Subtyping of Insomnia

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

Summary

ID

NL-OMON48782

Source
ToetsingOnline

Brief title
Subtyping of Insomnia

Condition

- Sleep disorders and disturbances

Synonym
insomnia, sleeplessness

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: Ministerie van OC&W,Philips

Intervention

Keyword: CBT-I, cluster analysis, insomnia, subtyping

Outcome measures

Primary outcome

The primary endpoints of the study are the different subtypes of insomnia and their relevant characteristics.

Secondary outcome

The fist secondary endpoint of the study is the difference of the characteristics of the subtypes, regarding the following parameters:

- Demographic parameters (age, gender, educational level)
- CBT-I treatment result
- Results of emotional priming test
- Results of time estimation tests
- Results of questionnaires
- Use of hypnotics
- (Psychiatric) comorbidities, depression

The second secondary endpoint is the validity and reliability of HF measured by wrist-worn PPG.

Study description

Background summary

Chronic insomnia is a widespread problem, affecting about ten percent of the adult population. Apart from an unsatisfactory sleep pattern, insomnia additionally involves daytime complaints such as fatigue, attentional disturbances and mood disturbances, causing serious problems for quality of life, general health and labor productivity.

A generic and effective treatment for insomnia that targets hyperarousal is Cognitive Behavioural Therapy for insomnia (CBT-I). However, part of the insomnia patients does not respond to CBT-I and patients who do respond have variable outcomes. Scientific literature is increasingly becoming aware of the idea that insomnia is a general term for a number of subtypes consisting of different sleep complaints and having different causes. As a consequence, the effectiveness of (non-pharmacological) treatment of a patient is likely to be strongly dependent of the patient*s individual characteristics. To date, no validated stratification method to subtype insomnia is available.

In this study we aim to better understand underlying mechanisms of insomnia and the heterogeneity in treatment response in a broad patient population, using cluster analysis as a tool for detecting subtypes. Subtypes will be detected with primary use of physiological parameters. Eventually, this study could lead towards finding clinically relevant subtypes, personalizing treatment and eventually even predicting if a non-pharmacological intervention for insomnia will be effective for an individual patient.

Study objective

The primary objective of this study is to identify clinically relevant subtypes of insomnia using mainly physiological parameters. Mainly macro and microstructural parameters of the EEG will be used, as well as parameters from ECG and finger PPG.

Secondary objectives:
- to evaluate if subtypes differ regarding other demographic and clinical variables such as age, gender, educational level, neuropsychological test results, co-morbidities and CBT-I treatment result.
- to validate the HF measures obtained by the Philips ELAN logging device in insomnia subjects.

Study design

This study will be a cross-sectional study with a clinical follow-up.

Measurements will be done at the patient*s home, while patients are on the waiting list for their intake at Kempenhaeghe. The measurements will consist of one week of keeping a sleep diary, one night of ambulatory PSG and neuropsychological tests (a time estimation task and an emotional priming task) and questionnaires. Additionally, wrist-worn PPG measurements will be done during the same week of the sleep diary.

During the analysis, which is exploratory, important parameters for the subtyping of insomnia will be identified. For the identification of subtypes we will use cluster analysis. Macro- and microstructural characteristics of the

EEG will primarily be reviewed, as well as cardiovascular characteristics measured by ECG and finger PPG.
Important parameters are:
- Total sleep time (TST)
- Wake-time After Sleep Onset (WASO)
- Sleep Onset Latency (SOL)
- HRV measured by ECG
- Ratio of low frequent to high frequent EEG power
- Amount of microarousals during REM and non-REM sleep
- Number of K-complexes

Additionally, the ELAN logging device will be validated.

Study burden and risks

Participating in the study does not result in large health risks, nor is it likely to cause major physical discomfort. Taking part in ambulatory PSG might result in a night of poorer-than-normal sleep. Furthermore, wearing the Philips wearable optical sensing platform for two weeks might cause minor discomfort. Due to the psychological aspects of insomnia, great emphasis will be given to the fact that the measurements are not part of the treatment. This way, the influence of the research participation on the treatment of insomnia will be minimalized.

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 who are referred to Kempenhaeghe for CBT-I
- Age older than 18
- Subjective problems with falling asleep or maintaining sleep
- A duration of insomnia of more than three months
- The sleep disturbance causes clinically significant distress or impairment
Patients who 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.

Exclusion criteria

-Patients with conditions which will prevent taking part in neuropsychological tests, for example due to language problems
- Pregnancy
- Insomnia that occurs exclusively during the course of a mental disorder or due to medication or drug abuse
- Patients who are incompetent to provide informed consent
- Patients who are not able to adhere to the study protocol due to severe neurologic or psychiatric disorders, for example schizophrenia or alcohol abuse

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-09-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	29-05-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-03-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-01-2019
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: 28159
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL60994.015.17

Study results

Date completed: 03-10-2019

Results posted: 14-09-2020

First publication
14-09-2020