Timely identification of cognitive decline in multiple sclerosis (part of the Don*t be late! study)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54277

Source
ToetsingOnline

Brief title
Don't be late! WP1

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Cognition, Digital tools, Employment, Multiple Sclerosis

Outcome measures

Primary outcome

The main outcome measures are: Sensitivity, specificity, negative and positive predictive value of Multiple Screener© compared to the gold standard (MACFIMS).

Secondary outcome

Secondary outcome measures include the test-retest reliability of the Multiple Screener© and the relationships between cognitive functioning (as measured with the Multiple Screener© and the MACFIMS test batter) and psychological, work-related and qualty of life measures. Additionally, the experiences with the discussion and assessment of cognitive functioning are secondary outcome measures.

Study description

Background summary

Up to 70% of patients with multiple sclerosis (MS) develop cognitive deficits, which often lead to unemployment and negatively affect patients* quality of life. In order to prevent (or delay) the development of severe cognitive impairment, early identification of cognitive decline might be crucial. Unfortunately, neuropsychological testing is currently not part of standard care (due to lack of time and trained personnel) and is often only performed when problems are already too advanced. The recently developed Multiple Screener©, a self-explanatory digital screening tool, aims to assess cognitive performance in a time-efficient manner without the need of a test-leader. While the Multiple Screener© has already been tested in healthy subjects and norm scores are available, a validation in patients with MS is an essential next step in allowing timely identification of cognitive decline in this group.

Study objective

The main objective of this study is to determine how well the Multiple Screener© can differentiate between patients with no cognitive deficits, mild cognitive deficits and cognitive impairment. Additionally, we aim to confirm the observed accuracy of the Multiple Screener© in an independent sample of MS patients and determine test-retest reliably of the Multiple Screener©. Lastly, we will investigate how cognitive, psychological, work-related and quality of life outcomes relate to each other.

Study design

A cross-sectional multicenter study

Study burden and risks

All participants will undergo a neuropsychological assessment (120-150 min) at a hospital close to their home and fill out online questionnaires (45-60 min) regarding psychological, work-related and quality of life measures. Additionally, a subset (N= 30) of participants will be reassessed with the Multiple Screener© within 1-3 weeks after the initial hospital visit for the test-retest measurement. Undergoing neuropsychological testing and answering questionnaires on psychological, work-related and quality of life measures may be confronting for some participants. However, as for most patients these issues are not unexpectedthe burden of this study is primarily the time-investment and a minimal risk is expected for participants.

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

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

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 Dutch

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	19-07-2022
Enrollment:	750
Type:	Actual

Medical products/devices used

Generic name:	Multiple Screener
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-05-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2023
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	NL78850.029.21