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

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This is the first study to create and investigate the effectiveness of a multi-component intervention protocol in students with sleep problems. The aim is that such an intervention, combining cognitive-behavioural therapy for insomnia, mindfulness,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON46359

Source
ToetsingOnline

Brief title
The SMILE study

Condition

- Sleep disorders and disturbances

Synonym
sleep problems

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: mood, sleep, students, therapy

Outcome measures

Primary outcome

The primary outcome will be improvement in self-reported sleep parameters (Insomnia Severity Index and sleep diary).

Secondary outcome

Secondary outcomes will be: improvement in objective sleep measures (actigraphy) at posttest. Depression, Anxiety symptoms, as well as quality of life both at post-test and follow-up. Mediators: Cognitions about sleep and arousal; ecological momentary assessments will be analysed to examine which aspects (e.g. mood, fatigue) improved during the intervention.

Study description

Background summary

It is well established that students suffer from a variety of sleep problems and are at an age group which has a high risk of developing psychological disorders. Sleep problems also proceed full-blown manifestations of depression and anxiety disorders.
Several protocols have been developed to improve sleep problems, from sleep education to cognitive behavioral therapy for insomnia. No single prevention protocol in students so far has integrated and addressed a range of problems (e.g. sleep, mood, lifestyle, stress). Such factors are interrelated in the daily lives of students and are likely to cause a vicious circle.

Study objective

This is the first study to create and investigate the effectiveness of a multi-component intervention protocol in students with sleep problems. The aim

is that such an 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 sleep disorders but also depression and anxiety disorders in the long run.

Study design

Randomized-controlled trial

Study burden and risks

No risks are expected and foreseen from participating in this research. The only burden is time that participants spend on assessments and intervention. Participants are free to withdraw at any point.

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

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

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2018

Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 24628
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64330.058.17
OMON	NL-OMON24628