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Investigating the effects and practicalities of delivering sleep strategy workshops in secondary schools

Submission date
06/08/2024

Recruitment status
No longer recruiting

Registration date
06/08/2024

Overall study status
Completed

Last Edited
28/08/2025

Condition category
Nervous System Diseases

[X] 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
Adolescents are vulnerable to sleep problems, including insomnia, due to an array of biopsychosocial changes. Depression is also common in adolescents, and sleep disturbance is a precursor to the development of depression. Negative thinking is thought to be important in this link between depression and sleep in adolescents, however, more research is needed. This study aims to assess if it is practical and possible to deliver three sleep workshops to adolescents in secondary schools. The study also aims to look into the relationships between negative thinking, sleep and depression.

Who can participate?
Participants will include 12-16-year-olds in schools who agree to take part in the study.

What does the study involve?
Students in certain schools will be invited to agree to take part in the study and complete some questionnaires to see if the study is right for them. Students who have certain sleep experiences will be invited to attend sleep workshops. Students will be randomly allocated to one of two groups by school. Those in the first group will immediately receive three sleep workshops. Those in the second group will receive these workshops four weeks later. The sleep workshops will take place in schools. They will be run in groups of up to 15 students led by Education Mental Health Practitioners. Participants in the group which immediately receive the workshops will be asked to complete three assessments: one before workshops, one after workshops and one three months later. Those who receive the intervention four weeks later will also complete another assessment before starting the workshops. Each assessment takes around 35 minutes to complete.

What are the possible benefits and risks of participating?
The workshops are designed to help young people's sleep behaviours therefore participants may find these improvements, which can also impact wellbeing, attention and energy among other things. Additionally, the information gained from the research will benefit the understanding of sleep workshop interventions and whether running these in schools is possible.

Some people may find it upsetting to talk about their thoughts and feelings, however, participants do not have to answer any questions they do not want to, and can withdraw (leave) from the study at any time. Participants will be given resources to access support. Taking part does include a time commitment:
• The series of questionnaires that participants will be asked to complete will take around 35-40 minutes each time.
• The 7-day sleep diary will take a couple of minutes each day.
• The questionnaires and 7-day sleep diary will be completed 3-4 times throughout the study.
• There will be three 1-hour workshops during school, which will happen once a week.
• If participants choose to take part in the interview, this will be around 30 minutes.

The total time commitment will be approximately 7-8 hours over roughly 6-7 months. Participants will be compensated with vouchers for the time taken to help with the research.

Where is the study run from?
The University of Sussex (UK)

When is the study starting and how long is it expected to run for?
January 2021 to August 2025

Who is funding the study?
Economic and Social Research Council

Who is the main contact?
Dr Faith Orchard, iBLISS@sussex.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Faith Orchard

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
iBLISS (Investigating Benefits to Lifestyle from Improved Sleep Strategies): A brief early intervention for sleep disturbance in adolescents, to improve sleep and low mood: protocol for a feasibility cluster-randomised controlled trial

Acronym
iBLISS

Study objectives
Investigate whether it is feasible and acceptable to carry out a randomised control trial of a brief sleep intervention, using CBT-informed techniques within a secondary school-setting, using Mental Health Support Teams services. Feasibility and acceptability will be assessed by the number of participants who consent, are screened and attend the intervention. The secondary aim is to collect pilot data on clinical measures as well as on the underlying mechanisms proposed to be changed by the intervention such as dysfunctional beliefs about sleep and pre-sleep arousal.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/05/2024, Brighton and Sussex Medical School Research Governance Ethics Committee (BSMS Medical Research Building, University of Sussex, Brighton, BN1 9PS, United Kingdom; -; rgec@bsms.ac.uk), ref: ER/FO93/6

Study design
Pilot feasibility interventional cluster-randomized controlled trial

Primary study design
Interventional

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

Health condition(s) or problem(s) studied
Subthreshold insomnia in adolescents

Interventions
All participants will be recruited from secondary schools that are part of the West Sussex Mental Health Support Teams (MHSTs). Schools that agree to take part will be randomised by school according to the cluster design, to the immediate or delayed intervention group. Randomisation will be done by computer generation. Schools will be allocated to the randomised group in the order of sequential numbers generated.

A double-blind design is not possible due to the nature of the intervention under investigation (the school and the young people will be aware as to whether they had a delayed start). However, as both groups are receiving the experimental intervention, this should help reduce any potential bias associated with group allocation.

Students who have received parental consent and provided their own consent will be screened. They will be invited to complete the Insomnia Severity Index (ISI) and the Pittsburgh Sleep Quality Index (PSQI), alongside demographic questions. The screening will be completed in students' own time. Eligible participants (see inclusion criteria; e.g. scoring 8 on ISI or 5 on PSQI) will be contacted and invited to attend the workshops, and students who are not eligible will be informed and provided with support information. Parents will also be informed of the outcome.

The intervention is a brief behaviourally focused sleep intervention, using CBT-informed techniques of sleep- and psycho-education, sleep hygiene, stimulus control and sleep scheduling. The sleep intervention workshops were piloted in schools as part of the preparatory work for the grant. PowerPoint slides were created as well as a therapist manual. As part of the study, the patient public involvement (PPI) groups will help to improve the appearance and content of the materials, and additional parent videos and workshop take-home handouts will be created. The language used in the workshop slides has been checked to ensure it is age-appropriate and comprehensible for adolescents.

The intervention will consist of three workshops. Students will complete workshops in groups of up to 15 students. Successful completion of the intervention is defined as attending the first session as this is when the majority of the content is delivered, with the following two sessions taking a problem-solving approach. The intervention will be aimed to be delivered weekly, i.e. the five sessions (inclusive of three workshops and two assessment sessions) should take place over 5-8 weeks depending on school holidays etc. This will be monitored as part of the feasibility of the trial.

Workshops will be led by a qualified Education Mental Health Practitioner (EMHP) based within the West Sussex Mental Health Support Team. The EMHPs will have received training in the intervention and will continue to access their usual supervision by a Clinical Psychologist within Sussex Partnership NHS Foundation Trust. The intervention will follow a written treatment manual and is accompanied by take-home handouts for both young people and parents. The group session will use PowerPoint slides to help engage the young people in the session. Parents will also be provided with short videos that will explain what their child is learning in the workshops.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcome:
Feasibility and acceptability of the intervention are measured by recording the numbers of eligible participants following screening in proportion to those willing to take part but are ineligible, recruitment rate of both schools and participants, retention rate, assessment and outcome measure completion rate, data completeness, attendance of intervention, incidence of unexpected adverse events throughout the trial, feedback questionnaires post-intervention and interviews post-intervention.

Key secondary outcome(s))
Principle clinical outcome:
1. Insomnia will be measured using the Insomnia Severity Index (ISI) and the Pittsburgh Sleep Quality Index (PSQI). These will be administered at baseline, post-intervention and at 3-month follow-up.

Other measures:
2. Sleep patterns will be measured using the Consensus Sleep Diary (CSD) during the week following baseline assessment, post-intervention assessment and at the 3-month follow-up.
3. Symptoms of major DSM-IV anxiety disorders and depression in youth will be measured using the Revised Children's Anxiety and Depression Scale (RCADS) at baseline, post-intervention and at 3-month follow-up.
4. Depressive interpretation bias will be measured using the Ambiguous Scenarios Test for Depression in Adolescents (AST-DA) at baseline, post-intervention and at 3-month follow-up.
5. Cognitive and somatic arousal in the pre-sleep period will be measured using the Pre-Sleep Arousal Scale (PSAS) at baseline, post-intervention and at 3-month follow-up.
6. Dysfunctional beliefs about sleep will be measured using the Short Version of the Dysfunctional Beliefs About Sleep (DBAS) for use with Children at baseline, post-intervention and at 3-month follow-up.
7. Factors associated with behavioural treatments for depression will be measured by the Behavioural Activation for Depression Scale (BADs) - Social and School impairment subscales. This will be administered at baseline, post-intervention and at 3-month follow-up.
8 Frequency and intensity of negative thoughts which may contribute to emotional distress will be measured using the Persistent and Intrusive Negative Thoughts Scale (PINTS) at baseline, post-intervention and at 3-month follow-up.
9. Sleep hygiene practices will be measured using the Cognitive/Emotional subscale of the Adolescent Sleep Hygiene Scale (ASHS) at baseline, post-intervention and at 3-month follow-up.

Completion date
30/08/2025

Eligibility

Key inclusion criteria
1. School year group 8-10
2. Aged 12-15 years old
3. Parent and child informed consent obtained online
4. Willing and able to engage in psychological intervention and assessment. Parents will consent if they see it as appropriate for their child to engage with this intervention. Additionally, schools will be allowed to raise concerns if taking part in the intervention seems inappropriate for any of the young people.
5. Scoring 8 or above on the Insomnia Severity Index (ISI) or 5 and above on the Pittsburgh Sleep Quality Index (PSQI) at the screening. These scores are the recognised cut off's for "subthreshold insomnia" on the ISI (Morin et al., 2011) and for "poor sleepers" on the PSQI (Buysse et al., 1989)

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
15 years

Sex
All

Key exclusion criteria
1. Unable to fluently communicate in English.
2. Unable to give informed consent.

Date of first enrolment
01/09/2024

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sussex
Sussex House
Falmer
Southern Ring Road
Brighton
Sussex
United Kingdom
BN1 9RH

Study participating centre
West Sussex Mental Health Support Team
Bridge House, Barrington Road, Goring-by-Sea
Worthing
United Kingdom
BN12 4SE

Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
Social Science Research Council, ESRC, SSRC, UKRI ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 003		06/08/2024	No	Yes
Participant information sheet	version 004		06/08/2024	No	Yes
Participant information sheet	version 004		06/08/2024	No	Yes