Cognitive impairment in Multiple Sclerosis: Investigating the temporal dynamics of functional reorganization, cognition, and the susceptibility to change after cognitive rehabilitation

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The aim of the proposed study is to obtain insight into the temporal dynamics of functional reorganization and cognition, and to assess the effect of cognitive rehabilitation on this adaptive mechanism and cognitive functioning.

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

Summary

ID

NL-OMON47185

Source
ToetsingOnline

Brief title
Cognitive rehabilitation in MS

Condition

- Demyelinating disorders

Synonym
MS, Multiple Sclerose

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: cognition, cognitive rehabilitation, functional reorganization, multiple sclerosis

Outcome measures

Primary outcome

1) Changes in brain activation and networks in relationship with cognitive

decline (5 year follow-up)

2) Changes in cognitive function after attention training

3) Changes in brain activation and networks in relationship after attention

training

Secondary outcome

- The effect of cognitive rehabilitation on subjective cognitive functioning

Study description

Background summary

Cognitive impairment is a frequent and highly disabling complaint in multiple sclerosis (MS). Important new insights into the pathophysiology of MS cognitive impairment have been gained, which are consistent with a *functional reorganization model*. This model implies that cognitive impairment is preceded by reorganization of brain function (as measured with functional magnetic resonance imaging (MRI)) and is regarded as a crucial compensatory mechanism that counterbalances on-going brain damage and delays the onset of MS cognitive decline. However, longitudinal studies are crucially lacking and required to understand the temporal dynamics of this compensatory mechanism. Recently, it-has been shown that functional reorganization can be enhanced via cognitive intervention, which might have beneficial effects on patients* cognitive functioning.

Study objective

The aim of the proposed study is to obtain insight into the temporal dynamics of functional reorganization and cognition, and to assess the effect of cognitive rehabilitation on this adaptive mechanism and cognitive functioning.

Study design

The proposed study is a 5-year follow-up of a well-defined cohort of 85 subjects (35 cognitively preserved (CP) and 20 cognitively impaired (CI) MS patients, 30 healthy controls). In the initial study, subjects received detailed neuropsychological testing and structural and functional MRI, which will be repeated for the follow-up study. Subsequently, a well-established cognitive rehabilitation program focusing on attention will be offered to the MS patients. Its effect on cognitive improvement and/or changes in functional reorganization will be assessed directly after intervention (short-term) and 3 months after intervention (long-term).

Intervention

A computer-based attention training will be provided for 7 weeks (once a week, 45 minutes per session) in the experimental group. The control group (waiting list) will not engage in any cognitive rehabilitation program

Study burden and risks

All subjects will visit our outpatient clinic to undergo neuropsychological testing (approximately 60 minutes) and MRI scanning (approximately 70 minutes). Patients are asked to participate in the cognitive rehabilitation program, for which they have to visit the outpatient clinic directly after intervention (same measures as first visit) and 3 months post intervention (only neuropsychological testing). Prior to each measurement, subjects have to fill in several questionnaires at home (approximately 30 minutes). Additionally, patients will undergo EDSS examination by telephone. The congitive rehabilitation program will last for 7 weeks, and patients have to train once a week for 45 minutes. Therefore, the burden for patients is relatively low.

There are no risks associated with participation, becasue MRI is a safe technique (subjects will be screened for exclusion criteria and earplugs will be provided to reduce scanner noise) and no adverse effects are expected related to the cognitive rehabilitation program.

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 definite MS
- Age between 18-68 years
- Meet safety criteria to undergo MRI examination
- Sufficient motor skills

Exclusion criteria

- History of drug abuse
- Neurological diseases (for paitents: other than MS)
- Psychiatric diseases
- For patients: relapse free and steroid treatment free for at least 4 weeks prior to

examination
-For patients: not allowed to participate in other intervention studies while they are participating in this study

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:	Recruitment stopped
Start date (anticipated):	13-02-2015
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL50248.029.14