Study Title: Investigating the feasibility, acceptability, and preliminary effectiveness of a sleep intervention for adolescents with comorbid insomnia and mental health difficulties.

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Study objectives:

1. To assess the feasibility of delivering the Strathclyde Sleep Intervention to adolescents with co-morbid insomnia and mental health attending a mental health services. The following feasibility benchmarks will be assessed: recruitment and retention, participant attendance, staff training, intervention fidelity and participant adherence.
2. To examine participant acceptability. The researchers will conduct qualitative interviews with the participants and delivery staff to examine the acceptability of the programme.
3. To investigate the preliminary effectiveness by assessing the following: sleep parameters, insomnia symptoms, Circadian phase preference (baseline only) and mental health symptoms. Data will be collected at baseline, post-intervention and 3-month follow-up.

Methods:

Design – The study will assess the feasibility, acceptability, and preliminary effectiveness of the intervention using a single-arm repeated measures design. Data to assess the feasibility objectives and benchmarks will be collected throughout. Acceptability will be explored via qualitative interviews following the delivery of the intervention. Outcomes will be measured at baseline, immediately post-treatment and at 3-month follow-up.

Participants - We intend to assess the feasibility of recruitment of adolescents from mental health services, therefore no formal power calculation has been conducted for this study. We aim to recruit up to 40 adolescents and up to 10 members of staff. This estimate was based on previous research conducted within adolescents in mental health services (Åslund et al., 2020; Bradley et al., 2018; Clarke et al., 2015; Palermo et al., 2017; Rollinson et al., 2021). The results of this study will inform sample size calculations for future RCT of the Strathclyde Sleep Intervention.

Eligibility criteria –

Inclusion criteria:

1. Adolescents aged 12-18 years

2. Meeting thresholds for insomnia disorder (determined by cut-off scores on the Sleep Condition Indicator (2) - <2 indicates probable insomnia, Luik et al., 2019)
3. Receiving support for mental health
4. Able to engage with intervention protocol

Exclusion criteria:

1. Active suicide ideation and/or recent suicidal attempts
2. Contraindicators for components of CBT-I (sleep restriction therapy) including seizure disorders/conditions including epilepsy, bipolar disorder, symptoms of psychosis, obstructive sleep apnea and parasomnias.
3. Diagnosis of Autism Spectrum Disorder, Attention Deficit Hyperactivity Disorder, Foetal Alcohol Spectrum Disorder (Neurodiversity)
4. Those who are currently completing, or have recently completed (in the past 6 months), CBT-I for insomnia elsewhere (or components of CBT-I including e.g. sleep restriction therapy, stimulus control, cognitive techniques). This will only include in-person, one-to-one methods of delivery.

Procedure - Staff will be identified by the service management and volunteer to receive training. We intend to train up to 10 members of staff to deliver the intervention. Staff will receive training, will be offered ongoing supervision (provided by the research team), and will utilize the intervention delivery manual to deliver the intervention. A list of common FAQs will also be provided to support the delivery. Staff within the service will use a referral form (accessible via Qualtrics) to assess eligibility and refer potential participants, they will also be responsible for sharing the participant information sheet and video link. Adolescents and caregivers will be advised that the researcher will be in contact with them in 2-3 working days to arrange a time to meet on Zoom. During the meeting, the researcher will re-check eligibility to ensure nothing has changed since the referral form was completed, to answer any questions and to obtain verbal consent. The adolescents and caregivers will also be sent a URL link to the written consent form (accessed online via Qualtrics). Written consent will be obtained from adolescents and parents/caregivers. Forms will inform participants about their right to withdraw from the intervention and/or data collection/analysis at any time, until the end of the follow-up assessment.

After receiving a signed consent form, participants will be sent an email with a link to complete a baseline assessment questionnaire. The participants will also be asked to complete a sleep diary for up to 2-weeks before the delivery of the Strathclyde Sleep Intervention. Participants will be invited to attend 4 weekly sessions for the delivery of the intervention. Trained staff will deliver the intervention to small groups of adolescents (up to 6). All sessions will be audio recorded. The participants will be asked to complete a sleep diary for the duration of the intervention. This will take approximately 2-3 minutes to complete and is necessary to ensure the sleep window can be appropriately titrated during sleep restriction therapy. Following the delivery of the intervention, all participants will be asked to complete the post-intervention assessment (questionnaire, 2-week sleep diary), and will be invited to attend semi-structured interviews with a member of the research team to explore the acceptability of the intervention. The staff will also be invited to attend semi-structured interviews to explore the acceptability of training, delivery, and future implementation. Staff will be asked to read an information sheet and provide informed consent prior to the interview. Interviews will be conducted following the completion of post-intervention assessments and will be audio-recorded. Three months following completion of the post-intervention assessment, the participants will be asked to complete the follow-up assessment (questionnaire, 2-week sleep diary). This will be the end of their participation in the study.

Data analysis plan - To examine the feasibility of delivering the intervention to adolescents attending mental health services, we will examine recruitment and retention rates, attendance logs and adherence to intervention components using frequencies and descriptive statistics. An intervention fidelity checklist will also be created, and the researchers will score the delivery of the intervention against the checklist. Qualitative data will be transcribed verbatim and analysed using Braun and Clarke's (2006) method of thematic analysis to examine acceptability. To examine preliminary effectiveness, we will compare changes in sleep parameters, insomnia and mental health symptoms from baseline, post-intervention and follow-up using mixed modelling analysis.