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Understanding brain networks in people with insomnia and low mood following behavioural sleep treatment

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2026	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/09/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/09/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
There is evidence that chronic sleep problems (insomnia) are characterised by altered functional brain activity, and these alterations may help explain the link between sleep problems and worse mental health outcomes. Behavioural sleep treatments are commonly used to help people improve their sleep. These treatments focus on changing sleep-related behaviours and routines or providing advice about factors that influence sleep. While such approaches can be effective in improving sleep and daytime functioning, it is not yet fully understood how they affect brain functional networks or how changes in the brain may relate to improvements in sleep and mood. The aim of this study is to compare two behavioural sleep treatments to understand how they affect brain function, sleep, and mental health.

Who can participate?
Adults aged 18-40 years who experience frequent difficulty with falling asleep and/or waking up during the night (insomnia) and elevated depression symptoms

What does the study involve?
People interested in taking part will first complete an online screening questionnaire about their sleep, mood and general health. Those who appear eligible will then be invited to take part in an interview (telephone/video) to confirm whether the study is suitable for them. Participants who are eligible will begin with a baseline assessment period lasting 7 days. This will start with a visit to the University of Oxford for an MRI scan.

At the MRI visit, participants will:
1. Provide written informed consent
2. Complete questionnaires about their sleep and mood
3. Be screened for MRI safety
4. Undergo an MRI scan lasting around 1.25 hours, which will include scans taken at rest and while completing simple tasks
5. Have heart rate, breathing, and skin conductance recorded during the scan

After the MRI visit, participants will:
1. Wear an activity watch (actiwatch) to measure rest and activity
2. Wear a light sensor to measure light exposure
3. Complete a daily sleep diary for 7 days
4. Use a home EEG device for three nights to measure brain activity during sleep

After completing the baseline period, participants will be randomly assigned (by chance) to one of two sleep treatments:
Sleep treatment 1: Participants will complete six online sessions over a 10-week period, designed to support changes in sleep patterns and sleep-related behaviours.
Sleep treatment 2: Participants will have access to online educational materials that provide advice about sleep and factors that may influence sleep, such as daily routines and the sleep environment.

At 5 weeks after starting the intervention, all participants will complete short questionnaires about sleep and mood. At the end of the 10-week intervention, participants will complete a second 7-day assessment period, which repeats the baseline measures. This includes:
1. A second MRI scan
2. Questionnaires
3. Actiwatch, light sensor, and sleep diary
4. Home sleep EEG recordings

In total, participation in the study will last about 12 weeks.

What are the possible benefits and risks of participating?
Participants may experience improvements in their sleep from taking part. Taking part will also help researchers better understand how sleep treatments works to modify brain function. Additionally, the research may lead to new insights on the role of sleep quality in optimal brain health and how changes in sleep might drive improvement in mental health.
There are no known serious risks associated with the study. Some people may feel uncomfortable during MRI scanning. MRI scans can be noisy and require lying still for a long period. Participants may also be asked questions about sensitive topics related to mental health. Participants can skip any questions they do not wish to answer and may withdraw from the study at any time. A change to your sleep pattern may be associated with a short-term increase in sleepiness. If you do feel sleepy during the study, we advise that you avoid activities that require a high degree of vigilance, such as driving or operating heavy machinery.

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

When is the study starting and how long is it expected to run for?
August 2026 to May 2029

Who is funding the study?
Wellcome Trust (UK)

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

Contact information

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Principal investigator

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Study information

Scientific Title
Sleep Treatment to Aid emotion Regulation (STAR): a randomised controlled trial examining the impact of digital cognitive behavioural therapy for insomnia on brain function

Acronym
STAR

Study objectives
To investigate if a 6-week programme of digital cognitive behavioural therapy for insomnia, compared to sleep hygiene education, modifies resting-state functional networks at baseline and 11 weeks post-randomisation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/03/2026, Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) (Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 (6)16577; ethics@medsci.ox.ac.uk), ref: 1889201

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Poor sleep (insomnia) in young people with low mood

Interventions
This study will compare two behavioural sleep interventions (sleep treatments) to understand which is more effective at modifying functional neural networks.

Randomisation will occur after the completion of the 7-day baseline period for eligible participants. Participants will be randomised (1:1) to Sleep Treatment 1 (100 participants) or Sleep Treatment 2 (100 participants) using 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 sex, age (18-29 years vs 30-40 years), baseline depression severity (PHQ-9 score: 0-16 vs 17-27), baseline insomnia severity (ISI score: 0-19 vs 20-28), and mental health medication use (yes/no), are balanced across the two groups. Researchers will not be able to influence randomisation but will manually contact participants to inform them of their allocated arm of the study.

Participants randomised to Sleep Treatment 1 will complete a questionnaire to establish key sleep issues and therapy goals. They will receive a digital sleep treatment made up of six weekly sessions, lasting between 12 – 20 minutes each, which will involve following a new personalised sleep schedule.

Participants randomised to Sleep Treatment 2 will learn about the science of sleep and be supported with advice on how changing specific lifestyle and environmental factors can improve sleep.

Intervention Type
Behavioural

Primary outcome(s)
1. Blood-Oxygen-Level-Dependent (BOLD) changes in functional networks measured using resting state fMRI (rs-fMRI) at 11 weeks post-randomisation

Key secondary outcome(s)
1. Whole brain Blood-Oxygen-Level-Dependent (BOLD) fMRI in areas of interest including the amygdala, medial prefrontal cortex (including the anterior cortex), and orbitofrontal cortex ; differential amygdala response to fearful and happy faces; accuracy and reaction times of gender identification measured using an emotional processing (Faces) task at 11 weeks post-randomisation

2. Self-reported depression severity measured using the Patient Health Questionnaire-9 (PHQ-9) at 5 and 11 weeks post-randomisation

3. Self-reported insomnia severity measured using the Insomnia Severity Index (ISI) at 5 and 11 weeks post-randomisation

4. Self-reported anxiety severity measured using the General Anxiety Disorder-7 (GAD-7) at 5 and 11 weeks post-randomisation

5. Self-reported positive and negative affect measured using the Positive and Negative Affect Schedule (PANAS) at 5 and 11 weeks post-randomisation

6. Self-reported morningness measured using the Morningness-Eveningness Questionnaire (MEQ) at 11 weeks post-randomisation

7. Sleep onset latency (SOL); wake after sleep onset (WASO); sleep efficiency (SE); time in bed (TIB); total sleep time (TST); sleep onset time; sleep offset time; relative amplitude (RA); interdaily stability (IS); intradaily variability (IV); interdaily stability (IS); start of the least active 5 hours(L5 start); start of the most active 10 hours (M10 start), activity in the least active 5 hours (L5 average); activity in the most active 10 hours (M10 average); midpoint of sleep; time spent in moderate and vigorous physical activity (MVPA); Sleep Regularity Index (SRI); number of valid hours of data, number of hours of data; and non-wear time percentage measured using wrist-worn actigraphy at 11 weeks post-randomisation

8. TST, TIB, SOL, WASO, SE, proportion of TST spent in non-rapid-eye-movement (NREM) sleep stage 1, 2, 3, rapid-eye-movement (REM) sleep; N3 sleep latency; REM sleep latency; and EEG spectral power; sleep spindle count and density; and slow oscillation count and density measured using sleep EEG at 11 weeks post-randomisation

9. SOL, WASO, SE, TST, TIB, sleep quality (SQ); time to bed (TTB); time out of bed (TOB); time of sleep attempt; time of final awakening measured using Consensus Sleep Diary (CSD) at 11 weeks post-randomisation

10. Light IS, Light IV, Light RA, brightest 10 hours start hour (B10 Start), darkest 5 hours start hour (D5 Start), average light in brightest 10 hours (B10), average light in darkest 5 hours (D10), time above threshold (TAT) for 250, 500, and 1000 photopic and melanopic lux, Light Regularity Index (LRI), photoperiod length, average photopic and melanopic lux in the wake period; TAT for melanopic equivalent daylight illuminance (mEDI) >1, >10, and >250 lux; light sensor coverage; light sensor wear time; number of light sensor recording days measured using light sensor at 11 weeks post-randomisation

11. Whole brain BOLD fMRI response in areas of interest (striatum, medial prefrontal cortex, and insular cortex); Behavioural task data: total amount participants won, total wins and losses, choice accuracy, percentage consistency (percentage choices identical to the preceding choice), response times measured using the Probabilistic Instrumental Learning Task (PILT) at 11 weeks post-randomisation

Completion date
31/05/2029

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female adults aged 18-40 years
3. Participant can follow study procedures as laid out in the participant information sheet
4. A positive endorsement of depressive symptoms on the Patient Health Questionnaire (PHQ-9)

≥10
5. Meet the following criteria for insomnia disorder symptoms assessed using the Sleep Condition Indicator
5.1. Sleep latency or WASO: ≥30 mins (Q1 orQ2 ≤2)
5.2. Frequency of disturbance: ≥3 nights a week (Q3 ≤2)
5.3. Sleep quality: average, poor, or very poor (Q4 ≤2)
5.4. Daytime functioning: Somewhat, much, or very much impaired (Q5 or Q6 ≤2)
5.5. Chronicity of problem: ≥3 months (Q8 ≤2)
6. Living within the UK to facilitate attendance at MRI assessments
7. Able to read and understand English to complete MRI tasks
8. Has access to a computer, smartphone or device with an internet connection for sleep treatment programs
9. Currently registered with a GP

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Participants with ferromagnetic objects in their bodies (e.g., metal implants, vessel clips, shrapnel injuries) or with implanted devices which may be damaged by the MRI magnet (e.g., heart pacemakers). Any other MRI contraindication following MRI safety screening.
2. Pregnant or planning a pregnancy in the next 6 months.
3. Another person in the household already participates in this trial.
4. Currently taking part in another trial, which may affect the outcome of this study.
5. Previous use of a digital sleep intervention called ‘Sleepio’ in any capacity
6. Taken part in a study that used similar computer tasks (MRI faces task) as those in the present study
7. Any other present or past medical condition that may interfere with the safety of the participant or the scientific integrity of the study, e.g., brain injury, central nervous system (CNS) tumours, neurological conditions.
8. Diagnosis of epilepsy or history of seizures.
9. Clinically-relevant symptoms of a probable additional sleep disorder (e.g., possible obstructive sleep apnea, restless legs syndrome).
10. Habitual night shift, evening, or rotating shift workers (assessed during the last month)
11. Current suicidal ideation with intent OR attempted suicide within the past 2 months as determined by the Columbia Suicide Severity Rating Scale (C-SSRS).

12. Currently taking hypnotic medication or medications that, in the opinion of the investigator, significantly affect sleep/the integrity of the study. Participants who take antidepressant medication and have been on a stable dose will be eligible.
13. Diagnosis of schizophrenia-spectrum disorder, bipolar disorder, or any significant personality disorder (e.g., borderline personality disorder).
14. Alcohol or drug-dependent assessed with the AUDIT alcohol use disorder and substance use dependence modules.
15. Smoking > 10 cigarettes per day, or vaping a comparable amount (>1 ml / half of a 2 ml vape)
16. Participant is unlikely to comply with the study protocol or for any other reason that the investigator deems the participant to be ineligible.
17. Contraindication to ambulatory EEG, such as extremely irritable or sensitive skin on the scalp, or allergies to plaster
18. Transmeridian travel (>=2 time zones) over the past one month or planned in the coming 3 months
19. Currently or recently (within last 2 months) received in-patient psychiatric treatment
20. Life expectancy less than a year / cancer treatment

Date of first enrolment
31/08/2026

Date of final enrolment
10/03/2029

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
University Offices
Oxford
England
OX1 2JD

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

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
Datasets generated during and/or analysed during the current study will be available upon reasonable request from the chief investigator Prof. Simon Kyle (simon.kyle@ndcn.ox.ac.uk).

Data which has had direct identifying information removed may be shared with other academic and commercial organisations in the future, including those outside of the UK and the EU. Participants will be informed of this, and specific consent to this is obtained within the Informed Consent Form.

Only data without personal information will be shared with any other organisations. Normalised MRI data may be added to an online scientific data sharing repository. Before being shared, facial features, direct identifiers, and participant IDs will be removed. The repository used will be within the UK, the European Economic Area, or a GDPR adequate country.

In line with open science principles, fully anonymised data sets may be added to open data repositories after data analysis and manuscript submission have been completed, for increased reproducibility. It is clear in the participant information sheet how the study data will be shared and we ask participants to consent to this use of their research data.

No shared data will be linked to any personally identifiable information.

To comply with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, personal data will be deleted as soon as possible after it is no longer needed for the study. Participants' identities will be retained until the end of the study, and participants have been sent a summary of the study results. This data will then be destroyed by deleting.

Participants who have agreed on the informed consent form to be provided with a summary of the study findings will be contacted via their preferred method (email or post) at the end of the study. Participants will be informed that they will not receive a summary of the study findings until the end of the study

IPD sharing plan summary

Available on request