APPS MS: smartphone monitoring in MS

Gepubliceerd: 12-06-2018 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27724

Bron
NTR

Verkorte titel
APPS MS

Aandoening

Multiple sclerosis (MS)

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: - Biogen
- Stichting MS Research
- TKI Life Sciences & Health

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

0, 3, 6, 9 and 12 months.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	125
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7070
NTR-old	NTR7268
Ander register	METc VUmc : 2017.576

Resultaten