ISRCTN55077169 https://doi.org/10.1186/ISRCTN55077169

Better sleep, better health: designing a school-based intervention in Uganda

Submission date
05/05/2025

Recruitment status
No longer recruiting

Registration date
06/05/2025

Overall study status
Ongoing

Last Edited
06/05/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Maintaining good sleep health, which encompasses behavioral and environmental practices that promote healthy sleep, is crucial for adolescents. The National Sleep Foundation and the American Academy of Sleep Medicine recommend that adolescents ideally obtain 8 to 10 hours of sleep per night for optimal health and functioning. However, research on sleep duration and sleeping difficulties in adolescents indicates that less than half achieve at least 8 hours and consequently, the majority of adolescents may be chronically sleep deprived.

School-based sleep health interventions have demonstrated effectiveness in improving sleep duration, quality, and awareness in high-income countries, including educational components on sleep hygiene, modifications to school policies and cognitive-behaviour therapy for insomnia (CBT-I). CBT-I is a comprehensive treatment approach that includes sleep hygiene education, stimulus control, sleep restriction, cognitive strategies, and relaxation techniques. It is the recommended first-line treatment for individuals with insomnia disorder including adolescents. Studies have shown that cognitive-behavioural techniques can effectively enhance adolescent sleep, while proper sleep hygiene acts as a protective factor. There is little data on the feasibility and acceptability of evidence-based sleep interventions for adolescents in low-resource settings.

In this study, we aim to assess the feasibility and acceptability of a sleep health intervention among adolescents in Ugandan schools using a mixed-methods approach, incorporating both school-level components such as sleep education sessions and structural changes to noise/light and school start times. Individual-level components, including CBT-I and completing sleep daily dairy. We addressed this aim through the following research questions.
1. How were the school and individual level intervention components implemented (focusing on fidelity, dose and reach)?
2. What is the feasibility and acceptability of implementing school level sleep interventions among school-going adolescents?
3. What is the preliminary effectiveness of the intervention on dimensions of sleep health, dysfunctional beliefs about sleep and mental health among participants with moderate or severe insomnia?

Who can participate?
Students in two selected secondary school in Wakiso District, Uganda.

What does the study involve?
Participants will be screened with tools including the Insomnia Severity Index (ISI) and UNICEF Measurement of Mental Health Among Adolescents at the Population Level (MMAP). All participants will be offered school-level sleep education session and there will be structural changes to school sleep schedules. Participants who screen positive for insomnia (ISI>15) will be invited to five weekly group CBT-I sessions led by psychologists. A subset of students, and teachers and parents, will be invited to participate in in-depth interviews and focus group discussions.

What are the possible benefits and risks of participating?
Benefits include potential improvement of sleep health and mental health symptoms. There are no risks of participating.

Where is the study run from?
The London School of Hygiene & Tropical Medicine (LSHTM) (UK), and the MRC/UVRI & LSHTM Uganda Research Unit, Entebbe, Uganda.

When is the study starting and how long is it expected to run for?
May 2024 to August 2025

Who is funding the study?
UK Medical Research Council

Who is the main contact?
Professor Helen Weiss, LSHTM, helen.weiss@lshtm.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Helen Weiss

ORCID ID
https://orcid.org/0000-0003-3547-7936

Contact details
LSHTM, Keppel Street
London
United Kingdom
WC1E 7HT
+44 7905070739
helen.weiss@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MR/Z503794/1

Study information

Scientific Title
Feasibility, acceptability and preliminary effectiveness of a sleep health intervention to improve insomnia among Ugandan secondary school students: A pilot one-arm intervention trial

Study objectives
A school-based sleep health intervention is feasible and acceptable in Ugandan secondary schools

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/03/2024, Uganda Virus Research Institute (Plot 51-59, Nakiwongo Road, Entebbe, Uganda, Uganda; +256 414 320 385; directoruvri@uvri.go.ug), ref: GC/127/819

Study design
Single-centre one-arm interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
School

Study type(s)
Prevention, Quality of life, Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Screening and treatment for insomnia among secondary school students in Uganda

Interventions
Cognitive behaviour therapy for insomnia (CBT-I): Students in two secondary schools in Wakiso District, Uganda, were screened for sleep and mental health conditions, using the Insomnia Severity Index (ISI) and Measurement of Mental Health Among Adolescents at the Population Level (MMAP) tools. Students who screened positive for insomnia (ISI greater or equal to 15) were offered five weekly group sessions of psychologist-delivered cognitive behaviour therapy for insomnia (CBT-I). These participants were asked to re-complete the baseline tools immediately after the intervention (T1), and 3 months later (T2).

Sleep education sessions: The team delivered sleep education sessions to three groups of participants: i) students (all female and males in S2 and S3), ii) all teachers who were available in schools and willing to attend and iii) parents of students in S2 and S3. Topics covered included an introduction to sleep, its importance for adolescents, how sleep improves well-being and academic performance, and ways to improve sleep health habits. Additionally, sleep awareness posters were designed and delivered to each school. These contained information on the basics of sleep-including recommended sleep hours, the benefits for physical and mental health, how sleep improves learning, and strategies to improve sleep, such as diet, lifestyle and nighttime routines.

Structural changes: The team supported schools in adjusting their school schedules, recommending changes to sleep and wake times, reducing the duration of evening prep sessions and delaying the school morning start time later to better align with recommended national school schedule guidelines and sleep durations for adolescents. These changes aimed to ensure that students had sufficient rest before beginning their daily academic activities. In addition, we implemented structural improvements to enhance the sleep environment. These included the installation of dim lightbulbs in dormitories to reduce exposure to bright artificial light at night, which can interfere with the natural sleep cycle. To address nighttime temperatures and improve comfort, we installed fans in school dormitories, creating a cooler environment, which is beneficial for sleep.

Each CBT-I participant received a CBT-I workbook, which contained exercises and notes to guide them through the sessions, as well as a sleep diary booklet to track their sleep patterns and daytime habits. Participants were asked to self-complete the diaries daily for five weeks, capturing data on sleep duration, sleep disturbances, caffeine consumption, mood fluctuations, and physical exercises. The clinical psychologists were supervised by a senior clinical psychologist every two sessions (or every two weeks) through review and progress meetings. These meetings aimed to troubleshoot challenges and make necessary adjustments to the intervention.

Intervention Type
Behavioural

Primary outcome measure
Insomnia, measured by the insomnia severity index (ISI) at baseline, 6 weeks and 3 months

Secondary outcome measures
1. Depression symptoms, measured by the PHQ-9 from the MMAP tool at baseline, 6 weeks and 3 months
2. Anxiety symptoms, measured by the GAD-7 from the MMAP tool at baseline, 6 weeks and 3 months

Overall study start date
28/05/2024

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Schools were eligible to participate if they were mixed-sex schools and had participated in a school-based cluster-randomised trial of a menstrual health intervention with approximately 40 Secondary 3 female students (from trial endline data), with day and boarding students.

Participant type(s)
Learner/student

Age group
Child

Lower age limit
13 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
350

Total final enrolment
358

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
07/07/2024

Date of final enrolment
27/02/2025

Locations

Countries of recruitment
Uganda

Study participating centre
MRC/UVRI & LSHTM Uganda Research Unit
Nakiwongo Road
Entebbe
Uganda
Uganda

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details
Keppel Street
London
England
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
rgio@lshtm.ac.uk

Sponsor type
University/education

Website
https://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journals, national and international dissemination with stakeholders.

Intention to publish date
31/08/2024

Individual participant data (IPD) sharing plan
The datasets generated will be stored at the LSHTM Data Compass publicly available repository and will be available upon request (https://datacompass.lshtm.ac.uk/)

IPD sharing plan summary
Stored in publicly available repository, Available on request