Study Title: SleepSure: a randomised controlled trial to assess the effects of eye masks and earplugs on the quality of sleep for patients in hospital.

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Chief Investigator:	Dr Adam Monk, Oxford University Hospitals NHS Foundation Trust
Investigators:	Andrew Finlay, FY2 at Royal Berkshire NHS Foundation Trust;
	Toshi Sherpa, FY2 at Royal Berkshire NHS Foundation Trust;
	Charlotte Lees, FY2 at Buckinghamshire Healthcare NHS Trust
	Professor Derick Wade
Sponsor:	Oxford University Hospitals NHS Foundation Trust
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Chief Investigator Signature:

There are no conflicts of interest to report.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	SleepSure: a randomised controlled trial to assess the effects of eye masks and earplugs on the quality of sleep for patients in hospital.	
Internal ref. no. / short title	SleepSure: a study aimed at improving sleep for hospital inpatients	
Study Design	Randomised Controlled Trial	
Study Participants	Patients admitted to adult general medical and surgical wards at Oxford University Hospitals NHS Foundation Trust	
Planned Sample Size	400	
Planned Study Period	01 February 2016- 31 January 2017 Pilot data collection 01 February 2016 to 14 February 2015 Recruitment 01 March 2016 – 31 May 2016 (last follow-up 14 June 2016)	
	Objectives	**Outcome Measures**
Primary	Do earplugs and eye masks help hospital patients to sleep better?	SleepSure Questionnaire, based on the validated Richards-Campbell Sleep Questionnaire
Secondary	Does the use of earplugs and eye masks lead to a reduced length of stay, reduced incidence of falls or reduced use of sleep aid medication? How many patients provided with earplugs and an eye mask choose to use them?	Length of stay (days) Number of falls recorded during stay Doses of zopiclone (sleeping tablet) used to help sleep during stay Use of earplugs and eye masks (SleepSure sleep questionnaire)

2. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General Practitioner
ICF	Informed Consent Form
NHS	National Health Service
NRES	National Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

3. BACKGROUND AND RATIONALE

Background

Patients consistently complain of lack of sleep due to noises throughout the night from: patients, staff, machines and buzzers as well as complaining about bright lights being left on, monitors left active and LEDs flashing throughout the night[1,13]. This has a severe negative impact on a patient's hospital experience[8], and has been associated with increased risk of acute confusion[2], increased medication usage[3] with their side-effects[4], delayed hospital discharge[5] (at a cost of £273 per day[6]) and worse health outcomes[7,8]. In this project we aim to investigate whether the simple solution of earplugs and an eye mask can improve the inpatient experience through enhancing sleep.

The question

Our question is simple: Does the provision of earplugs and eye masks improve the sleep of hospital inpatients?

Secondary questions are whether this provision leads to a reduced length of stay, reduced incidence of falls and reduced use of sleep aid medication. We also wish to discover how many patients provided with earplugs and an eye mask choose to use them.

The evidence

Whilst use of earplugs and eye masks has a limited evidence base as a sleep adjunct in general hospital wards, there have been a number of small scale randomised trials in the intensive care unit setting where their use has been associated with:

1) An objective improvement in night time sleep[9,10]
2) A subjective enhancement of patient experience[11]
3) A significant reduction and delayed incidence of acute confusion[12]
4) A reduction in the use of morphine[10]

The population

The population studied will be individuals admitted to Oxford University Hospitals NHS Foundation Trust during the study period onto any ward admitting eligible patients for at least one night. The precise inclusion and exclusion criteria will be defined more specifically later in the protocol.

Risks to participants

1) Allergies: Risk of patient or staff having an allergic reaction to the product.
   Likelihood: 1/5 Remote
   Severity: 4/5 Severe
   Total risk score: 4/25 low risk
   Mitigate risk by choosing earplugs and eye masks made from hypoallergenic materials, manufactured in quality plant approved with the CE mark. Earplugs and eye masks themselves or the literature provided with them will describe their composition/materials and they will only be provided to patients with the mental capacity to use them safely in an informed manner (similar to use on an aircraft).

2) Swallow/Choking risk: Risk of patients swallowing, breathing in and/or choking on earplugs.
   Likelihood: 1/5 Unlikely
   Severity: 4/5 Moderate risk
   Total risk score: 4/25 low risk
   Mitigate risk by restricting earplugs and eye masks to patient over 18 years old with capacity and awareness/ability to learning from information leaflets of how to use ear plugs/eye masks.

3) Infection risk: Risk of spreading infections from one patient to another and of increasing risk of patients getting otitis externa (outer ear infections).
   Likelihood: 3/5 Possible
   Severity: 2/5 minor
   Total risk score: 6/25 Low risk
   Mitigate risk by advising patients with ear infections not to use earplugs. Have earplugs and eye masks as single patient use (for disposal on discharge) and replace earplugs and eye masks if soiled or contaminated.

4) Pressure sores: Risk of earplugs and eye masks causing a pressure ulcer if left in the bed.
   Likelihood: 1/5 Remote
   Severity: 3/5 moderate
   Total risk score: 3/25 Low risk
   Mitigate risks by good nursing practice of checking the bed for anything lost on top of the mattress, making the bed daily and frequently turning patients with high risk of pressure ulcers, as well as pressure reducing mattresses and pressure removal from damaged sites.

5) Increased confusion/risk of falls: increased confusion as patients forget to remove ear plugs and or eye masks and attempt to walk with ear plugs/eye masks still in place. [NB/]There is no evidence that this occurs, but it is conceivable that it could.
   Likelihood: 2/5 unlikely
   Severity: 3/5 moderate
   Total risk score: 6/25 Low risk
   Mitigate risk by never applying earplugs and eye masks to a patient without their express and informed request. Removing/not supplying ear plugs/eye masks to confused/confused patients who do not have mental capacity to use the aids.

6) Missing alarms: risk of missing light and sound from fire alarms
   Likelihood: 2/5 Possible
   Severity: 2/5 Minor
   Total risk score: 4/25 Low risk
   Mitigate risk by ensuring nursing/healthcare staff wake and inform patients of fire alarm and mobilise them to the appointed safe place as is the routine fire protocol. Most patients are dependent upon healthcare staff to mobilise them regardless of their awareness of fire alarms. Most patients are also unable to distinguish between the differing alarms in hospital and are dependent upon staff for that information.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective Do ear plugs and eyemasks improve inpatient experience of sleep?	SleepSure sleep questionnaire	Questionnaire given >1 day after recruitment
Secondary Objectives A) How many patients provided with eye masks and earplugs choose to use them?	SleepSure sleep questionnaire	Questionnaire given >1 day after recruitment
B) Does the use of earplugs and eye masks lead to reduced length of stay?	Length of stay data from hospital administration system	After discharge
C) Does the use of earplugs and eye masks lead to reduced use of sleep aid medication?	Drug chart data from electronic records.	After discharge
D) Does the use of earplugs and eye masks lead to a reduced incidence of falls?	Falls data from centrally collated routinely collected information	After discharge

5. STUDY DESIGN

Randomised controlled trial

Pilot data collection 2 weeks from approval of study. 3 months data proper once pilot data has been reviewed and any required changes noted. Data collected from adult inpatients on 10 inpatient wards. Pilot data collection is to identify any problems with the data collection that may arise. If no changes to the protocol are made then this pilot data will be incorporated with the data proper.

Targeted recruitment population: 400 patients total including up to 20 from pilot data. Patients randomised to either intervention (earplugs and eye masks) or control (routine care).

Intervention will be allocated via pre-performed simple randomisation concealed in opaque envelopes with intervention and non-intervention envelopes indistinguishable from one another which will be distributed in batches to each ward engaged in the study.

SleepSure sleep questionnaire will be given to all patients >1 day after recruitment.

6. STUDY PARTICIPANTS

6.1. Study Participants

Participants will be recruited from adult inpatients who meet the eligibility criteria and admitted to any participating wards in Oxford University Hospitals NHS Foundation Trust.

6.2 Inclusion criteria:

Eligible candidates at the point of enrolment must:

- Be 18 years of age
- Be expected to stay in Oxford University Hospitals NHS Foundation Trust for at least one more night
- Be able to understand and use earplugs and eye mask.
- Have basic understanding of English reading and writing.
- Be considered likely to have the Mental Capacity to give consent for use of personal data in the study at the point of filling in the SleepSure Questionnaire (>1 day after recruitment). NB/ Data will not be collected from individuals who are unable to give consent with the filling in of the SleepSure questionnaire.
- Be expected to be able to fill in the SleepSure Questionnaire with or without assistance

6.3 The Exclusion Criteria

Candidates will be excluded from the trial if:

- They have or are expected to have an obvious medical contra-indication to the use of earplugs and eye mask at the point of enrolment eg. eye infection, as per clinical judgement of recruiter.
- They are unlikely to benefit from the intervention in the judgement of the recruiter (i.e. individuals who are deaf and blind).

7. STUDY PROCEDURES

7.1. Recruitment

A ward nurse, part of the direct care team on the ward, will approach potential participants on their arrival on the ward, usually as part of the admission assessment process. If they fulfil the inclusion criteria without exclusion characteristics the patient will be given a brief description of the study and a

Patient Information Sheet; with the permission of the patient any relatives present will also have the study explained and will be given a Patient Information Sheet. They will then be approached by the SleepSure research nurse who will consent and register the patient as a participant.

7.2. Informed Consent

Each patient considered eligible will be given a patient information sheet by a nurse on the ward, part of the direct care team. Following this they will be approached by the SleepSure research nurse who will give them a short verbal explanation that will cover:

- The goal of the study (i.e. to study how to improve sleep)
- The trial intervention (i.e. aircraft style earplugs and eye mask)
- The fact that only a 50% chance of getting intervention (random allocation)
- The collection of data (one questionnaire) >1 day after recruitment
- The collection and use of some routine hospital data (falls, use of sleeping tablets, length of stay)
- The option to withdraw consent at any time
- The specific action of having being presented with a SleepSure Questionnaire >1 day after recruitment, which if not filled in will be taken as a refusal of consent for the use of that data in the trial.

A written consent form will be used.

7.3. Screening and Eligibility Assessment

As described above, there will be no initial gap between first contact and recruitment.

7.4. Randomisation, blinding and code-breaking

Every patient recruited will first be registered by the SleepSure research nurse onto an electronic password-protected Participant ID log in a secure location on the Trust network. This will generate a trial number (e.g. WPH WdA 007 [hospital, ward, number]).

Randomisation:

Using a random number generator performing simple randomisation opaque numbered envelopes will be filled with a piece of paper stating control or intervention with an equal chance of each individual envelope containing a control or an intervention instruction. 50 sealed envelopes will be stacked into a box on each ward, each with a unique identifier number on the outside. When a potential participant is identified the SleepSure research nurse will go to the next envelope in the box and open it to determine if the patient is in the control or intervention arm.

If the patient is allocated to the trial arm, the research nurse will give the patient a set of earplugs and an eyeshade, and explain their use, checking that the patient can use and remove them safely giving instruction as required. The earplugs and eye mask will then be placed into a transparent plastic wallet, labelled with the patient's name, the study and placed within easy reach of the patient.

7.5. Baseline Assessments

No specific baseline assessment will be made, other than those needed to determine eligibility.

7.6. Subsequent Visits

At the final visit (>1 day after recruitment) the SleepSure research nurse will provide a SleepSure Questionnaire. After discharge the participant's anonymised ID number, age, gender, date of admission, date of discharge, length of stay, number of falls, doses used of zopiclone will be extracted from the notes and recorded by the SleepSure research nurse onto an Excel spreadsheet stored in a secure location on the Trust network with access only via a password-protected computer. The results of the SleepSure questionnaire will also be recorded onto this secure document at this time. (Please see section 11 for more information.)

7.7. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Withdrawal of Consent
- Allergy/ adverse event from intervention

If a patient withdraws, or is withdrawn, the reason will be recorded. If a patient dies during the admission, this will be recorded and the certified primary cause noted.

7.8 . Definition of End of Study

The end of study recruitment will be 3 months from the start date. Follow-up data will be collected for a further two weeks. Any patient remaining at that time will be given an outcome questionnaire, and will have their length of stay and other data will be censored at that point (i.e. it will be handled as the date of discharge); the fact of censoring will be noted.

8. INTERVENTIONS

One pack containing an eye mask and earplugs. Supplier: Delmore LTD. It will be kept in a patient labelled clear plastic pouch. It will contain minimal instructions on their use. Patients will be allowed to take them home when they leave.

9. SAFETY REPORTING

9.1. Definition of Serious Adverse Events

A serious adverse event is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect.

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

It is anticipated that patients will experience many events. With the exception of falls and deaths these will **not** be recorded because the likelihood of the intervention causing serious harm is considered very small, and collecting the data would be excessively burdensome and unjustified.

9.2. Reporting Procedures for Serious Adverse Events

A serious adverse event (SAE) occurring to a participant should be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the Chief Investigator becoming aware of the event, using the HRA report of serious adverse event form (see HRA website).

All SAEs (other than those defined in the protocol as not requiring reporting) must be reported on the Oxford University Hospitals NHS Trust SAE reporting form to OUH study team within 24 hours of the Site Study Team becoming aware of the event by email or fax.

In the unlikely event that a Serious Adverse Event is identified, it will be reported to the R&D office immediately. SAE reports should be faxed or emailed to: (01865) 572242 or ouhsae.reports@nhs.net

All SAE information must be recorded on an SAE form and faxed, or scanned and emailed, to R&D. Additional and further requested information (follow-up or corrections to the original case) will be detailed on a new SAE Report Form and faxed/emailed to R&D.

10. STATISTICS AND ANALYSIS

All data will be entered onto a secure computer database, with no patient-identifiable data. The patient registration number given will be used.

10.1. Description of Statistical Methods

There will be no interim analysis.

The primary analyses will be to compare the two groups on all items collected, using t-test and Mann-Whitney U tests as appropriate with two-tailed testing (i.e. accepting that harm is also possible). The expectation is that the intervention group will have:

- Better sleep on the questionnaire
- Less use of night sedation over their hospital stay
- Less falls over their hospital stay
- A shorter length of stay

Secondary analyses will investigate:

- Variation between wards on all measures, irrespective of patient group.
- Reported use of and problems with the earplugs and eye masks.

10.2. The Number of Participants

There is no data to allow sample size calculation, nor are there data on recruitment and loss of patients. We estimate that it should be possible to recruit a total of 400 patients, which should be sufficient to detect any worthwhile benefit.

10.3. Analysis of Outcome Measures

All participant data will be used excluding those that withdrew consent or did not complete the study questionnaire.

11. DATA MANAGEMENT

11.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

11.2. Data Recording and Record Keeping

Hard copies of data (consent forms and SleepSure questionnaire) will be kept in a locked filing cabinet in a secure hospital location. The SleepSure research nurse and the SleepSure team will have access to this data.

Electronic data will be kept in the form of the participant ID log and excel database. The participant ID log will be a password-protected document where the MRN of the patient and the anonymous patient ID will be stored, this will be completed when the anonymous ID is allocated upon recruitment. This will be in a different location to the excel database. They will both be kept in a secure location on the trust

network accessed by a password-protected computer. The SleepSure nurse and the SleepSure team will have access to this data.
Personal information i.e. the Participant ID log will be destroyed within 3 months after the study has ended.

As per Oxford University Hospital NHS Foundation Trust's policy both electronic and hard copy data will be kept for a minimum of 5 years after the study period. The anonymised electronic database will continue to be stored in a secure location on the Trust intranet. Once the data collection period is complete the hard copy data will be kept in a locked filing cabinet in the Oxford Centre of Enablement offices (place of work of the Chief Investigator). During this period only members of the SleepSure team will have access to this data. At the time of destruction (estimation 5 years) the hard copies will be destroyed as per Trust guidelines.

12. QUALITY ASSURANCE PROCEDURES

The study will be monitored via the study amendments and end of study report. The study may be monitored or audited in accordance with the current approved protocol, ICH GCP, relevant regulations and standard operating procedures.

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

13.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

13.3. Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

13.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

13.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. This will occur at patient recruitment when they will be assigned an anonymous ID number. The participants will from then on be identified only by a participants ID number on the electronic excel database as well as on the SleepSure questionnaire.

13.6. Expenses and Benefits

No expenses will be paid (none will arise), but patients in the intervention group may keep the equipment if they wish.

13.7. Other Ethical Considerations

Patient who cannot apply the eye masks and earplugs for themselves will not be included.The only ethical and practical issue is what could or should be offered to controls in order to balance expectation bias. Information leaflets on sleep could be considered. On balance it seems best to offer nothing. If the study shows benefit then a trial of information leaflets against earplugs/eye masks could be undertaken to determine effect of expectation.

14. FINANCE AND INSURANCE

14.1. Funding

£10,500 awarded by Challenge 2023.

14.2. Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical research study as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. Therefore Oxford University Hospitals NHS Foundation Trust cannot agree in advance to pay compensation.

In exceptional circumstances an ex-gratia payment may be offered.

15. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that Challenge 2023 funded the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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