Assessing fatigue, disease activity and progression through smartphone surveillance in multiple sclerosis

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to develop and explore measuring methods using conventional smartphones to quantify fatigue, disease activity, and short term and long progression in a day-to-day setting in patients with MS. Key research questions: - Are the NeuroKeys and MS Sherpa...

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

Summary

ID

NL-OMON46691

Source
ToetsingOnline

Brief title
APPS MS: smartphone monitoring in MS

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: Biogen,Stichting MS Research,TKI Life Sciences & Health,TKI Life Sciences & Health;Stichting MS Research en tevens Stichting MS

Research voor het amendement.

Intervention

Keyword: Disease activity and progression, Fatigue, Multiple sclerosis, Smartphone-based assessment

Outcome measures

Primary outcome

- Fatigue: mobile application metrics (NeuroKeys and MS sherpa) and clinical outcomes (FSS, Fatigue Severity Scale; CIS20R, Checklist Individual Strength; and MFIS, Modified Fatigue Impact Scale).

- Disease activity: mobile application metrics (NeuroKeys and MS Sherpa) and clinical outcomes (occurrence of MS relapse, new or enlarging T2 lesions, T1 gadolinium (Gd)-enhancing lesions).

- Disease progression: mobile application metrics (NeuroKeys and MS Sherpa) and clinical outcomes (EDSS, Expanded Disability Status Scale; MSFC, Multiple Sclerosis Functional Composite; BICAMS, Brief International Cognitive Assessment for MS; AMSQ, Arm function in Multiple Sclerosis Questionnaire; retinal nerve fibre layer and ganglion cell layer-inner plexiform layer thickness, brain volume).

Secondary outcome

Quality of life

Degree of physical activity/mobility

Sleep

Study description

Background summary

The frequency of clinical visits in the current care for pwMS is limited and current methods of monitoring clinical outcomes, such as fatigue, disease activity and disease course, might not capture important clinical events. For example, limitations include high subjectivity and the obtrusive nature in which fatigue is currently assessed. Day-to-day digital self-monitoring might provide useful for clinical use.

Study objective

to develop and explore measuring methods using conventional smartphones to quantify fatigue, disease activity, and short term and long progression in a day-to-day setting in patients with MS. Key research questions:
- Are the NeuroKeys and MS Sherpa mobile applications valid, reliable and responsive in measuring fatigue?
- Is it possible to measure and predict disease activity and disease progression with the data collected through either or both mobile applications on both the short and long term?

Study design

Prospective observational cohort study

Study burden and risks

The burden of participation consists of 6 clinical visits of 2 hours each at the Amsterdam UMC (physical tests and examinations, cognitive tests, magnetic resonance imaging, and optical coherence tomography), questionnaires at home (7 times 1 hour), and performing tasks on the mobile phone (5 minutes a week). Aside from intravenous injection of gadolinium, no invasive procedures will be performed. The risks are the same as during standard clinical practice. There is no direct benefit for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age between 18 and 65 years.
- Diagnosis of MS (revised McDonald 2017 criteria)
- Regular usage of a smartphone with iOS 10 (or higher) or Android 5.0 (or higher), front-facing camera, and minimal screen size of 3.7 inches or 9.4 centimeters.

Exclusion criteria

- EDSS 7.5 or higher at baseline screening.
- Clinical or radiological disease activity or changes in disease modifying drugs two months prior to baseline screening.
- Clinically relevant visual disturbances
- Confirmed (history of) relevant mood disorders, and symptoms of the mood disorder at baseline screening
- Co-morbid sleeping disorders

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-08-2018
Enrollment:	125
Type:	Actual

Medical products/devices used

Generic name:	NeuroKeys / MS Sherpa
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-06-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-02-2024
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	NL63705.029.17