Sleep Measuring with Non-Invasive Applications: the HealthBed Database

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28017

Source
NTR

Health condition

Healthy
Sleep
non-invasive applications
database
PSG

Sponsors and support

Primary sponsor: Kempenhaeghe

Sterkselseweg 65, 5591 VE Heeze

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

To build a reference database containing PSG and non-invasive sleep monitoring applications in healthy participants.

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 (data derived from study METC nummer N16.073).

To validate the correspondence between objective snoring measures and subjective snoring assessment received from an expert manually scoring the snoring sounds recorded in the PSG measurement.

To determine the correlation between objective snore measures and PSG data.

To evaluate the feasibility of automatic sleep stage classification using a camera in comparison with simultaneously acquired polysomnography (PSG).

To investigate the opinion of healthy sleepers about the non-invasive advanced sleep monitoring techniques.

Verdere uitkomsten: Geslacht, leeftijd, lengte, gewicht, opleidingsniveau, ISI, PSQI, HADS

Study description

Background summary

In the HealthBed database we will include observational data. At the study site, the participants will be asked to undergo a polysomnography (PSG) procedure. Polysomnography

is a standard diagnostic procedure used to monitor sleep and possible sleep disorders. Polysomnography records brain activity, heart rate and breathing, as well as eye and leg movements during the night. The participants in this study will be asked to come to the sleep center in the evening for polysomnography to record their nighttime sleep patterns. Simultaneously we will record sleep related data with non-invasive new monitoring techniques.

As a primary endpoint, the PSG room will be equipped with unobtrusive high quality microphone sensors to measure the acoustic signals in the room, photo-plethysmography (PPG) and 3D accelerometer (ACC) based wearable sensing technology (also called Philips Elan device) and camera-based vital signs measurements).

All potential participants will receive information about the study and the different sleep monitoring techniques. This study requires one visit to the sleep clinic where a PSG recording is performed. Three advanced sleep monitoring systems are added to the PSG measurement and the snoring detection system. All additional techniques for sleep are non-invasive and minimally obtrusive.

An anonymized copy of the PSG will be combined with data of the new sleep monitoring techniques and stored in a database. Primarily, this database will be used as a set of referene values. Furthermore we aim to validate and potentially improve the PPG and ACC based sleep algorithm in the wrist worn device, the current acoustic signal analysis sensor system and the camera-based vital signs measurement in healthy participants. Finally, with this database we can study the combination of different sensor modalities in the future. We can use it as a reference dataset for (future) patient studies using the same sensors.

Study design

1 night

Intervention

-

Contacts

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Eligibility criteria

Inclusion criteria

- age between 18 and 65 years old

- being able to speak Dutch

Exclusion criteria

- Any diagnosed sleep disorders

o Note: If the PSG indicates a sleep disorder after the measurement (after informed consent and enrollment), the data will be stored in the healthbed database for healthy participants. However, we will label these data so that we know that these participants were not ¡°healthy¡± related to sleep disorders. Furthermore, this will be reported as an incidental finding to Philips Q&R (Email: QandRoffice.pre@philips.com)

- PSQI ≥

- 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 clinically relevant neurologic or psychiatric disorders or other somatic disorder, that influences sleep or is limiting the ability to adhere to the study procdures (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
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-05-2018
Enrollment:	0
Type:	Unknown

Ethics review

Positive opinion

Date:	17-10-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46794
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6950
NTR-old	NTR7206
CCMO	NL63360.015.17
OMON	NL-OMON46794

Study results