Using day-to-day behavior on smartphones to improve epilepsy management

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Ethical review	Approved WMO
Status	Completed
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON54668

Source
ToetsingOnline

Brief title
Smartphone behavior and epilepsy management

Condition

- Seizures (incl subtypes)

Synonym
convulsions, epileptic seizures

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: Christelijke Vereniging voor de Verpleging van Lijders aan Epilepsie

Intervention

Keyword: Behavior, Epilepsy, Seizure

Outcome measures

Primary outcome

Change in touchscreen interactions (tapping speed, texting speed, apps used,

location, sleep-wake cycles) surrounding reported epileptic seizures.

Secondary outcome

Niet van toepassing

Study description

Background summary

The unpredictability of seizures and the unclear behavioral outcomes are major concerns for people with epilepsy and may surface as increased anxiety about independence. This unpredictability is also a true obstacle in capturing and studying seizure-related neurobehavioral alterations themselves. Also, seizures often impact consciousness and thus may go unnoticed. As a result, subjective seizure diaries are unreliable. Continuous smartphone-based monitoring of behavioral output is a fast-emerging topic and proven fruitful in monitoring other neurological disease states. In the field of epilepsy, these tools are yet to be introduced.

Study objective

We hypothesize that quantifying smartphone behavior will help obtain a detailed and objective behavioral map of seizures that can complement existing subjective seizure diaries and thereby improve the way we evaluate epilepsy treatments in daily practice.

Study design

Observational prospective cohort study with 3 months follow-up.

Study burden and risks

As this concerns observational research, no direct risk is involved with participation in this study. All app data will be encrypted before being send into the cloud, to minimize risk of privacy violation.

Contacts

Public
Stichting Epilepsie Instellingen Nederland

Achterweg 3
Heemstede 2103 SW
NL
Scientific
Stichting Epilepsie Instellingen Nederland

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Heemstede 2103 SW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- >= 18 years of age
- clinical diagnosis of refractory focal epilepsy meeting ILAE criteria
- supported by at least one of the following; (1) interictal EEG with epileptiform discharges, (2) epileptogenic lesion on MRI corresponding to the presumed seizure onset zone, or (3) seizure recorded during a video-EEG
- have a seizure frequency of >= 1 per month
- only one seizure type, or in case of multiple seizure types only seizures

that correspond to one probable onset zone (e.g. focal and focal to bilateral tonic-clonic seizures)
- have daytime seizures (exclusively or both daytime and night-time seizures)
- mentally competent and with no learning disabilities
- able to keep a seizure diary including time and date (as judged by the treating physician)
- have an Android-operating smartphone
- use their phone with at least 5 distinct smartphone apps at a minimum of 5 days a week
- gave informed consent

Exclusion criteria

not fulfilling the above mentioned inclusion criteria

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-10-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	28-09-2020
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	08-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	08-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	17-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL70839.058.19