

A guided web-based intervention for insomnia: a pilot study

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As part of the development of the guided web-based self-help intervention for insomnia we want to conduct a pilot study. The aim is twofold: (1) we want to know how satisfied people are with this course. Specific questions are: what are the...

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

Summary

ID

NL-OMON32913

Source

ToetsingOnline

Brief title

A guided web-based intervention for insomnia

Condition

- Sleep disorders and disturbances

Synonym

insomnia, sleep disorders

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Keyword: cognitive-behavioral treatment, insomnia, Internet, self-help, sleep initiation and maintenance disorders, treatment

Outcome measures

Primary outcome

The main focus in this pilot study is to learn from the experience of the participants in order to improve our course. We will focus on the website (navigation through the course etc) as well as on the course (is the information clearly presented, are the exercises useful etc). To explore these topics all participants will be sent a questionnaire after they finished the intervention.

Secondary outcome

The second aim of the study is to determine possible effects. We will measure: (1) sleep estimates such as sleep efficiency, sleep onset latency, total sleep time, sleep quality, use of benzodiazepines; (2) subjective evaluation of the severity of the insomnia (3) fatigue (4) anxiety (5) depression (6) quality of life.

Study description

Background summary

Insomnia is a common problem: about one third of the general population suffers from one or more symptoms [1]. About 10% of the general population suffers from daytime consequences due to these symptoms, including daytime fatigue, difficulties in cognitive performance, mood swings and psychological distress [1*2]. Insomnia often leads to a reduced quality of life, a diminished work productivity and absenteeism. Furthermore, it is frequently associated with other physical and psychiatric conditions.

Treatment usually consists of prescribing benzodiazepines. Unfortunately, there are a number of important side effects associated with use of hypnotics such as confusion, falls, traffic accidents and cognitive decline. The GP guidelines therefore recommend to refrain from prescribing sleep medication. However, there are no good alternatives. Even though research has indicated that face-to-face sleep therapy (based on cognitive behavioral therapy) is at least as effective as benzodiazepines, sleep therapists are almost unavailable in the Netherlands.

Therapists in other countries (US, UK, Sweden) have converted this sleep therapy in selfhelp format (book or Internet). A recent meta-analysis demonstrated that these selfhelp therapies are effective in reducing sleep problems. Selfhelp therapies might enhance access to evidence-based sleep therapy.

Study objective

As part of the development of the guided web-based self-help intervention for insomnia we want to conduct a pilot study. The aim is twofold: (1) we want to know how satisfied people are with this course. Specific questions are: what are the characteristics of the users? What is the drop-out rate? Which elements of the course are most useful? And which elements are least useful? (2) We like to have some indication of possible effects. Specific questions are: is there a reduction in sleeping problems? Is there a reduction in the use of sleep medication?

Based on the experience of the participants we will optimise the intervention.

Study design

We will perform a randomised trial (RCT). We will recruit 100 participants through newspapers and Internet. Participants will be randomly assigned to: the web-based intervention or a waiting list. Participants are asked to fill out a baseline questionnaire and follow up measurements will take place 6 and 13 weeks thereafter. Participants on the waiting list can start the intervention after the last follow up measurement.

Intervention

The course will be offered through the Internet and consists of 6 weekly lessons. The following topics will be discussed: psycho-education, sleep hygiene, improve sleep-wake rhythm, rumination, relaxation, and dysfunctional cognitive thoughts. The course consists of information and exercise. A coach will give weekly feedback through e-mail.

Study burden and risks

n/a

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

18 years and older

sleep problem (at least 3 nights a week awake for 30 minutes per night or more for at least 3 months)

Exclusion criteria

severe symptoms of anxiety or depression

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): | 01-05-2010 |
| Enrollment: | 100 |
| Type: | Actual |

Ethics review

| | |
|--------------------|--------------------|
| Approved WMO | |
| Date: | 25-11-2009 |
| Application type: | First submission |
| 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

ID: 27579

Source: Nationaal Trial Register

Title:

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL29947.029.09 |
| OMON | NL-OMON27579 |