A study on the effectiveness of a guided e-health sleep and biological clock intervention in university students (i-Sleep & BioClock)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53645

Source
ToetsingOnline

Brief title
i-Sleep & BioClock for students

Condition

- Other condition

Synonym
Sleeping problems

Health condition

Insomnia, slaapstoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO (the Netherlands Organisation for Scientific Research)

Intervention

Keyword: CBTi, effectiveness, randomized controlled trial, university students

Outcome measures

Primary outcome

The primary outcome will be insomnia severity (Insomnia Severity Index).

Secondary outcome

Secondary outcomes will be depression (PHQ-9), anxiety (GAD-7), daily functioning (WSAS), quality of life (MHQoL), and sleep & light exposure diary outcomes. Outcomes will be measured at baseline, at post-treatment (6 weeks after baseline), and at 4.5 months follow-up. Mediators such as shift in chronotype and light exposure will be examined at baseline, mid-treatment and post-treatment.

Study description

Background summary

University students often suffer from sleep problems which affect their mood, energy levels, daily functioning, and quality of life. Irregular sleep-wake patterns contribute to the disruption of their circadian rhythms. Recent systematic reviews have found strong associations of insomnia with mental disorders, such as depression and anxiety. When untreated, persistent insomnia also increased the risk of suicidal ideation. University students are an especially vulnerable group as their age group is the most common for the onset of several mental health disorders, which is why early preventative

interventions are crucial in this population. Although CBTi interventions have been proven effective in adults, research in university students is still limited.

Study objective

The aim of this randomized controlled trial is to assess the effectiveness of a guided e-health sleep and biological clock intervention on sleep, mental health symptoms (depression and anxiety), functioning, and quality of life in university students.

Study design

Randomized controlled trial

Intervention

The *i-Sleep & BioClock* intervention for students is based on the i-Sleep intervention which was developed by Prof. Annemieke van Straten and Dr. Jaap Lancee. The intervention was developed based on the existing literature and uses evidence-based techniques (cognitive behavioural therapy for insomnia). We adapted i-Sleep to the specific needs of university students and added elements of the biological clock (e.g. light exposure and timing of exercise and meals). The new version of the intervention was named i-Sleep & BioClock and it consists of five modules:

(1) psychoeducation on insomnia, the biological clock, and sleep hygiene,
(2) stimulus control and sleep restriction,
(3) worrying and relaxation,
(4) cognitive therapy to change dysfunctional thoughts about sleep, and
(5) summary module, relapse prevention, and plan for the future.

The modules consist of text, question boxes, exercises, and audio-visual components (e.g. summary video*s and relaxation audio*s). Each module lasts about 30 to 60 minutes and it is recommended to complete one module per week. Therefore, the duration of the i-Sleep & BioClock intervention will be approximately 5 weeks. In addition, students are asked to keep daily record of their sleep and light exposure habits in form of a diary.

Study burden and risks

This study involves a low-risk intervention. Research has shown that self-guided CBT interventions have a lower rate of negative outcomes on symptoms than control conditions. We expect the chance of severe incidents occurring as very unlikely. No adverse events have been reported in a previous trial examining the effectiveness of i-Sleep among depressed adults with

insomnia. We want to emphasize again that participation is completely voluntary and participants can always withdraw consent if they feel impaired by the intervention. Appropriate protocols are in place in case of crisis situations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Being fluent in Dutch and/or English
- Being enrolled as a student (Bachelor, Master or PhD) in one of the Caring Universities partner universities
- Being >= 16 years old
- Having self-reported sleep problems; Insomnia Severity Index >= 10

Exclusion criteria

- Presence of current suicidal ideation
- Not being able to adhere to the intervention guideline due to regular night shifts (at least once per week)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	192
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-07-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL83395.058.23