

Subtyping of Insomnia

No registrations found.

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

Summary

ID

NL-OMON28159

Source

NTR

Health condition

Insomnia, insomnie, slapeloosheid

Sponsors and support

Primary sponsor: Sleep Center Kempenhaeghe

Source(s) of monetary or material Support: Philips Electronics Nederland B.V. will give material support

Intervention

Outcome measures

Primary outcome

The primary endpoints of the study are the different subtypes of insomnia and their relevant characteristics. We will mainly look at macro and microstructural characteristics of the EEG (measured by at home polysomnography during one night), as well as heart rate variability.

Secondary outcome

The secondary endpoints of the study are the characteristics of the subtypes, changes of ECG, finger PPG and microstructural EEG parameters observed after CBT-I treatment and 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. Insomniacs form a heterogeneous group. As a consequence, a substantial part of the patients does not respond to the generic cognitive behavioral therapy (CBT-I). Large discrepancies between objective macrostructural characteristics of sleep evaluated by polysomnography and subjective reports of complaints have been found in insomnia patients. Therefore, increasing emphasis has been given to study microstructural characteristics of the EEG. Current research on EEG microstructure indicates that patients with insomnia have decreased sleep stability, possibly reflecting hyperarousal. Here, we aim to better understand underlying mechanisms of insomnia and heterogeneity in treatment response, assessing macro- and microstructural EEG parameters. Eventually, this could lead towards finding clinically relevant subtypes, personalizing treatment and even predicting individual treatment success.

Overall, 250 insomnia patients who are referred for CBT-I treatment to the Sleep Medicine Center Kempenhaeghe will take part in this study. Before the start of CBT-1, one night of ambulatory polysomnography (PSG) will be recorded at home. Cluster analysis will be used to detect groups of co-occurring macro- and microstructural EEG characteristics. We will focus on spectral power analysis, structural characteristics of REM-sleep, sleep protection mechanisms and (micro)arousals. We will evaluate these characteristics together, in order to study their relevance for phenotyping and their mutual relationships.

Study objective

Chronic insomnia is a widespread problem, affecting about ten percent of the adult population. 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 (nonpharmacological) 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 design

The study will be divided into two stages with a duration of approximately 15 and 21 months respectively.

Intervention

None

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Referred to sleep center Kempenhaeghe for CBT-I
- Age older than 18
- Subjective problems with falling asleep, maintaining sleep or early awakening
- 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 deficiency
- Pregnancy
- Insomnia that occurs exclusively during the course of a mental disorder or due to medication or drug abuse
- Patients who lack the functional capacity 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
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2017
Enrollment:	325
Type:	Anticipated

Ethics review

Positive opinion	
Date:	09-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48782

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6448
NTR-old	NTR6626
CCMO	NL60994.015.17
OMON	NL-OMON48782

Study results