Insomnia and affect

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46531

Source
ToetsingOnline

Brief title
Insomnia and affect

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
depressive symptoms, primary insomnia, sleep problems

Health condition

insomnia

Research involving
Human

Sponsors and support

Primary sponsor: VU Medisch Centrum, Amsterdam UMC
Source(s) of monetary or material Support: ERC Grant

Intervention

Keyword: Chronobiological therapy, Cognitive behavioural therapy, Depressie, Insomnia

Outcome measures

Primary outcome

The primary outcome of the RCT is the severity of depressive symptoms during one year following the treatment. Depressive symptoms are measured with the Inventory of Depressive Symptomatology Self Report (IDS-SR). The primary effect of interest is the integrated treatment effect on IDS-SR at T1 to T4 relative to T0.

Secondary outcome

A secondary endpoint is a diagnosis of Depression based on a Composite International Diagnostic Interview * Short Form (CIDI-SF), which will be performed at baseline (to exclude patients with a DSM-5 depression diagnosis) and at 12 months. Other secondary outcome measures of the RCT are the severity of insomnia and the cost-effectiveness of each treatment calculated form health care and work absenteeism. Severity of insomnia will be measured with the Insomnia Severity Index (ISI), Consensus Sleep Diary (CSD) and actigraphy recordings. Cost-effectiveness will be asses with the Trimbos and iMTA questionnaire on Costs associated with Psychiatric illness (TIC-P).

Study description

Background summary

Major depression is among the most burdening and costly chronic health hazards. Its prognosis is poor and treatment effectiveness is at best moderate. With a

prevalence of 4-10% in the general population chronic insomnia is the most frequent complaint in general practice. Insomnia, which represents a heterogeneous mix of different subtypes, contributes to cognitive and health care problems, including risk of developing of developing depression. Meta-analysis shows that ±13% of people with insomnia develop depression within a year. The proposed project will address how the insomnia subtype that is prone to depression can be identified early by means of differences in psychological traits, behavioral habits, environmental exposures and in brain structure and function. Moreover, the project will address which of the currently available interventions, including internet-based cognitive behavioral therapy for insomnia (CBT-I), chronotherapy (CT), or a combination of these, works best to treat their insomnia and to prevent depression.

Study objective

The current project aims (1) to unravel underlying mechanisms for the insomnia subtype that has a high risk to convert to depression by evaluating their profile of psychological traits, health history, life events, behavioral habits, environmental exposure, brain structure and brain function, and (2) to compare effectiveness of interventions for insomnia and their possible secondary gain of preventing depression.

Study design

Randomized single-blind repeated measures intervention study combined with cross-sectional case-control comparison. The study involves a 9-day observational ambulatory measurement period, 1 night of HD-EEG measurements, MRI scan and filling in questionnaires. The insomnia group that is at high risk of developing a depression will be included in an RCT and will undergo a second MRI scan.

Intervention

Of the 130 people suffering from ID that participate in the RCT participants, at least 30 will be randomly assigned to one of the following three conditions: CBT-I, CT or CBT-I combined with CT. It is estimated that at most ten will not be assigned because they don't want to receive an intervention.

Study burden and risks

Both CBT-I and CT have very low risks. Participants will not be exposed to risks any different than in their everyday life. Light exposure, body temperature manipulations and physical activity intensity will not exceed individual capacity. The burden associated with participation is mostly the demands on the participants* time and effort.

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 have to be at least 18 years old and less than 70 years old.
- Additional inclusion criteria for the insomnia group specifically:
* a diagnosis of insomnia according to the International Classification of Sleep Disorders (ICSD-2)
* an Insomnia Severity Index score (ISI) *10
- Additional inclusion criteria for the RCT specifically:
* a high score on the ISQ (cut-off to be determined).

Exclusion criteria

- a current clinical diagnosis of major depressive disorder or a diagnosis of major depressive

(DSM-4) assessed with the Composite International Diagnostic Interview * Short Form (CIDI-SF)
- Diagnosed sleep apnea syndrome (OSAS) (AHI >15), restless leg syndrome (RLS) or periodic limb movement (PLMD) (PLMI > 25). Using the screening survey, we will exclude candidates with moderate to very severe RLS according to an IRLS scale score > 15 and candidates with a high risk of OSAS according to the Berlin questionnaire. In candidates suspect for PLMD according to the Duke Structured Interview for Sleep Disorders, the PLMI will be determined from the polysomnographic recordings of the pre-assessment; cases with a PLMI of 25 or more will be advised to consult a sleep specialist.
- a known eye condition incompatible with light exposure
- a history of light-induced migraine or epilepsy, or severe side effects to bright light in the past.
- MRI contraindications such as non-MR compatible metal implants, claustrophobia, pregnancy
* Current treatment with antidepressant medication
* Night work or rotating shift-work

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-12-2018
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO

Date:	22-02-2018

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-11-2018
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

ID: 22122
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63139.029.17
OMON	NL-OMON22122