Cognitive rehabilitation and mindfulness in multiple sclerosis

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27244

Bron
Nationaal Trial Register

Verkorte titel
REMIND-MS

Aandoening

Multiple sclerosis (MS), Cognitive problems

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Dutch MS Research Foundation (Stichting MS Research), project number 15-911 MS.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Subjective cognitive complaints

Toelichting onderzoek

Achtergrond van het onderzoek

The REMIND-MS study is a dual-centre randomised controlled trail (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.

Doel van het onderzoek

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). Secondarily, 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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Control condition: enhanced treatment as usual (ETAU).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-07-2017
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6285
NTR-old	NTR6459
Ander register	CWO-nr. 16-14 : METC 2017.009

Resultaten