Een internetinterventie voor mensen met slaapproblemen.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27579

Source
NTR

Health condition

sleepproblems
insomnia
slaapproblemen
slapeloosheid

Sponsors and support

Primary sponsor: VU university
Source(s) of monetary or material Support: Nuts-Ohra

Intervention

Outcome measures

Primary outcome

Sleep diary (sleep onset latency, total sleep time, sleep efficiency, sleep quality).

Secondary outcome

1. Insomia severity;

2. Fatigue;

3. Depressive symptoms;

4. Anxiety symptoms;

5. Quality of life.

Study description

Background summary

Insomnia is very prevalent. About 33% of the population suffers from one or more symptoms. Treatment usually consists of sleepmedication which has a number of important drawbacks. Cognitive-behavioral therapy is at least as effective but is seldomly offered because it is not available. We developed an internet intervention based on the usual CBT face-to-face treatment. In this pilot study we want to examine (1) feasibility and (2) effectiveness.

Study objective

In this pilot study we test the feasibility and effectiveness of a internet based intervention for sleep problems.

Study design

Baseline, 6 and 13 weeks.

Intervention

Intervention:

The intervention, which is based on existing psychological treatment for sleep problems, will be offered through the Internet. It focuses on the following elements: (1) psycho-education about sleep and sleep disorders (2) stimulus-control (only going to bed when tired, getting out of bed at the same time every day) (3) sleep restriction (reduction of the time spent in bed to the average number of hours slept) (4) sleep hygiene (information about helpful and harmful daily habits) (5) relaxation, and (6) cognitive restructuring (modifying dysfunctional beliefs about sleep and insomnia). The intervention consists of 6 weekly lessons. In every lesson the patients finds new information and is asked to do homework. The patients will receive online feedback on this homework by coaches.

Control:
There is a waitlist control group. The people in the control group will receive the internet intervention 3 months after randomization (after the follow-up measurement).

Contacts

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Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Having sleep problems (being awake for at least 30 minutes a night, for at least 3 nights a week, for at least 3 months).

Exclusion criteria

Very high scores on depression or anxiety questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-12-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32913
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2015
NTR-old	NTR2132
CCMO	NL29947.029.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32913

Study results

Summary results
N/A