Sleep Measuring with Non-Invasive Applications: the HealthBed Database

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON46794

Source
ToetsingOnline

Brief title
the Healthbed database

Condition

- Sleep disturbances (incl subtypes)

Synonym
sleep disorders

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: EIT Health,Philips

Intervention

Keyword: monitoring, sleep, snoring

Outcome measures

Primary outcome

To verify the snoring detection audio system in healthy subjects. To validate the snoring detection audio system in healthy subjects to see whether it is possible to distinguish healthy snoring from (sleep)disorder related snoring obtained in a prior study.

Secondary outcome

To validate the different non-invasive advanced sleep monitoring techniques against the gold standard polysomnography (PSG) for healthy participants. To validate the different non-invasive advanced sleep monitoring techniques compared to the performance in patients with various sleep disorders.

Study description

Background summary

Diagnoses for most sleep disorders are made based on a combination of the subjects sleep history and sleep recordings based on polysomnography (PSG). The complex setup for PSG requires patients to sleep in an unfamiliar environment with many sensors attached to their head and body. New technologies are being developed, with the potential to improve sleep monitoring, inclusnig wearable sensing technology, acoustic signal analysis (such as snoring sounds) and camera based vital signs measurements. These advanced techniques have in common that they are easy to use over longer periods of time and (for some of them) applicable in the home situation.

These promising techniques are developed and tested in controlled laboratory settings and in clinical settings on patients. However, test data in clinical settings with healthy subjects is limited. For proper development of these techniques, a clinical validation of these applications in healthy participants

is essential, taking into account the normal variations in sleep in the population.

Study objective

Sleep Medicine Center Kempenhaeghe has a unique opportunity to combine clinical PSG with different advanced non-invasive sleep monitoring techniques as mentioned in the former paragraph. In the center, data are currently obtained in a cohort of patients with sleep disorders (the SOMNIA Study, METC N16.074). Here, we aim to build a database containing PSG and non-invasive sleep monitoring data of healthy participants. The acquired database will be used to validate the individual new techniques and obtain normative data from the healthy population. Finally, these data are important to determine the specificity of new diagnostic methods in the future.

Study design

Observational study, comparing new non-obtrusive sleep monitoring technologies against the current gold standard (polysomnography)

Study burden and risks

Burden is limited to spending one night in the sleep lab, undergoing a standard sleep recording (PSG) together with the non-obtrusive new technologies. The PSG will not be assessed by a clinician to actively look for signs of clinical pathology. However, it may be possible that clinically relevant findings are detected, for example heart rhythm abnormalities. Such findings will be communicated with the subject and the general practitioner of the subject. If subjects do not want this to happen, they will be excluded from participation.

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

For this study we aim to include 100 healthy participants, both males and females between 18 and 65 years old. Furthermore, participants should live at a driving distance of less than approximately 70 km from Kempenhaeghe. This includes the regions Limburg-Noord, Brabant-Noord, Brabant-Zuidoost, Midden-Brabant and Gelderland-Zuid. Furthermore, participants must be able to read and speak Dutch.

Exclusion criteria

- Any diagnosed sleep disorders
o
- PSQI *6
- ISI >7
- Indication of depression or anxiety disorder meausered with the HADS (score >8)
- Pregnancy
- Participants who lack the functional capacity to provide informed consent
- Participants who suffer from any clinically relevant neurologic or psychiatric disorders or other somatic disorder, that influences sleep or is limiting the ability to adhere to the study procedures (for example schizophrenia or alcohol abuse)
- Shift-workers
- Use of any medication, except for birth control medicine

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):	04-05-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-04-2018
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: 28017
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63360.015.17
Other	Registratie zal zsm plaatsvinden
OMON	NL-OMON28017