 2. Barthel Index (BI activity level): with the Barthel Index the degree of independent performance of daily activities is measured. Several versions exist. In this study an assessment form with a 20 points scale will be used. The BI has 10 items. Scores per item vary from a 2- (0-1) to a 4-point (0-3) Likert Scale. The BI is a reliable and valid test. The test is known to have a ceiling effect. Therefore, it seems more useful in the first six months post stroke. Values are assigned to each item based on the need for physical assistance to perform the activity. The minimum score is 0 and the maximum score is 20. The higher the score the greater the independence
- 3. Nine Hole Peg Test (NHPT function [activity] level): the NHPT is a measuring instrument in which the speed of the fine hand coordination is assessed. The patient has to take nine little pins from a tray, one at a time, as fast as possible and place them in a pegboard. The time needed to complete the attempt is recorded. Only the hand that is being assessed may be used. The reliability and validity are sufficient
- 4. Rivermead Mobility Index (RMI activity level): this is a staff-completed questionnaire to

measure mobility disability after head injury, Multiple Sclerosis (MS), stroke and other conditions. It comprises of 14 questions (activities scored range from turning over in bed to running) and one direct observation of standing for 10 seconds. Each answer is scored Yes (1) or No (0). The minimum score is 0 and the maximum score is 15. The higher the score the better the mobility

- 5. 10-metre walking test (TML activity level): the 10-metre walking test can be used in patients able to walk independently with or without walking aids and/or orthoses. Patients should walk at a comfortable speed. The test is reliable, valid and responsive. Furthermore, a significant relation between the comfortable walking speed during the TML and the quality with which patients walk has been established. Codes for not able (yet) and independent in wheelchair are 0 and 1 respectively
- 6. Timed Up and Go (TUG activity level): the TUG measures the time a patient needs to stand up from a chair, walk 3 metres at a comfortable speed, turn around, walk back and sit down. The patient is allowed to use his/her own walking aids, but no physical assistance may be given by the researcher or therapist. The test is practical and simple. The internal consistency, reliability, validity and responsiveness are sufficient
- 7. Other study parameters (if applicable):
- 7.1. Optional: Quantitative Electroencephalogram (QEEG) (Brain-activity neurophysiological level): in addition to the QEEG as a prognostic value, the mu suppression is used as an evaluative measure to assess progress in imagery techniques during the six weeks intervention period. Suppression of the mu waves can be interpreted as movement related information processing. Measures of brain activity will be performed with a universal amplifier (MPAQ, Maastricht Instruments) and data acquisition software (IDEEQ, Maastricht Instruments). Eight sensors will be placed above the sensorimotor cortex at both hemispheres according to a standardised protocol. To ensure low skin impedance (less than 5 kU), the skin will be cleaned with a lotion and a non-allergic gel will be used for better transmitting of the signal (Ten20 conductive gel). Results will be expressed in % of suppression of mu activity. Patients may refuse QEEG measures at T1 and T2 due to the additional load of 20 minutes per assessment. If necessary due to allergy, nickel-free electrodes will be used

Overall study start date 01/10/2007

Completion date 30/09/2009

Eligibility

Key inclusion criteria

- 1. Clinically diagnosed adult stroke patient; there is no evidence that Mental Practice (MP) only works in first ever strokes, moreover, it is not certain whether a clinically diagnosed first stroke is indeed the first
- 2. Sufficient cognitive level and communication skills to engage in mental practice; this is a clinical judgement. Patients need to be able to follow simple instructions

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

70

Key exclusion criteria

Severe additional impairments prior to stroke.

Date of first enrolment

01/10/2007

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Netherlands

Study participating centre Centre of Expertise in Life Sciences

Heerlen Netherlands 6400 AN

Sponsor information

Organisation

Zuyd University (Hogeschool Zuyd) (The Netherlands)

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Sponsor type

University/education

Website

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ROR

https://ror.org/02m6k0m40

Funder(s)

Funder type

University/education

Funder Name

Zuyd University (Hogeschool Zuyd) (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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	protocol	01/06/2006		Yes	No
Protocol article		15/10/2007	14/11/2022	Yes	No