Effectivity of cognitive behavioral therapy in treating insomnia in a chronic psychiatric population with a depressive disorder.

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Will a sleep training consisting of CBT in a chronic, psychiatric population with depressive disorder and insomnia lead to a decline of sleeping problems and a increase in sleep quality? Will the results from a normal and non chronic population will...

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

Summary

ID

NL-OMON36294

Source
ToetsingOnline

Brief title
Cognitive behavioral therapy for insomnia with chronic depression

Condition

- Sleep disorders and disturbances

Synonym
insomnia

Research involving
Human

Sponsors and support

Primary sponsor: Delta Psychiatrisch Centrum (Portugaal)

Source(s) of monetary or material Support: Delta Psychiatrisch Centrum

Intervention

Keyword: cognitive behavioral therapy, depression, insomnia, sleep quality

Outcome measures

Primary outcome

The main parameters are the amount of sleep complaints and the quality of sleep before and after the CBT and waiting list condition and between both conditions after the training. Sleep complaints and quality consist of different parameters: subjective sleep quality, sleep onset, sleep efficiency, amount of sleep habits and sleep distortions. The are measured with a sleep diary and a questionnaire.

Secondary outcome

Depressive symptoms are measured with the help of the Beck Depression Inventory (21 items focussing on symptoms in the past week). The quality of life questionnaire OQ-45 is used to measure quality of life and the DBAS 16 (dysfunctional beliefs about sleep) is used to measure negative thought about sleep.

Study description

Background summary

Insomnia is a very common complaint within the psychiatric population and is often seen comorbid to a depressive disorder. The last decennia non psychopharmacological treatment has become focus of interest. Especially treatment with cognitive behavioral therapy has produced promising results in short and long term effects on treating insomnia. With the increase of research focused on insomnia and depression, there is also an increase in the

versatility of hypotheses and research protocols. It is striking to see the limited amount of research in the chronic psychiatric population (>2 years of psychiatric care and treatment for depressive complaints and insomnia). This study will focus on verifying if CBT, besides the offered care as usual, has an effect on insomnia, depression and quality of life as results for now in non chronic populations are showing.

Study objective

Will a sleep training consisting of CBT in a chronic, psychiatric population with depressive disorder and insomnia lead to a decline of sleeping problems and a increase in sleep quality? Will the results from a normal and non chronic population will be replicable?
Hypotheses:
1. CBT for insomnia will lead to a significant decrease in sleep problems and sleep quality compared to a control waiting list condition.
2. CBT for insomnia will lead to an increase in general quality of life
3. CBT for insomnia will lead to a decrease in depressive disorder compared to the control waiting list condition.

Study design

In this experimental randomized intervention design participants will be assigned to an experimental (CBT) or control (waiting list) condition. Participants first have to fill out different questionnaires with a minimal score of 18 on the BDI depression inventory and meet the criteria for insomnia. During a second intake and 2 other moments during this study questionnaires about sleep habits, thoughts about sleep, sleep quality and a sleep diary will be handed out. The CBT condition consists of 8 weekly sessions and one follow up session. Participants assigned to the waiting list condition will be offered to attend CBT for insomnia afterwards.

Intervention

Participants will be assigned to either a treatment or control condition. Treatment consists of 8 weekly 90 minutes sessions and one more follow up session after 4 weeks. The treatment will be added to care as usual. The trainer will be a psychologist or a GZ psychologist.
The treatment consists of 3 parts specifically aimed at insomnia: psycho education, cognitive behavioral therapy and relaxation therapy.
Sleep hygiene will be the main part of psycho education. Participants will receive information about the sleeping cycle, and the influence of behavior on the sleep pattern.
The role of negative thoughts in maintaining sleeping problems will be the focus of CBT. Most thoughts are present for years and are viewed as reality and impossible to change. This conception will be challenged through different

methods.
The final part of the treatment will be relaxation therapy practicing exercises like progressive relaxation and autogenic training.
The control condition will be a waiting list and participants in this group will be offered the treatment after an 10 week waiting list.

Study burden and risks

Risks for participants are minor. Participants can quit at any time. Besides 2 indivuals appointments, they have to visit the hospital to attend the training 9 times in total. There are 3 measurement moments (2 after a session)for the experimental condition and they have to fill out the sleep diary daily for 14 weeks. The waiting list condition has 2 (individual) measurement and have to fill out the sleep diary for 10 weeks.

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

1. Age between 18 and 65 years old.
2. Chronic patient, meaning more than 2 years in treatment
3. BDI depression score > 18
4. Meeting the criteria of insomnia according to DSM IV criteria
5. Fixed medication administration during participation

Exclusion criteria

1. Acute psychiatric illness interfering with participation of treatment, consuming information, accomplishing homework. I.e. manic episode or PTSD.
2. Participating in psychotherapy during research
3. Seasonal mood disorder
4. Intelligence < 75
5. Sleeping problems with a treatable organic cause
6. More than average alcohol usage. More than 2 units a day, independent from sex
7. Current drug abuse
8. Insufficient skill of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-01-2011
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2011
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL33196.097.10