Triggers and prediction of attacks in migraine: smartphone behaviour and E-diary

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Headaches
Study type	Observational non invasive

Summary

ID

NL-OMON52185

Source
ToetsingOnline

Brief title
Triggers and prediction of attacks in migraine

Condition

- Headaches

Synonym
Hemicrania

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,NWO

Intervention

Keyword: Cortical excitability, Migraine, Smartphone behaviour, Tappigraphy

Outcome measures

Primary outcome

(1) To identify the tappigraphical patterns correlating with migraine attacks

as reported in the E-dairy and if tappigraphy can identify behavioural patterns

preceding (early) signs of upcoming migraine attacks.

Secondary outcome

(1) To correlate patient-reported triggers to migraine attacks based on the

E-diary;

(2) To correlate E-diary recorded data for sleep with tappigraphical patterns.

Study description

Background summary

The unpredictability of migraine attacks and the impact on daily life are major concerns for migraine patients and may results in increased anxiety, depression, and feelings of loss of control. Unpredictability is also an obstacle in studying attack-related neurobehavioral alterations. Headache diaries may provide insight into attack pattern and provoking trigger mechanisms. However, self-reported registration will not offer continuous information or the opportunity for detecting minimal behavioral alterations preceding an attack. Smartphone-based monitoring of behavioral output (tappigraphy) provides the ability for detailed monitoring of neurological disease states. Furthermore, patient-reported triggers will be added to provide information on known triggers such as sleep, menstruation, (relief of) stress and diet. In the field of migraine, these tools are yet to be explored.

Study objective

The general aim of this study will be to unveil that day-to-day variations in smartphone tappigraphy reflect dynamic changes in brain states that can be linked to the migraine attack cycle and triggers. We will use our

self-developed and verified headache E-diary to identify triggers and detailed characteristics of migraine attacks and link this to the tappigraphy registrations from the TapCounter app. All data will be collected during a period of 3 months in a group of migraine patients in order to phenotype the course of a migraine attack, detect patient-specific trigger factors, and early warning signs to eventually predict migraine attack occurrence.

Study design

Observational longitudinal cohort study

Study burden and risks

This is an observational study which does not include any intervention. As such no direct risk is involved for the participants of this study. Data collected using the TapCounter app will be encrypted in order to prevent any kind of privacy violation.

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

• At least be 18 years of age
• Fulfil ICHD-III criteria for migraine
• Patients must experience active migraine, which is defined for this study as at least 1 attack per month.
• Willing to participate for at least 3 and for a maximum of 12 months

Exclusion criteria

• Unable or unwilling to use (digital) headache dairy and smartphone behaviour app on a daily basis
• Diagnosed with other (chronic) neurological diseases such as Parkinson*s disease, epilepsy etc. that may interfere with the results of this study.
• Chronic migraine as defined by the ICHD-3
• Severe depression and/or panic disorders and/or schizophrenia and/or psychiatric disorders.
• Inability to differentiate between migraine and other headache diagnoses.
• Diagnosed with cluster headache or other TACs

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	27-07-2022
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	08-07-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-10-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-10-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-12-2024
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	NL74778.058.21