An integrated approach to sleep improvement

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Primary objectives:* To evaluate the relative effectiveness of web-based CBT-I and three different types of CT (light, temperature and physical activity) and their interaction as compared to placebo treatment. * To evaluate whether different...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44905

Source
ToetsingOnline

Brief title
On Time

Condition

- Other condition

Synonym
primary insomnia, sleep problems

Health condition

insomnia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: STW

Intervention

Keyword: chronobiological therapy, cognitive behavioral therapy, insomnia, phenotypes

Outcome measures

Primary outcome

The primary outcome measure is the change from week 1 to week 6 on subjective sleep efficiency. In both weeks, the complaints are queried daily through internet diary. It should be noted that the diagnosis and treatment evaluation of insomnia is primarily based on these subjective complaints. The composite measure includes morning diary ratings of difficulties falling asleep, difficulties maintaining sleep, early morning awakening and non-restorative sleep. It moreover includes evening diary ratings of the nine major daytime functioning complaints.

Secondary outcome

Secondary outcome measures are meant to support the subjective evaluations, and concern actigraphically estimated objective sleep parameters including sleep onset latency, sleep duration, wake after sleep onset, sleep efficiency and the average durations of unperturbed periods of sleep and wakefulness.
At three time points during the protocol, participants will fill out additional questionnaires through the NSR website. One addresses the expectations of treatment effect (to verify the placebo), or the subjective view on treatment outcome. Other surveys address possible dysfunctional beliefs and attitudes

regarding sleep (DBAS), depression and anxiety (HADS), arousal (PSAS and AROUS), functional health (SF-36), mood (PANAS), sleep effort (GSES), self-efficacy (SSES) and sleep locus of control (SLOC). A final questionnaire quantitatively estimates the costs associated with insomnia (TiC-P). The Composite International Diagnostic Interview * Short Form (CIDI-SF) will be administered at three years follow-up to assess depression and the Life Experiences Survey will be used for assessing life experiences.

Study description

Background summary

Insomnia is a condition that affects about 10% of the Western population. insomnia has severe consequences for health (increased risk of depression, obesity and cardiovascular problems) and society (reduction in productivity, increased sick leave and care request). These consequences place a high economic burden on the health care system and society. Adequate treatment is necessary.

At present, the most common solution provided by primary care givers (general practitioners) is pharmacological treatment. However, pharmacological treatments have a high prevalence of negative side effects, such as daytime drowsiness, risk of abuse and addiction, and rebound insomnia on withdrawal. Two more recently developed treatments are chronobiological treatment (CT) and cognitive behavioral therapy (CBT). They appear safer and have more sustained effects.

A problem facing implementation of CBT-I is that there are hardly any skilled therapists. Web-based CBT-I may this alleviate this problem. A second opportunity for optimization of treatment is based on the contention that the people with insomnia most likely represent a heterogeneous mix of different subtypes, with different underlying causes and expected treatment response. These subtypes, or phenotypes, may not only be distinguished by type of sleep problems. Other factors such as personality traits, medical complaints and medical history, the ability to perceive comfort etc. may play a role as well. Currently our research group is conducting a large-scale study using web-based questionnaires to collect data on these factors (the Netherlands Sleep Registry, NSR, www.slaapregister.nl). The use of latent class analysis on these

data will allow for the classification of participants into different phenotypes.

This is the first step in the development of a protocol for individualized optimal treatment for specific phenotypes of insomnia, where each phenotype may show different CT and CBT-I demands. The project described in this protocol will define the optimal treatment for the four most prominent phenotypes found in the NSR study. In a systematic way the effectiveness of CT, CBT-I and their combination will be evaluated. Additionally, this study will evaluate whether insomnia subtype moderates the effectiveness of the individual and combined treatments

Study objective

Primary objectives:
* To evaluate the relative effectiveness of web-based CBT-I and three different types of CT (light, temperature and physical activity) and their interaction as compared to placebo treatment.
* To evaluate whether different phenotypes of chronic insomnia respond differently to individual and combined treatments mentioned above.
Secondary objectives:
* To evaluate whether the effect of CBT-I is enhanced by prior CT.
* To evaluate the cost effectiveness of CT, CBT-I and their combinations.
* To evaluate whether CBT-I and CT or a combination or a combination thereof approve long-term (after 3 years) behavioral changes.
* To evaluate the long-term (after 3 years) effects of CBT-I and CT or a combination thereof on insomnia and affect.

Study design

The study is a double blind, randomized, placebo controlled clinical trial. 160 participants will be recruited through the NSR, who will be randomly assigned to each one of eight limbs in a repeated measures design with two factors (CBT-I and CT) of respectively 2 (active treatment versus waitlist monitoring) and 4 (light, physical activity, body warming and placebo) levels. This yields 8 groups of 20 participants. Assessment will be done at baseline, at the end of a four-week treatment period (last week of treatment and the week after) and at the end of a four-week follow-up period. There will be a follow-up measurement after three years.

Intervention

CBT-I.
All participants will receive web-based, personalized cognitive behavioral treatment (SOMNIO), the first treatment factor, for four weeks. Half of the participants will be randomized to receive the CBT-I during the first four

weeks after the baseline assessment; the other half to a waitlist for CBT-I. Cognitive behavioral therapy (CBT) is a combination of psychological and behavioral treatments. When these treatments focus on sleep improvement, the term CBT-I is often used (cognitive behavioral therapy for insomnia). CBT-I combines stimulus control (i.e. association of bed with sleeping), sleep restriction (i.e. restrict time in bed to average sleep time), relaxation training, cognitive therapy (i.e. change misconceptions about sleep) and sleep hygiene (e.g. general guidelines about health and environmental factors influencing sleep). For ethical reasons, the participants that were randomized to be at a waitlist for CBT-I , will receive it afterwards, in week 7 to 10.

CT.
During the first four weeks after the baseline assessment (week two to five, see table 1 and figure 1), participants will be randomized to one of the four CT treatment conditions listed below, forming the second treatment factor.

Physical Activity. At enrollment participants are asked to fill out questionnaires to assess their health status as well as the habitual level and timing of activity. The answers will provide the necessary information to determine the specific personalized implementation if they are randomized to the physical activity condition. More specifically, in the active treatment limb, the most intense physical activity that participants report to habitually maintain for at least half an hour (e.g. (walking, running, cycling) will be (re)scheduled to be performed daily for half an hour preferably starting three hours before scheduled bedtime, and never ending closer than two hours prior to scheduled bedtime. The physical activity will thus at no point exceed the participants usual amount and intensity, but will be set to a specific time of the day (evening, between two to three hours before bedtime) and will be proposed to be performed every day.

Temperature Manipulation. Participants randomized to the temperature condition are instructed to take a warm bath daily for half an hour preferably starting three hours before ideal bedtime, and never ending closer than two hours prior to ideal bedtime. The physical activity and temperature manipulation procedures will result in elevated skin temperature at bedtime, which can enhance sleep onset.

Bright Light Treatment. Participants randomized to the bright light treatment will receive two Philips goLITE BLU light devices (therapy lights). They will be instructed to install the lights on a table facing a window or lamp to minimize glare by reducing contrast between the relatively small bright light source and the background. They will be asked to sit facing the light in close proximity for half an hour at a fixed time each morning at their earliest convenience after scheduled wake-up time, for example during breakfast.

Placebo CT. Participants randomized to the placebo treatment will receive a deactivated Ionizer device. They will be instructed to install the device on a

table where they can sit in close proximity to it for half an hour each morning at their earliest convenience after ideal wake-up time, for example during breakfast. This placebo has been applied successfully in several studies in the USA, but not yet in the Netherlands, making it unlikely to be recognized as a placebo.

Study burden and risks

The burden of participating is fitting chronobiological and cognitive behavioral therapy into daily routine as well as filling out a daily sleep diary online. Added burden during the assessment weeks (week 1, 6 and 11 of the protocol) is wearing an accelerometer and filling out some additional questionnaires (which take an approximately an hour in total).
Benefit of participating is that participant receive chronobiological therapy and CBT for free.
Ultimately this study develops a clear cut guide line for the treatment of insomnia, which is beneficial for all insomniacs.

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

Participants will only be included if they can be classified to one of the four most prevalent insomnia phenotypes. Participants have to be at least 18 years old and less than 70 years old

Exclusion criteria

People will be excluded if they report an eye disease incompatible with light treatment (aphakia or retinopathy).
People diagnosed with any cardiovascular or movement disorder will be excluded.
People doing shiftwork will be excluded,
Participants will be excluded if their baseline level and timing of activity, bright light or warming before bedtime is similar to the CT interventions planned.
People currently diagnosed with a psychiatric or neurological disorder are excluded from participation.
People using sleep medication will also be excluded (or asked to stop at least 3 months prior to enrolling in the study).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-01-2014
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL42867.029.12