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

No registrations found.

Ethical review   Not applicable
Status   Pending
Health condition type -
Study type   Observational non invasive

Summary

ID

NL-OMON22867

Source
Nationaal Trial Register

Brief title
TBA

Health condition

chronic insomnia disorder
sleep related breathing disorders
circadian rhythm disorder
nonrestorative sleep
primary hypersomnia

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Kempenhaeghe
Neurocast
TUE

Intervention

Outcome measures

Primary outcome

Primary Objectives:
• Investigate whether and to what extent smartphone interaction metrics can unobtrusively monitor rest-activity patterns in patients suffering from sleep disorders.
• Investigate whether and to what extent fatigue and sleepiness during the wake phase can be monitored and quantified objectively by means of smartphone-derived keystroke dynamics features among patients suffering from sleep disorders.

Secondary outcome

Secondary Objective:
• Investigate whether and to what extent smartphone derived metrics based on keyboard interactions (potentially complemented with health kit and sensor data) are sensitive (responsive) to changes in clinical status. Sensitivity to changes will be investigated in the following: rest-activity patterns, fatigue-related complaints during the wake phase, and excessive daytime sleepiness due to clinical interventions as part of care as usual,

Tertiary / Exploratory Objective(s):
• Investigate the accuracy of machine learning methods to differentiate between participants with different clinical sleep diagnoses (e.g., insomnia or circadian rhythm sleep disorders) based on Neurocast platform metrics.
• Investigate whether and to what extent Neurocast platform metrics can be used to assess pre-sleep arousal and/or predict sleep quality and insomnia severity.
• Assess user experiences with the Neurocast platform.

Study description

Background summary

Background of the study:
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.

Objective of the study:
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 population:
Cohort of 200 patients with various sleep and circadian rhythm disorders, a minimum age of 18 years old and with daily smartphone
usage.

Primary study parameters/outcome of the study:
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;

Secundary study parameters/outcome of the study (if applicable):
Fatigue and sleepiness, assessed with self-reports and objectively with keystroke dynamics features derived from patients' keyboard
use on smartphones.

Study objective

Smartphone derived metrics can be used to monitor rest-activity paterns,fatigue and sleepiness in sleep-disordered patients.

Study design

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 three time points; after intake, after 3 months and after 6 months.

Contacts

Public
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Geert Peeters

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL
Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52351
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9283
CCMO	NL76468.015.21
OMON	NL-OMON52351

Study results