Need for speed: a pilot study on feasibility of cognitive rehabilitation for patients with progressive multiple sclerosis (MS)

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

Summary

ID

NL-OMON46532

Source
ToetsingOnline

Brief title
Cognitive rehabilitation in progressive MS

Condition

- Demyelinating disorders

Synonym
attention), cognitive problems, problems in thinking abilities (such as memory

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Stichting MS Research (collectebusfonds)

Intervention

Keyword: Cognition, Information Processing Speed, Multiple Sclerosis, Rehabilitation

Outcome measures

Primary outcome

Change in cognitive performance and subjective well-being perceived on

cognitive functioning, mood, fatigue, and quality of life before and after the

interventions are the main outcome parameters.

Secondary outcome

Not applicable.

Study description

Background summary

Rationale: Worldwide, approximately one million patients suffer from the most progressive forms of MS. Cognitive impairment is extremely prominent and incapacitating, particularly in these patients, limiting their quality of life to a great extent.
Recently, the cognitive profiles of patients with progressive MS requiring assisted living were comprehensively described from a neuropsychological perspective, demonstrating major problems in several cognitive domains, but most profoundly in information processing speed (Kant et al., submitted for publication).
Since there are no disease modifying treatment options available for patients with progressive MS (contrary to patients in the relapsing remitting stage of the disease), this group is in urgent need of options to improve their cognition and quality of life to lower the burden of the disease.
In patients with relapsing remitting MS, significant improvement of cognitive functioning is demonstrated after a variety of cognitive interventions (i.e. retraining of function). Next to retraining cognitive functioning, research has shown that psychoeducation and learning *tips and tricks* (i.e. learning compensatory strategies) to cope with the cognitive deficits improve the quality of life and subjective cognitive functioning significantly. Although training of compensatory strategies already is provided as part of usual care,

cognitive function training is not. It is as yet unknown whether cognitive function training is feasible and effective in progressive MS patients.

Study objective

The aim of this pilot study is to investigate the feasibility and to gain preliminary information on the effectiveness of a cognitive rehabilitation program in patients with (severe) progressive MS, i.e. a speed of processing training (SPT).
Hypothesis: Speed of processing training and strategy training are expected to be feasible in progressive MS patients, with adaptations to the standard protocol. They are both expected to positively affect quality of life.
Moreover, SPT is expected to improve speed of processing and overall cognitive functioning.

Study design

The proposed pilot study is a randomized controlled intervention study of a well-defined cohort of 18 patients with severe progressive MS (9 participating in speed of processing training, and 9 in a control group receiving i cognitive strategy training focusing on memory). Quality of life and cognitive functioning will be assessed before and directly after intervention.

Intervention

A computer based speed of processing training, based on the method of retraining, will be provided for 5 weeks (2 times a week, 60 minutes per session) to the experimental group (intensity to be adjusted when needed).
Patients in the control condition will participate in an internet skills training with the same duration, intensity and frequency.
cognitive strategy training focusing on memory
Patients in the strategy training group will participate in a 10-week (once a week, 2 hours per session) strategy training (coping with cognitive impairment) which is given standard of care in Nieuw Unicum, and is based on a well described standardized protocol (adjusted to the target population, keeping cognitive load and intensity low).

Study burden and risks

Patients will need to undergo a 90 minutes neuropsychological assessment twice, including questionnaires about their subjective wellbeing. The tests will be administered at the clinic were the participants reside or are temporarily admitted. Since the interventions are non-invasive, no adverse effects are expected.

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

1) at least 18 years of age
2) confirmed diagnosis of progressive MS
3) mentally competent to give informed consent
4) able to follow instructions and to respond autonomously to questionnaires
5) sufficient motor skills to perform the computer-based trainings

Exclusion criteria

1) individuals with impaired vision to such extent that they cannot distinguish the stimuli of the SPT intervention
2) individuals with (a history of) other major neurological disorders (e.g. stroke)

3) individuals with current major psychiatric disorders (e.g. bipolar disorder)
4) individuals with a history (or current situation) of extensive drug abuse
5) no changes in medication use (antidepressants and psycho-active drugs) are allowed for the last 4 weeks (stable treatment regime)
6) individuals that already recently participated in cognitive rehabilitation (within the last year) are excluded from participation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2018
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	23-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2018
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	NL62300.029.17