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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22122

Bron
NTR

Aandoening

Insomnia, Depressive symptoms, Insomnie, Depressieve symptomen

Ondersteuning

Primaire sponsor: Netherlands Institute for Neuroscience
Overige ondersteuning: ERC Advanced Grant 2014

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-11-2018
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46531
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten