Mild cognitive complaints in MS: pilot-evaluation of a standardised educational and treatment program.

Published: 04-11-2009
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The objective of this study is the effect of a psycho educational program for cognitive complaints in MS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON33693

Source
ToetsingOnline

Brief title
Psychological treatment of cognitive complaints in MS.

Condition

- Demyelinating disorders
- Cognitive and attention disorders and disturbances

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive complaints, MS, treatment

Outcome measures

Primary outcome

Primary study parameters are self-reported cognitive complaints, if goals that

were set were met, health status and quality of life.

Secondary outcome

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Study description

Background summary

Many MS-patients complain about cognitive functioning. Fatigue and cognitive disfunction are strong predictors of problems in work, family life and leisure activities. Knowledge about the way these complaints can be effectively dealt with is scarce. Although cognitive rehabilitation is helpful in other neurological populations, an effective intervention for cognitive complaints is not available.

Study objective

The objective of this study is the effect of a psycho educational program for cognitive complaints in MS.

Study design

The study has a parallel design with repeated measures, with two groups. The intervention-group is compared to a waiting list group. Half of the participants are tested for a baseline score. All participants are tested at follow-up, 10 week after treatment.

Intervention

A psycho educational program that focuses mainly on cognitive complaints. It offers compensatory cognitive-strategies, energy-conservation techniques and

teaches stressmanagement skills.

Study burden and risks

Participants visit the hospital 12 times. Each of the eight treatment sessions take an hour. Testing at the start of the study takes 3 hours. The following two of three testing sessions each take an hour. For half a year participants are connected to the study.

The risk of participating is threefold. Participating can be demanding. Participants have to visit the hospital twelve times over a period of six months and have to do homework for approximately 5 minutes a day. The second risk is a rise in awareness of cognitive complaints. A third risk is that the program won't be effective.

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

MS, 25-55 years old, cognitive complaints

Exclusion criteria

physical, emotional, conditional impairments that interfere with participating in the program.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2010
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	04-11-2009
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	NL24647.068.09