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

<b>Submission date</b> 05/05/2025	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>
		☐ Protocol
Registration date 06/05/2025	<b>Overall study status</b> Ongoing	Statistical analysis plan
		☐ Results
<b>Last Edited</b> 06/05/2025	Condition category  Mental and Behavioural Disorders	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** 

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#### 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