Sleep Measuring with Non-Invasive Applications: the HealthBed Database

Gepubliceerd: 17-10-2017 Laatst bijgewerkt: 19-03-2025

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28017

Bron
NTR

Aandoening

Healthy
Sleep
non-invasive applications
database
PSG

Ondersteuning

Primaire sponsor: Kempenhaeghe

Sterkselseweg 65, 5591 VE Heeze

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

1 night

Onderzoeksproduct en/of interventie

-

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- age between 18 and 65 years old

- being able to speak Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	0
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	17-10-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46794
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten