APPS MS: smartphone monitoring in MS

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27724

Source
NTR

Brief title
APPS MS

Health condition

Multiple sclerosis (MS)

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: - Biogen
- Stichting MS Research
- TKI Life Sciences & Health

Intervention

Outcome measures

Primary outcome

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

- Disease activity: mobile application metrics (NeuroKeys and Mijn Kwik) and clinical outcomes (occurrence of MS relapse, MRI-lesions).

- Disease progression: mobile application metrics and clinical outcomes (EDSS, Expanded Disability Status Scale; MSFC, Multiple Sclerosis Functional Composite; BICAMS, Brief International Cognitive Assessment for MS; MRI; OCT, Optical Coherence Tomography).

Secondary outcome

- Quality of life (MSIS-29, Multiple Sclerosis Imapct Scale; SF-36, Short Form Health Survey).

Study description

Background summary

The main objective of this study is to explore the use of two mobile software applications (apps) for their use to measure fatigue, disease activity and disease progression in multiple sclerosis. The apps uses built-in sensors of the smartphone to measure eye movement and keystroke dynamics. The sensor data will be compared with clinical measures obtained during five clinical visits over the course of one year.

Study objective

Fatigue is a common symptom in multiple sclerosis (MS) leading to diminished ability to work, decrease in social activities and quality of life. Available measuring methods for fatigue are limited due to the often obtrusive and subjective nature of assessment, and restrictions based on time interval between measurements. The same applies to assessment of disease activity and disease progression in MS. To circumvent these limitations, two performance-based software applications have been developed to quantify changes in the day-to-day setting using built-in sensors of conventional smartphones.

Study design

0, 3, 6, 9 and 12 months.

Contacts

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Eligibility criteria

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 non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2018
Enrollment:	125
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-06-2018
Application type:	First submission

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
NTR-new	NL7070

Register	ID
NTR-old	NTR7268
Other	METc VUmc : 2017.576

Study results