Internet-based self-help for Insomnia: Factors that are associated with succes of the intervention

Published: 31-08-2010
Last updated: 03-05-2024

The object of this study is to determine variables associated with therapy-success of a cognitive behavioral self help intervention for insomnia.

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

Summary

ID

NL-OMON34377

Source
ToetsingOnline

Brief title
Internet-based self-help 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: Ministerie van OC&W

Intervention

Keyword: Insomnia, Self-help, Sleep

Outcome measures

Primary outcome

Insomnia Distress caused by insomnia

Sleep complaints.

Secondary outcome

Anxiety rating

Depression Ratings

Sleep medication

Study description

Background summary

With a prevalence of 8-10% is insomnia a common disorder. 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 15% of all sleep disordered persons seeks and gets adequate treatment, most likely due to a lack of sleep awareness by the general public - and health professionals. Most sleep disorders, however, can be effectively treated. Two meta-analysis, and two systematic reviews concluded that for insomnia, non-pharmacological therapy in the form of cognitive behavioural 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 behavioural 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 for insomnia seems to be effective in reducing insomnia. Variables associated with therapy success should now be determined.

Study objective

The object of this study is to determine variables associated with

therapy-success of a cognitive behavioral self help intervention for insomnia.

Study design

All participants will receive a web-based intervention.

Intervention

In this study all participants receive an online self-help CBT manual consisting of information (psycho-education) about sleep and cognitive-behavioural 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 8 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

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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 addess

Exclusion criteria

Being suicidal
Schizophrenic or having a psychotic episode
Regular cannabis use
Alcohol abuse
Sleep apnea

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)

| Control: | Uncontrolled |
| Primary purpose: | Health services research |

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-10-2010
Enrollment:	732
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2010
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	NL31993.041.10