Validation of smartphone-derived metrics for prolonged unobtrusive monitoring of rest-activity patterns, fatigue and sleepiness in sleep-disordered patients.

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To evaluate the use, reliability and validity of smartphone output data obtained with the Neurokeys App, for the detection and monitoring of rest-activity patterns, fatigue and sleepiness in patients with various sleep disorders including such as...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52351

Source
ToetsingOnline

Brief title
Smartphone monitoring of restpatterns, fatigue, and sleepiness.

Condition

- Other condition

Synonym
circadian rhythm disorders, Insomnia

Health condition

Slaapstoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Kempenhaeghe
Source(s) of monetary or material Support:
Kempenhaeghe;Neurocast;TUE,Neurocast,TUE

Intervention

Keyword: Keystroke dynamics, Rest-activity patterns, Sleepdisorders, Sleepiness

Outcome measures

Primary outcome

The rest-activity patterns (based on timing of the rest and active period),

assessed with self-reports and objectively with last smartphone-based

keyboard interaction before and the first keyboard interaction after the

longest time interval without keyboard interaction (i.e., keystroke-absence

period) during the subjective night;

Secondary outcome

Fatigue and sleepiness, assessed with self-reports and objectively with

keystroke dynamics features derived from patients* keyboard use on smartphones.

Study description

Background summary

Disturbances in the circadian rhythm and sleep have a severe effect on overall health and everyday functioning. This is particularly observed in patients suffering from various sleep disorders which can cause excessive fatigue, sleepiness and a lack of attention during the wake state. Unfortunately, there are very limited objective measures for these important complaints. As smartphones are intensively used, smartphone-derived data, like keystroke logging and sensor data, offers the possibility to unobtrusively and objectively measure patient*s rest-activity patterns and fatigue-related

complaints during the wake phase. This innovative tool could then be used for prolonged monitoring of these aspects, for example for treatment follow up.

Study objective

To evaluate the use, reliability and validity of smartphone output data obtained with the Neurokeys App, for the detection and monitoring of rest-activity patterns, fatigue and sleepiness in patients with various sleep disorders including such as insomnia.

Study design

The study is an observational study that will take place in the tertiary sleep centre of Kempenhaeghe. Patients are referred for diagnosis and treatment of possible sleep disorders and during the study will receive care as usual. Participants are asked to use the Neurokeys App during their clinical follow up for six months and 2 weeks, and fill in 2-week sleep diary and questionnaires at several time points

Study burden and risks

Patients are asked to complete a questionnaire regarding sleep quality, fatigue and sleepiness at months 0, 1.5 and 3 (~15 minutes), to complete sleep diaries (7 consecutive days, at months 0, 1.5 and 3 , ~2-3 minutes per day), and optionally report on current fatigue levels (1 time per day, ~30 seconds per day), and use the Neurokeys keyboard (smart keyboard that replaces the original keyboard, ~1 -3 minutes for installation , once) for three months and 2 weeks. The study is observational in nature, with measurements integrated into usual care and no treatment study. Risks are considered minimal. Completing the repeated (short) questionnaires and using the keyboard may cause some discomfort due to (minor) disruptions to the daily routine and habits.

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

Sleep disordered patiënts referred to Kempenhaeghe
A minimum 18 year of age
Able to read and speak Dutch
Regular use of smartphone on a daily basis

Exclusion criteria

Cognitive impairments that make use of smartphones and/or completion of questionnaires difficult or unreliable.
Other somatic disorders that can cause fatigue and/or excessive daytime sleepiness.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-09-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	03-04-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22867
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76468.015.21
Other	NL9283
OMON	NL-OMON22867