# The effect of cognitive rehabilitation therapy and mindfulness based cognitive therapy on cognitive functioning in multiple sclerosis.

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

## Summary

### ID

NL-OMON45542

**Source**
ToetsingOnline

**Brief title**
Cognitive rehabilitation and mindfulness in multiple sclerosis (REMIND-MS)

### Condition

- Demyelinating disorders

**Synonym**
multiple sclerosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** stichting MS research

## Intervention

**Keyword:** Cognitive functioning, Cognitive rehabilitation therapy, Mindfulness, Multiple Sclerosis

## Outcome measures

### Primary outcome

The primary outcome measure is subjective cognitive complaints.

### Secondary outcome

Secondary outcome measures are objective cognitive functioning, resting state

(RS) FC, functional brain network organization, psychological symptoms,

well-being, QoL, and daily life functioning.

# Study description

### Background summary

Patients with multiple sclerosis (MS) often suffer from cognitive impairments, which have a huge impact on quality of life (QoL) and psychosocial functioning. Prevalence rates between 30 and 70% have been reported. Objective cognitive decline as determined by neuropsychological testing corresponds with grey matter pathology in MS. Altered functional connectivity (FC) between brain regions as assessed by functional magnetic resonance imaging (fMRI) and magnetoencephalography (MEG) might also underlie these cognitive problems. So far, studies indicate that current disease modifying therapies do not significantly affect subjective and objective cognitive impairments in MS. This highlights the need to create evidence based treatment options and to gain additional knowledge about the aetiology of cognitive complaints among patients with MS.

### Study objective

The main aim of the current study is to investigate whether two promising therapies, namely cognitive rehabilitation therapy (CRT) and mindfulness based cognitive therapy (MBCT), may improve cognitive functioning of patients with MS. Additionally, MEG and modern network theory will be used to gain additional

knowledge about the aetiology of subjective and objective cognitive dysfunction as determined by functional network changes at baseline, and to unravel if cognitive improvements (subjective or objective) after both interventions are associated with functional brain network changes.

## Study design

In a dual-centre, single-blinded, parallel group randomized controlled trial (RCT), 120 patients with MS will be assigned to either one of the therapies or an enhanced treatment as usual (ETAU) condition. Both CRT and MBCT consist of a structured 9-week program. Assessments will be performed at baseline, post-intervention, and 6 months after the end of the intervention.

## Intervention

CRT consists of a combination of cognitive training, psycho-education, compensatory strategy training, and homework assignments aimed at applying the learned strategies in daily life situation. CRT focuses on the domains of speed of information processing, memory, executive functioning, and mental fatigue. MBCT is an intervention in which aspects of mindfulness meditation are combined with aspects of cognitive behavioral therapy. MBCT focuses on increasing awareness of the present moment. ETAU consists of one appointment with an MS specialist nurse and is focused on psycho-education.

## Study burden and risks

The burden in the study consists of participating in three repeated measurements, therapy sessions, and homework assignments. For all participants, the measurements consist of an objective neuropsychological assessment (approximately 90 minutes) and MEG scan (approximately 45 minutes) at the VU University Medical Center, and questionnaires which can be filled out at home (approximately 60 to 90 minutes). Participants assigned to the CRT group will have nine 2,5-hour group sessions and participants assigned to the MBCT group will have eight 2,5-hour group sessions and one silent day. For both the CRT and MBCT group, participants are required to participate in home practice sessions of 45 minutes for 6 days per week. Participants in the ETAU group will attend one appointment with an MS specialist nurse. The interventions take place at one of the participating centres (VU medical centre or Klimmendaal Rehabilitationspecialists). Anticipated benefits of CRT and MBCT are improvements in subjective and objective cognitive functioning and psychosocial functioning.

# Contacts

**Public**
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
**Scientific**
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- between 18 and 65 years of age;
- confirmed MS according to the McDonald 2010 criteria;
- sufficient cognitive complaints

## Exclusion criteria

- Psychosis
- Suicidal ideation
- An inability to speak or write Dutch
- Previous experience with a similar intervention.;On an individual level we will discuss and evaluate with each potential participant whether physical or cognitive disabilities,

comorbidities or treatments interfere too much with the interventions to enroll in this study.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-07-2017 |
| Enrollment: | 120 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 03-04-2017 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 20-06-2017 |
| 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 | NL60302.029.16 |