Mental Practice in Stroke Rehabilitation

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26337

Source
Nationaal Trial Register

Brief title
MIND (Moving In a New Direction)

Health condition

Stroke, Rehabilitation, Autonomy, Mental Practice, Movement Imagery

CVA, Revalidatie, Autonomie, mentale training (voorstellingsvermogen)

Sponsors and support

Primary sponsor: Dr. A. Beurskens, Hogeschool Zuyd, lector kenniskring Autonomie & Participatie, Nieuw Eyckholt 300, 6400 AN Heerlen, Nederland, tel: 045-4006295 (s.beurskens@hszuyd.nl)
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Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

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:
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

1. Motricity Index (MI ¡V 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.(43) 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 ¡V activity level)
With the Barthel Index the degree of independent performance of daily activities is measured.(44) Several versions exist. In this study an assessment form with a 20 points scale will be used.(44) 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.(43) Therefore, it seems more useful in the first 6 months post stroke. Values are assigned to each item based 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 ¡V 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. (45-47);
4. Rivermead Mobility Index (RMI ¡V activity level). This is a staff-completed questionnaire to measure mobility disability after head injury, MS, stroke and other conditions. It comprises of 14 questions (activities scored range from turning over in bed to running) and 1 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 meter walking test (TML - activity level). The 10 meter 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. (43) Furthermore, a significant relation between the comfortable walking speed during the TML and the quality with which patients walk has been established. (48) Codes for not able (yet) and independent in wheelchair are 0 resp. 1.
6. Timed up and go (TUG - activity level)
The TUG measures the time a patient needs to stand up from a chair, walk 3 meters 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. (49-53)
7. Other study parameters (if applicable)
Optional:
a. QEEG (Brain-activity ¡V 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 6 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 standardized protocol. To ensure low skin impedance (< 5 kÙ), 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.

Study description

Background summary

Rationale: Mental practice as an embedded or additional therapy is getting increased attention in stroke rehabilitation around the world. A systematic review of the studies undertaken so far in stroke shows that although there may be some evidence 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 quicker and/or a 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).
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.
Study population: Adult stroke patients in the (sub)acute and chronic phase of stroke recovery will be recruited from the stroke ward of the Klevarie nursing home in Maastricht and Nursing Home St. Camillus in Roermond, The Netherlands. After giving informed consent, 70 patients will be assigned randomly to one of two rehabilitation programs (35/35).
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).
Main study parameters/endpoints: The primary outcome measure is patient-perceived effect on performance of ‘drinking from a cup and walking’ as assessed by an 11-point Likert Scale. Secondary outcomes are on functional status: Motricity Index, Nine Hole Peg Test, Barthel Index, Timed up and Go, 10 metres walking test, Rivermead Mobility Index. A quantitative electro-encephalogram (QEEG) is performed at T0 to investigate its 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 in each group for both sites) 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 objective

It is hypothesized, 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.

Intervention

All patients included in the study will receive 6 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 ¡Vprinciples 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 standardize 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 ¡V 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).

Contacts

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Eligibility criteria

Inclusion criteria

1.Clinically diagnosed adult stroke patient; there is no evidence that 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.

Exclusion criteria

1. Severe additional impairments prior to stroke.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-06-2007
Application type:	First submission

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
NTR-new	NL966
NTR-old	NTR993
Other	:
ISRCTN	ISRCTN27582267

Study results

Summary results

Braun SM, Beurskens AJHM, Borm PJA, Schack T & Wade DT (2006). The effects of mental practice in stroke rehabilitation: a systematic review. Arch Phys Med Rehabil, 66, 842-852.

Braun SM, Schack T, Marcellis RG, Oti KC, Schols JM, Wade DT & Beurskens AJHM. (2007, in press). Is it possible to use the SDA-M to investigate representations of motor actions in stroke patients? Clinical Rehabilitation

Braun SM, Beurskens AJHM, van Kroonenburgh S, Demarteau J, Schols JM, Wade DT (submitted). Effects of Mental Practice embedded in daily therapy compared to therapy as usual in adult stroke patients in Dutch Nursing Homes: Design of a randomised controlled trial.

Braun SM, Schack T, Beurskens AJHM, Wade DT (in progress). Guidelines for using mental practice in stroke rehabilitation: a tool-box for professionals.

Crüts B, Braun SM, Beurskens AJHM, Wade DT, Borm PJ. EEG mu wave activity during mental practice in stroke. 2007 (in progress)