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Oxford Behavioural Intervention for Shiftwork (OxBIS)

PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: MS IDREC 961131

1. Introduction

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why is this research being conducted?

Shift work can often lead to significant sleep disruption because the work schedule overlaps with the usual time for sleep. Problems with sleep (e.g., falling asleep, staying asleep, sleepiness) are common consequences of shift work, and this can have a considerable impact on health and well-being. 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. Our feasibility study will examine whether our intervention is acceptable to participants, and will help us prepare for a larger study to assess its impact on sleep and other aspects of health.

3. Why have I been invited to take part?

The study is being run at the Oxford University Hospitals NHS Foundation Trust (OUH) and Oxford Health NHS Foundation Trust (OH). We are aiming to recruit 30 participants for the study and are contacting all NHS staff in both Trusts.

You can take part in this study if you:

- Aged **over 18 years**
- are **employed by the NHS**
- work **shifts** that involve **working after 6pm or before 7am** (defined as non-standard hours) and
- have worked non-standard hours for a **minimum of 3 months**
- have **problems with your sleep** (frequent difficulty with falling asleep and/or staying asleep and/or waking up, and/or feeling sleepy during work).

There are some reasons that you may not be able to take part in the study, including:

- If you have a diagnosis of mild cognitive impairment or dementia
- If you have a diagnosis of bipolar disorder or schizophrenia spectrum disorders
- if you are pregnant or planning pregnancy in the next 5 months

- if you are currently receiving cancer treatment

4. Do I have to take part?

No, taking part in the study is entirely voluntary. If you decide not to take part, it will not affect your employment or legal rights. If you decide to take part, you will be asked to keep this information sheet and sign a consent form. You can withdraw yourself from the research at any time, by advising us of your decision. You do not have to provide a reason if you wish to leave the study. In this event, we will use any data collected up until the point of your withdrawal.

Please note that the intervention offered as part of this study is in addition to any care you currently receive or will receive in the future from a healthcare professional, and should not be seen as an alternative to this care. If you are concerned about your mental or physical health at any time during the study, then we advise that you speak with your general practitioner.

5. What will happen to me if I take part in the research?

Figure 1 gives an outline of what will happen if you decide to take part and when it will happen.

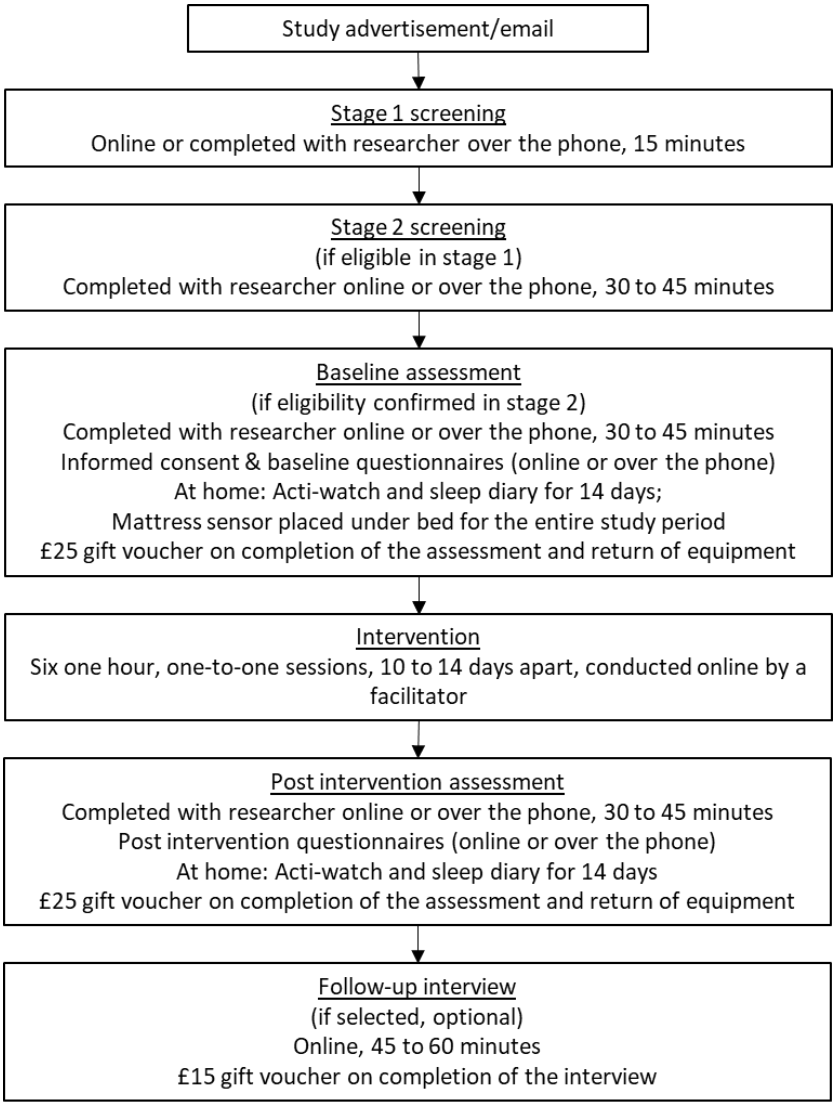

Figure 1: Study flow chart

Stage 1 screening

- If you are interested in taking part in this study, we will first ask you to complete a questionnaire (either online or over the phone, which will take around 15 minutes) to determine whether the study is suitable for you. The questionnaire will ask about your work, sleep and your general health.
- Once you have completed the screening questionnaire, and if you are eligible at this stage, we will ask for your consent to be interviewed and to provide us with your contact details (telephone and/or email address), a preferred method and time of contact and your GP details. This information is collected so that a member of the research team can contact you to arrange a stage 2 screening interview (online or telephone).
- If you are not eligible during the first screening questionnaire, you will be informed of this immediately and will not be contacted. Your responses will remain anonymous, and we will not ask for your contact details. This anonymised data will be stored securely until the end of the study and then deleted as per procedures. Please refer to sections 9 and 11 for more details on this.

Stage 2 screening

- If you are found to be eligible at stage 1 screening, a member of the study team will contact you to arrange an interview. The interview will take place over the phone or online, via Microsoft Teams, depending on your preference. The purpose of the stage 2 screening interview is to check if you meet the eligibility criteria, and to determine if the study is suitable for you.
- In this interview, the researcher will ask you questions about your sleep, and physical and mental health and will take approximately 30 to 45 minutes.
- If you are not eligible, you will be informed of this by the research team either immediately during the call or shortly thereafter and will no longer be contacted for the study. All data collected until this point will be stored securely until the end of the study and then deleted as per procedures. Please refer to sections 9 and 11 for more details on this.
- If you are eligible, you will proceed to the baseline assessment stage. You will be asked to provide your preferred postal address to arrange postage/delivery of the sleep assessment devices and sleep diary, including instructions on their use (see below). The researcher will aim to find the best way for these to be delivered to you (e.g. delivered to your place of work, royal mail, other courier) and a time for delivery that fits around your shift schedule in advance of the scheduled baseline assessment.

Baseline assessment

- If you decide to take part in this study, and are considered eligible following the two stages of screening, you will be invited for a baseline assessment with a member of the research team.
- The baseline assessment will take place online or over the phone and is expected to last approximately 30 to 45 minutes.
- During this appointment, the researcher will talk to you about the study. They will check that you are happy to take part and give you the opportunity to ask questions. If you agree to proceed, you will be asked to complete an electronic consent form.

- The researcher will then ask you to complete a questionnaire about yourself, your work, physical and mental health, sleep patterns/behaviours, and quality of life. You can complete this questionnaire online or over the phone with the research team
- During this appointment, the researcher will explain the sleep assessment equipment that has been posted to you which includes:
    (i) An actigraphy device (acti-watch, MotionWatch 8, CamNTech Ltd. - see picture below), to wear on your wrist for 14 days, 24 hours a day starting only after the baseline appointment. An acti-watch is a wrist-worn device similar to a Fitbit that measures movement, allowing us to estimate your sleep-wake pattern. This should be worn day and night and should only be removed for showering, bathing, washing up, or water sport activities. This can be worn in combination with an existing watch or fitness tracker and should be worn on your non-dominant wrist or up on your non-dominant arm when working in a role where your arm has to be bare below the elbow.

    (ii) A paper daily sleep and activity diary for the 14 days as above to monitor your sleep pattern (this can also be completed electronically if you prefer).
    (iii) An under-mattress sensor (Withings Sleep Analyser) to be used for the duration of the study. Once the device is set up via temporary use of an app on your phone, and with phone/online support of a study researcher, the device will record your sleep, breathing rate, heart rate, and snoring whenever you are lying on your bed.

    (iv) Pre-paid envelopes to return the Acti-watch and the diary after the 14 days.
- You will receive a £25 gift voucher upon completion of the baseline assessment and return of the sleep assessment equipment.

Intervention

- Once you return the acti-watch and the daily sleep and activity diary after 14 days, you will be sign-posted to a facilitator who will guide you through the behavioural sleep intervention.

- The facilitator will be a research nurse or a member of the research team who has received training to deliver this intervention.
- The intervention will focus on your shift work-related sleep disruption.
- The intervention will be delivered online as six one-to-one sessions (each session running for approximately one hour).
- The sessions will be scheduled according to your preferences and work schedule within the constraints of the facilitator's schedules.
- Sessions will be scheduled every 10 to 14 days according to your availability.
- The intervention will follow a structured format and be provided through an interactive PowerPoint presentation.
- If you consent, your sessions with the facilitator will be audio-recorded using encrypted portable audio recorders. This is to allow the research team to monitor if the intervention is being delivered as per procedure. This is optional and you can continue to receive the intervention even if you decide that you do not want the sessions to be recorded.
- You will be sent a tote bag containing a programme book, session journals, highlighters, eye mask, ear plugs, sleep diaries for the intervention, and light goggles. You can also receive the printed materials in an online format if you wish. The session journals will include activities for you to undertake during and after the sessions. The programme book will include all the material discussed within the session along with additional information on the topics for your independent reading.
- The tote bag will be delivered to you via the same method as the sleep monitoring equipment. From this bag, only the light goggles need to be returned at the end of the intervention.

Post intervention assessment

- After you have completed the six sessions of the intervention, the research team will send you the sleep assessment materials (acti-watch and sleep diary; similar to the baseline assessment) and arrange an appointment with you (online or telephone).
- Your appointment is likely to be 16 -18 weeks after your first baseline assessment and is expected to last approximately 30 to 45 minutes.
- At this appointment, the researcher will ask you to complete a questionnaire about your physical and mental health, sleep patterns/behaviours, quality of life and acceptability of the intervention. You can complete this questionnaire online or over the phone with the research team.
- Similar to the baseline assessment, you will need to wear the acti-watch for 14 days alongside completing the daily sleep and activity diary (starting only after the post-intervention appointment). The daily sleep and activity diary can be completed electronically if you prefer.
- At the end of the 14-day monitoring period you will be asked to return the acti-watch, sleep diary, the under-mattress sensor and the light goggles from the intervention.
- You will receive a £25 gift voucher upon completion of the post-intervention assessment and return of the sleep assessment equipment.

Follow-up interview

- Once you complete the intervention, we may invite you to take part in a semi-structured interview to share your experiences on shift working, the intervention and the study procedures. This is optional and you can decide to take part or not.
- This is likely to happen within three weeks of completing the post intervention appointment (18-21 weeks after your baseline assessments).
- The interviews will be conducted over the telephone or online and last approximately 45-60 minutes.
- With your consent, the interviews will be audio-recorded using portable audio recorders.
- You will receive a £15 gift voucher upon completion of the interview.

6. What are the possible disadvantages and risks in taking part?

We do not anticipate that there are any risks in taking part. However, there is a small chance that you may find answering questions about your sleep problems and/or health upsetting. If you do not feel comfortable answering such questions, we would discourage you from taking part in the online screening phase and participating in the study.

There are no known serious side effects from taking part in this study; however, changes 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. If you find you are sleepier on your shift, we would advise you to speak to your facilitator to explore if modifications are needed to the intervention for you and to speak to your line manager/occupational health team.

The acti-watch can occasionally cause localised skin irritation for some people. If this happens, we would encourage you to stop using the device(s) and contact the research team.

Light googles that emit a 20-minute pulse of light will be used as part of the intervention from session 2 onwards. These goggles are not suitable for participants experiencing eye disease or participants with photosensitivity or photosensitive migraines/epilepsy. Participants will be asked about this at stage 2 screening and for those experiencing such problems, the light googles will not sent in the tote bag. The facilitators will be informed of this and they will recheck again during the session and provide alternate advice for light. For other participants, there is a small risk that you may experience headaches or photosensitivity when using the light goggles. If this occurs, we would encourage you to stop using the light goggles immediately and speak with your intervention facilitator who will modify the sessions accordingly.

If you have any concerns in relation to the topics raised in the study or if you believe that you require immediate help during the study, we advise you to contact your general practitioner or visit your local emergency healthcare services.
You may also find the following number useful:

- Samaritans: 116 123 (freephone). Calls to this helpline number do not appear on phone bills.

7. Are there any benefits in taking part?

You may benefit from improved sleep from taking part in this study. You will also contribute to research, which may help develop better treatments for people experiencing sleep problems because of working shifts.

8. Expenses and payments

You will receive gift vouchers for completion of each stage of the study as below:

- £25 for completion of baseline assessment including return of equipment
- £25 for completion of post intervention assessment including return of equipment and light googles (if provided)
- £15 for completion of follow-up interview

In total, you will receive £65 in gift vouchers if you complete the entire study.

9. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

We will collect the following information from you at different stages:

- *Stage 1 screening:*

  Consent to screening, information on your work, sleep and general health to determine your eligibility for the study.
  If eligible, consent to screening interview, GP details and personal contact details
- *Stage 2 screening:*

  Confirmation of personal contact and GP details.
  Information about your work, sleep and your physical and mental health to determine your eligibility for the study.
- *Baseline assessment, during the intervention, and post intervention assessment:*

  Information about yourself (e.g. age), your work, physical and mental health, sleep patterns/behaviours and quality of life through questionnaires.
  Sleep/activity and light exposure data from the acti-watch; sleep/activity data from the sleep diary; and sleep, activity, breathing rate, heart rate, and snoring from the under-mattress sensor.
  Analysis of this data will give us an indication if the intervention is working or not and will help us to prepare for the bigger study to test this intervention.
- *Follow up interview*:

  Your experience on shift working, the intervention and the study procedures to help us modify the intervention and the study procedures accordingly.

In section 11, we have explained how we will store any personal information collected from you and for how long. Any information collected about you during this study will be kept strictly confidential. We will use the minimum personally identifiable information possible. You will be assigned a unique participant identification number and only that will be used throughout the study (pseudonymised). The document linking your name and the unique participant identification number will be stored securely and separately from the research data. This document will be deleted securely at the end of the study and the research data collected will be considered anonymised. We will store the anonymised research data (responses to stage 1 screening questionnaire from eligible participants,

stage 2 interview responses and screening questionnaire from eligible participants, baseline assessment questionnaires, post intervention assessment questionnaires, follow-up interview, acti-watch data, under-mattress sensor data, and sleep diary data) indefinitely after the end of the study on a secure server on the University of Oxford's network. Only the research team will have access to the research data.

The reason for keeping the anonymised research data indefinitely is that we may include it in future studies. **You will not be identifiable from this dataset.**

Responsible members of the University of Oxford and the two participating NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines.

Please refer to section 11 for more information on data protection.

10. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research may be written up as academic publications, conference presentations, on social media, or as an online report commissioned by the funders. Your individual results will not be identifiable, nor will you be identified in any report or publication. After the end of the study an anonymised dataset will be created and stored for as long as it is useful and may be shared with other researchers.

If you have expressed an interest in receiving a copy of the study results and your data from the acti-watch on the consent form, then we will send these to you via your preferred contact method after the results have been published.

11. Data Protection

- Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.
- All data use will strictly be within the terms of the UK General Data Protection Regulation (UK GDPR).
- We will be using an online survey provider (REDCap or Qualtrics) which is recognised as UK GDPR secure for the two stages of screening and baseline and post intervention assessments.
- The consent to interview form that eligible participants complete at the end of the stage 1 screening will be exported from the digital provider database and then deleted from the database. The downloaded data will be saved on a secure server on the University's network and kept for 10 years before deletion.
- Contact details collected from eligible participants at the end of stage 1 and stage 2 screening (name, email address, phone number, GP details, postal address) will be exported from the digital provider database as an Excel spreadsheet and kept as password-protected files on a secure server on the University's network for 12 months after the study ending or until public release of the research to inform participants about the results of the study.

- The electronic consent forms completed at the baseline assessment will be stored on a secure server on the University's network for 10 years after the study has been completed and then will be permanently deleted.
- Data from the under-mattress sensor will be automatically uploaded to the Withings cloud server, accessed via the Withing's Health Mate app (or online equivalent). However, all data from this device will be pseudonymised, as the account associated with your data will only use a participant identification number. You will not be directly identifiable from this dataset. The storage of the data on this external cloud server complies with GDPR, and the privacy policy can be found at https://www.withings.com/uk/en/legal/privacy-policy. As soon as your data is downloaded from the server by one of our trained team (within one week of removing the mattress sensor), the user account associated with your data on the server will be deleted. However, Withings may use anonymised sensor data for the purpose of optimising and improving their services prior to account deletion, in line with their terms and conditions (please see here) prior to deletion. The company is also registered on the University of Oxford's InfoSec Third Party Register.
- The follow-up interview will be audio-recorded onto a safe (encrypted) portable device. Audio files will be transferred by the researcher to secure, University of Oxford servers, and deleted from the portable device as soon as is practical. The data collected will be typed up word by word by a professional with a confidentiality agreement with the University of Oxford. The typed documents (transcripts) will be securely returned to the research team, who will remove all personal information (i.e. anonymised), and store on secure internal computer drives. Upon receipt of the transcripts, the researchers will listen to the recordings and make any necessary amendments to the transcripts to ensure anonymity. Then the audio recordings will be deleted.
- With your permission, we may use direct quotes from your follow-up interview in publications. The quotes will be anonymised, and no information identifying you will be included.
- Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights. The Data Protection Officer can be contacted at data.protection@admin.ox.ac.uk.
- You can find out more about how we use your information by contacting Dr Forrest Chueng (Email: OxBISstudy@ndcn.ox.ac.uk, or Telephone: 01865 618697).

12. Who is funding the research?

The project is funded by the National Institute for Health Research (NIHR) Programme Grants for Applied Research (reference number: NIHR203667).

13. How have patients and the public been involved in this study?

A Public Co-Applicant who is an NHS shift worker was involved in the development and funding application for this study. A Research Advisory Group including the Public Co-applicant and a diverse group of NHS shift workers has informed the development of this study by sharing their experiences, insights and ideas drawing on their lived experiences. This group has informed the research

programme including developing the content of the intervention, advising on practicalities of the intervention delivery and reviewing the participant- facing materials.

14. Who has reviewed this research?

This research has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee (Ethics reference: MS IDREC 961131).
Local Research and Development departments at participating NHS organisations have also reviewed the study and granted permission for the study to take part at their organisation.

15. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this study, please speak to Dr Forrest Cheung, Post-Doctoral Researcher, Email: OxBISstudy@ndcn.ox.ac.uk, or Telephone: 01865 618697) or the Principal Investigator (Professor Simon Kyle, Email: simon.kyle@ndcn.ox.ac.uk), who will do their best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with.

If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on 01865 616480.
The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

16. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:
Dr Forrest Cheung
Sleep and Circadian Neuroscience Institute,
Nuffield Department of Clinical Neurosciences,
Dorothy Crowfoot Hodgkin Building,
South Parks Road,
University of Oxford
OX1 3QU
Email: OxBISstudy@ndcn.ox.ac.uk
Telephone: 01865 618697

Thank you for taking the time to read this participant information sheet.

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