Telemonitoring and connected care applied to Multiple Sclerose: Effect on quality of life

Published: 07-10-2021
Last updated: 21-09-2024

The primary endpoint (equal or improved MSQoL-54 and Eq5d) at which the value of telemonitoring is determined is t = 2 years.Mapping the effects of digital consultations or hospital visits, for MS patients, informal carers and the Isala...

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

Summary

ID

NL-OMON50143

Source
ToetsingOnline

Brief title
MonSter studie

Condition

- Demyelinating disorders

Synonym
MS, Multiple Sclerose

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Connected care, Multiple Sclerose, Telemonitoring

Outcome measures

Primary outcome

Primary outcome measure

The primary endpoint (equal or improved MSQoL-54) at which the value of telemonitoring is determined is t = 2 years.

If the lower bound of the confidence interval is above the non-inferiority margin (-8), then non-inferiority will be demonstrated. If the lower bound of the confidence interval is above 0, superiority will also be demonstrated.

Secondary outcome

Secundary parameters

The secondary outcomes are the endpoints of the study parameters, described in section 4. (page 16)

Superiority question (patients):

Number of physical outpatient checkups (in hospital) and patient empowerment (IPA, PIH, MSESS and Eq5d) after t = 2 years

Number of physical outpatient checks

An MS patient comes to the clinic on average 4 times a year; 2x with the neurologist and 2x with the nurse specialist. During this study, every 3 months a record is made of how many physical checks there have been and this value is entered manually in the research manager. Cumulative numbers over the period of

2 years will be compared between research arms by means of mixed model analysis.

Patient empowerment

This concerns the results of the questionnaires IPA, PIH, MSESS and Eq5d. These endpoints will be analyzed through mixed model analysis, examining both the difference between and within research arms.

Non-inferiority research question (informal caregivers):

The assessment of the informal care situation, the severity of providing informal care and the degree of happiness of the informal caregiver. Averages and the confidence interval of the difference will be calculated. This analysis is explorative.

The outcomes of the Carelqol questionnaire from both groups are compared

Study description

Background summary

Multiple sclerosis (MS) is the most common neurological disease (1: 500-1000) by young adults. It leads to permanent disability and has a profound impact on all aspects of human functioning. This disease includes comprehensive fatigue and often cognitive problems that negatively affected on quality of life, which also has a negative effect on the consultations in the hospital.
It is important to ensure the patient*s autonomy from the start of diagnosis but also when limitations increase and someone becomes more dependent. You only get autonomy if you have sufficient, objective, knowledge to make appropriate choices yourself.
Self-management can contribute to an increase in knowledge about one's own situation and illness, which, among other things, increases adherence to therapy.

MS cannot be cured. However, new treatments have become available in recent

years. These are much more effective (slow down or even stop MS) but also have more side effects and are more expensive. Careful monitoring based on effect and side effects is therefore important. The consequence is a high frequency of hospital visits and a great burden for the patient. This great burden manifests itself in an increase in the fatigue and cognitive problems that are already present, as a result of which the consultation in the hospital provides less information and is less efficient than desired.

In this research we work with three applications: MSmonitor (MSM), *Beterdichtbij* (video-calling) and the Research Manager

MSM has been specially developed by MS neurologists for MS patients. With this program, MS patients can keep track of their signs and symptoms and share them with an MS neurologist and nurse specialist. With the application *Beterdichtbij*, MS patients can make video calls to the MS neurologist or nursing specialist.

All MS patients actively receiving treatment within Isala are eligible for this study. It is randomized, comparing home monitoring (working with MSmonitor) with standard treatment.

One group (104) continues with the standard treatment (consultations at the clinic). The remaining group (104) will perform home monitoring with MSmonitor (MSM) and will start video calling. In this group, 50% of the consultations will be replaced by video calling.

Both groups complete questionnaires every 3 to 6 months via the Research Manager application (= online research program) during the research. These are about general health, MS, care consumption, self-management, autonomy and quality of life.

The informal caregivers of MS patients are also involved in this study. When participating, they complete questionnaires that relate to the care they provide to the MS patient and the cognition of the MS patient.
Questions are also asked about the informal caregiver, such as his or her economic and social situation. The informal caregivers also use the Research Manager application to complete the questionnaires in a separate account

Study objective

The primary endpoint (equal or improved MSQoL-54 and Eq5d) at which the value of telemonitoring is determined is t = 2 years.

Mapping the effects of digital consultations or hospital visits, for MS patients, informal carers and the Isala hospital

Based on the results of this study, we will look at whether we can optimize

personal care for MS patients while maintaining the safety and quality of care.

Investigate whether home monitoring and video calling reduce the check-up frequency in the hospital, so that the quality of life remains the same or increases.

Investigate whether the use of MSM increases the autonomy of the MS patient. (IPA)

Investigate whether the self-management behavior of the MS patient improves by using MSM. (PIH)

Investigate whether the use of telemonitoring and video calling makes the consultation more effective compared to standard care (less medication changes, fewer hospital admissions MS)

Study design

Single center, prospective randomized clinical trial

Intervention

1.6 Interventions for the research groups
1.6.1 Telemonitoring group
Patients in the home monitoring group will record developments / symptoms related to their MS disease and general health by completing psychometrically validated MS specific questionnaires, inventory lists and diaries in MSM. 50% of the regular check-ups in the hospital will be replaced by video calling with the nurse specialist/MS-neurologist. On indication, hospital checks may take place more often or even less often, depending on the results of the questionnaires in the MSM.
Prior to a check (physical or video calling), this group answers the questionnaires that have been prepared in MSM. Preparing specific questionnaires can also be done by the healthcare provider himself or herself, if he or she considers it necessary.
Within this study, we will have each patient complete the same questionnaires in MSM prior to a consultation with the neurologist or nurse specialist in order to be able to make a good comparison.

1.6.2 Control group
For the control group, they receive standard care, through regular physical check-up visits to the neurology clinic in the hospital and more often if necessary. This group does not use MSM or starts video calling

Both groups (telemonitoring group and control group) complete questionnaires

through the program the research manager. The Research Manager is an online research program. The times at which the questionnaires will be completed are the same for both groups.

Informal carers
The informal caregivers of MS patients are also involved in this research. This population is asked to complete a questionnaire (iMTA Valuation or Informal Care Questionnaire) when participating at baseline and after that once a year. This questionnaire is about the specific aspects surrounding the informal caregiver. This group also completes the Carelqol every 6 months and to complete the CFQ (Cognitive Failure Questionnaire) at baseline and every six months, relating to the person who is being given informal care (MS patient)

Study burden and risks

There are no additional risks associated with this research. The care provided to all MS patients participating in this study remains the same.
The quality and safety of care when using MSM is ensured by authorizing caregivers to view and use the completed patient data.
Change in results are quickly visible to any healthcare provider. This means there is double control over the course of the disease over time.
EDSS Score (Expanded Disability Status Scale) drug switching and clinical admissions will be recorded every 3 months in the research manager. As a result, a course of time can be seen of the most important values that register any increase in disease activity.

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 patient is treated in the Isala.
Agrees to participate and has signed the ICF.
Is 18 years of age or older.
Is be prepared to replace 50% of the consultations with video calling.
Is be prepared to work with the MSM program.
The doctor considers the patient suitable for participation (considering possible underlying suffering)

The informal caregiver is the informal caregiver of the MS patient
Is over 18 years old
Is prepared to participate in the survey and fill in the questionnaires specifically for the informal caregiver.

Exclusion criteria

The patient does not master the Dutch language sufficiently.
Patient has insufficient computer skills.
Incapacitated adults are excluded from the study

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):	27-04-2021
Enrollment:	208
Type:	Actual

Medical products/devices used

Generic name:	MSmonitor health program and program BeterDichtbij (video calling)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-10-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-08-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL75251.075.20