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Investigating an environmental intervention for office workers with poor sleep

Submission date
11/03/2025

Recruitment status
No longer recruiting

Registration date
13/03/2025

Overall study status
Completed

Last Edited
13/03/2025

Condition category
Nervous System Diseases

[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
This study is being conducted to explore whether changes in how office workers - individuals who spend most of their workday seated at a desk indoors - interact with their environment can improve their sleep quality. Sleep difficulties are common among adults and can lead to problems such as poor concentration and reduced productivity. This research aims to assess an intervention that could enhance sleep, ultimately benefiting daily well-being and performance.

Who can participate?
Adults aged 23 to 65 years old who are experiencing difficulties with their sleep and are currently employed in a job where they spend the majority of their day sitting at a desk, indoors (i.e., an office worker), working full-time (usually from 9 AM to 5 PM, Monday to Friday) within Oxford.

What does this study involve?
At the start of the study, participants will receive study equipment, instructions, and an intake questionnaire. The study lasts six weeks, beginning with a two-week baseline phase, followed by a four-week intervention phase.

Throughout the study, participants will:
• Wear an actigraph and a Button device for the full 6 weeks.
• Complete daily sleep and activity diaries('My Sleep' upon waking and 'My Day' before bedtime).
• Record significant events in a "My Events" Log.
• Wear a HSM sleep EEG device for one night at the end of Week 2 and Week 6 (total: 2 nights).
• Complete six to eight questionnaires at the end of Week 2, Week 4, and Week 6, plus two final questionnaires at the study's conclusion.

For the intervention, participants will receive two educational booklets and attend five researcher-led sessions—one in person and four online (via video conferencing, e.g., Microsoft Teams). All study activities will take place within participants' regular routines. At the end of the study, all equipment must be returned. Some participants may also be invited to a follow-up interview to discuss their experiences with the study and intervention.

What are the possible benefits and risks of participating?
Benefits:
There will be no direct benefit to participants taking part in this study, other than potential improvements to their sleep.

Participants will receive a £100 Amazon voucher for participating in the full study. They will receive a £20 Amazon voucher for completing the first two weeks of the study (Weeks 1 and 2). For completing the last 4 weeks of the study (Weeks 3 to 6 + Study End), they will receive an £80 Amazon voucher. Payment will be given once they have successfully returned the sensors after the six-week study period. To simplify the payment process, they will be given the full payment of vouchers (£100) at the end of the study, unless they request otherwise. If a participant takes part in the follow-up interview, they will receive an additional £15 Amazon voucher for their time.

Risks:
1. Wearing the Sensors: The actiwatch needs to be worn both day and night, and the button sensor throughout the day. To take part in the study, this would need to be feasible within the participant's daily routine, job responsibilities, or any other tasks they undertake. They may experience some irritation from wearing the actiwatch; if this is the case, alternative arrangements will be made.
2. Emotional Repercussions from questionnaires: The questionnaires will ask about participants' mental health. Reflecting on certain emotions can sometimes be distressing. These questionnaires are for data collection only and are not meant as a treatment or diagnosis. If participants feel overwhelmed or distressed during the study, they can reach out to the study team immediately. More generally, if they are concerned about any aspect of their health during the study, it is recommended that they contact their GP. For additional support or information, participants can consider the following resources:
- https://oxfordshirerecoverycollege.org.uk/signposting/
- https://www.oxfordshire.gov.uk/residents/social-and-health-care/health-recovery-and-wellbeing/mental-wellbeing?utm_term=nil
3. Privacy Concerns About Sensor Data: Some participants might be concerned that the sensors could reveal specific activities they engage in. These sensors are designed to track sleep-wake patterns and cannot determine the exact nature of activities participants are involved in. It is important to note, however, that the HSM device records sound in the environment, however, this is heavily filtered such that conversations cannot be heard (the audio is highly muffled). Whether participants choose to wear this device or not is entirely optional.

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 2023 to January 2026

Who is funding the study?
1. NIHR Oxford Biomedical Research Centre (BRC)
2. Better Sleep: NIHR Oxford Health BRC
3. Dr Mortimer and Theresa Sackler Foundation

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Investigating the feasibility and acceptability of an environmental Intervention foR offIce workers with poor Sleep

Acronym
IRIS

Study objectives
Primary [Feasibility]
Recruitment:
1. To assess the percentage of individuals eligible to participate in the trial.

Intervention Fidelity:
2. To assess the average percentage of intervention content delivered in each intervention session.
3. To assess the average percentage of intervention sessions attended.

Data Completeness:
4. To assess the percentage of participants that provide complete Insomnia Severity Index data at the primary endpoint.

Primary [Acceptability]
5. To assess participants' self-report assessment of the overall acceptability of the intervention and study procedures.

Secondary
1. To assess the potential effectiveness of our intervention, we will evaluate changes in time spent exposed to environmental factors during the day (wake-up to 8 pm).
2. To assess the potential effectiveness of our intervention, we will evaluate changes in time spent exposed to environmental factors during the evening (8 pm to bedtime).
3. To assess the potential effectiveness of our intervention, we will evaluate changes in time spent exposed to environmental factors at night (bedtime to wake-up).
4. To assess the effect of our intervention on insomnia symptoms, we will evaluate changes in the Insomnia Severity Index (ISI) score.

Exploratory
1. To assess the potential effectiveness of our intervention, we will evaluate changes in time spent exposed to environmental factors during the day, evening, and night using a different quantity to our secondary objectives.
2. To assess the potential effectiveness of our intervention, we will evaluate the rate of change in time spent exposed to environmental factors across the day (wake-up to 8 pm), evening (8 pm to bedtime), and night (bedtime to wake-up).
3. To assess the potential effectiveness of our intervention, we will evaluate the rate of change in self-reported exposure to environmental factors.
4. To assess the effect of the intervention on the regularity of exposure to environmental factors.
5. To assess the effect of the intervention on environmental exposure timing variability, we will evaluate changes in mean environmental timing for daytime, evening, and night.
6. To assess how environmental exposure differs between settings (Home, Office, Hybrid, Off-Work) and how these differences change over time. Specifically, we will evaluate time spent exposed to environmental factors during the day (wake-up to 8 pm).
7. To assess the agreement between self-reported and objective measures of environmental exposure, we will conduct a modified Bland-Altman analysis. Additionally, we will determine whether participants improve in their accuracy of their self-reported environmental exposure estimations.
8. To assess the effect of our intervention on insomnia symptoms, we will also compare changes in the Insomnia Severity Index (ISI) mid intervention.
9. To evaluate the effect of our intervention on sleep and circadian rhythms using data from actigraphs (ActTrust 2), sleep EEG (HST REM), and the Consensus Sleep Diary (CSD).
10. To assess the impact of our intervention on fatigue symptoms, using the Flinders Fatigue Scale (FFS).
11. To assess the effect of our intervention on sleep hygiene behaviours using the Sleep Hygiene Index (SHI).
12. To assess the effect of our intervention on chronotype using the Reduced Morningness-

Eveningness Questionnaire (rMEQ) and Ultra Short Munich ChronoType Questionnaire.
13. To assess the effect of our intervention on anxiety symptoms using the Generalised Anxiety Disorder questionnaire (GAD-7).
14. To assess the effect of our intervention on depressive symptoms using the Patient Health Questionnaire (PHQ-9).
15. To assess the effect of our intervention on work performance using the Work Productivity and Activity Impairment questionnaire (WPAI:SHP).
16. To assess the effect of our intervention on activity using self-report data from our My Day diary.
17. To investigate whether changes in environmental exposure mediate improvements in insomnia symptoms, sleep and circadian rhythms, fatigue, chronotype (shift towards morningness/early-type), anxiety, depressive symptoms, and work productivity.
18. To assess the bidirectional relationship between environmental exposure and sleep hygiene over time.
19. To assess the perceived credibility of our intervention (acceptability).
20. To qualitatively assess the acceptability of the intervention and study procedures using the Theoretical Framework of Acceptability.
21. To assess the barriers and facilitators faced by participants when carrying out the intervention behaviours in terms of their Capability, Opportunity, and Motivation (COM-B).
22. To identify whether self-report screening variables predict low baseline environmental exposure.
23. To explore whether satellite-based measurements of environmental data reflect personal environmental exposure.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 15/11/2023, University of Oxford's Medical Sciences Interdivisional Research Ethics Committee (Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Oxford, OX3 7GB, United Kingdom; +44 (0)1865(6)16577; ethics@medsci.ox.ac.uk), ref: MS IDREC R86336/RE001

2. approved 13/02/2025, University of Oxford's Medical Sciences Interdivisional Research Ethics Committee (Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Oxford, OX3 7GB, United Kingdom; +44 (0)1865(6)16577; ethics@medsci.ox.ac.uk), ref: MS IDREC R86336/RE002

Study design
Single-centre single-arm interventional feasibility and acceptability trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Modifying the behaviour of office workers to improve sleep

Interventions

The intervention will be delivered to participants through a combination of in-person and video conferencing sessions (e.g., Microsoft Teams). The intervention consists of five sessions conducted over four weeks. Participants will receive two educational booklets after the first session. These materials are to be studied by participants.

The first session will be conducted in person, with the option to use video conferencing software if necessary. This session will include an educational component lasting approximately 10–20 minutes, followed by a review of the participant's environmental data. Barriers and facilitators to healthy environmental behaviours will be identified, and the researcher will work with the participant to set personalised environmental behaviour goals to be achieved before the next session. The first session will last approximately one hour.

The subsequent four sessions will be conducted via video conferencing (e.g., Microsoft Teams), although participants may opt to attend in person at the Dorothy Crowfoot Hodgkin Building, University of Oxford. These sessions will focus on reviewing the participant's environmental data, addressing barriers and facilitators, and setting new environmental behaviour goals. Each of these follow-up sessions will last approximately 30–45 minutes.

Participants will not be randomised into arms, as this is a single-arm intervention. The primary focus is on encouraging participants to improve their environmental behaviours.

Intervention Type
Behavioural

Primary outcome(s)
Primary [Feasibility]
Recruitment:
1. Eligibility percentage will be determined using output from the Qualtrics screening survey and screening call. Measured pre-baseline, assessed monthly.

Intervention Fidelity:
2. Intervention Fidelity will be measured using audio recordings of the intervention sessions. Measured during each intervention session (1, 2, 3, 4, and 5) and assessed per intervention session.

3. Intervention attendance will be measured using an attendance register during the intervention sessions. Measured during each intervention session (1, 2, 3, 4, and 5) and assessed per intervention session.

Data Completeness:
4. Data Completeness will be assessed using output from the REDCap hosted Insomnia Severity Index Questionnaire. Primary end point assessed at 4 weeks post initial delivery of the intervention.

Primary [Acceptability]
5. The overall acceptability of the intervention and study procedures will be assessed using a custom Acceptability Questionnaire; the results will be reported as the mean and median Likert values. Additionally, the percentage of participants who selected each Likert option (completely unacceptable, unacceptable, no opinion, acceptable, completely acceptable) will be reported. Measured and assessed at the end of the study.

Key secondary outcome(s))

Secondary outcome measures:
1/2/3. Environmental data will be recorded using the Button device. Objective environmental data will be measured continuously across the 6-week study period. Changes from baseline will be assessed at 1 week following the delivery of the fourth intervention session.

4. Insomnia symptom severity measured using the Insomnia Severity Index (ISI) at the end of Week 2, Week 4, and Week 6 (fortnightly). We will assess changes from baseline at 4-weeks post initial delivery of the intervention.

Exploratory outcome measures:
1/2. Objective environmental data measured using the Button device continuously across the 6-week study period, changes assessed at 1 week following the delivery of the fourth intervention session.
3. Subjective time exposed to environmental factors measured using the 'My Day' questionnaire daily across the 6-week study period, rate of change assessed at 1-week post-delivery of the fourth intervention session.
4. Environmental data regularity scores measured using the Button device weekly across the intervention period, compared to baseline.
5. Environmental data mean timing scores measured using the Button device weekly across the intervention period, compared to baseline.
6. Environmental data measured using the Button device continuously across the intervention period, compared to the last week of baseline.
7. Environmental exposure data measured using the Button device and 'My Day' diary across the intervention period, agreement assessed.
8. Insomnia symptom severity measured using the Insomnia Severity Index (ISI) at the end of Week 2, Week 4, and Week 6, changes assessed at 2-weeks post initial delivery of the intervention.
9. Sleep quality (e.g., sleep latency, sleep efficiency, wake after sleep onset), sleep quantity (e.g., total sleep time), and circadian activity rhythms (e.g., inter-daily stability, intra-daily variability, M10, L5, and relative amplitude) measured using ActTrust 2 continuously across the 6-weeks, changes assessed at 2-weeks and 4-weeks post initial delivery of the intervention.
The Consensus Sleep Diary (CSD) will be used to collect self-report measures of sleep (including total sleep time, sleep latency, number of awakenings, length of awakenings, quality of sleep, sleep efficiency, naps, and length of naps).
The Home Sleep Test REM (HST REM; SOMNOmedics GmbH, Randersacker, Germany) will be used to capture sleep EEG to look at sleep continuity, sleep architecture, and spectral density (relative and absolute).
10. Fatigue measured using the Flinders Fatigue Scale (FFS) at the end of Week 2, Week 4, and Week 6; changes assessed from baseline at 2-weeks and 4-weeks post initial delivery of the intervention.
11. Sleep hygiene behaviours measured using the Sleep Hygiene Index (SHI) at the end of Week 2, Week 4, and Week 6; changes from baseline assessed at 2-weeks and 4-weeks post initial delivery of the intervention.
12. “Biological” chronotype measured using the Ultra Short Munich ChronoType Questionnaire (μMCTQ) and the “psychological” chronotype measured using the Reduced Morningness-Eveningness Questionnaire (rMEQ) at the end of Week 2 and Week 6. Sleep timing will be assessed across the study period. We will assess changes in chronotype and sleep timing from the end of Week 2 to 4 weeks post initial delivery of the intervention.
13. Anxiety symptoms measured using the Generalised Anxiety Disorder questionnaire (GAD-7) at the end of Week 2, Week 4, and Week 6; changes from baseline assessed at 2-weeks and 4-weeks post initial delivery of the intervention.
14. Depressive symptoms measured using the Patient Health Questionnaire (PHQ-9) at the end

of Week 2, Week 4, and Week 6; changes from baseline assessed at 2-weeks and 4-weeks post initial delivery of the intervention.
15. Work productivity and activity impairment (absenteeism, presenteeism, overall work impairment, and impairment in non-work-related activities) measured using the Work Productivity and Activity Impairment questionnaire (WPAI:SHP) at the end of Week 2, Week 4, and Week 6; changes from baseline assessed at 2-weeks and 4-weeks post initial delivery of the intervention.
16. Intensity of main exercise measured using the 'My Day' questionnaire self-reported throughout the study period; changes from baseline assessed at 2-weeks and 4-weeks post initial delivery of the intervention.
17. Improvements in insomnia symptoms, sleep and circadian rhythms, fatigue, chronotype, anxiety, depressive symptoms, and work productivity measured using previously stated validated tools. Changes in environmental exposure (the mediator) and outcomes will be assessed from baseline at 2 weeks and 4 weeks post initial delivery of the intervention.
18. Sleep hygiene behaviours measured using the Sleep Hygiene Index (SHI) at baseline and at 2-weeks and 4-weeks post initial delivery of the intervention.
19. Perceived credibility measured using the Credibility/Expectancy Questionnaire (CEQ) after delivery of the intervention materials (start of Week 3).
20. Acceptability of the study intervention and procedures measured using a follow-up interview with a subset of participants that is audio recorded after the final delivery of the intervention.
21. Barriers and facilitators recorded within each intervention session, measured during each intervention session (1, 2, 3, 4, and 5) and assessed per intervention session.
22. Environmental exposure measured using self-report at screening and objective environmental data at baseline.
23. Environmental data measured using satellite-based measurement at the end of the study.

Completion date
18/01/2026

Eligibility

Key inclusion criteria
1. Aged 23-65 years old
2. Currently employed (working for pay/stipend) and intend to remain employed over the next 4 months
3. An “office worker” (work sitting at a desk, indoors, for your working day)
4. Working within Oxford, full-time (“9-5”, Monday-Friday), over the next 4 months
5. Living within Oxford, full-time (Monday-Sunday), over the next 4 months
6. Insomnia symptoms (ISI; ≥11)
7. Low self-reported levels of environmental exposure
8. An iPhone (iOS 15 or later) smartphone user with a consistent internet connection indoors and outdoors
9. Able to read and understand English
10. Able to follow study procedures as laid out in the participant information sheet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
23 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Severe anxiety symptoms (GAD-7; ≥15)
2. Severe depressive symptoms (PHQ-9; ≥15)
3. Suicidal ideation/self-harm (PHQ-9 item 9; ≥1)
4. Diagnosis or being treated for a mental health disorder
5. Shift or night worker in the past 3 months
6. Diagnosis of the following sleep disorders: Sleep-Related Breathing Disorder, Central Disorder of Hypersomnolence, Circadian rhythm Sleep-Wake Disorder, Parasomnia, Sleep-Related Movement Disorder, Other
7. Currently being treated for the following sleep disorders: Sleep-Related Breathing Disorder, Central Disorder of Hypersomnolence, Circadian rhythm Sleep-Wake Disorder, Parasomnia, Sleep-Related Movement Disorder, Other
8. Sleep problem fully explained by caring responsibilities, being woken up by children, noises in your environment, a physical/surgical condition
9. Prescribed or “over the counter” sleep medication
10. Habitual smoker/vape user
11. Photosensitising medication
12. Underweight and obese BMI
13. Planning major surgery in the next 2 months
14. Neurological disorder
15. Serious head injury in the past year
16. Physical disability/health condition/pain preventing moderate exercise [e.g., 30-minute walk]
17. Eye disease
18. Photosensitivity
19. Lactating or pregnant
20. Active implanted stimulator [e.g., pacemaker]
21. Undergone light therapy in the last month/plan to have light therapy within the next 2 months
22. Currently receiving psychological therapy for sleep/plan to start within the next 2 months
23. Currently taking part in a study involving a drug or behavioural intervention/will be taking part in such a study in the next 2 months
24. Another member of your household has taken part in this study/is currently taking part in this study
25. Regularly cover up eyes outdoors for religious/moral reasons (e.g., burqa/burka)
26. Regularly cover up skin outdoors for religious/moral reasons (e.g., burqa/burka)
27. Taken a flight that crossed 3 or more time zones in the last 2-weeks/plan to take one in the next 2 months

Date of first enrolment

17/03/2025

Date of final enrolment
18/11/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sir Jules Thorn Sleep and Circadian Neuroscience Institute (SCNi), Nuffield Department of Clinical Neurosciences
Dorothy Crowfoot Hodgkin Building, South Parks Road, University of Oxford
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
Dr Mortimer and Theresa Sackler Foundation

Alternative Name(s)

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 are/will be available upon request from 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	Participant information sheet	11/11/2025	11/11/2025	No	Yes