An intervention study on the effect of digital self-monitoring-based management of relapsing and remitting multiple sclerosis on self-efficacy, clinical outcomes and cost-effectiveness

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To evaluate the effect of digital self-monitoring-based management of relapsing and remitting multiple sclerosis on self-efficacy, clinical outcome measures and cost-effectiveness

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

Summary

ID

NL-OMON54476

Source
ToetsingOnline

Brief title
Multiple sclerosis self-monitoring (MSSM)

Condition

- 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,Nationaal MS fonds

Intervention

Keyword: Multiple sclerosis, Patient empowerment, Self-efficacy, Self-monitoring

Outcome measures

Primary outcome

The difference in the Multiple Sclerosis Self-Efficacy Scale Control score

between patients in the intervention group and patients in the control group.

Secondary outcome

- To evaluate the degree to which MS sherpa reduces the uncertainty in the

clinical decision-making process, with regards to start/switch/discontinuation

of disease-modifying therapies, use/non-use of paraclinical tests, scheduling

of follow-up consultations, and referral to specialized MS caregivers, and the

degree to which MS sherpa reduces disease activity and progression.

- To evaluate the effect on quality of life and cost-effectiveness of the MS

sherpa app compared to care as usual without MS sherpa.

- To investigate the experiences, needs and wishes of users (MS patients and

healthcare providers) of the MS sherpa intervention, which can lead to the

development of empirically informed guidelines for the successful adoption of

self-monitoring-based disease management in the MS healthcare ecosystem.

Study description

Background summary

Increasingly, the value of digital self-monitoring through smartphone apps and smart wearables is acknowledged for empowering patients to self-manage chronic conditions by providing insight and a sense of control over disease, thereby enhancing patients' autonomy and control self-efficacy (the degree in which a person is confident to complete tasks and reach goals in specific situations). We will investigate if the control self-efficacy of multiple sclerosis (MS) patients is improved and if treatment decisions are made earlier if the MS sherpa smartphone application is used in addition to standard care.

Study objective

To evaluate the effect of digital self-monitoring-based management of relapsing and remitting multiple sclerosis on self-efficacy, clinical outcome measures and cost-effectiveness

Study design

Multicenter, prospective, randomized controlled trial (RCT).

Intervention

One group receives the MS sherpa application (~6 min/week self monitoring through a questionnaire, walking test and cognition test) in addition to standard care and the other group receives standard care.

Study burden and risks

The burden consists of expenditure of time by the participant during the study follow-up of one year: this is 4,5 hours for the controlgroup and 9,5 hours for the interventiongroup. For each regular visit with their treating physian patients will be asked to fill in additional questionnaires. This will take an extra 35 minutes for each extra visit. Patients in the intervention group can participate in interviews or a focus group. The interviews cosist of a series of three interviews of 45-60 minutes each. The focus group is a one time event, which will take approximately 2 hours. Potential risks are only applicable for participants in the interventiongroup, who are at risk that decisions in the clinical decisionmaking process are based on 'false-positive' and/or 'false-negative' results of the MS sherpa measurements. This risk, however, is small since the MS sherpa app will be used in conjuction to standard clinical instruments.

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. A minimum age of 18 years.
2. Have a definite diagnosis of RRMS according to the revised McDonald 2017 criteria.
3. Have a length of disease duration of >=12 months, from date of MS diagnosis.
4. Have clinical disease activity (reported relapses) and/or radiological disease activity (new/enlarged T2 lesions or contrast-enhancing lesions) within the past 12 months.
5. Willing and able to install and use MS sherpa on own smartphone with Android (version 4.4 or higher) or iOS (version 9 or higher) operating system.
6. Willing to stay for treatment with the same hospital during the year of study.
7. Willing to follow the rules of conduct as described in Appendix A during the year of study.

Exclusion criteria

1. EDSS of > 6.5 at baseline screening. 2. Presence of a cognitive, visual or upper extremity deficit that disables the use or measurements of MS sherpa on the smartphone, as judged by the investigator. 3. Concomitant use of health monitoring apps or devices for MS during the study. 4. Concomitant participation in another intervention trial in MS.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-08-2022
Enrollment:	210
Type:	Actual

Medical products/devices used

Generic name:	MS sherpa
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-06-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	10-08-2023
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	NL75687.029.22