

Online self-help CBT for insomnia: With or without feedback?

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The objective of this study is to determine whether providing feedback enhances self-help CBT for insomnia.

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

Summary

ID

NL-OMON36137

Source

ToetsingOnline

Brief title

Online CBT for insomnia

Condition

- Sleep disorders and disturbances

Synonym

Insomnia, sleeplessness

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Fonds Psychische Gezondheid & Innovatiefonds Zorgverzekeraars

Intervention

Keyword: Insomnia, Online, Self-help

Outcome measures

Primary outcome

Diary sleep measures

Secondary outcome

Anxiety rating; Depression rating; Sleep medication

Study description

Background summary

Insomnia is a common disorder with a prevalence of 10-15%. Bad sleep causes fatigue and distress during the day; furthermore insomnia is associated with psychological problems. The problem that needs to be addressed is that, notwithstanding their impact, sleep disorders receive little attention in the general health care. A minority of all sleep disordered persons seeks and gets adequate treatment, most likely due to a shortage of well trained health professionals. Insomnia, however, can be effectively treated. Two meta-analysis, and two systematic reviews concluded that for insomnia, non-pharmacological therapy in the form of cognitive behavioral therapy (CBT) is the treatment-of-choice.

Problematic is that even if professionals are properly trained to treat sleep problems, treatment may not be accessible. The growing demand for cognitive behavioral therapy for several mental disorders may only be met by less intensive approaches than standard face-to-face therapy, such as self-help interventions. Self-help CBT is effective in treating insomnia complaints, however, not all patients benefit from this treatment. Support on progress and feedback might encourage more patients to complete all exercises. This RCT addresses whether feedback can enhance the effects of self-help CBT for insomnia

Study objective

The objective of this study is to determine whether providing feedback enhances self-help CBT for insomnia.

Study design

All participants will receive a web-based intervention (N = 300). Participants will be randomized into two groups: 1) intervention with feedback; 2) intervention without feedback.

Intervention

In this study all participants receive an online self-help CBT manual consisting of information (psycho-education) about sleep and cognitive-behavioral exercises. The techniques used throughout the self-help manual are all effective in reducing insomnia: 1) Stimulus control: patients should only go to bed when sleepy, use the bed and bedroom for sleep (and sex) only, maintain a regular rising time, avoid daytime naps and get out of bed and go into another room when unable to fall asleep within 15-20 minutes (return only when sleepy). 2) Progressive muscle relaxation. 3) Sleep hygiene education (improving health and environmental factors that affect sleep). 3). Sleep restriction, whereby participants will stay only the time in bed that they sleep. 4) Cognitive therapy to challenge and dispute incorrect and unhelpful thoughts about sleep (e.g. I must sleep at least eight hours; otherwise I'll be a wreck tomorrow).

Study burden and risks

The current study has minimal risks and it is highly unlikely that there will be lasting negative effects. Participants may sleep a little less during the intervention, but that is part of the treatment. This will not be problematic as the sleep will not fall below five hours a night. The time investment for the participants is small (seventeen hours over twelve months). In our view conducting this study is warranted because of the probable positive effects, the small time investment, and the low risks.

Contacts

Public

Universiteit Utrecht

Postbus 80.140
3508TC Utrecht
NL

Scientific

Universiteit Utrecht

Postbus 80.140

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Suffering from insomnia
- Acces to internet
- A valid e-mail address

Exclusion criteria

Being suicidal; schizophrenic or having a psychotic episode; regular cannabis use; alcohol abuse; sleep apnea.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO	
Date:	22-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (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	NL36297.041.11