# Multiple Screening: a tool to identify cognitive deficits in individuals with Multiple Sclerosis in an early stage. The acquisition of normative data.

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The purpose of the current study:Aim ITo investigate the understandability, feasibility, and independence of an already manufactured digital cognition tool (Multiple Screening app) in individuals with MS. The patients will be asked to evaluate the...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Demyelinating disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON45675

**Source**
ToetsingOnline

**Brief title**
Multiple Screening for individuals with Multiple Sclerosis

### Condition

- Demyelinating disorders

**Synonym**
Cognition; attention, memory and concentration

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Farmaceutisch bedrijf Sanofi Genzyme,Genzyme

## Intervention

**Keyword:** Cognition, Multiple Sclerosis, Normative data

## Outcome measures

### Primary outcome

Determining the understandability, feasibility, and independence of using the Multiple Screening app in MS patients, in that the fully understandable, feasible, and independent Multiple Screening app can be executed by a group of healthy participants to determine normative data for the digital cognitive tests within the app. The scores on the paper-and-pencil version and the digital version of the tests will subsequently be compared by administering both versions of the tests in sixty participants.

### Secondary outcome

N.A.

# Study description

### Background summary

50-70% of the individuals suffering from multiple sclerosis (MS) experience cognitive deficits. Although these problems result into a decrease in quality of life, the physical problems are often more apparent and require priority during an appointment with the neurologist. To ensure a fast diagnosis of the cognitive problems in MS patients as well, a quick, reliable cognitive evaluation is needed. An evaluation that may help the neurologist to set out certain treatment plans.

The Brief International Cognitive Assessment for MS (BICAMS) is a well-known international neuropsychological test battery. The battery is short (15 minutes) and reliable (the tests within this battery measure the most affected

cognitive domains in individuals with MS). However, a test administrator (neuropsychologist or MS-nurse) is still needed for execution of the BICAMS, which will hold back the actual administration of this cognitive test battery. In an ideal situation the patients would have already performed the test battery before entering the room of the neurologist. The purpose of this study will be the development of a digital BICAMS in which the patients will be able to perform the tests independently, and the outcomes of the tests will be send directly to the neurologist. In order to generate a result of the test scores for the MS patients, norm scores need to be obtained and implemented in the digital test battery. This specific sub-question is the objective of the proposed study, which will take place via a two-steps model:
Aim 1) Evaluate the digital BICAMS app (Multiple Screening) according to understandability, feasibility, and independence in a small group of individuals with MS; 2) Obtain normative data for the digital cognitive tests using a group of healthy volunteers, of which the first group (N=60) will also do the paper-and-pencil version of the tests for validation purposes.

**Study objective**

The purpose of the current study:

Aim I
To investigate the understandability, feasibility, and independence of an already manufactured digital cognition tool (Multiple Screening app) in individuals with MS. The patients will be asked to evaluate the app via a questionnaire, which enables us to ensure independent use of the app in MS patients. Possible improvements to the app will be integrated before using the app in acquiring normative data. The evaluation questionnaire is added to the protocol (see appendix on page 50), and subsequently, a short interview will follow to be certain everything about the Multiple Screening tool will be discussed.

Aim II
A group of healthy participants (N=250) will execute the digital BICAMS via an app on an iPad to acquire normative data of the digital cognitive tests. The obtained norm scores will be integrated in the Multiple Screening app, which will eventually be used to put the scores of an MS patient directly into perspective. Sixty healthy volunteers will perform both the digital as the paper-and-pencil version of the test to investigate whether we are allowed to compare the scores on both tests directly. Half of the participants (N=30) will first perform the paper-and-pencil version and the digital version after. The other half will perform the digital version first, following the paper-and-pencil version. A parallel version of the neuropsychological tests that are integrated in the Multiple Screening app will be used for the paper-and-pencil tests.

**Study design**

Aim I
Fifteen MS patients will execute the Multiple Screening app on the iPad in an enclosed area. Subsequently, they will be asked to evaluate the Multiple Screening app via an evaluation questionnaire (see appendix on page 50). Afterwards, a short interview of 10 minutes will take place. The appointment will last approximately 30 minutes in total. Genzyme Sanofi and the app developers will be informed about the outcomes of the evaluation questionnaire. The cognitive domains that will be investigated are information processing speed, visual memory, and verbal memory. After integrating the improvements in the app, we expect that the Multiple Screening app is suitable to be used by the regular individual with MS. To verify this, we will test the improved Multiple Screening app again in 5 independent (not tested before) MS patients. We will optimize the app again when problems occur during the second test phase. Although we do not expect this to occur.

Aim II
For this phase of the study, N=250 healthy participants execute the Multiple Screening app in an enclosed area with the purpose of acquiring normative data. This will take approximately 15 minutes for the participant. We will also administer the paper-and-pencil version of the tests to the first 60 participants to investigate whether the scores on both methods can be used interchangeably.

**Study burden and risks**

For this study, both the MS patients as the healthy participants will be tested only once. The MS patients will be asked to execute the Multiple Screening app on an iPad, to fill in an evaluation questionnaire, and to do a short interview of approximately 10 minutes. Altogether, the appointment will last for about 30 minutes. When the Multiple Screening app is fully optimized, healthy participants will be asked to be available for 15 minutes to perform the Multiple Screening on the iPad. The first sixty participants will also perform the paper-and-pencil version of the test, to be able to compare the scores of both test versions. As this study is only asking the participants to work with an iPad, and no intervention is being investigated, will let us to conclude that it will be unlikely that the participants are at risk for any damage.

# 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

The MS patients:
- All patients are diagnosed with clinically definite MS following the revised McDonald criteria (Polman et al., 2011).
- Patients are at least 18 years of age
- The patients are able to use an iPad.
- Patients are willing to sign an informed consent prior to participation.;The healthy participants:
- Healthy participants (no neurological and/or psychiatric illnesses) that are at least 18 years of age.
- The participants are able to use an iPad.
- The first sixty participants are willing to do both the digital as the paper-and-pencil version of the tests that are in the Multiple Screening app.

## Exclusion criteria

- Neurological (other than MS for the patients) and psychiatric illnesses.
- A history of drug- and/or alcohol abuse (including present)

- Inability to execute a neuropsychological examination on an iPad (e.g. due to eye-related problems, fatigue, language barrier or motor difficulties.

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-02-2017 |
| Enrollment: | 300 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 22-12-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

Approved WMO

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|---|---|
| Date: | 10-08-2017 |
| 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 | NL58474.029.16 |