Effect of treatments for insomnia on depressive symptoms in persons with insomnia prone to depression

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22122

Source
NTR

Health condition

Insomnia, Depressive symptoms, Insomnie, Depressieve symptomen

Sponsors and support

Primary sponsor: Netherlands Institute for Neuroscience
Source(s) of monetary or material Support: ERC Advanced Grant 2014

Intervention

Outcome measures

Primary outcome

The primary outcome is the severity of depressive symptoms during one year following the intervention. 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 (7 weeks, directly after the six-week intervention) to T4 (52 weeks) relative to T0 (baseline).

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 T0 (baseline) and at T4 (52 weeks). Other secondary outcome measures 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 assessed with the Trimbos and iMTA questionnaire on Costs associated with Psychiatric Illness (TIC-P).

Another secondary outcome measure is the effect of the intervention (CBT-I and/or CT) on brain structure and function (assessed with MRI) at T1 relative to T0.

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. This trail will address which of the currently available interventions, including internet-based cognitive behavioral therapy for insomnia (CBT-I), chronobiological therapy (CT), or a combination of these, works best to treat their insomnia and to prevent depression. The current project aims to compare effectiveness of interventions for insomnia and their possible secondary gain of preventing depression.

Study objective

To compare effectiveness of interventions for insomnia and their possible secondary gain of preventing depression.

Study design

Repeated assessments take place at baseline (T0), during the 6-week treatment period (Tintervention), and at 4 follow-up periods (T1;week 7, T2;week 26, T3;week 39, T4; week 52).

Intervention

Participants will be randomised in one of the following 4 groups:

1. A six-week online guided Cognitive Behavioural Treatment for Insomnia (CBT-I), aimed at reducing insomnia symptoms.

2. A six-week online guided chronobiological therapy (CT). This consists of a combination of chronobiological therapy conditions including: bright light treatment, body warming and physical activity.

2. A combination of CBT-I and CT (1 and 2 mentioned above)

3. Care as usual.

With n=30 in each of the 4 groups.

Contacts

Public
Netherlands Institute for Brain Research
Meibergdreef 33

E.J.W. Someren, van
Meibergdreef 33
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5665497
Scientific
Netherlands Institute for Brain Research
Meibergdreef 33

E.J.W. Someren, van
Meibergdreef 33
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5665497

Eligibility criteria

Inclusion criteria

1. Age ≥ 18 years and < 70 years

2. Diagnosis of insomnia according to the International Classification of Sleep Disorders

(ICSD-3) and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V).

3. Insomnia Severity Index score ≥10

4. Persons with insomnia prone to depression defined by the Insomnia Type Questionnaire (ITQ)

Exclusion criteria

1. A current clinical diagnosis of major depressive disorder or a diagnosis of major depressive assessed with the Composite International Diagnostic Interview – Short Form (CIDI-SF).

2. People in whom symptoms of obstructive sleep apnea syndrome (OSAS), restless legs syndrome (RLS) and periodic limb movement disorder (PLMD), are a major cause of disturbed sleep will be excluded. First, we will ask people if they have been clinically diagnosed with one of these sleep disorders. If they have been diagnosed indeed, they will be excluded in case of a polysomnographically assessed apnea hypopnea index (AHI) of 15 or more or periodic limb movement index (PLMI) of 25 or more. Second, using the screener survey, we will exclude candidates with moderate to very severe RLS according to an IRLS scale score > 15 17 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 ≥ 25 will be advised to consult a sleep specialist.

3. A known eye condition incompatible with light exposure

4. A history of light-induced migraine or epilepsy, or severe side effects to bright light in the past.

5. MRI contraindications such as non-MR compatible metal implants, claustrophobia, or pregnancy

6. Current treatment with antidepressant medication

7. Night work or rotating shift-work

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-11-2018
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46531
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7359
NTR-old	NTR7567
CCMO	NL63139.029.17
OMON	NL-OMON46531

Study results