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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24628

Bron
Nationaal Trial Register

Verkorte titel
SMILE

Aandoening

Sleep; mood; negative thoughts; slaap; stemming

Ondersteuning

Primaire sponsor: Leiden University (Clinical Psychology)
Leiden Treatment and Expertise Center (Leiden Universitair Behandeling en Expertise Centrum)
Overige ondersteuning: Clinical Psychology dept. of Leiden University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Insomnia Severity Index
2. Subjective sleep quality (as assessed with a sleep diary).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Group therapy vs. waiting list

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-09-2018
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46359
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten