(Cost-)effectiveness of a guided online CBT intervention in comparison to care-as-usual for patients with insomnia in general practice

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Primary Objective: To determine the effectiveness of guided CBT compared to care-as-usual in treating insomnia in the general practice.Secondary Objective(s): Secondary objectives include investigation of cost-effectiveness. Several variables will...

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

Summary

ID

NL-OMON44867

Source
ToetsingOnline

Brief title
(Cost-)effectiveness of guided online CBT for insomnia

Condition

- Sleep disorders and disturbances

Synonym
Insomnia, sleeplessness

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Faculteit Gedrags- & Bewegingswetenschappen,

afdeling Klinische Psychologie
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: insomnia CBT treatment guided selfhelp online

Outcome measures

Primary outcome

Insomnia Severity Index. See section 8 of the research protocol for more information.

Secondary outcome

Sleep estimates derived from the sleep diary, multiple measures of daytime functioning, fatigue, anxiety and depression, and quality of life. Moreover, we will estimate health care costs. See section 8 of the research protocol for more information.

Study description

Background summary

In the Netherlands, most patients that refer to their GPs with sleeping problems receive medication. Behavioral interventions (psycho-education, cognitive behavioral therapy) are known to be more effective, but are not often offered. The present proposal is focussed around an online course (5 sessions) aimed at treating insomnia.

Study objective

Primary Objective:
To determine the effectiveness of guided CBT compared to care-as-usual in treating insomnia in the general practice.

Secondary Objective(s):
Secondary objectives include investigation of cost-effectiveness. Several variables will be included as potential moderators of treatment effects, e.g.

age, medication use, duration of the sleep problem, and alcohol use.

Study design

The proposed study entails a randomized controlled intervention study with two conditions:
(1) the E-health intervention supported by psycholgical wellbeing practitioners (PWPs), (2) care-as-usual*. The control group will
gain access to the intervention six months after inclusion.

* Care-as-usual:
In July 2014 an updated version of the Dutch guideline for insomnia in general practice was published (Workgroup Insomnia NHG, 2014). We will provide the participating GPs in our study with a written version of the new guideline (which is also available online as is usual after publication of a guideline). The guideline distinguishes specific sleep disorders (such as sleep apnea and restless leg syndrome) from the DSM-5 Insomnia Disorder. The guideline estimates that 90% of the people presenting with sleep problems suffer from insomnia disorder, rather than from any other specific sleep disorder. The core message of the guideline is formulated as:

(1) the preferred insomnia treatment is non-pharmacological,
(2) the GP might consider medication in exceptional situations, and only short term,
(3) the preferred treatment for short-term sleep problems is psycho-education and information about sleep hygiene,
(4) for longer term sleep problems the preferred treatment is a combination of stimulus-control, sleep restriction, relaxation and structured exercise.

The patients in the usual-care (control) group might be treated within the GP practice (either by GP or PWP), be referred to specialized sleep courses (practically unavailable in the Netherlands) or be referred to the website of Teleac where patients can purchase a self-help book (including video material, but unguided). We will not interfere with the usual care that the individual GPs offer their patients. It must be noted that even though previous guidelines also advised to refrain from medication this is still the most offered treatment for insomnia although there is a high practice variation.

More information can be found in the study protocol, chapter 4.E.

Intervention

The intervention under study, developed at the VU university, is a 5-week CBT-based program consisting of psycho-education, sleep hygiene, sleep restriction, stimulus control, and cognitive restructuring (tackling worrying and promoting relaxation). A Psychological Wellbeing Practitioner (PWP, Dutch:

POH-GGZ) will offer guidance and feedback to increase motivation and adherence.

Study burden and risks

The sole burden of participation in this trial will be adhering to the program, i.e. completing homework assignments and questionnaires. No physical or physiological fatigue associated with participation is expected. There are no known risks associated with the investigational treatment.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- diagnosis of insomnia (DSM5)

- >18 years of age
- Dutch proficiency
- access to a computer and the internet

Exclusion criteria

- presence of sleep apnea
- patients working night shifts
- preganancy or breast feeding
- current suicidal ideation
- current psychosis
- currently undergoing psychological treatment

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:	Recruitment stopped
Start date (anticipated):	19-11-2015
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	15-09-2015

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-04-2017
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL51849.029.15
Other	NTR (TC=5202)