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Addressing Sleep and Sleepiness In ShifT workers (ASSIST)

Submission date
01/09/2026

Recruitment status
Recruiting

Registration date
10/11/2026

Overall study status
Ongoing

Last Edited
10/11/2026

Condition category
Nervous System Diseases

[ ] 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 conflicts with the usual time for sleep and can confuse our body clock. When a shift work schedule causes problems with falling asleep, staying asleep, or excessive sleepiness, it is known as shift work disorder (SWD), which can have a major impact on health and well-being. This study aims to compare two different approaches that may help improve sleep in shift workers who experience these difficulties.

Who can participate?
NHS shift workers who meet the criteria for SWD can take part in this study.

What does the study involve?
Participants' eligibility will be checked in two stages: first through an online questionnaire, and then via a brief online or telephone interview with a member of the research team. If eligible, participants will give their consent and complete online questionnaires on sleep, fatigue, quality of life, mental health, and overall health. They will also complete a sleep diary on a digital sleep app for 14 consecutive days.

Participants will then be randomly assigned to receive either the OxBIS intervention or sleep hygiene education (SHE). The Oxford Behavioural Intervention for Shift work (OxBIS) intervention involves six one-to-one online sessions with a trained facilitator. The sessions will take place 1 to 2 weeks apart and will last about one hour each. Participants in the SHE group will receive a booklet containing information and practical tips to help improve their sleep.

Follow-up assessments will be completed at 13, 26, and 52 weeks after randomisation.

What are the possible benefits and risks of participating?
Participants may benefit from improved sleep and from learning more about their sleep and ways to improve it. By taking part, participants will also help researchers understand how to improve sleep problems in people who work shifts, which may benefit others in the future.

No serious risks are expected from taking part in the study. However, some participants may find questions about their sleep or health upsetting. Changes to sleep patterns may also lead to increased sleepiness for a short time. If this happens, participants will be asked to take extra care with activities that require a high level of alertness, such as driving or operating machinery. If participants feel unusually sleepy while working, they will be advised to speak to their line manager or occupational health team.

Where is the study run from?
University of Oxford, UK.

When is the study starting and how long is it expected to run for?
October 2026 to March 2029.

Who is funding the study?
The National Institute for Health Research (NIHR) Programme Grants for Applied Research, UK.

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
370552

Central Portfolio Management System (CPMS)
73381

National Institute for Health and Care Research (NIHR)
203667

Study information

Scientific Title
Clinical and cost-effectiveness of a behavioural sleep intervention for shift work sleep disorder: A randomised controlled trial

Acronym
ASSIST

Study objectives
Primary Objective
To evaluate the effectiveness of the Oxford behavioural intervention for shiftwork (OxBIS) compared with sleep hygiene education (SHE) in reducing insomnia severity

Secondary Objectives
1. To explore the effectiveness of the OxBIS compared with SHE on secondary clinical outcomes
2. To evaluate the cost-effectiveness of the OxBIS compared to SHE

Tertiary Objective
To conduct a mixed-methods process evaluation to explore the mechanisms of action, contextual factors, and implementation processes associated with OxBIS delivery and the study procedures

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/07/2026, 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, United Kingdom; -; ethics@medsci.ox.ac.uk), ref: 3237445

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

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

Interventions

Randomisation
Randomisation will be done using a secure, validated, and compliant web-based randomisation system. Allocation will be at a ratio of 1:1 and will be carried out using a non-deterministic minimisation algorithm, stratified by site, sex (male/female/other), age (18-45, >45 yrs), circadian preference (early/intermediate/late), and baseline ISI score (<16, 16+). Given the nature of the intervention, participants and the facilitators delivering the intervention will not be blinded to allocation. The facilitators will not be involved in the collection of trial outcomes. Outcomes will be self-completed, limiting the possibility of observer/interviewer bias. Should participants want to complete questionnaire outcomes over the phone, we will ensure that the researcher is blind to group allocation.

Description of study intervention (OxBIS)
Participants randomised to the intervention arm will receive the Oxford Behavioural Intervention for Shift Work (OxBIS). OxBIS is a behavioural intervention developed to manage SWD by targeting behavioural, cognitive, and circadian factors that contribute to the manifestation and perpetuation of SWD symptoms. Key intervention targets include sleep and circadian knowledge, reviewing and optimising the sleep-wake schedule based on participant's weekly sleep records, optimising the sleep environment and light-dark exposure, advice on lifestyle factors for consolidating circadian entrainment, behavioural strategies for managing insomnia (e.g., stimulus control), and skill training to manage potential stresses that arise from either shift work or the conflict between shift work and family and social life.

OxBIS consists of six sessions, with the first session running for approximately 90 minutes and the remaining sessions running for approximately 45-60 minutes. The intervention will be provided via video conferencing in a one-to-one format with flexible scheduling to accommodate participant preferences. The intervention is designed to be completed within 13 weeks, and participants will be encouraged to attend one session approximately every 1-2 weeks.

The intervention will be delivered by trained facilitators such as NIHR RRDN staff members (i.e., research nurses and clinical research practitioners), suitable professionals from the research sites (e.g., research nurses from the Trust Research and Development department), or members of the University research team (i.e., research assistants).

Description of the control arm intervention (SHE)
Participants randomised to the control arm will receive sleep hygiene education (SHE) in the form of a self-guided booklet. Following randomisation, participants will be provided with a digital copy of the SHE booklet (or a printed copy upon request).

The booklet will cover: 1) psychoeducation on sleep and circadian rhythm, 2) psychoeducation on the impact of shift work on sleep, 3) optimising bedroom environment, 4) generic guidance on light exposure and caffeine use, 5) general guidance on lifestyle factors relevant to sleep (e.g., exercise, use of sedatives), and 6) community resources, including any relevant websites. All information will be drawn from existing advice and guidance available online. The booklet will not constitute a novel intervention. Instead, it will be a consolidation of routinely accessible information in a structured format.

Intervention Type
Behavioural

Primary outcome(s)

1. Self-rated insomnia severity at 26 weeks, measured using the Insomnia Severity Index (ISI) questionnaire, at baseline, 13, 26, and 52 weeks post randomisation

Key secondary outcome(s)
1. Sleepiness measured using the Epworth Sleepiness Scale (ESS) at baseline, 13, 26, and 52 weeks post randomisation

2. Fatigue measured using the Flinders Fatigue Scale (FFS) at baseline, 13, 26, and 52 weeks post randomisation

3. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 13, 26, and 52 weeks post randomisation

4. Impact/impairment measured using the Work Productivity and Activity Impairment questionnaire (WPAI) at baseline, 13, 26, and 52 weeks post randomisation

5. Health-related quality of life (HRQoL) measured using the EuroQoL (EQ-5D-5L) (also used for the cost-effectiveness evaluation) at baseline, 13, 26, and 52 weeks post randomisation

6. Pre-sleep arousal measured using the Pre-Sleep Arousal Scale (PSAS) at baseline, 13, 26, and 52 weeks post randomisation

7. Sleep hygiene behaviours measured using the Sleep Hygiene Index (SHI) at baseline, 13, 26, and 52 weeks post randomisation

8. Sleep-related quality of life measured using the Glasgow Sleep Impact Index (GSII) at baseline, 13, 26, and 52 weeks post randomisation

9. Shift work disorder (SWD) measured using the Shift Work Disorder Index (SWDI) at baseline, 26 and 52 weeks post randomisation

10. Sleep parameters, such as sleep onset latency (SOL), wake time after sleep onset (WASO), total sleep time (TST), time in bed (TIB), and sleep efficiency (SE), measured using the Sleep diary (2-weeks) at baseline, 26 and 52 weeks post randomisation

11. Resource use measured using the Adapted Client Service Receipt Inventory (CSRI) at 13, 26, and 52 weeks post randomisation

12. Adverse events measured using a custom adverse events questionnaire at 13, 26, and 52 weeks post randomisation

13. Experiences of participants in the intervention arm measured using an interview after completing the assessment at 13 weeks post randomisation

14. Satisfaction measured using a custom satisfaction questionnaire at 13 week post randomisation

Completion date
31/03/2029

Eligibility

Key inclusion criteria
The participant may enter the study if ALL of the following apply:
1. Willing and able to give informed consent for participation in the study
2. Aged 18 years or above
3. Employed by the NHS and working at a participating Trust
4. Worked non-standard hours (defined as work scheduled after 6 pm or before 7 am) for a minimum of 3 months.
5. Meets the DSM-5 criteria for SWD according to self-reported items on the shift work disorder index (SWDI), and a semi-structured interview. This includes the presence of insomnia and/or excessive sleepiness associated with a recurring work schedule outside of standard work hours (minimum of one non-standard shift per week) and that overlaps with or restricts one's desired sleep schedule. Symptoms must have persisted for 3 months or more and not be better explained by another sleep, medical, or mental disorder.
6. Has stable internet access and access to technology (e.g., computer, tablet, or smartphone) required to participate in online sessions, if assigned to the intervention arm.

NOTE: Participants will need to have a basic understanding of English to take part in the study, as the intervention and study materials will be delivered in English, and translation services cannot be provided due to the nature of the intervention. As participants will all be NHS staff, we expect this requirement to be met, as a sufficient level of English proficiency is required to undertake NHS roles. We therefore do not anticipate that this requirement will exclude any eligible participants. Hence, this has not been explicitly mentioned as an inclusion/exclusion criterion.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
A participant will not be eligible for the study if ANY of the following apply:
1. Non-NHS-employed staff (e.g., agency staff, students on placement, honorary staff, contractors)
2. Not currently working (e.g. long-term absence due to illness, parental leave)
3. Sleep difficulty better explained by other co-occurring health conditions or factors (e.g., caring responsibilities)
4. Currently receiving formal psychological treatment for sleep difficulties from a healthcare professional.

5. Untreated comorbid sleep disorder (e.g., sleep-disordered breathing or sleep-related movement disorder). Comorbid sleep disorders are permitted provided they are actively managed.
6. Diagnosis of mild cognitive impairment or dementia.
7. Current suicidal ideation with intent OR attempted suicide within past 6 months
8. Currently receiving cancer treatment
9. Planned major surgery during the next 4 months
10. Taking part in another research study that may affect the outcomes of the present study.
11. Another member of the same household is taking part in the trial
12. Previously took part in the OxBIS feasibility study

Date of first enrolment
01/10/2026

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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