Postponing cognitive decline and preventing early unemployment in patients with multiple sclerosis - strengthening the brain and mind (part of the Don't be late! study)

Published: 27-03-2023
Last updated: 21-12-2024

(1) To compare the efficacy of two innovative preventative interventions with a control intervention in improving quality of life, cognition, work participation and productivity, brain plasticity and resilience, (2) to gain insight into the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON53491

Source
ToetsingOnline

Brief title
Don't be late! WP 2 and 3

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: NWO,Merck Sharp & Dohme (MSD),Sanofi-aventis

Intervention

Keyword: Cognition, Employment, Lifestyle, Multiple Sclerosis

Outcome measures

Primary outcome

The primary outcome is change in quality of life as measured with the 36-item Short Form.

Secondary outcome

Changes in cognitive performance (as measured with the neuropsychological examination) will serve as secundary parameter. Additionally, changes on questionnaires (concerning neuropsychological symptoms, work challenges and participation, fatigue, anxiety and depression, resilience, stress and worry, ability to participate in social roles and activity) will be included. Brain changes will also be observed using MRI.

Study description

Background summary

Up to 70% of the patients with multiple sclerosis (MS) develop cognitive deficits that severely affect daily life functioning and patients* quality of life. Moreover, approximately 65% of all patients end up unemployed within five years after diagnosis. Current treatments mostly focus on symptom management and return to work, which may be too late. We hypothesize that timely interventions will help prevent or delay cognitive decline and work-related problems in patients with MS, thereby improving quality of life.

Study objective

(1) To compare the efficacy of two innovative preventative interventions with a control intervention in improving quality of life, cognition, work participation and productivity, brain plasticity and resilience, (2) to gain insight into the experiences of patients and professionals regarding the process and outcomes of the interventions using qualitative research methods, and (3) to compare the cost-effectiveness of the interventions.

Study design

A randomized controlled trial with three arms and three follow-up visits for 16 months. Semi-structured interviews followed by focus groups will be used to reflect on the process and outcome of the interventions.

Intervention

Strengthening the brain (4 month-program) consists of weekly 30 minutes 1-on-1 exercise and lifestyle coaching in combination with two moments per week unsupervised exercises at home and a home-based online computerized cognitive training. *Strengthening the mind* (4 month-program) consists of biweekly contact with work coaches who are all diagnosed with MS themselves.

Study burden and risks

Cognitive and neurological assessments will be performed at the Amsterdam UMC at four times (at baseline, post-intervention (month 0), short-term follow-up (month 6), and long-term follow-up (month 16)). Additionally, online questionnaires will be filled out at home at each timepoint after baseline. Structural and functional brain MRI and blood sampling will be performed at baseline, post-intervention and long-term follow-up. Additionally, an economic evaluation will take place at all time points using an online questionnaire. Risks are limited due to the often used and well-tolerable measurements and interventions.

Contacts

Public
Amsterdam UMC

Van der Boechorstraat 7
Amsterdam 1081BT
NL
Scientific

Amsterdam UMC

Van der Boechorstraat 7
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Confirmed MS diagnosis according to McDonald 2017 criteria
- Age between 18 and 67
- No changes in disease modifying therapy prior to inclusion (i.e. no changes in last 3 months)
- No current relapse or steroid treatment in the six weeks prior to the study visits
- Sublinical cognitive impairment

Exclusion criteria

- Patients with neurological (other than MS) and psychiatric disorders
- A current or history of drug or alcohol abuse
- Being unable to speak or read in Dutch
- Currently on sick leave and working for less than 12 hours for a period of 3 months or longer

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2023
Enrollment:	270
Type:	Actual

Medical products/devices used

Generic name:	Multiple Screener (wel CE-markering);BrainGymmer (geen CE-markering)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-03-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-10-2024
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	NL82007.018.23