Explorative study on unobtrusive sleep monitoring technologies: prolonged in-home measuring in the sleep-disordered population (PRISM study)

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The aim of this study is to research if the same measures of macrostructural sleep parameters and abnormal sleep behavior can be obtained with home monitoring technologies as with a clinical PSG.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON51152

Source
ToetsingOnline

Brief title
Prolonged In-home Sleep Monitoring (PRISM)

Condition

- Sleep disorders and disturbances

Synonym
apnea, Insomnia, periodic limb movement disorder

Research involving
Human

Sponsors and support

Primary sponsor: Technische Universiteit Eindhoven

Source(s) of monetary or material Support: Topconsortium voor Kennis en Innovatie: Hightech Systemen en Materialen (TKI HTSM)

Intervention

Keyword: In-home, Monitoring, Prolonged, Sleep

Outcome measures

Primary outcome

Macrostructural sleep parameters:

- Hypnogram

- Sleep stages: Wake, N1, N2, N3, REM

- Total Sleep Time (TST)

- Sleep Onset Latency (SOL)

- Wake After Sleep Onset (WASO)

- Sleep Efficiency (SE)

- Time In Bed (TIB)

- Sleep stage transitions

Heart rate (variability)

Respiratory activity

Apnea-hypopnea index (AHI, events per hour)

Oxygen saturation

Brain activity parameters: Delta (<4 Hz), Theta (4-8 Hz), Alpha (8-12 Hz), Beta

(12-30 Hz), and Gamma (>30 Hz) activity

Night-to-night variability in parameters

Secondary outcome

N/A

Study description

Background summary

Polysomnography (PSG) enables to simultaneously monitor a wide variety of sleep-related physiological signals, including brain activity (electroencephalography, EEG), eye-movements (electrooculography, EOG), muscle tone (electromyography, EMG), cardiac activity (electrocardiography, ECG), nasal and oral airflow, thoracic and abdominal respiratory movement with belts, and oxygen saturation using pulse oximetry. Despite being the gold standard for sleep disorder diagnostics since the 1960*s, some limitations of a PSG must be considered. A PSG requires a minimum of 22 wires attached to the patient and is performed in an artificial clinical setting, which negatively affects the patient*s sleeping experience and makes the it prone to first-night effects. Furthermore, a PSG is often performed over one or two nights and is therefore unable to capture the night-to-night variability in sleep and symptoms. But most importantly, the setup requires dedicated facilities, trained experts, and complex specialized equipment, making cost and access primary barriers. Although being a fundamental diagnostic tool for sleep assessment, its restricted availability contributes to the underdiagnosis of sleep disorders. Recent advances in sleep monitoring techniques offer new opportunities to accessibly measure sleep. These technologies include wearable EEG, actigraphy (ACT), photoplethysmography (PPG), and ballistocardiography (BCG). They have the ability to measure sleep and sleep-related physiological signals in an unobtrusive manner for prolonged periods at home. Currently, these monitoring technologies are not widely utilized for the assessment of sleep since they lack validation in the clinical population. Therefore, in this study, we aim to research whether it is possible to obtain the same measures of macrostructural sleep parameters and abnormal sleep behavior with home monitoring technologies as with a clinical PSG. Furthermore, the study assesses whether it is possible to capture the night-to-night variability in these measures, and whether multimodal approaches improve measuring macrostructural sleep parameters and abnormal sleep behavior.

Study objective

The aim of this study is to research if the same measures of macrostructural sleep parameters and abnormal sleep behavior can be obtained with home monitoring technologies as with a clinical PSG.

Study design

This study will be an observational study. The study design was chosen to make it possible to collect large amounts of data and to investigate the sleep characteristics of the study population. The design fits the study since the

study aims to research monitoring technologies in a heterogenous patient population. Participants include patients referred to the Kempenhaeghe Center for Sleep Medicine with the suspicion of a sleeping disorder.

As part of the routine clinical investigation, first an intake with the clinical sleep expert will take place. If the patient is scheduled for a clinical PSG, the patient will be asked to participate in the study. Generally, there is a waiting period for the clinical PSG of multiple weeks. The sleep of the patient can be monitored during this waiting period for 7 days using three monitoring technologies (BCG bed sensor, EEG headband, and ACT + PPG watch) and a sleep diary. If the waiting period for the clinical PSG is shorter as the in-home monitoring time, the in-home measures will completed after the clinical PSG. During the clinical PSG, the three monitoring technologies will be placed and will record simultaneously with the PSG sensors, while also the sleep diary is included.

Study burden and risks

For the patients participating in the study, there are no direct benefits since the data obtained with the study will not be used for their diagnosis. However, they will benefit on the long term from increased understanding of sleep disorder monitoring. Also, the general outcomes of the study will be communicated with the participants.

The risk of participating in this study is low since there is no use of investigational products nor are there any interventions in the study. Participants will only be subject to additional measures, without intervening with the regular clinical routine. Furthermore, since the in-home monitoring is done during the waiting period for the PSG, this will also not intervene with the clinical routine. Anticipated adverse product effects are related to wearing the products, which might lead to an uncomfortable feeling or skin irritation whether products are worn too tightly for a prolonged period.

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

- Patients with the suspicion of sleep disorders which are referred to Kempenhaeghe Center of Sleep Medicine for a clinical evaluation.
- Planned for a clinical polysomnography at Kempenhaeghe
- 18 years or above
- Wi-Fi at home that can be used

Exclusion criteria

- Suspicion of too complex comorbid sleep disorders (assessed by the clinical sleep expert)
- Suspicion of underlying severe neurological or psychiatric disorders
- Known allergies for hard plastic or elastic band material
- Presence of wounds, injuries, or inflammation on the skin where the wristband or headband will be placed

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2022
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2021
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL77366.015.21