The SMILE study:Sleep Mood Intervention: Live Effectively a group intervention in students with sleep problems

No registrations found.

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

Summary

ID

NL-OMON24628

Source
Nationaal Trial Register

Brief title
SMILE

Health condition

Sleep; mood; negative thoughts; slaap; stemming

Sponsors and support

Primary sponsor: Leiden University (Clinical Psychology)
Leiden Treatment and Expertise Center (Leiden Universitair Behandeling en Expertise Centrum)
Source(s) of monetary or material Support: Clinical Psychology dept. of Leiden University

Intervention

Outcome measures

Primary outcome

1. Insomnia Severity Index

2. Subjective sleep quality (as assessed with a sleep diary).

Secondary outcome

1. Objective sleep quality and quantity (as assessed with actigraphy); outcomes typically involve sleep efficiency, total sleep time, sleep onset latency and wake time after sleep onset.

2. Self-reported depressive symptoms (Beck Depression Inventory, BDI)

3. Self-reported anxiety symptoms (Hospital Anxiety and Depression scale – Anxiety Subscale, HADS-A)

4. Self-reported quality of life (Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form, Q-LES-G-SF)

6.1.3 Other study parameters (if applicable)

Covariates: Demographic characteristics (age, gender), ethnicity, medication use, alcohol use, smoking, relationship status, children in household will be assessed at baseline via online questions.

Mediators: Ecological Momentary Assessments (positive /negative affect, alertness and fatigue). Online questionnaires: Dysfunctional Beliefs and Attitudes about Sleep (DBAS) and Pre-Sleep Arousal Scale (PSAS).

Study description

Background summary

We created a multi-component intervention which combines different therapeutic elements in order to improve the sleep quality and mood of students. The intervention includes four 2-hour sessions (in groups of 6 participants). During the sessions we target a range of issues including: sleep hygiene, negative thoughts, worrying, stress and arousal, relaxation techniques, as well as perfectionistic tendencies, time planning and burnout. The aim is to

give students ‘a bag of psychological tools’ to improve their sleep habits, mood and quality of life. The study design is a randomized-controlled trial, where participants are randomized to either the intervention group or to a waiting-list control group that receives the intervention at a later time point. Assessments include online questionnaires, but also ecological momentary assessments (mobile phone app questions that participants can answer in real time about their mood, energy levels, etc.) Participants will also wear a watch that measures activity and sleep quality before and after the intervention/waiting list.

Study objective

The aim is that the SMILE intervention, combining cognitive-behavioural therapy for insomnia, mindfulness, stress, and lifestyle components will improve sleep quality, mood and quality of life and prevent onset of depression, anxiety in the long run.

Study design

3 timepoints (pre-, post- and follow-up (6 months).

Intervention

Group therapy vs. waiting list

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Self-reported sleep complaints (ISI score of >=10).

2. Currently enrolled as a student.

3. Aged 18-years or older.

4. Adequate proficiency in both written and spoken English.

5. Willingness to participate in a four-week group intervention program

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

6. No self-reported severe sleep complaints (ISI score of <10).

7. The presence of clinically significant psychopathology (as based on DSM IV criteria from the psychiatric interview); exclude current disorders: Major Depressive Disorder, Bipolar Disorder, Panic disorder, Social Anxiety Disorder, Post-traumatic Stress Disorder, Attention Deficit Hyperactivity Disorder, Eating disorders and Psychotic disorders.

8. The presence of a sleep disorder (incl. narcolepsy, sleep apnea).

9. The presence of an acute somatic (physical) illness that may interfere with the intervention.

10. Current use of medication known to influence sleep (hypnotics, anxiolytics, recent onset of antidepressants, stimulants). When treatment with an antidepressant has started more than 3 months prior to study entry and dosage remains stable participants can be included.

11. Current substance use dependence.

12. Concurrent psychotherapy (CBT, including past CBT for sleep or depression).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-09-2018
Enrollment:	72
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46359
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7284
NTR-old	NTR7516
CCMO	NL64330.058.17
OMON	NL-OMON46359

Study results