SleepSure: A pilot 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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Abstract

Objective   To determine the short-term effects of supplying hospital inpatients with earplugs and eye masks, preparatory to a full-scale trial.

Design   A single centre open-label, two-arm, parallel group, randomised controlled trial.

Setting   Thirteen medical and surgical wards in a large teaching hospital in the United Kingdom.

Participants   Everyone admitted to hospital aged 18 years or older, who stayed overnight, and had the mental capacity and sufficient understanding of English to give consent, the ability to complete the study questionnaire, and the ability to use earplugs and eye masks unaided was considered.

Interventions   The intervention group were provided with earplugs and eye masks for use the following night, and the control group received standard care.

Main measures Sleep quality assessed using the SleepSure questionnaire after the first night of using the intervention; use of earplugs and eye masks; number of falls throughout their inpatient stay; use of zopiclone during inpatient stay; length of stay; recruitment rate.

Results 1,600 patients admitted, 626 (39%) eligible, 206 (13% total, 33% eligible) recruited (intervention group, 109). The intervention group's mean sleep quality score was 6·33 (95% CI: 5·89 to 6·77), compared with 5·09 (95% CI 4·66 to 5·52) in the control group (p<0·001]. There were no differences in use of zopiclone, falls, or length of stay between the groups. Ninety-one (86%) of the intervention group reported using the earplugs and/or eye masks.

Conclusions The intervention seems feasible, and effective, but trial eligibility rate and rate of recruitment into the study were limited.

Introduction

Up to 40% of hospital inpatients suffer poor sleep quality and reduced sleep duration, [1][2] and in stroke patients it is associated with higher levels of dependence at the time and at six months. [3] It may have other adverse effects such as worsening pain, [2] and cognitive impairment. [3] The level of light and noise in a hospital at night may be a significant factor causing this. [4][5] Inpatients with a disability and needing rehabilitation may be particularly prone to the effects of sleep disturbance, because they are often in hospital for a long time. Improving sleep quality and duration could be of great importance.

Despite widespread use, pharmacological interventions probably do not improve the quality or quantity of sleep in hospitalised patients. [6] Several non-pharmacological interventions to improve hospitalised patients' sleep have also been evaluated, [7][8] including earplugs and eye masks. There are several trials of earplugs and/or eye masks, mostly in the intensive care environment. The evidence is not yet conclusive, [9][10][11][12] and trials in other hospital environments are needed. Although there is little evidence available concerning either risks or benefits, some hospitals in the UK offer earplugs and eye masks routinely to all adult inpatients.

This study is an early, relatively large scale study investigating the potential risks and benefits of proving eye masks and earplugs as a routine to patients admitted to acute medical and surgical wards. Its goals included determining the potential size of any

benefits and risks, and to determine feasibility both in terms of clinical use, and in terms

of setting up a larger trial.

Methods

The study ran between November 2017 and February 2017. It was funded by a small

NHS service improvement grant with additional support from the hospital. The

funding agency had no influence over the conduct of the trial, or its reporting. The trial

was approved by the North-West England Ethics Committee (16/NW/0318). All

participants provided written informed consent. The trial was registered with

ClinicalTrials.gov, registration number NCT02732912.

No patients were involved in setting the research question or the outcome measures,

nor were they involved in developing plans for recruitment, design, or implementation

of the study. No patients were asked to advise on interpretation or writing up of results.

There are no plans to disseminate the results of the research to study participants, but

results will be shared with the wards' staff involved in the study. The study participants

were given the opportunity to add comments, to help in the development of future

studies.

This trial was a pilot single-centre parallel two-arm randomised-controlled trial with

participants being allocated on a 1:1 ratio to the intervention or control group. The trial

was conducted at the John Radcliffe Hospital, a large 800 bed teaching hospital in

Oxford, United Kingdom, with a mix of general, local services, and specialist regional or national services.

The research nurse invited the managers of those wards that did not score highly in a national survey of inpatient experience of sleep quality, and invited them to participate in this study. Thirteen adult medical and surgical wards at the John Radcliffe Hospital were recruited.

The study participants were then recruited from these wards, as soon as possible after admission. They were initially identified by ward personnel, who gave the name to the research nurse, or directly by the research nurse who assessed eligibility and obtained consent.

Participants were eligible if they were aged 18 years or older, were expected to stay in hospital overnight, had the mental capacity and sufficient understanding of English to give consent, were considered able to complete the questionnaire, and had the ability (i.e. understanding, and dexterity) to use earplugs and eye masks unaided (in the opinion of the research nurse).

Patients were excluded if, in the opinion of the research nurse and ward staff, they had or were expected to have a medical contra-indication to the use of earplugs and eye mask (e.g. ear infection), or were unlikely to benefit from the intervention (e.g. total

deafness and blindness). At the point of screening, eligible participants were approached regardless of their length of stay in hospital.

The research nurse then randomly assigned consecutive consenting and eligible participants to either the intervention or control group, using sequentially numbered sealed opaque envelopes containing allocation cards. Members of the research team who had no participant contact or involvement in data collection pre-prepared these envelopes. The randomisation sequence was computer-generated with equal blocks (www.random.org). Due to the nature of the intervention, blinding of participants, ward staff, and research staff was not possible.

Following randomisation, the intervention group were given a pack of two earplugs and an eye mask (supplied by Delmore Ltd.[1]). The research nurse advised the participants in the intervention group to use the earplugs and eye mask the following night when attempting to sleep, and explained how to use the items. No written instructions were provided. The control group were not provided earplugs or eye masks.

The research nurse provided all participants the same verbal and written information, instructing participants to complete the questionnaire (see below) provided after the

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[1] 94 Hampstead Avenue, Mildenhall, Suffolk IP28 7AS, UK

following night's sleep. No advice about sleep in hospital was given to either group.

The research nurse recorded participants' baseline data from their medical records after

enrolment. Follow up data were collected at the end of the study.

The primary outcome was quality of sleep, assessed using a composite score from the

SleepSure questionnaire. This questionnaire was specifically developed for this study,

as an adaptation of the validated Richards-Campbell Sleep Questionnaire. [13][14] It

was rescaled to give a discrete number scale of 1-10 instead of the original RCSQ visual

analogue scale of 0-100, to simplify use by participants and to facilitate analysis. Five

additional questions (Questions 6 to10) were also added (Appendix 1) to; provide an

overall perception of quality of sleep (Question 6), assess the effectiveness of earplugs

and eye masks in mitigating noise and light disturbances (Question 7-8), and record

availability and use of earplugs and eye masks (Questions 9-10). Participants were also

given the opportunity to add any further comments to the SleepSure questionnaire.

The questionnaire used is shown in Appendix 1. The SleepSure questionnaire was

completed by participants, with the aid of the research nurse if required. The quality of

sleep score was simply the scores from questions one to eight, summed and divided by

eight (i.e. the mean score for the patient).

Appendix one

The other measures used were:

- recruitment rate,

- compliance with the intervention (assessed from additional questions in the
  SleepSure questionnaire),

- number of falls during the whole inpatient stay (assessed from Hospital Incident
  Reports), and

- number of dosages of zopiclone since trial entry until discharge (assessed from
  prescribing records in medical records).

Statistical analysis

As this was a pilot study primarily aimed at assessing feasibility, acceptability, and

safety of the intervention, sample size calculations were not performed. The study

duration was limited by the funding.

Analyses were performed using IBM SPSS Statistics Version 25.0 by members of the

research team with independent reviews performed by statisticians from the University

of Bristol to confirm appropriateness of analyses. Statistics compare intervention against

control groups on all items collected on SleepSure questionnaire, using intention to treat

two-tailed 2-sample t test, or two-tailed Mann-Whitney U test if criteria for parametric

data were not met.

Qualitative data of the patients' comments included in the questionnaire was

summarised using aspects of thematic analysis. [15]

Results

The researcher screened 1600 potential participants, and the patient flow is shown in figure one. The baseline demographic information is shown in table one, and the timing of the first night in relation to admission is shown in table two. There are some disparities between the groups; for example the control group were older. The commonest night studied was the second night of a patient's stay.

Figure one

Table one

Table two

The primary and secondary outcome results are shown in Table three. The primary finding was a statistically significant difference in sleep quality (mean of scores summed over first eight questions) between the groups, favouring the intervention group (difference in means 1.24, p < 0.001). The scores in the individual questions also favoured the intervention group, as shown in table four (supplementary data).

Table three

Table four (supplementary data)

Table five shows the reported use of the earplugs and eye masks in both groups. One participant in the control group had and used their own earplugs and eye mask. A few adverse effects of the intervention were reported by 22 (28%) participants from the 79 people in intervention group who definitely used at least one item. They are shown in table six.

Table five

Table six (supplementary data)

In total 114 participants (55%) provided further information in the comments box of the SleepSure questionnaire; 37 from the control arm and 77 from the intervention arm.

The comments from the control group mainly referred to factors that affected their sleep, including: noise and light (n= 17), health issues (n= 3), and nursing activities (n= 3). Seven participants also reported using other methods to help them sleep: prescribed sleep medication (n= 6) and music (n= 2).

Twenty-eight participants from the intervention group provided comments reporting that the earplugs and eye masks helped block noise and light disturbance, which improved their sleep compared to other night/s in hospital without these. Six participants in the intervention group reported that earplugs and eye masks were helpful, but their sleep was still interrupted by pain and nursing activities.

Twenty-three participants from the intervention group provided comments explaining why they had chosen not to use the earplugs and/or eye masks. Reasons included:

- being moved to side rooms where a better sleeping environment existed,
- interruption by nursing activities (e.g. checking vital signs and administering medication),
- the ward was quiet,

- it was too soon after surgery (participants still felt sedated),

- pain or health conditions such as ear irritation and facial surgery, and

- they preferred to be aware of their own surroundings.

Discussion

Routine provision of earplugs and eye masks to inpatients in a general hospital significantly improved the quality of sleep measured over one night in hospital. It did not increase the incidence of falls or affect the use of sleep medication (zopiclone). There was a slight reduction of the overall length of hospital stay in the intervention group by 1.16 days; this was not a statistically significant difference. The intervention seemed feasible, with 73% of those provided with earplugs and eye masks using at least one component. No major adverse effects were noted.

The only large studies investigating earplugs and eye masks in hospital have been in intensive care units; we are unaware of any trials involving patients on general hospital wards. Our results are consistent with studies in intensive care units, [9] suggesting a beneficial effect on sleep without significant risk of harm. This provides a strong justification for a larger, more definitive trial before this policy is recommended for widespread use.

The study shows that it is possible to study the intervention in a randomised controlled trial in a busy general hospital. Nonetheless some facts are worth noting. Surgical

wards were easier to recruit from compared to medical wards, but many patients on short stay surgical wards were discharged and did not stay overnight in hospital. Furthermore, many patients were reluctant to participate immediately before or after an operation because they were anxious or still recovering from general anaesthesia.

In contrast, medical wards, especially geriatric wards, have a slow turnover reducing the rate at which people could be recruited. In addition, more of the patients had cognitive losses, reducing the number who could give informed consent.

The SleepSure questionnaire was feasible and acceptable to the general hospital inpatient population. Approximately two thirds of enrolled participants completed the questionnaire.

The earplugs and eye masks provided were not used by all participants, and some participants had problems using them. The data in our trial suggest that the earplugs and eye masks provided could be improved, which might lead to more benefit for more participants. In particular, 38 (35%) participants did not use the earplugs, and 24 (22%) participants did not use the eye mask provided. This was mainly because these did not fit well or were uncomfortable, particularly the earplugs. Similar comments in relation to comfort and ease of use of earplugs and eye masks were also reported in other studies. [16][17]

The study did find a statistically significant difference in sleep quality favouring the intervention group. The clinical significance of this difference (1.24 points out of 10) is unknown. It is of interest that the length of stay was slightly shorter, but otherwise there are no data to evaluate the significance of this effect. Only 7/206 patients used night sedation, so no effect upon the use of night sedation could be detected. The study did not find any evidence of adverse effects.

This is the largest study investigating the effects of ear plugs and eye masks, and the first to examine their effects in general hospital inpatients. The diversity and the mixture of medical and surgical inpatients from various wards allow the evidence to be generalised across inpatient population within acute hospital settings.

Nonetheless this trial has several limitations. It included many different types of patients, which increases its generalisability but the small number and limited resource did not allow for identification of individuals more (or less) likely to benefit. The lack of long-term follow-up did not allow the assessment of whether continued use will occur and, if so, whether benefits increase or decrease and whether adverse events become evident.

Excluding patients that lack capacity to consent to the study excluded many elderly patients with dementia, who may represent the population with highest risk of delirium and the greatest potential to benefit from earplugs and eye masks. [11] Given the nature

of the intervention there was no blinding, which might have introduced ascertainment

bias, the effect of which could have biased the primary outcome to being a positive

result.

Finally, whilst the SleepSure questionnaire was based upon the validated Richards-

Campbell Sleep Questionnaire, it has not been independently validated; the changes in

wording and move from a visual analogue scale to a discrete number scale diminishes

the ability to draw direct comparison with previous studies that employed the

Richards-Campbell Sleep Questionnaire in intensive care units.

A multi-centre randomised controlled trial of earplugs and eye masks with a larger

sample and a longer follow-up (in patients who stay more than one night), is required

to confirm these study results before implementation.

Our experience suggests the following changes should be considered. First, given the

absence of any serious adverse effects, and the evidence of cognitive benefit within the

intensive care unit, [11] it would seem reasonable to recruit patients who are unable to

give fully informed consent - with suitable precautions - as they may benefit more.

Second, any future study should consider encouraging the use of earplugs and/or eye

masks throughout a patient's stay. Outcome should be measured, if possible at fixed

intervals (say after two days, seven days and then weekly) and certainly on the day of

discharge.

Other outcomes should be considered. Recovery of independence, measured using a scale such as the Barthel Activities of Daily Living scale [18] should be assessed, and not simply in rehabilitation wards. Length of stay should be measured. At the same time, efforts should be made to improve the earplugs and eye masks, to make them more effective and reduce the discomfort of earplugs.

Although this study was carried out in an acute general hospital, the effects and benefits are likely to generalise across all healthcare settings including rehabilitation wards. Future research should be undertaken in all other settings, such as psychiatric wards, and even possibly short-stay assessment units where patients often stay several days without formal admission.

Clinical messages

- The routine provision of an eye mask and ear plugs to recently admitted hospital inpatients is associated with improved sleep quality over one night

- The intervention was acceptable to at least 60% of participants, and used by 73%

- Larger scale trials in different settings and including longer-term patients would be feasible.

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Contributors

SS contributed to the literature search, recruited wards and participants, collected the data, and analysed the qualitative data with input to the quantitative data analysis. AF is the original initiator and overall lead of project, co-grant holder, developed study materials, and performed randomisation and quantitative data analysis. CL led the study design, wrote the trial protocol, and co-ordinated ethics approval. AM is the Chief Investigator, recruited clinical staff, and performed randomisation. TS co-initiated the project and a co-grant holder. DW advised on practical execution, undertook trial registration, and advised on data selection and analysis. AF, CL, TS and DW contributed to the study design. All authors participated in manuscript writing and contributed to the final report. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Declaration of interests

All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work other than that detailed above; no financial relationships in the previous three years with any organisations that might have an interest in the submitted work; and no other relationships or activities that could appear to have influenced the submitted work. DW is editor of this journal, but the article was reviewed by three people unaware of this.

Data sharing statement

No additional data are available.

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Figure one
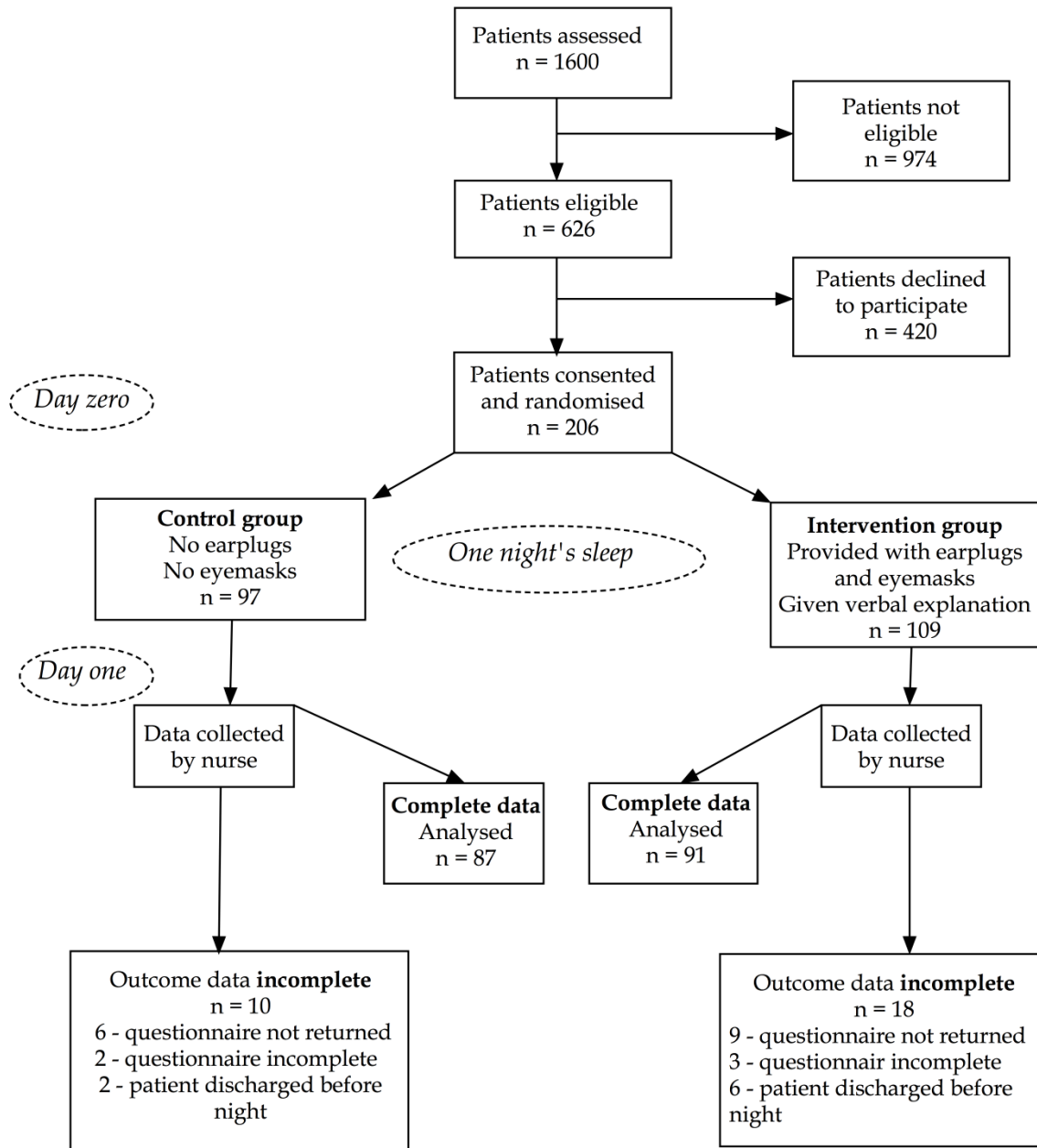
Patient flow chart

Table one

Demographic information

Characteristic	Group	
	Control (n = 97)	Intervention (n = 109)
Age (years)		
Mean (range)	55.3 (18-95)	48.4 (21-87)
Gender		
Female total (%)	51 (52.6)	70 (64.2)
Male total (%)	46 (47.4)	39 (35.8)
Ward (n); number of patients		
Surgical (5); patients (%)	53 (54.6)	54 (49.5)
Neuroscience (4); patients (%)	21 (21.6)	21 (19.3)
Gynaecology (1); patients (%)	14 (14.4)	26 (23.9)
Acute medical (1); patients (%)	5 (5.2)	6 (5.5)
Geriatric (2); patients (%)	4 (4.1)	2 (1.8)

Table two

Timing of night's sleep evaluated, in nights after admission

Timing of outcome data collection	Control Group n (%)	Intervention Group n (%)
First night	6 (6.2)	4 (3.7)
Second night	41 (42.3)	52 (47.7)
Third night	9 (9.3)	16 (14.7)
Fourth night	12 (12.4)	7 (6.4)
Fifth night	8 (8.2)	6 (5.5)
Sixth night ≥	13 (13.4)	12 (11)
Not completed/ Unknown	8 (8.2)	12 (11)

Table three

Outcome data

Measure	Control	Intervention
	N = 97	N = 109
Sleep quality*	N = 87	N = 91
	Mean (SD) 5.09 (2.05)	Mean (SD) 6.33 (2.13)
	[95% CI 4.66, 5.52]	95% CI 5.89, 6.77
Number of falls	0	0
Length of stay (days)	N = 96	N = 108
	Mean (SD) 4.83 (6.21)	Mean (SD) 3.67 (3.71)
	95% CI 3.59, 6.07	95% CI 2.97, 4.37
Number of patients using zopiclone during stay	2	5

*Sleep quality measured as mean of scores in the first eight questions of the SleepSure

questionnaire. Score range is 1 (worst) to 10 (best)

SD = standard deviation

CI = confidence intervals

Table four (supplementary data)

Scores on the individual items of the SleepSure questionnaire

Item		Control	Intervention	Comparison
		Group		
		Control	Intervention	
		n= 97	n=109	p-value
Depth of sleep	Mean	4·85	6·03	0·001
	95% CI	4·39, 5·31	5·54, 6·52	
	SD (n)	2·20 (89)	2·47 (96)	
Ease of getting to sleep	Mean	4·89	5·92	0·01
	95% CI	4·37, 5.41	5·36, 6.48	
	SD (n)	2·52 (89)	2·81 (96)	
Frequency of waking	Mean	4·4	5·17	0·06
	95% CI	3·82, 4·98	4·62, 5·72	
	SD (n)	2·79 (89)	2·70 (93)	
Ease of Getting back to sleep	Mean	4·65	6·33	<0·001
	95% CI	4·04, 5·26	5·78, 6·88	
	SD (n)	2·92 (88)	2·76 (95)	
Quality of sleep	Mean	5·07	6·09	0·007
	95% CI	4·54, 5·60	5·57, 6·61	
	SD (n)	2·54 (89)	2·60 (96)	
Length of sleep	Mean	5·13	6·22	0·003

	95% CI	4·64, 5·61	5·71, 6·73	
	SD (n)	2·34 (89)	2·55 (96)	
Noise disturbance	Mean	5·42	6·75	0·001
	95% CI	4·79, 6·04	6·24, 7.26	
	SD (n)	3·00 (88)	2·54 (96)	
Light disturbance	Mean	6·55	7·47	0·021
	95% CI	5·94, 7·16	6·98, 7·96	
	SD (N)	2·94 (89)	2·44 (95)	

CI = Confidence Intervals
SD = Standard Deviation

Table five

Use of earplugs and eye masks in the two groups [n (%)

Earplug and eye mask use*		Control (n= 97)	Intervention (n= 109)
Used earplugs and eye mask	n (%)	0 (0)	65 (60)
Used earplugs only	n (%)	1 (1)	1 (0.9)
Used eye mask only	n (%)	1 (1)	13 (12)
Did not use earplugs or eye mask	n (%)	87 (90)	15 (14)
No information	n (%)	8 (8.2)	15 (14)

*All participants in the intervention group received earplugs and eye masks. Three

participants from the control group had their own earplugs (n= 2) and eye mask (n= 1),

but did not use them.

Table six (supplementary data)

Adverse effects from using the intervention (n = 79)

Adverse effect	Number (%)
Uncomfortable earplugs	16
Uncomfortable eye mask	2
Feeling of confusion	1
Hearing own heartbeat when using the earplugs	1
Claustrophobia from the eye mask	1
Distortion of perceived time	1

Appendix 1 (supplementary data)

SleepSure Questionnaire

(1) Last night the depth of my sleep was:									
Very deep									Very light
1	2	3	4	5	6	7	8	9	10

(2). Last night getting to sleep was:									
Very easy									Very difficult
1	2	3	4	5	6	7	8	9	10

(3) Last night I woke from sleep:									
Not at all									A lot
1	2	3	4	5	6	7	8	9	10

(4) Last night when I woke, getting back to sleep was:									
Very easy									Very difficult
1	2	3	4	5	6	7	8	9	10

(5) Last night I slept:									
Not at all									**All night**
1	2	3	4	5	6	7	8	9	10

(6) Last night overall my sleep was:									

Terrible									**Excellent**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
(7) Last night the noise level was:									
Not at all disrupting									Very disturbing
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
(8) Last night the light level was:									
Not at all disrupting									Very disturbing
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
(9) Last night to help me sleep I had the option to use:									
Circle all that apply									
Eye mask			**Earplugs**		**Sleeping tablets**			**None of these**	
(10) Last night to help me sleep I used:									
Circle all that apply									
Eye mask			**Earplugs**		**Sleeping tablets**			**None of these**	
Comments:									

Questions 1-5 - based upon the original five point Richards Campbell Sleep

Questionnaire Score (RCSQ)

Question 6 - used by many studies as an addition to the original five point RCSQ.

Question 7-8 - used to reflect the effectiveness of earplugs and eye masks mitigating

noise and light disturbances.

Questions 9-10 - used to record availability and use of sleep aides.

Sleep Quality score = (sum questions one to eight)/8