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Testing a sleep improvement programme for shift workers

Submission date
10/06/2025

Recruitment status
No longer recruiting

Registration date
13/06/2025

Overall study status
Ongoing

Last Edited
13/06/2025

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
Shift work can often lead to significant sleep disruption because the work schedule overlaps with the usual time for sleep and can be confusing for our body clock. Significant problems with falling asleep and staying asleep, or excessive sleepiness due to shift work is called shift work sleep disorder (SWD) and this can have a considerable impact on health and well-being. We aim to develop and test an intervention for SWD in shift workers employed in the National Health Service (NHS). This feasibility study will examine whether the intervention can be delivered in a safe and acceptable way.

Who can participate?
NHS shift workers who meet the study criteria for SWD from local NHS Trusts

What does the study involve?
Eligibility will be checked in two stages: an online questionnaire followed by a brief interview. Questionnaires on sleep, fatigue, quality of life, mental health and overall health will be collected at baseline (online or telephone). Participants will also be asked to complete a sleep diary and wear an acti-watch (wrist-worn device similar to a Fitbit that measures movement) for 14 consecutive days; and place a mattress sensor under their bed for the entire study period for sleep estimation. They will then receive six fortnightly, one-to-one, online sessions of the behavioural sleep intervention. Each session will last around one hour and will be delivered by a trained research nurse/member of the research team (termed 'facilitator'). Questionnaires will be collected at the end of the intervention.
A small group of participants and facilitators will be interviewed (online or by telephone) about their experience of the intervention and the study. Data on people coming into and staying in the study and their use of the intervention will be recorded. Based on the study results, a decision will be made on whether we can proceed to a larger trial.

What are the possible benefits and risks of participating?
Benefits:
The participants may benefit from improved sleep by taking part in this study. They will also contribute to research, which may help develop better treatments for people experiencing sleep problems because of working shifts.

Risks:
We will make clear in participant-facing documents that, if a participant is in any way concerned about their health, they should consult with their GP directly. The participant information sheet will also make it clear that study participation will in no way affect usual care. The intervention provided as part of this study is in addition to usual care and therefore participants will be able to access/continue to access support relevant to their health during the study.
The intervention proposed for this study is considered low risk and, therefore, the likelihood of serious adverse events is low. Previous similar research on CBT-I and sleep hygiene education has not reported any serious adverse events attributed to treatment.
Few potential risks have been identified and steps taken to address these are outlined below:
Emotional discomfort: There is a small chance that the participants may find answering questions about their sleep problems and/or health upsetting. If they do not feel comfortable answering such questions, we would discourage them from participating in the study or taking part in the online screening phase.
Risk of suicide or acute mental distress: Suicidal ideation with intent or recent suicide attempt is part of the study exclusion criteria and will be assessed at the eligibility phase via interview (stage 2 screening). Should we identify participants with current suicidal ideation with intent (or acute mental distress) we will provide them with standardised information on where to seek support and inform the participant's GP practice so that appropriate follow-up can take place. Study consent will require participants to agree to the research team contacting their practice if there is concern about their health at any point during the study.
Short-term increase in sleepiness: As the intervention targets sleep and sleepiness, it is anticipated that participants will encounter improvements in sleep quality and/or alertness. However, changes to the sleep pattern may engender short-term increases in sleepiness for some participants. All participants will be alerted to this possibility and be provided with advice in relation to managing sleepiness (which is also a target of the intervention) as well as avoiding activities that require a high degree of vigilance, such as driving. If the facilitators believe excessive sleepiness is conferring an increased risk within the participants' roles, they will recommend that the participants speak with their line managers/occupational health services.
Contraindications for phototherapy: During the stage 2 screening, participants will be asked about conditions that may be exacerbated by using phototherapy. This includes, but is not limited to, eye disease, photosensitive migraines, and photosensitive epilepsy. Although not an exclusion criterion, if the participant indicates a contraindication, light goggles will not be sent in the intervention material pack. Regardless, before initiating phototherapy using the goggles in session 2 of the intervention, the facilitators will recheck for conditions that could be exacerbated using phototherapy. If indicated, the participant will be told not to use the light goggles and focus on natural sources of light instead.
Acti-watch skin irritation: The acti-watch can occasionally cause localised skin irritation for some participants. If this happens, we will encourage them to stop using the device(s) and contact the research team.
If participants have any concerns in relation to the topics raised in the study or if they believe that they require immediate help during the study, we will advise them to contact their general practitioner or visit their local emergency healthcare services. The helpline number of Samaritans will also be provided.

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

When is the study starting and how long is it expected to run for?
April 2023 to March 2026

Who is funding the study?
This research programme of work on shift work sleep disorder is funded by the National Institute for Health and Care Research (NIHR) as part of their Programme Grants for Applied Research programme (NIHR203667).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
350739

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 67765; Grant Code: NIHR203667

Study information

Scientific Title
Developing and testing an intervention for shift work sleep disorder in NHS workers: a feasibility and acceptability study

Acronym
OxBIS

Study objectives
As this is a feasibility study, there is no study hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2025, Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) (Research Governance, Ethics & Assurance, Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, UK; Tel: not applicable; ethics@medsci.ox.ac.uk), ref: 961131

Study design
Non-randomized; Interventional; Design type: Treatment, Complex Intervention, Other

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Shift work sleep disorder

Interventions

The aim of our study is to develop and test a new behavioural intervention for NHS shift workers who experience sleep problems due to working shifts. This feasibility study will examine whether the intervention is acceptable to participants and will help prepare for a larger trial to assess its impact on sleep and other aspects of health. The study will use a single-arm, mixed-methods feasibility and acceptability design.

Up to 30 participants will be recruited from two NHS Trusts in Oxford (Oxford University Hospitals NHS Foundation Trust and Oxford Health NHS Foundation Trust). The study will be promoted to all shift workers in both Trusts through the communication team via existing channels (e.g., weekly staff bulletin, trust social media platforms such as X) and recruitment posters displayed in the staff areas.

Eligibility will be assessed in two stages; first through an online screening questionnaire, followed by a brief interview with the research team (for those identified as potentially eligible from stage 1). Baseline assessments (online or over the phone) will be arranged for eligible participants. During this assessment, informed consent will be obtained, and baseline questionnaires will be completed. Following the baseline assessment, participants will be asked to complete a sleep diary and wear an acti-watch for 14 consecutive days, and place a mattress sensor under their bed for the entire study period. The first intervention session will be scheduled following the return of the baseline equipment (sleep diary and acti-watch). There will be six online intervention sessions with approximately one session every two weeks, depending on the participant's shift schedule. The duration of each session will be approximately one hour. The intervention will be delivered by trained NIHR Research Delivery Network (RDN) nurses, Research Nurses or a member of the research team (termed 'facilitator'). At the end of the intervention, the research team will contact the participant to complete the post-intervention outcome measures (online or over the phone), including 14-day sleep diary and an acti-watch. Semi-structured interviews on the experience of the intervention and the study procedures will be conducted by one of the researchers with purposively selected participants (n = 15) following completion of the post-intervention assessment. Interviews will last for approximately 45 to 60 minutes and will be audio recorded. Similar semi-structured interviews on the experience of delivering the intervention will be conducted with the facilitators (n = approximately 5) at the end of the study by one of the researchers.

The study will be using an online survey provider that is recognised as UK General Data Protection Regulation (UK GDPR) secure for the screening questionnaire and for the collection of outcome measures at baseline and post-intervention (REDCap or Qualtrics).

Intervention Type

Behavioural

Primary outcome(s)

Feasibility:
1. Participant recruitment will be measured by the number of participants recruited per month and the total time taken to reach full recruitment at the end of the study
2. Participant retention will be measured by the proportion of participants who complete the end-of-study assessments at the end of the study
3. Intervention engagement will be measured by the proportion of sessions attended by

participants at the end of the study
4. Intervention fidelity will be measured by the proportion of the intervention components covered by the facilitators during the delivery of the intervention at the end of the study

Key secondary outcome(s))
Acceptability and experiences:
1. Acceptability will be measured by the adapted theoretical framework of acceptability (TFA) questionnaire at post-intervention
2. Adverse events will be measured by the custom adverse events questionnaire at post-intervention
3. Experiences of participants will be explored through semi-structured interviews at the end of the study
4. Experience of facilitators will be explored through semi-structured interviews at the end of the study

Process measures:
1. Pre-sleep arousal will be measured by the Pre-Sleep Arousal Scale (PSAS) at baseline and post-intervention
2. Sleep hygiene behaviours will be measured by the Sleep Hygiene Index (SHI) at baseline and post-intervention

Indicators of clinical effectiveness:
1. Self-rated insomnia severity will be measured by the Insomnia Severity Index (ISI) at baseline and post-intervention
2. Self-rated sleepiness will be measured by the Epworth Sleepiness Scale (ESS) at baseline and post-intervention
3. Self-rated fatigue will be measured by the Flinders Fatigue Scale (FFS) at baseline and post-intervention
4. Self-rated health-related quality of life (HRQoL) will be measured by the EuroQoL (EQ-5D-5L) plus the sleep bolt-on at baseline and post-intervention
5. Self-reported depression symptoms will be measured by the Patient Health Questionnaire-9 (PHQ-9) at baseline and post-intervention
6. Impairment will be measured by the Work Productivity and Activity Impairment questionnaire (WPAI) at baseline and post-intervention
7. Sleep onset latency (SOL), wake time after sleep onset (WASO), total sleep time (TST), time in bed (TIB), sleep efficiency (SE), and sleep quality (Likert scale) will be obtained from the sleep diaries at baseline and post-intervention
8. Sleep onset latency (SOL), wake-time after sleep onset (WASO), total sleep time (TST), time in bed (TIB), and sleep efficiency (SE) will be obtained from the acti-watches at baseline and post-intervention
9. Measures of time in bed regularity, sleep stability, sleep structure, and sleep continuity will be collected from the under-mattress sensor at baseline and post-intervention

Exploratory:
1. The use of services and resources will be measured by the Adapted Client Service Receipt Inventory (CSRI) at post-intervention

Completion date
23/03/2026

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Aged 18 years or above
3. Employed by the NHS
4. Meets criteria for SWD according to self-reported items on the shift work disorder index (SWDI) and semi-structured interview:
4.1. Evidence of insomnia and/or sleepiness attributed to shift work
4.2. Evidence of distress or impairment to occupational/social functioning
4.3. Working non-standard hours (defined as shifts that involve working after 6 pm or before 7 am) for a minimum of 1-3 times a week for at least 3 months
5. Has stable internet access

Facilitators must be willing and able to give informed consent to participate in the follow-up interviews

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Sleep difficulty explained by another co-occurring health condition or other factor (e.g., caring responsibilities)
2. Not currently working (e.g. long-term absence due to illness or paternity/maternity)
3. Currently receiving formal psychological treatment for sleep difficulties from a healthcare professional
4. Untreated co-morbid sleep disorder (e.g., sleep disordered breathing or sleep-related movement disorder). Comorbid sleep disorders are permitted provided they are actively managed.
5. Diagnosis of bipolar disorder or schizophrenia-spectrum disorders
6. Diagnosis of mild cognitive impairment or dementia
7. Current suicidal ideation with intent OR attempted suicide within the past 12 months
8. Currently pregnant or pregnancy planned in the next 5 months
9. Currently receiving cancer treatment
10. Planned major surgery during the next 5 months
11. Unable to understand spoken or written English
12. Taking part in another research study that may affect the outcomes of the present study
13. Unable or unwilling to provide informed consent for the study

14. Unable or unwilling to comply with the study procedures and/or intervention
15. Non-NHS employed staff (e.g., agency staff, students on placement, honorary staff, contractors)

There are no specific exclusion criteria for the facilitators to participate in the follow-up interviews.

Date of first enrolment
23/06/2025

Date of final enrolment
23/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Oxford Health NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
Littlemore
Oxford
United Kingdom
OX4 4XN

Sponsor information

Organisation
University of Oxford

ROR

https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	17/04/2025	12/06/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes