ISRCTN51219397 https://doi.org/10.1186/ISRCTN51219397

Understanding the mechanisms of how behavioural sleep improvement programmes work in young adults with depression and anxiety

Submission date
11/06/2025

Recruitment status
Recruiting

Registration date
17/06/2025

Overall study status
Ongoing

Last Edited
17/06/2025

Condition category
Mental and Behavioural Disorders

[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
Symptoms of depression and anxiety are common and often distressing. There are reasons to think that poor sleep is an important contributor to depression and anxiety, and if sleep could be improved, depression and anxiety might improve too.
Previous research has shown that we can improve sleep quality using behavioural interventions. While there is evidence that these behavioural treatments improve one's quality of sleep and daytime functioning, it is less clear how they affect the biology of sleep or circadian rhythms (the 'body clock'), especially in people who experience depression and /or anxiety.
In this study we want to compare two behavioural sleep interventions to understand which is more effective in changing sleep, the timing of the body clock, and mental health. Such information may help us develop new and tailored interventions for people with mental health difficulties.

Who can participate?
People aged between 18 and 30 years who experience depression and/or anxiety and frequent difficulty with falling asleep and/or waking up during the night (insomnia)

What does the study involve?
Participants are recruited from general practice and the community who experience sleep disruption (insomnia) and either depression or anxiety. GPs will search medical records and send out study invitations. They will also make patients aware of the study during consultations. We will also advertise the study on social media and relevant websites, as well as on posters in GP practices and in communal places around Oxford. People who are interested in taking part in the study will be asked to complete a short questionnaire and a phone interview with a member of the research team to determine if the study is suitable for them. Eligible participants will be allocated at random, by a computer, to one of two behavioural sleep improvement programmes taking place over six weekly sessions. Sleep improvement programme 1 will involve meeting with a trained researcher each week for 6 weeks and following a personalised daily sleep

schedule. Sleep improvement programme 2 will involve meeting with a trained researcher each week for 6 weeks and receiving education and advice on how lifestyle and environmental factors impact our sleep.
All participants will complete assessments at baseline (before the random allocation of treatment), and at 4 weeks, 8 weeks and 26 weeks after random allocation to treatment. This will help us to determine whether the treatments have worked. We will measure symptoms of depression and anxiety using questionnaires. We will measure sleep using questionnaires, sleep diaries, actigraphy (a watch-like device that measures movement), and through measurement of electrical brain activity recorded twice in participants' homes. We will also take a measure of participants' 'biological clock' from samples of saliva, collected in a laboratory, as well as biomarkers of inflammation from blood samples. We will also collect information on medication prescriptions and any other treatments that participants may access during the study.

What are the possible benefits and risks of participating?
Participants may benefit from improved sleep and mental health from taking part in this study. Participants will also contribute to research, which may help develop better treatments for people experiencing mental health problems. Furthermore, all participants who are interested in receiving a summary of the study findings will also be sent a copy of this at the end of the study. We do not anticipate that there are any risks in taking part. However, involvement in the study will involve answering questions about sensitive and potentially upsetting topics. If participants do not feel comfortable answering such questions, the team will discourage them from participating in the study or taking part in the online eligibility questionnaire. There are no known serious side effects from taking part in this study; however, a change to sleep patterns may be associated with a short-term increase in sleepiness. Participants will be informed that if they do feel sleepy during the study, they should avoid activities that require a high degree of vigilance, such as driving or operating heavy machinery.

Where is the study run from?
Nuffield Department of Clinical Neurosciences, University of Oxford (UK)

When is the study starting and how long is it expected to run for?
June 2024 to May 2027

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Prof. Simon Kyle, simon.kyle@ndcn.ox.ac.uk, spectrum.study@ndcn.ox.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Simon Kyle

ORCID ID
https://orcid.org/0000-0002-9581-5311

Contact details

Sleep and Circadian Neuroscience Institute
Department of Clinical Neurosciences
Dorothy Hodgkin Crowfoot Building
South Parks Road
Oxford
United Kingdom
OX1 3QU
+44 (0)1865617828
simon.kyle@ndcn.ox.ac.uk

Type(s)
Public, Scientific

Contact name
Dr Nicola Barclay

ORCID ID
https://orcid.org/0000-0002-6500-9909

Contact details
Sleep and Circadian Neuroscience Institute
Department of Clinical Neurosciences
Dorothy Hodgkin Crowfoot Building
South Parks Road
Oxford
United Kingdom
OX1 3QU
+44 (0)1865618665
nicola.barclay@ndcn.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
350096

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 65265

Study information

Scientific Title
A randomised controlled trial examining the sleep and circadian mechanisms of sleep restriction therapy in young adults with depression and anxiety

Acronym
SPECTRUM

Study objectives
The primary hypothesis is that Sleep Restriction Therapy (SRT) compared to Sleep Hygiene Education (SHE) will increase non-rapid eye movement (NREM) delta power at 8 weeks post-randomisation.

The primary mediation hypothesis is to test if changes in NREM delta power (week 4) mediate improvement in depression and anxiety severity at post-treatment (8 weeks).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/05/2025, City and East Research Ethics Committee (London Centre, London, E20 1JQ, United Kingdom; +44 (0)207 1048171; cityandeast.rec@hra.nhs.uk), ref: 25/LO/0349

Study design
Individual randomized superiority parallel group clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia and symptoms of mental health difficulties (anxiety and depression)

Interventions
This study will compare two behavioural sleep interventions (sleep improvement programmes) to understand which is more effective at modifying EEG delta power during NREM sleep. Following baseline assessments, participants will be eligible for randomisation. Eligible participants will be randomised (1:1) to Sleep Improvement Programme 1 (79 participants) or Sleep Improvement Programme 2 (79 participants) using a secure, validated and compliant web-based randomisation system (Sortition® - trademarked software from Oxford University Innovation), with a non-deterministic minimisation algorithm to ensure age (18-24 yrs vs. 25-30 yrs), sex (male, female, other), baseline insomnia severity (ISI score: <22 vs. 22-28), depression severity (PHQ-9 score: <20 vs. 20-27), anxiety symptom severity (GAD-7 score: <15 vs. 15-21) and mental health medication (yes, no) are balanced across the two groups. As this trial is not blinded, both the researcher and the participant will know which treatment group they have been allocated to.

Participants randomised to Sleep Improvement Programme 1 will be supported to follow a new personalised sleep schedule, which will be reviewed and adjusted each week. Participants randomised to Sleep Improvement Programme 2 will learn about the science of sleep and be supported with advice on how changing specific lifestyle and environmental factors can improve sleep. Both Sleep Improvement Programmes involve researcher-delivered manualised behavioural intervention over six brief weekly sessions. The six sessions will comprise one in-person session (session 1) and five remote review sessions (2-6), although all sessions could be

delivered in-person or remotely if a participant requests this. Participants will be provided with an intervention pack involving an information guide, sleep diaries, and worksheets to guide implementation of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
Relative NREM Delta power measured using polysomnography at 4 weeks and 8 weeks (primary end-point) after randomisation.

Key secondary outcome(s))
1. In-laboratory timing of circadian phase from Dim Light Melatonin Onset (DLMO) collected from saliva at 8 weeks post-randomisation
2. In-laboratory measure of circadian phase angle from saliva (difference between sleep attempt and DLMO) at 8 weeks post-randomisation
3. Measures of sleep continuity and sleep architecture (EEG variables to include: total sleep time, sleep onset latency, wake after sleep onset, sleep efficiency, absolute values of and proportion of total sleep time spent in stage NREM1, NREM2, NREM3, and REM sleep, NREM3 latency, and sleep-state transition probabilities) measured at 4 and 8 weeks post-randomisation
4. Self-reported depression severity measured using the Patient Health Questionnaire-9 (PHQ-9) at 4, 8 and 26 weeks post-randomisation
5. Self-reported anxiety severity measured using the Generalised Anxiety Disorder 7 (GAD-7) at 4, 8 and 26 weeks post-randomisation
6. Self-reported insomnia severity measured using the Insomnia Severity Index (ISI) at 4, 8 and 26 weeks post-randomisation
7. Sleep-related quality of life measured using the Glasgow Sleep Impact Index (GSII) at 4, 8 and 26 weeks post-randomisation
8. Chronotype measured using the reduced morningness-eveningness questionnaire (rMEQ) at 8 weeks post-randomisation
9. Self-reported pre-sleep arousal measured using the pre-sleep arousal scale (PSAS) at 4, 8 and 26 weeks post-randomisation
10. Cortical arousal measured using pre-sleep and NREM beta power (relative and absolute) derived from polysomnography at 4 and 8 weeks post-randomisation
11. Vigilance assessed hourly during DLMO protocol using the psychomotor vigilance test (PVT) at 8 weeks post-randomisation
12. State sleepiness measured hourly with the Karolinska Sleepiness Scale (KSS) at 8 weeks post-randomisation
13. Mediation analysis: Relative NREM delta power (measured with PSG) at week 4 as a mediator of PHQ-9 and GAD-7 at 8 weeks post-randomisation
14. Mediation analysis: Wake-time after sleep onset (measured with PSG) at week 4 as a mediator of PHQ-9 and GAD-7 at 8 weeks post-randomisation
15. Actigraphy-derived sleep and rest-activity patterns (sleep onset latency [SOL]; Wake-time after sleep onset [WASO]; Sleep efficiency [SE]; Total sleep time [TST]; Relative amplitude [RA]; sleep regularity index, intra-daily variability [IV]; inter-daily stability [IS]; timing of least active 5 [L5] hours and timing of most active 10 hours [M10]), measured at 8 weeks post-randomisation
16. C-reactive protein (CRP) measured from blood drawn at 8 weeks post-randomisation
17. Treatment adherence measured using time in and out of bed derived from mattress sensor, actigraphy and sleep diary during treatment (weeks 1-8 post-randomisation)
18. Regularity, absolute, and threshold levels of light exposure from ambulatory light sensor comparing overall and morning vs evening light, measured at 8 weeks post-randomisation

Completion date
04/05/2027

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female, aged between 18 and 30 years
3. Participant is able to follow study procedures as laid out in the participant information sheet
4. Sleep efficiency <85% (Pittsburgh Sleep Quality Index [PSQI] items)
5. Screening positive for depressive symptoms on the Patient Health Questionnaire (PHQ-9 [≥10]) and/or anxiety symptoms on the Generalised Anxiety Disorder assessment (GAD-7 [≥10]]
6. Screen positive for insomnia symptoms on the Sleep Condition Indicator, and meet criteria for insomnia disorder:
6.1. Sleep latency or WASO: ≥30 mins (Q1 or Q2 ≤2)
6.2. Frequency of disturbance: ≥3 nights a week (Q3 ≤2)
6.3. Sleep quality: average, poor, or very poor (Q4 ≤2)
6.4. Daytime functioning: Somewhat, much or very much impaired (Q5 or Q6 ≤2)
6.5. Chronicity of problem: ≥3 months (Q8 ≤2)
7. Typical sleep period takes place within the hours of 9 pm and 10 am
8. Currently registered with a GP practice
9. Able to read and understand English
10. Living within the Oxford area to facilitate at-home polysomnographic recordings
11. Has access to a computer, tablet or smartphone and an internet connection at home, or elsewhere, for treatment sessions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Key exclusion criteria
1. Previously received sleep restriction therapy
2. Currently receiving psychological treatment for insomnia from a health professional or taking part in an online treatment programme for insomnia
3. Another person in the household already participates in this trial
4. Currently taking part in another clinical trial which could affect outcomes in SPECTRUM

5. Currently or recently (within the last 2 months) received inpatient psychiatric treatment
6. Currently taking hypnotic medication or other psychotropic medication that, in the opinion of the investigator, significantly affects sleep. Participants who take antidepressant medication and have been on a stable dose will be eligible.
7. Pregnant/pregnancy planning in the next 6 months
8. Additional sleep disorder diagnosis (e.g., obstructive sleep apnoea) or positive following screening
9. Alcohol or drug-dependent
10. Epilepsy
11. Diagnosis of schizophrenia-spectrum disorder or bipolar disorder, or screening 'positive' for possible bipolar disorder
12. Current suicidal ideation with intent OR attempted suicide within the past 2 months
13. Night, evening, early morning or rotating shift-work, or other uncontrollable sleep disturbances such as caring responsibilities or night feeding
14. Transmeridian travel (>=2 time zones) over the past 1 month or planned in the coming 3 months
15. Contraindication to polysomnography such as extremely irritable or sensitive skin on scalp, or allergies to plaster adhesive
16. Any other reason that the investigator deems the participant to be ineligible

Date of first enrolment
23/06/2025

Date of final enrolment
05/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sleep and Circadian Neuroscience Institute (SCNI)
Dorothy Crowfoot Hodgkin Building
Department of Clinical Neurosciences
University of Oxford
South Parks Road
Oxford
United Kingdom
OX1 3QU

Sponsor information

Organisation

University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Nicola Barclay (nicola.barclay@ndcn.ox.ac.uk) or Prof. Simon Kyle (simon.kyle@ndcn.ox.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		02/05/2025	16/06/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes