The effect of an additional short group cognitive behavioural therapy for insomnia (CBT-I) on depressive complaints in patients with a unipolar depressive disorder and insomnia

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON47194

Source
ToetsingOnline

Brief title
The effect of group CBT-I on depressive compaints

Condition

- Mood disorders and disturbances NEC

Synonym
depression, Major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Noord-Holland-Noord
Source(s) of monetary or material Support: GGZ Noord-Holland Noord

Intervention

Keyword: CBT-I, Depression, Grouptherapy, Insomnia

Outcome measures

Primary outcome

The severity of the major depressive disorder is measured by the Inventory of Depressive Symptoms - Self Report (IDS-SR), which is validated for the Dutch population (Schulte-van Maaren et al., 2013)

Secondary outcome

The severity of insomnia is measured by the Pittsburgh Sleep Quality Index (PSQI)

Study description

Background summary

Insomnia is defined by the presence of difficulty falling asleep or staying asleep, for the duration of at least one month (APA, 2000). About one third of the adults face sleeping problems at some point in their lives, about 10% has to deal with chronic insomnia. The prevalence of insomnia is 1,5 times higher for women than men, especially after the beginning of the menopause (Vandereycken et al., 2008).
Insomnia is a common comorbid disorder with many disorders on Axis 1 of the DSMI IV TR, especially with a major depressive disorder (Ford et al., 1989)
The start of a major depressive disorder is often preceded by insomnia (Ford et al., 1989; Ohayon et al., 2003): between 41% and 69% of patients with major depressive disorder reports the occurrence of insomnia preceding other depressive symptoms (Ohayon et al., 2003; Johnson et al., 2006)
The chance of developing a major depressive disorder is three times higher for patients with insomnia, compared to those without insomnia.
Perlis et al. (2007) found that patients with a recurrent depression

experienced insomnia during a couple of weeks preceding the other depressive symptoms. Possibly, insomnia precedes other symptoms that are associated with major depressive disorder. This implies that insomnia. could be a predictor for the recurrence of a depressive episode.
After a successful cognitive behavioral treatment (CBT) of a .depressive episode, generally about half of the patients still have trouble sleeping (Carney et al., 2007), which results in a higher risk for the recurrence of the depression(Perlis et al., 2007).
Cognitive behavioral therapy for insomnia (CBT-I) is a commonly used evidence-based therapy for insomnia and consists of three components: 1) Sleep restriction, which concerns the limitation of the number of hours spent in bed to improve the sleep. 2) stimulus control, which means that the bedroom should only be used for the purposes of sleeping or sex. 3) Cognitive restructuring, which includes challenging negative thoughts about sleep to reduce the anxiety for insomnia (Koffel et al., 2015).
Six studies have shown that CBT-I leads to a significant remission of both insomnia and depressive symptoms in patients with both disorders (Taylor et al., 2007; Manber et al., 2008; Manber et al., 2011; Watanabe et al., 2011; Wagley et al., 2013; Ashworth et al., 2015; Norrel-Clarke et al., 2015).
Significant effect of CBT-I on both insomnia and depressive symptoms is demonstrated in three of these studies. One study involved a comprehensive group CBT-I consisting of seven sessions (Manber et al., 2008), the other two studies involved an individual CBT-I consisting of four sessions (Watanabe et al., 2011; Ashworth et al , 2015).

Study objective

Whether a CBT*I of four sessions is also effective when offered as a group therapy in the treatment of major depressive disorder with co-morbid insomnia has not been studied sufficiently. So far the CBT-I group therapy is only studied as a stand-alone treatment in comparison with relaxation therapy. No study have been done into the effects of CBT-I group therapy as an addition to treatment as usual (TAU) for depression in patients with major depressive disorder and comorbid insomnia.

Aims of this study:
In the current study we want to compare the effects of four sessions CBT-I group therapy added to the treatment as usual for depression, with the effects of treatment as usual on patients with a major depressive disorder and comorbid insomnia. With this study we aim to optimize the treatment of patients with a major depressive disorder and comorbid insomnia.

Japanese research (Watanabe et al., 2011) concluded that the addition of an abbreviated version of four individual sessions CBT-I, is probably cost-effective for patients with persistent sleeping problems and depressive symptoms (Watanabe et al., 2015).

Research Question
Primary research question: Is Cognitive Behavioral Group Therapy efficacious as an adjunctive treatment to the treatment as usual in patients with a major depressive disorder and comorbid insomnia on depressive symptoms?

Hypothesis:
It is hypothesized that four sessions of group CBT-I, in addition to TAU, in patients with major depressive disorder as the primary diagnosis and comorbid insomnia, will lead to a greater reduction in both depressive symptoms and insomnia, compared to only treatment as usual (CBT for depression).

Study design

In a randomized controlled trial patients will be offered either four sessions of group CBT-I in addition to the treatment as usual (TAU) of depression or to the TAU for depression only. The patients are randomly assigned to one of the two conditions groups after inclusion. The CBT-I consists of four biweekly group sessions. Measurements are carried out at the start of the CBT-I, after the CBT-I (after 8 weeks) and one month after completing the CBT-I. Timing and the contents of these measurements are the same for both conditions. As soon as the experimental condition ends, participants from the waiting list condition will be offered the CBT-I treatment.

Intervention

Five CBT-I group session are offered by a experienced Mental Health care-psychologists, and an experienved cognitive behavioral groupworker, with a frequency of once in every two weeks.The group will consist of a minimum of four and a maximum of six participants. The sessions have a duration of a 120 minutes each time. Every 10 weeks a new group will start or, if there are sufficient participants every five weeks, in which case there will be two groups simultaneously.
The CBT-I is offered according to the CBT-I protocol. The protocol is based on the published protocol of Carney and Edinger (2008). Translation to Dutch is done by abbreviating and adjusting the Dutch protocol 'treatment of long-term insomnia (Verbeek and van de Laar, 2015). The first author of this original protocol have been responsive in the drafting of the study. The following topics are covered: Information about sleep, recommendations about sleep hygiene and abdominal breathing exercises (Session 1) Stimulus control, sleep restrictions, and progressive muscle relaxation (session 2), cognitive restructuring and imaginary relaxation exercise (session 3) and self-management, relapse prevention and mindfulness relaxation (session 4).

Study burden and risks

This study will cost the participants about 10 hours in total, including 8

hours for the group therapy and about one and half to two hours to fill in questionnaires (distributed on three occasions). No known risks are associated with participating in cognitive behavioral therapy for insomnia.

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

The criteria for inclusion include:
Age 18 to 65 years
Moderate to severe major depressive disorder
Insomnia

Exclusion criteria

The exclusion criteria include: Bipolar depressive disorder, dysthymic disorder, psychotic disorders, seasonal affective disorder, substance abuse, not being able to follow an eight week therapy (four bi-weekly sessions), changes in sleepmedication in the eight weeks before participating and insufficient understanding of the dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL59307.029.16