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To create and evaluate an online support programme that will use young people's smartphones to detect and treat early onset sleep problems and early mental health problems

Submission date	Recruitment status	[X] Prospectively registered
11/11/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/11/2022	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The majority (60-70%) of young people's mental health problems go undetected and untreated despite the existence of effective interventions for both treatment and prevention. Young people don't seek help because they are either unaware of their symptoms or risk, have concern about stigma, or have limited/no access to mental health services. Identifying insomnia symptoms is an innovative mechanism to identify young people at risk, and those with early onset mental health problems. Most young people with mental health problems have symptoms of insomnia (e.g., difficulty getting to sleep, waking at night and finding it hard to go back to sleep, waking frequently or waking early). Insomnia symptoms increase the risk for developing subsequent mental health disorders 2-4 fold. Adolescents with three insomnia symptoms have a 6-fold increased risk of suicidal ideation, a 10-fold increased risk of a suicide attempt and an increased risk of completing suicide.

The study aims to develop and optimise a novel, accessible, engaging public health intervention (STTAMP). This will be ready in 2025 to be used at scale to identify young people (aged 14-18) developing mental health problems early and offer them immediate access to effective treatment online.

Who can participate?

14 – 18 year olds from participating schools and colleges.

What does the study involve?

Participants will download an app which will monitor their sleep for 6 weeks. Those found to have early signs of insomnia will be offered three interventions: (1) advice in the form of engaging audio / visual modules, (2) an adapted teen version of the effective adult SHUTi program and (3) effective automated online and signposting to NHS treatment. All participants

will be asked to complete 6 and 12 month questionnaires and some participants will be interviewed to discover their experiences of the study. Participants will take part in the study for 1 year and the total duration of follow-up is expected to be 29 months.

What are the possible benefits and risks of participating?
Benefits include free access to a new sleep tracker app, a 3-step intervention package designed to improve sleeping and mental health and increased self-worth by being part of a nationwide research project improving the quality of life of many young people_
Risks: Participants could experience stress and anxiety from participating in the study: from their phoned passively monitoring their sleep, completing questionnaires or taking part in research interviews.

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

When is the study starting and how long is it expected to run for?
July 2022 to January 2026

Who is funding the study?
The Prudence Trust (UK)
University of Bristol (UK)

Who is the main contact?
Nicholas Christoforou, n.christoforou@bristol.ac.uk

Study website
https://bristol.ac.uk/academic-child-health/research/research/pmhealth/sleepwell/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321940

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 321940

Study information

Scientific Title
STTAMP - Sleep Tracking & Treatment for Adolescent Mental Health

Acronym
STTAMP

Study objectives
To create and evaluate an online support programme (STTAMP) that will use children and young people's (CYP) smartphones to detect and treat early onset sleep problems and early mental health problems. Most CYP with mental health problems don't get the help they need. Sleep problems (also called insomnia symptoms) can be both a cause and a consequence of mental health problems. Insomnia symptoms are very common when CYP are becoming anxious, depressed or even suicidal. The University of Bristol have developed an app (Sleep Tracker) that detects when insomnia symptoms start. We want to combine this with treatment using CYP's smart phones in a programme called STTAMP. We need to make sure CYP (including those from poorer backgrounds and different cultural backgrounds) will use STTAMP.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/07/2024, North West - Greater Manchester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; None provided; gmcentral.rec@hra.nhs.uk), ref: 23/NW/0129

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
School

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Early detection of insomnia and mental health problems in 14 to 18-year-olds and a program of treatment thereafter.

Interventions
Participants will download an app which will monitor their sleep for 6 weeks. Those found to have early signs of insomnia will be offered three interventions:
1. Advice in the form of engaging audio/visual modules
2. An adapted teen version of the effective adult SHUTi program
3. Effective automated online and signposting to NHS treatment.

All participants will be asked to complete 6 and 12 month questionnaires and some participants will be interviewed to discover their experiences of the study. Participants will take part in the study for 1 year and the total duration of follow-up is expected to be 29 months.

Intervention Type
Behavioural

Primary outcome measure
1. For participants aged 14-18 at the time of 6 and 12 month follow-up, the Revised Children's Anxiety and Depression Scale (RCADS) will be used to measure anxiety and depression symptoms at 6 and 12 months
2. For participants aged over 18 at the time of 6 and 12 month follow-up, the Patient Health Questionnaire (PHQ) and General Anxiety Disorder Questionnaire (GAD) score will be used to measure anxiety and depression symptoms at 6 and 12 months
3. Assessment of long term impact of STTAMP will be measured using linkage to NHS Digital data and the Nation Pupil Database/Longitudinal Education Outcomes Database (NPD/LEO) through the ONS Secure Research Service. Educational attendance/attainment, economic productivity and access to NHS services, benefits and mental health services will be assessed at approximately 5 years.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2022

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Aged 14-18 years
2. Attend secondary school or college

3. Have an Android mobile phone
4. Have received adequate information about the study and understand they can withdraw from the study at any time

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
14 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
1000

Total final enrolment
1048

Key exclusion criteria
1. Aged 14 or 15 years and do not have the consent of their parent/carer.
2. Ae receiving clinical treatment for their insomnia and/or mental health difficulties.

Date of first enrolment
01/09/2023

Date of final enrolment
04/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Academic Child Health
Bristol Medical School
University of Bristol
Canynge Hall
Third Floor
39 Whatley Road

Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol

Sponsor details
Research Governance Team
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University of Bristol
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Sponsor type
University/education

Website
http://bristol.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
University/education

Funder Name
University of Bristol

Alternative Name(s)
Universitas Bristolliensis, bristoluniversity, bristoluni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
The Prudence Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/01/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (A secure server at the University of Bristol). Participant details, study data and data obtained from NHS Digital and the Nation Pupil Database/Longitudinal Education Outcomes Database will be stored in strict accordance with data protection rules and regulations on secure University of Bristol servers with only authorised users given access. The data will for stored for two years after the final participant has been recruited.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 6	06/02/2024	21/05/2024	No	Yes
Participant information sheet	Parent/carer version 6	07/02/2024	21/05/2024	No	Yes
Protocol file	version 6	20/02/2024	21/05/2024	No	No
Protocol file	version 7	14/06/2024	03/03/2025	No	No