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Effects of a sleep program on sleep, performance and health in university students

Submission date
07/10/2025

Recruitment status
Not yet recruiting

Registration date
15/10/2025

Overall study status
Ongoing

Last Edited
13/10/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Insomnia is highly prevalent among university students and is linked to impaired mental and physical health, cognitive performance, and academic outcomes. Existing treatments, such as CBT-I, are effective but often inaccessible and difficult to scale. This study aims to evaluate the effectiveness of a pragmatic, group-based sleep program in improving sleep quality, reducing insomnia symptoms, and enhancing health, cognitive functioning, and academic performance over 12 months.

Who can participate?
Full-time university students aged 18–30 years who meet diagnostic criteria for chronic insomnia disorder.

What does the study involve?
Participants will be randomly allocated to either the intervention group (group-based sleep program) or a wait-list control group. The program consists of 12 weekly 90-minute group sessions, followed by monthly follow-up meetings for nine months. Data will be collected at baseline, 12weeks and 12 months, including self-reported questionnaires, sleep diaries, activity monitoring (ActivPAL), a reaction-time test (PVT), and optional blood samples for biomarker analysis.

What are the possible benefits and risks of participating?
Participants may improve their sleep, health, cognitive function, and academic performance. Risks are minimal; some may experience temporary fatigue or discomfort when applying behavioral strategies such as sleep restriction. No medical treatments or medications are administered.

Where is the study run from?
The University of South-Eastern Norway (USN), Campus Vestfold, Norway.

When is the study starting and how long is it expected to run for?
The trial is expected to start in 2026 and will run until 2031, including follow-up and data analysis.

Who is funding the study?
The USN (Universitetet i Sørøst-Norge, Notodden), Norway.

Who is the main contact?
Associate Professor Eivind Andersen, USN, eivind.andersen@usn.no

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1326

Study information

Scientific Title
Effects of a sleep program on sleep, performance and health in university students

Study objectives
The primary aim is to determine whether the program improves sleep outcomes among students with chronic insomnia.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 07/10/2025, Regional Committees for Medical and Health Research Ethics (Kongens gate 14, Oslo, 0153, Norway; +47 98 20 32 23; post@forskningsetikk.no), ref: 950880

Study design
Pragmatic two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia

Interventions
This study is a pragmatic two-arm randomised controlled trial to assess the short- and long-term effects of a sleep program on students with insomnia in a Norwegian University.

The intervention is a pragmatic, group-based sleep program for university students with insomnia. It runs over 12 weekly 90-minute sessions, followed by monthly group meetings for nine months (one year in total). Groups (≈20 students) are led by trained coaches in an interactive, discussion-based format emphasizing autonomy, collaboration, and peer learning. The program integrates principles from CBT-I, Self-Determination Theory, and Stress and Coping Theory, aiming to build intrinsic motivation, strengthen self-regulation skills, and provide relapse-prevention strategies.

Session themes include:
Sleep mechanisms and health
Sleep disorders and causes
Sleep diary & goal setting
Sleep hygiene
Sleep restriction
Stimulus control
Physical activity and diet
Stress, anxiety, depression
Relaxation techniques
Light therapy and complementary methods
Cognitive techniques (thought reframing)
Summary, consolidation, and maintenance planning

Sessions combine short inputs, reflection, peer discussion, and homework tasks (e.g., sleep diaries, stimulus control, relaxation). The self-help book "Better Sleep" complements the program.

The maintenance phase (monthly follow-ups) focuses on relapse prevention, sustaining motivation, and peer support.
Comparison group

A wait-list control group will receive the program after completing a 12-month follow-up. All participants receive a basic sleep-hygiene leaflet at baseline; co-interventions will be recorded.

Participants will be randomly allocated to the intervention group or the waiting list comparison group in a 1:1 ratio. The method of randomised permuted blocks will be used, with random block lengths (4 or 6).

Intervention Type
Behavioural

Primary outcome(s)
Insomnia severity is measured using the Bergen Insomnia scale (BIS) and the Insomnia Severity Index at baseline, 12 weeks and 12 months. A seven-day sleep diary is used to derive standard continuity and timing metrics, including sleep onset latency (SOL), wake after sleep onset (WASO), time in bed (TIB), total sleep time (TST), sleep efficiency (SE = TST/TIB × 100), and sleep midpoint/bed- and rise-times.

Key secondary outcome(s))
All secondary outcome measures are assessed at baseline, 12-weeks and 12-month follow-up, unless stated:
1. Mental health and wellbeing are measured using the Patient Health Questionnaire, Generalized Anxiety Disorder – 7 items, Perceived Stress Scale, World Health Organization – Five Well-Being Index and EuroQol 5 Dimensions – 5 Levels
2. Cognitive function is measured using the Psychomotor Vigilance Task
3. Academic attainment is obtained from university records for periods overlapping post-programme and 12-month follow-up
4. Free-living physical activity, PA and sedentary time, will be assessed using the activPAL monitor (model activPALTM micro; PAL Technologies Ltd, Glasgow, UK) and the International PA Questionnaire Short Form
5. Diet and beverages screener captures frequency of sugar-sweetened beverages/energy drinks, estimated daily caffeine intake from coffee/tea/energy drinks, fruit/vegetable intake, breakfast frequency, and late-evening eating
6. Alcohol and drug use are measured using the Alcohol Use Disorders Identification Test and Drug Use Disorders Identification Test
7. Tobacco and snus use is recorded using the Fagerström Test for Nicotine Dependence
8. Height is measured using a stadiometer, weight with a calibrated scale, and waist circumference is measured using a measuring tape (midpoint between the lowest rib and the iliac crest at end-expiration)
9. Resting blood pressure is measured with an automated sphygmomanometer
10. Body composition is assessed by bioelectrical impedance
11. Maximal oxygen uptake (VO2max) will be assessed through a maximum exercise test on a treadmill. Gas exchange will be continuously sampled in a mixing chamber every 30 s by having the subjects breathe into a Hans Rudolph two-way breathing valve (2700 series, Hans Rudolph Inc., Kansas City, USA). The breathing valve is connected to a Vyntus CPX (Vyaire Medical, Illinois, USA), which is used to analyze the oxygen and carbon dioxide content.
12. Biomarkers: Salivary cortisol is used to characterise hypothalamic–pituitary–adrenal (HPA) axis dynamics via the cortisol awakening response (CAR) and diurnal slope from timed samples (awakening, +30, +45 min, and evening); analysis yields AUCi and slope parameters, with adherence windows prespecified. Fasting serum/plasma analytes include low-grade inflammation (high-sensitivity C-reactive protein [hs-CRP], IL-6, Tumor Necrosis Factor alpha (TNF-α)), glycaemia (glucose, HbA1c), insulin secretion/resistance, lipids (total cholesterol, HDL, LDL, triglycerides), thyroid function (TSH, free T4), prolactin, and BDNF. Samples are processed with accredited methods under a unified SOP. Pre-analytic conditions (morning, fasted;

avoidance of vigorous exercise/caffeine/alcohol beforehand) are standardised and documented to reduce variability. Samples are stored at 4°C and processed within 24h, and then frozen at -80° C.

Completion date
31/12/2031

Eligibility

Key inclusion criteria
1. Meet the criteria for chronic insomnia disorder based on the Bergen insomnia scale (BIS)
2. Student at the University of southeast Norway (USN), campus Vestfold, with at minimum of two years remaining in your studies
3. Aged 18-30
4. Understand and speak a Scandinavian language
5. Consent to randomisation

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Key exclusion criteria
1. Receiving pharmacological or non- pharmacological treatment for sleep problems
2. Sleep apnea, restless legs or periodic limb movements, because this may suggest that other sleep disorders may explain the insomnia symptoms
3. Unstable or severe medical/neurological conditions that substantially affect sleep
4. Current nightshift or rotating-shift work (≥1 night shift per week within the past month or anticipated during the trial)
5. Moderate or severe mental illness
6. Moderate or severe health issues related to their insomnia diagnosis
7. Having children
8. Pregnancy

Date of first enrolment
01/05/2026

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
Norway

Study participating centre
University of South-Eastern Norway
Raveien 214
Borre
Norway
3184

Sponsor information

Organisation
University of South-Eastern Norway

ROR
https://ror.org/05ecg5h20

Funder(s)

Funder type
University/education

Funder Name
Universitetet i Sørøst-Norge

Alternative Name(s)
University of South-Eastern Norway, The University of South-Eastern Norway, Universitetet i Sørøst-Norge, Notodden, USN

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

Norway

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from:
Project leader: Eivind Andersen, Associate Professor, University of South-Eastern Norway (USN)
Email: eivind.andersen@usn.no

Type of data to be shared:
De-identified participant-level data (questionnaire responses, sleep diaries, activity monitor data, cognitive test results, and biomarker data for those who consent). Metadata, codebooks, and statistical syntax files will also be available.

When the data will be available:
Data will be available after publication of the main trial results and up to 5 years after project completion (December 2030).

Access criteria and with whom data will be shared:
Data will be shared with qualified researchers affiliated with academic or public health institutions, upon submission of a reasonable research proposal and data use agreement.

For what types of analyses:
Secondary analyses related to sleep, health, lifestyle, stress, coping, and related behavioural or physiological outcomes.

By what mechanism:
Requests should be directed to the project leader. Approved users will receive access to de-identified datasets via USN's secure research data repository.

Consent from participants:
Informed consent includes permission for data to be stored in de-identified form and shared with other researchers for secondary analyses.

Data anonymisation:
All data will be pseudonymised (ID code replacing personal identifiers). The key linking participants to ID codes will be stored separately and destroyed after project completion.

Ethical and legal restrictions:
Data handling complies with GDPR and the Norwegian Health Research Act. Only de-identified data will be shared, and transfer will require a signed data access agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			13/10/2025	No	No