

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	Completed	[] Results
Last Edited	Condition category	[] Individual participant data
27/01/2026	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

Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

321940

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s))

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

14 years

Upper age limit

18 years

Sex

All

Total final enrolment

1048

Key exclusion criteria

1. Aged 14 or 15 years and do not have the consent of their parent/carer.
2. Are 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

United Kingdom

England

Study participating centre

Centre for Academic Child Health

Bristol Medical School

University of Bristol

Canynge Hall

Third Floor

39 Whatley Road

Bristol

England

BS8 2PS

Sponsor information

Organisation

University of Bristol

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

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 be 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?
Other publications	Crowdsourcing remote co-design	02/06 /2025	27/01 /2026	Yes	No
Other publications	Description of co-production process	02/06 /2025	27/01 /2026	Yes	No
Other publications	Development of the Sleep Solved app	31/10 /2024	27/01 /2026	Yes	No

<u>Other publications</u>	Systematic review of digital interventions for anxiety and depression in adolescence	23/07 /2025	27/01 /2026	Yes	No
<u>Participant information sheet</u>	version 6	06/02 /2024	21/05 /2024	No	Yes
<u>Participant information sheet</u>	Parent/carer version 6	07/02 /2024	21/05 /2024	No	Yes
<u>Protocol file</u>	version 6	20/02 /2024	21/05 /2024	No	No
<u>Protocol file</u>	version 7	14/06 /2024	03/03 /2025	No	No
<u>Study website</u>		11/11 /2025	11/11 /2025	No	Yes