Metamemory intervention in stroke patients: long-term effects on social participation and quality of life

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

Summary

ID

NL-OMON31498

Source
ToetsingOnline

Brief title
Metamemory intervention in stroke

Condition

- Central nervous system vascular disorders
- Vascular injuries

Synonym
Cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Kinder Fonds Adriaanstichting

Intervention

Keyword: Metamemory, RCT, Rehabilitation, Stroke

Outcome measures

Primary outcome

Primairily, the effect of MSE on social participation and quality of life will be measured using the SF-12, EQ 5D, IPA and WhoQol. MSE will be measured using the MIA. Social participation and quality of life are expected to improve due to the experimental MSE training.

Secondary outcome

Secondly, the effect of an increase in MSE social participation and quality of life on memory performance and coping style will be investigated. Memory performance will be measured using the 15 word test and the two story test from the RBMT. Coping will be measured using the assimilation-accommodation coping scale. Furthermore, usage of care will be measured in order to gain insight in the relation between MSE and the use of care long term after stroke.

Study description

Background summary

Metamemory and specifically memory self efficacy (MSE) is well studied in healthy populations. Several findings indicate that improved MSE has a positive effect on social participation and quality of life in healthy subjects due to improved insight in memory functioning. Improved MSE can also enhance memory performance in this population. MSE is barely studied in stroke and effects of improved MSE on social participation, quality of life and memory functioning are not yet established in this population.

Study objective

The aim of this study is to investigate the effect of a MSE intervention on social participation and quality of life in chronic stroke patients. This MSE intervention will be compared to a controlgroup in order to measure the additional effect of MSE training on top of aspecific groupeffects. Increase of insight in memory functioning is expected to be related to improved social participation and quality of life. Also, the effects of improved MSE on memory performance and coping will be investigated.

Study design

The design of the study is a Randomized Controlled Trial blinded for both the investigator who performs the measures and the participating patient. All patients will be divided at random between the MSE intervention and the controlgroup after the first measurement. After the experimental phase, patients will be measured a week, six months and twelve months after the grouptraining. MSE, social participation, quality of life, memory performance and coping will be measured during these sessions.

Intervention

The intervention consists of 10 meetings of an hour, twice a week. The experimental group is based on a valid method for healthy subjects to improve MSE through topics as depression, coping and motivation. This training will be adapted for stroke patients in the first weeks of the study. The control group consists of fellow sufferers of stroke exchanging experiences under supervision of an experienced trainer. This group is designed to control for aspecific groupeffects so the effect of MSE as result of the MSEintervention will be more clear.

Study burden and risks

There are no risks expected following the participation of this study. The first weeks of the study are time consuming due to the intervention phase. There are no physical measurements necessary to participate in the study.

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

First and only stroke
A minimum of 18 months post onset
Between 18 and 80 years of age
Capable to handle additional burden of care
Patients have to report memory complaints
independent living

Exclusion criteria

Progressive neurological disorders
Insufficient understanding of the Dutch language
Drug or alcohol abuse
Subarachnoidal haemmorhage, subdural haematoma

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-04-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	10-04-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-09-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20160
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL21004.078.08
OMON	NL-OMON20160