

Treatment of chronic insomnia via a Smartphone application

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28062

Source

Nationaal Trial Register

Sponsors and support

Source(s) of monetary or material Support: This study was funded by Philips and Technology Foundation STW, Nationaal Initiatief Hersenen en Cognitie NIHC under the Partnership program Healthy Lifestyle Solutions.

Intervention

Outcome measures

Primary outcome

Insomnia Severity Index (ISI), Dysfunctional beliefs about sleep (DBAS), Anxiety (HADS), Depression (CES-D), Sleep (PSQI)

Secondary outcome

Secondary Outcomes: sleep diary (average total sleep time, sleep efficiency)

Study description

Study objective

About 10-15% of the population suffers from chronic insomnia. Structurally poor sleep can have unpleasant consequences for people's health and quality of life. Therefore, proper treatments are of great importance. Fortunately, Cognitive Behavioral Therapy for Insomnia (CBT-I) shows long-term effects. This study researches whether CBT-I can also be offered via a Smartphone application.

Health Conditions or Problems studied: Insomnia, Sleep disorder, Insomnie, Slaapprobleem, Cognitive Behaviour Therapy for Insomnia

Study design

pre-measure (week 0), post-measures (week 7), 3-month follow-up

Intervention

The therapy for insomnia is presented through a smartphone. The therapy consists of a) relaxation exercises, b) sleep hygiene, c) registering the own sleep, and d) sleep restriction. The lessons can be done in six weeks. Participants will have seven weeks to complete the training. The app will send reminders for the exercises, and adjust the exercises if needed.

Contacts

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Eligibility criteria

Inclusion criteria

insomnia according to DSM-5, at least 18 years old, stable medication, valid e-mail address, internet connection, Android (version 4.2 or higher) Smartphone

Exclusion criteria

On average less than five hours of sleep reported in the online sleep diary (pre-measure), ISI score below 7 previous cognitive behavioral therapy for insomnia, start psychotherapy in the last six months, psychosis / schizophrenia, alcohol or drug abuse, complaints indicating sleep apnea, shiftwork, women who are pregnant or breastfeeding, current depressive episode

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	180
Type:	Actual

Ethics review

Positive opinion

Date: 26-08-2015
Application type: First submission

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
NTR-new	NL5426
NTR-old	NTR5560
Other	: 2014-CP-3798

Study results