

# Cognitive rehabilitation and mindfulness in multiple sclerosis

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27244

### Source

Nationaal Trial Register

### Brief title

REMIND-MS

### Health condition

Multiple sclerosis (MS), Cognitive problems

## Sponsors and support

**Primary sponsor:** VU University Medical Center

**Source(s) of monetary or material Support:** Dutch MS Research Foundation (Stichting MS Research), project number 15-911 MS.

## Intervention

## Outcome measures

### Primary outcome

Subjective cognitive complaints

### Secondary outcome

- Objective cognitive function (neuropsychological examination based on the Minimal Assessment of Cognitive Function in MS (MACFIMS)),
- Functional brain networks (magnetoencephalography (MEG)),
- Psychological symptoms (depression, anxiety, fatigue, rumination),
- Quality of life,
- Well-being (the ability to be mindful, self-compassion, and emotional, psychological and social well-being),
- Daily life functioning.

## Study description

### Background summary

The REMIND-MS study is a dual-centre randomised controlled trial (RCT) that will primarily investigate the effect of cognitive rehabilitation therapy (CRT) and mindfulness-based cognitive therapy (MBCT) on subjectively experienced cognitive problems among MS patients. The study will also investigate the effect of CRT and MBCT on the secondary outcome measures, and we will investigate which factors predict a beneficial effect of the interventions.

Furthermore, resting-state magnetoencephalography (MEG) data will be obtained to gain additional knowledge about the aetiology of subjective and objective cognitive problems with respect to functional brain networks, and to explore the role of functional brain network changes in the effect of the interventions.

In addition, it will be evaluated whether alterations in the secondary outcome measures are mediating factors that determine subjective cognitive function.

### Study objective

We hypothesize that both cognitive rehabilitation therapy (CRT) and mindfulness-based cognitive therapy (MBCT) positively affect the primary outcome measure subjective cognitive function compared to enhanced treatment as usual (ETAU). Secondly, we expect positive effects on the secondary outcome measures objective cognitive functioning, functional brain network measures, psychological symptoms, well-being, quality of life and daily life

functioning. Additionally, we will exploratory evaluate whether there are differences in intervention effects between CRT and MBCT.

## **Study design**

Baseline, post-intervention, 6-months follow-up

## **Intervention**

Cognitive rehabilitation therapy (CRT) and mindfulness-based cognitive therapy (MBCT).

Control condition: enhanced treatment as usual (ETAU).

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

Participants are eligible to participate if they meet the following criteria:

(1) between 18 and 65 years of age,

(2) confirmed MS according to the McDonald 2010 criteria,

(3) a minimum score of 23 on the Multiple Sclerosis Neuropsychological Questionnaire – Patient version (MSNQ-P), which measures subjective cognitive complaints.

## Exclusion criteria

Participants who meet any of the following criteria are excluded from participation:

- (1) psychosis,
- (2) suicidal ideation,
- (3) an inability to speak or read Dutch,
- (4) previous experience with a similar intervention,
- (5) physical or cognitive disabilities, comorbidities or treatments that would interfere too much with the interventions to enrol in this study (to be evaluated on an individual level).

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	11-07-2017
Enrollment:	120
Type:	Anticipated

## Ethics review

Positive opinion

Date: 31-05-2017

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	NL6285
NTR-old	NTR6459
Other	CWO-nr. 16-14 : METC 2017.009

## Study results