Full title: Improving adolescent mental health by automating and optimising remote support using STTAMP (Sleep Tracking & Treatment for Adolescent Mental health Problems).

Short title: The STTAMP Study.

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Contents

Abbreviations

CYP	Children and Young People
iCBT	Internet-based Cognitive Behavioural Therapy
PPIE	Patient and Public Involvement and Engagement
UoB	University of Bristol
REDCap	Research Electronic Data Capture
STTAMP	Sleep Tracking and Treatment for Adolescent Mental health Problems

1. Summary

We aim to create and evaluate an online support programme that will use children and young people's (CYP) smartphones to estimate sleep disturbance and provide advice on sleep hygiene. 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 a mobile application (app) called Phone Downtime that aims to estimate phone use during the young person's planned sleeping period. We want to combine this with two apps using CYP's smartphones. Phone Downtime will run on smartphones using the Android operating system, and phone use is based on screen on/off events and an accelerometer to measure movement. The first web-based app consists of audio-visual content that will encourage CYP to engage in standard insomnia prevention techniques. The second web-based app will be an adapted version of the highly effective adult SHUTi program. The third is a web-based programme called *Bite Back* that has been shown to improve wellbeing in people aged 12 to 18. We will make these web-based apps as relevant to young people from diverse and disadvantaged backgrounds as possible.

We have worked with CYP and creative teams to co-produce short audio-visual content to better support CYP (aged 14-18) to improve their sleep. We have also worked with CYP to adapt SHUTi, an internet-delivered cognitive behavioural programme (iCBT) for insomnia symptoms. We aim to offer the support programme to 1000 young people (aged 14-18 years) to test and improve it. Using questionnaires and qualitative interviews, we will learn from their experiences over a 2-year period.

2. Background

Justification

The majority (60-70%) of CYP's mental health problems go undetected and untreated, despite the existence of effective interventions for both management and prevention (1,2). CYP 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 (3,4). Identifying insomnia symptoms is an innovative mechanism to identify young people at risk, and those with early onset mental health problems. Most CYP 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. CYP 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 (5,6).

Addressing insomnia reduces mental health problems and the risk of suicide. Automated internet-based cognitive behavioural therapy (iCBT) for adults reduces insomnia and depression with medium effect sizes (7). Most studies have been conducted in those with chronic insomnia, but early identification and support for "acute" (i.e., less than 3 months) insomnia symptoms may be more effective (8). In CYP, iCBT for insomnia is effective in reducing insomnia symptoms mediating a reduction in psychopathology and an improvement in wellbeing. However, studies to date have been relatively small feasibility studies (9–11).

Digital interventions delivering automated iCBT are effective for CYP with anxiety/depression with small to medium effect sizes (12). Automated iCBT has several advantages including: delivering support for CYP at scale; delivering support asynchronously so CYP can complete modules privately without fear of stigma; being able to target support to those with symptoms; self-completion is empowering (13). However, automated iCBT for insomnia has sub-optimal adherence. On average only ~50% of modules are completed (7,9–11). Brief, single-session approaches are effective for insomnia in adults and are likely to improve engagement with those from deprived backgrounds or those with mild cognitive impairments (14,15). Therefore, using smartphones to detect insomnia symptoms and offer intervention provides a novel mechanism to improve insomnia and mental health problems.

Development and Adaptation

A novel app has been developed at the University of Bristol with significant input from CYP from different backgrounds, designers and clinical/behavioural experts. The app (Phone Downtime) runs on phones using the Android operating system and collects data (e.g., screen on/off events, movement) passively (without active user involvement) to infer sleep disturbance (including changes seen in circadian misalignment). Screen on/off events may be more effective at detecting being awake and at rest than accelerometery. Around 99% of CYP own smartphones, and 89% have a device in their bedroom which most use near bedtime/when awake.

Since August 2022, the study's co-production team (young people from diverse backgrounds, arts creatives, digital, clinical, and behavioural experts) have been meeting at least twice a month, following best practice for authentic co-production to (16):

1. Develop a brief behavioural web-based application as a series of engaging audio-visual modules (suitable for economically disadvantaged young people and those from different cultural backgrounds). These will encourage and support adolescents to engage with core behavioural/psychoeducation ingredients of good sleep hygiene (e.g., less time in bed).
2. Adapt SHUTi for UK adolescents including those from economically disadvantaged backgrounds. Adapting SHUTi will address the special needs of this population (e.g., school timing, provision of age norms, lower health literacy); increased information designed for young people; additional stories from young people from different cultural backgrounds.

We are using the Person-Based Approach (PBA) to evaluate and continue to improve our materials (web-based applications) (17). This will enable us to evaluate both the identification (using the sleep app) of sleep disturbance and mental health symptoms. The PBA is an iterative process of using user feedback to improve an intervention, supplementing stakeholder and PPIE co-production with in-depth qualitative research with a diverse sample of users. This will ensure our behavioural approach will be grounded in a deep understanding of the different perspectives, practices and psychosocial contexts of CYP who take part in the study.

We are currently conducting 'think-aloud interviews' with PPIE members to obtain immediate reactions to all elements and materials of the study. We are using purposive sampling to ensure we interview young people from different cultural, ethnic and socio-economic groups focussing on economically disadvantaged young people (who are at increased risk of developing mental health problems). Although analyses is ongoing, we analyse, tabulate, and discuss potential changes with the co-production team until there are no further changes required. We aim to maximise accessibility, usability, and credibility of our materials via our co-production team throughout the present study.

3. Aims & Objectives

Overall aim: To develop, optimise and evaluate a novel, accessible, engaging public health intervention.

The following research questions are designed to enable us to achieve our aim:

1. What are the most acceptable, and engaging co-produced brief smart-phone-delivered interventions for insomnia and mental health symptoms for young people aged 14-18 (especially those from economically disadvantaged backgrounds)?
2. How should we adapt SHUTi (which works for adults), for young people so it is engaging for those with acute (6 weeks) insomnia symptoms?
3. Are automated mental health interventions that have been shown to work for young people presenting to mental health services, acceptable for this group of young people?
4. How effective is the detection of early mental health symptoms using insomnia symptoms?
5. Do mental health symptoms reduce following a) STEP 1 online advice on improving sleep hygiene and b) STEP 2 adapted modular SHUTi insomnia programme?
6. How do young people experience the technology?
7. What is the most effective method to communicate with young people and our stakeholders to ensure rapid dissemination and widespread national take up?

4. Methodology

Overarching Design

A stepped care approach improves access to appropriate care. We propose the following staged approach:

- STEP 1: Online advice on improving sleep hygiene provided as automated accessible audio-visual materials suitable for economically disadvantaged young people and those from different cultural backgrounds.
- STEP 2: If symptoms persist, participants will be offered adolescent SHUTi (automated iCBT for insomnia) delivered in 6 modules.
- STEP 3: If participants are seeking further advice for their mental health, they will be signposted to *Bite Back* (a web-based well-being programme).

Optimisation and Evaluation

An observational cohort with integrated qualitative methodology will provide the infrastructure to develop the web-based applications, test the feasibility and acceptability of passive data collection, online screening and data linkage. Follow up questions on insomnia, anxiety and depression symptoms at 6-weeks, 6- and 12-months will enable us to test detection efficacy. We will synthesise quantitative and qualitative data to explore the acceptability and feasibility of recruitment, the web-based applications, data collected, and retention.

Recruitment:

Participants (aged 14-18) will be recruited through our established collaborations with:

- The Association of Colleges (https://www.aoc.co.uk) (93% of all further education and 6th form colleges).
- E-Act Multi-academy trust (https://www.e-act.org.uk/) who have links with academies throughout the UK.

Recruitment will focus on schools and colleges from across the UK, with the aim to ensure participation of CYP from diverse and disadvantaged backgrounds. A poster describing the study will be shared within each school/college to encourage young people to participate. By scanning a QR code, participants will be directed to the participant information sheet on their smartphones. If the poster is shared electronically, participants will be asked to type the relevant URL into their mobile browser or text the study mobile number (via Twilio) which will send an automated reply with a link to the online participant information sheet.

All participants will receive two £10 vouchers as a thank you for their time. One after their baseline survey, and another after their 6-week (second) survey. If a participant decides to participate in a one-to-one interview, they will be rewarded with a £40 voucher.

Sample size:

A sample size of 1000 is a pragmatic choice as an achievable recruitment target and sufficient to answer research questions. If we assume 20% attrition, recruiting 1000 young people will provide data

on 800, of which 240 (30%) will have insomnia symptoms at enrolment and 180 (75%) will also have mental health symptoms. Of those with healthy sleep, if the incidence of acute insomnia (one month or less) is similar to adults then 150 -210 (27-37%) will develop insomnia each year (of which 72% will recover). A cohort of this size will put confidence intervals around these assumptions.

Inclusion and Exclusion Criteria

Included: Young people:

- Aged 14-18,
- Who attend secondary school or college,
- Who have a mobile phone.

Excluded: Young people:

- Aged 14 or 15 who do not have the consent of their parent / carer,
- Who are receiving treatment for their insomnia and/or mental health difficulties.

Consent

All assent and consent data will be collected via Research Electronic Data Capture (REDCap) – a web-based data capture system for research. Assent will be collected from 14 and 15-year-olds. Consent from their parent/carer will be collected also. The REDCap form will prevent young people under the age of 16-years from continuing if parent/carer consent has not been obtained. Consent will be collected from 16-18-year-olds. An electronic signature will be requested from all individuals to ensure we are collecting verified consent. To participate in an interview and/or provide data linkage will be optional. Upon turning 16 years old, participants will be re-approached and re-consented.

Materials:

All participants will receive STEP 1 (Sleep Solved) throughout their participation. Phone Downtime app infers sleep disturbance through movement and screen on/off events on phones using the Android operating system. Only users with an Android phone will be offered to use this app. If high levels of sleep disturbance persist at and beyond 6-weeks, the participant will be signposted to STEP 2 (adapted SHUTi programme). STEP 2 will include approximately 6 modules (in-depth advice) on sleep hygiene and mental health. Notably, Sleep Solved will be available to all participants throughout their participation. Some participants will also be signposted to STEP 3 (*Bite Back*).

Sleep Solved provides advice (called 'sleep hacks') on habits that promote good sleep hygiene (e.g., setting an alarm at the same time each morning). The web-based application has been developed by the research team, in collaboration with PPIE members, the Sleep Charity and the McPin Foundation. The Sleep Solved prototype is currently undergoing further development in partnership with PPIE participants using qualitative research methods.

SHUTi has been selected for the study as PPIE feedback from a focus group of CYP who tried different iCBT interventions for insomnia and chose SHUTi. The SHUTi web-based application was developed by our collaborator and partner Professor Ritterband. SHUTi is a multi-component web-based application where participants can work through a series of six modules, each taking around 30-minutes to complete. It makes recommendations based on users inputting symptoms with high levels of user engagement. SHUTi has been extensively tested in adult populations (7 completed studies, 10 ongoing

studies) with significant improvements in measures of insomnia, sleep efficiency, night-time waking compared to a control group who did not receive SHUTi. These benefits were maintained at 6-month follow-up (18). The SHUTi web-based application has been adapted for older adults and for minority ethnic women (19,20).

Bite Back is a web-based positive psychological programme developed by the research team at the Black Dog Institute in Australia. This six-week interactive and self-guided programme was designed to promote well-being and enhance resilience among young people between 12 and 18 years of age. Bite Back is openly accessible and has been evaluated through randomised controlled trials, demonstrating significant improvements in well-being, resilience, and life satisfaction as well as reduction of anxiety and depression symptoms in a non-clinical sample (21). More information about the Bite Back programme provided by the Black Dog Institute can be found on: https://www.blackdoginstitute.org.au/resources-support/digital-tools-apps/bite-back/; Link to the Bite Back website: https://www.biteback.org.au.

The Phone Downtime app will only be offered to Android users and will undergo further optimisation throughout the study. The *Phone Downtime* app runs on phones using the Android operating system, and sleep disturbance is based on screen on/off events and an accelerometer to measure the movement. In this study, we aim to improve the software engineering to make it more extensible and flexible; investigate the trade-offs between the computational demands (data/memory), battery of additional modalities and potentially improved accuracy. In other words, we aim to minimise battery usage. The target sample size is significantly larger than the pilot studies that have been conducted with the app. This will enable us to develop more accurate and reliable algorithms and group-specific models for groups with different sleep patterns (e.g., minority ethnic groups). Data analysis is detailed further below.

Data collection:

Quantitative Data	Qualitative Data
We will collect data on the percentage of eligible young people at each stage (recruitment, during participation, retention). The sleep app (Phone Downtime) will collect data passively while participants use the Sleep Solved and/or SHUTi web-based application. <u>Via REDCap</u> At recruitment: full name, date of birth, name of school/college, postcode, and contact details. We will also collect parent/carer contact details if the participant is under the age of 16 years. At baseline, 6-weeks, 6- and 12-months participants will be invited via email to complete: • sex at birth, • gender, • ethnicity, • Insomnia Severity Index (ISI), • Revised Children's Anxiety and Depression Scale (RCADS). If they are over 18 years old at follow up, they will be asked to complete • the Patient Health Questionnaire (PHQ) and, • the General Anxiety Disorder Questionnaire (GAD). We will send participants text and/or email reminders when a survey is required to be completed.	All participants who take part will be invited via REDCap to participate in a one-to-one interview via Microsoft Teams or Zoom. We aim to conduct at least 60 in-depth interviews to understand: • Perceptions, • Web-based application use, • The barriers/facilitators that influence engagement, • The social issues of sleep the web-based application addresses, • How sleep is reconfigured in a digital-social world. The in-depth qualitative interviews (estimated 60 for data saturation of participants at different time points) will explore participant understandings and attitudes towards sleep and how the boundaries/shape of the 'night-world' are influenced through interactions with others. We will explore how dilemmas get managed and moulded in everyday life, how the digital web-based application alters the landscape of sociality and expertise and whether the web-based application(s) had an impact and if that effect is altered by context. Questions will be explored through use of a topic guide, with changes made to questions based on iterative feedback from participants. Participants who are interviewed may also be invited to keep diaries (audio/web logs, visual/written) to reflect on the behaviour change approaches (e.g., sleep restriction) which can be used as interview prompts. Details regarding how this data will be collected and stored is in Section 8 of the protocol.

5. Analyses

Analyses will be ongoing. Qualitative methodology will be applied to the audio and written data. Specifically, iterative thematic analysis grounded in participant views (concordant and discordant). Quantitative analyses will also be performed in the study. We will use the probable threshold for anxiety and depression of the RCADS at 6-weeks, 6- and 12-month follow up (adjusted for age/sex at birth) and conduct receive operator characteristic (ROC) analyses with appropriate confidence intervals to determine the sensitivity of insomnia screening. We will also compare anxiety and depression scores before and after each step and report whether we have found a signal.

The Phone Downtime app (for Android users only): We will apply machine learning algorithms based on time series characterisation, Bayesian methods for change point detection, and outlier detection enhanced with data visualisation to understand the population data structure (e.g., to find sub-populations and outliers). The data is relatively low frequency (estimated sleep timings and durations measured daily), so we expect existing algorithms to be adequate. We will use Bayesian learning algorithms to account for individual variation. Algorithms will be server-based enabling us to alert participants. Characteristics that predict when sleep patterns in an individual predict insomnia (and not a single broken night/weekend) are likely to be subject-dependent. Therefore, we will use a data-based grouping of subjects with similar characteristics (using Bayesian inference to identify appropriate group sizes) and create models based on multiple individuals whilst providing variations in models that capture differences between subjects. Using the prevalence estimates of insomnia symptoms of 30%, a sample size of 236 is required for sensitivity and specificity of 0.9 (precision +/- 5%). We will separate complete time courses to create model training and testing sets but retain each subject's whole data set within each group.

6. Project Management

The Core Management Group (CMG), consisting of the Chief Investigator (CI) and Project Manager (PM), will meet weekly to ensure the programme is delivering against its objectives. The Core Research Team (CRT) consisting of the CI, PM, co-applicants and researchers will be responsible for ensuring research delivery is integrated and timely. The CRT will meet every 6-weeks to discuss workstream milestones, outputs and risks, and PPIE outputs.

The Advisory Group includes experts in Sleep (Lee Ritterband (SHUTi developer), Sociology (Susan Halford, Co-director of Bristol Digital Futures Institute) and Mental Health (Carol Joinson, Professor of Developmental Psychology). It includes expertise in education and policy with representatives from the Department of Education (Catherine Newson, Team Leader, Mental Health, Character and Wellbeing Analysis), established links with the Association of Colleges, and secondary schools (E-Act Multi-Academy Trust). Lord Knight was a Schools Minister (as an MP) and has extensive networks and contacts in education and Parliament. The AHSN (Nigel Harris) will support dissemination. The Advisory Group will meet with the CRT every 6-months to provide advice on mitigating or overcoming barriers and embedding the proposed stepped approach.

The Independent Steering Group will oversee governance (programme progress and risks) and provide insight and advice. Members (70% independent) will include at least 1 clinical academic, 1 social science academic, 1 lay member. They will meet annually with the Core Research Team (who will be accountable to them) to review reports on overall progress and the risks. Other meetings that will feed into the overall management and governance are the PPIE meetings and the large dissemination meeting (two-day meeting with all the co-investigators, early career researchers, partners, PPIE members and stakeholders).

7. Ethical Issues

Risks:

A number of risks have been identified. Our mitigation measures are in italics.

- **Safeguarding issues raised in qualitative interviews**. *Our participant information sheets provide information on disclosure to ensure the participant is aware of the necessary procedures that are in place. Our researchers have or will have received high quality training on how to deal with safeguarding issues. In addition, we will regularly review the research processes to ensure we are minimising this risk further.*
- **Risk of disclosure.** *We will follow the guidance of our PPIE group, and the literature in this area, by not disclosing participant data to the parents/carers of participants unless the CI is concerned, they are at risk of harming themselves or others.*
- **Concern over the wellbeing of study participants.** *Should any study team member become concerned with the physical or mental wellbeing of a study participant then they will follow the procedure in place for reporting both Adverse Events and Serious Adverse Events. The relevant school/college will be involved in the process.*
- **Schools/colleges anxious over phone use**. *We will work with our stakeholders in education to improve communication, explain current rates of phones in bedrooms (~90%), and reassure schools regularly.*
- **Peer researcher struggles**. *A peer researcher has been employed to improve the relatedness of the study. They use their lived experience and contextual understanding of a social or geographical community to help generate information about their peers for research purposes. We will provide training and mentoring, counselling, and support. If required, the peer researcher will be redeployed.*
- **Low follow-up**. *Follow-up rates will be improved by experienced researchers conducting light touch contacts with study participants in order to remind them to complete study questionnaires.*
- **Digital security**. *We will conduct a thorough risk assessment, e.g., a Data Protection Impact Assessment (DPIA). Data will be stored securely on University servers and regularly reviewed in management meetings. Further detail regarding data security is outlined in Section 8.*
- **Software costs to participants**. *All apps and digital programmes will be provided free of charge. We have also estimated the cost of running the sleep app, and the web-based applications, as being minimal for study participants as they use very little battery life and data usage.*

- **Data privacy concerns.** *Participants may be concerned regarding the data privacy of the app. Details regarding the data that the app collects are clearly explained to participants within the participant information sheet and consent form.*
- **Low recruitment rate**. *Increase the number of recruiting colleges from networks and improve recruitment strategies using PPIE groups and our peer researcher.*

Benefits to participants:

- Study participants will have free access to a new sleep app and Sleep Solved that could help them to sleep better and therefore improve their mental and physical wellbeing.
- If found to be experiencing sleep disturbance, participants will get free access to an adapted version of the SHUTi app which has been proven to work with adults. This app could also help them sleep better and therefore improve their mental and physical wellbeing.
- If after using the adapted SHUTi app participants continue to experience sleep disturbance or mental health symptoms, they will be signposted to local NHS support services and *Bite Back*, an evidence-based online positive psychology programme, which has been designed to improve resilience and wellbeing in young people aged 12-18.
- Participants might enjoy contributing to a national research project that could increase the quality of life for many young people.

Research benefits:

- Findings from a large observational mixed-methods study of young people's experiences of using sleep tracking plus our proposed stepped approach.
- A large young people's cohort (n=1000) with passive sleep data and self-completed mental health data.
- 10 research papers (e.g., uptake, effectiveness, epidemiology).

Benefits to wider society:

- Possible improvements in attendance and attainment in schools/colleges.
- Possible reduction in the use of NHS services for those participating.

8. Data Protection and Participant Confidentiality

Data will be entered into REDCap which is a secure system used by multiple institutions for large multicentre studies. Participants will enter their own data into REDCap. Participants will be sent a web link to REDCap which will only allow access to their data. REDCap also has an auto-log out system that will log participants out after 30 minutes if they have stopped using the database.

Data will be managed according to the following procedure. Participants will be allocated a unique research identification number. A list of names and corresponding identification numbers will be kept separately and securely on a password protected University of Bristol server or OneDrive folder. Personal information will be kept on consent forms which will have contact details. Consent forms will then be stored securely on a password protected University of Bristol server or OneDrive folder. Interview recordings (both audio and video files) will also be securely stored on a password-protected University of Bristol server or OneDrive folder.

The sleep app will be linked to a secure online database implemented using Amazon Web Services (AWS). AWS provides on-demand cloud computing platforms. It allows synchronisation of data in real-time whilst the app is still running. It also provides security for the collected data and ensures that authentication occurs before accessing the database. AWS offers strong encryption for customer data in transit or at rest. AWS has in place effective technical and organisational measures for data processors to secure personal data in accordance with the GDPR including specific measures such as encryption of personal data, the ability to ensure the ongoing confidentiality, integrity, availability, and resilience of processing systems and services, and the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident. In order to reduce the likelihood of non-authorised personnel accessing the participant's data, we will create two separate databases. This is to prevent personal data being linked to mobile sensor data. We will have:

- Database 1: To store personal information such as name, email, age, and ethnicity.
- Database 2: To store data collected from the mobile sensors and survey score.

To increase the granularity of the data, a range of data has strict rules that cannot be modified or updated once it is submitted. The data stored in database 1 does not permit the user to update or modify personal information. In database 2, data related to the sleep app, the users can only read the daily data about sleep duration and total movements during sleep duration. The only data modification or update permissible to the user is their sleep and wake-up times.

9. Dissemination and Outputs

To ensure effective rollout with widespread uptake and implementation, we need effective communication, problem solving and dissemination with young people; education (teachers, schools, colleges); health (commissioners and providers), researchers and policy makers to overcome barriers in uptake, funding, and implementation.

Once the study is open to recruitment, we will expand our Advisory Group and invite: The schools, students and teachers' network (SSAT, https://www.ssatuk.co.uk/); The National children's bureau; the National Foundation of Education Research (NfER); The PSHE association for PSHE (Personal, Social, Health and Economic education). We will produce a detailed communication plan. We will use a wide variety of health and education networks to disseminate our findings including: The Emerging Minds Network; Public Health England's Every Mind Matters digital campaign; TES.com, (network of 13.5 million registered users); Whole Education (network of 500 schools/partners); the National Association of Colleges policy group; SSAT. This will culminate in our 2-day dissemination event.

a) *Young people*: We will work iteratively with the PPIE groups, The McPin Foundation, The Sleep Charity and the Peer researcher to: (i) find out how young people use the materials and how this varies across different ethnic, socio-economic groups using the data; (ii) test pieces of communication (written, video, blogs) to ensure communication is as effective as possible in the different sectors given the different information needs of young people from different backgrounds; (iii) decide if the use of influencers (for free) will be helpful or harmful for dissemination; (iv) understand which networks are effective for dissemination for young people.
b) *Education*: The Advisory Group has been chosen with representatives from DfE, the Association of Colleges, and secondary schools and they will provide advice on

communication, language, how to engage teachers and how to embed this approach after the study has finished. We will present findings at education conferences and networking events.

c) *Health*: We will work with commissioners, and health providers, the national Academic Health Sciences Network (AHSN), the national Applied Research Collaboration (ARC) network (ARCWest, Healthier Childhoods Theme lead, Macleod, Director) and HDR UK Southwest Better Care Partnership (Macleod Associate Director) for advice and support on implementation.

d) *Researchers*: We will work with implementation researchers in ARCWest to improve uptake. Our research outputs will be of interest to researchers in mental health, sleep and computer science. We want to increase capacity, and to conduct further studies with the large observational cohort. Therefore, we will present our findings at conferences in the UK, Europe and the USA; host a large 2-day dissemination event; disseminate through our networks; publish 10 peer reviewed papers.

e) *Policy makers*: We will work with Catherine Newsome (Department for Education, Mental Health Team Leader) and Lord Knight (previous Minister for School Standards) from our Advisory Group, Vicky Beevers (The Sleep Charity) and the AHSN and ARC networks to make links and overcome barriers to ensure roll-out is successful.

This research will be the first of a portfolio of studies, progressing through to Health Research Authority (HRA) approval in the future.

10. Research Governance

The study will be sponsored by the University of Bristol. HRA and HCRW Approval (including NHS REC review) will be sought, and confirmation of capacity and capability will be obtained from the NHS Trusts.

11. Insurance

The University of Bristol (UoB) holds Clinical Trial Insurance to cover their legal liability, as Research Sponsor, for harm to participants arising from the design and management of the research by UoB staff or students.

12. Adverse Events

The study will report adverse events to the CI and the relevant school/college. We will collect the necessary details (e.g., safeguarding procedures) from each participating school/college when they join the study. This information will be kept on a password protected University of Bristol server or OneDrive folder.

13. Archiving

Anonymised data will be uploaded to a RDSF (i.e., a university research data secure storage facility) for other researchers to use for 2-years after the study has stopped. We will not keep the study data

open access longer than this as we do not currently have funding for long term storage, and we consider that 2-years is sufficient time for other researchers to use the data.

14. Summary of Changes to the Protocol

Previous version of protocol	Date	New version of protocol	Date	Summary of changes
Protocol V3	25-07-23	Protocol V4	10-08-23	Added Step 3 content (Bite Back).
Protocol V4	10-08-23	Protocol V5	18-10-23	Added Katharine Pike as clinical lead and changed inclusion/exclusion criteria.
Protocol V5	18-10-2023	Protocol V6	20-02-2024	Removing data linkage from data collection.

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