

# An insomnia self-help study

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The object of this study is to determine the effect of a cognitive behavioral self help intervention for insomnia. It will be tested if internet delivered self-help differs from self-help via a booklet.

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

## Summary

### ID

NL-OMON31992

### Source

ToetsingOnline

### Brief title

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, Intervention, 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 with or without brief consultations. To date six randomised controlled trials found positive effects of self-help interventions. The design of the studies did not make it possible to determine whether digitalized self-help works better than self-help delivered by a booklet.

### Study objective

The object of this study is to determine the effect of a cognitive behavioral self help intervention for insomnia. It will be tested if internet delivered self-help differs from self-help via a booklet.

## **Study design**

This study has an experimental design; the type of self help will be manipulated (internet / paper) The effects on insomnia, sleep quality and mental complaints will be measured. Participants are randomly assigned to one of the three conditions: two experimental (self-help / self-help with therapist interaction), and one control (waiting list). After twelve weeks the control group also gets a self-help intervention.

## **Intervention**

In this study all participants finally will receive a 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). One condition will in addition to that receive minimal therapist support.

## **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

Access to internet

A valid e-mail address

### **Exclusion criteria**

Severe Depression

Being suicidal

Schizophrenic or having a psychosis episode

Regular cannabis use

Alcohol abuse

Sleep apnea

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Health services research

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2009
Enrollment:	626
Type:	Actual

## Ethics review

Approved WMO	
Date:	16-12-2008
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

CCMO

### ID

NL22501.041.08