

Quality sleep using earplugs in the intensive care unit: the QUIET pilot randomised controlled trial

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There is a high incidence of delirium in patients admitted to the intensive care unit. Its occurrence results in distress and is associated with substantial morbidity, mortality and cost.^{1,2} Sleep disruption is common in patients admitted to the ICU and is associated with the development of delirium. Patients treated in the ICU are also exposed to high sound levels and cite noise as a substantial contributor to sleep disruption.³⁻⁶ However, interventions aimed at reducing noise in the ICU have not proven to be effective.^{7,8}

Earplugs are a simple, low-cost, noise-abatement intervention that may improve sleep and reduce delirium in patients admitted to the ICU, but definitive evidence of effectiveness has not been established and earplugs are not in widespread use.⁹ There is a compelling rationale to conduct a large-scale trial with sufficient statistical power to determine if the routine use of earplugs can reduce the occurrence of delirium.^{10,11} However, a range of issues that inform the design and feasibility of such a trial have not been investigated.

Our primary aim in this pilot study was to assess the feasibility of a definitive randomised controlled trial of earplugs as a noise-abatement strategy to improve sleep and reduce delirium in patients admitted to the ICU. Our secondary aim was to measure noise abatement, ease of insertion and comfort associated with earplugs use. The primary hypothesis was that a Phase III trial of earplugs was feasible because of the high level of acceptability of the intervention to eligible patients, and the high level of compliance with the protocol in relation to delivery of the assigned treatment arm.

Methods

Between 28 October 2015 and 24 April 2016, we conducted a single-centre, randomised, open-label trial in a 10-bed ICU of a large, private hospital in Perth, Western Australia. The study protocol was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12615001125516) and was approved by the hospital human research ethics committee (HREC) before commencement. Prospective consent was obtained from all participants.

Study population

Patients were eligible for participation if they were listed for surgery that included a planned ICU admission and were expected to be undergoing mechanical ventilation (MV)

ABSTRACT

Objective: To assess the feasibility of a definitive, randomised controlled trial of earplugs as a noise-abatement strategy to improve sleep and reduce delirium in patients admitted to the intensive care unit.

Design and setting: An open-label trial of 40 patients randomised in a 1:1 ratio to receive earplugs in addition to standard care, or standard care alone, conducted in a 10-bed ICU of a large, private hospital in Perth, Western Australia.

Participants and intervention: Patients were eligible for participation if they were expected to be undergoing mechanical ventilation (MV) on admission to the ICU. Patients assigned to receive earplugs had earplugs placed on admission to the ICU and were offered earplug placement between 10 pm and 6 am for the first night in the ICU once they were extubated. Earplugs were not provided for patients assigned to standard care.

Main outcome measure: The primary outcome of study feasibility was assessed using criteria for acceptability of the intervention and protocol compliance.

Results: Of the 20 participants randomised to receive earplugs, 19 had earplugs placed within 6 hours of ICU admission, corresponding to 76% of the MV time (mean time with earplugs, 7.5 hours [SD, 5.3 hours]). Earplugs were placed for 18 of 20 participants during their first full night after extubation, corresponding to 78% of the total overnight time (mean time with earplugs, 6.2 hours [SD, 2.5 hours]).

Conclusion: A definitive study of earplugs as a noise-abatement strategy for patients admitted to the ICU is feasible on the basis of participant acceptability of the intervention and protocol compliance.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12615001125516.

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on admission to the ICU. Exclusion criteria were: age < 18 years, pre-existing hearing difficulties requiring the use of a hearing aid, suspected or confirmed tympanic membrane rupture, unwillingness to have earplugs placed for sleep promotion in the ICU, and the treating clinician deeming that enrolment was not in the best interests of the patient.

Randomisation and blinding

Eligible patients were randomly assigned in a 1:1 ratio to receive earplugs in addition to standard care, or standard care alone. The randomisation sequence was generated by an online randomisation resource (<http://www.randomization.com>). Allocation concealment was maintained by using permuted block randomisation and sealed, opaque, consecutively numbered envelopes. By necessity, the study was open label.

Study treatments

An assessment of noise abatement associated with earplug placement was conducted with a sample of 10 volunteer participants using the VeriPRO system (Honeywell). Participants were unaware of their allocation status at the time of undertaking VeriPRO testing. The details of the system are provided in the Appendix (online at cicm.org.au/Resources/Publications/Journal).

The earplugs used were single-use, expandable, polyurethane foam earplugs with a contoured T-shaped base for ease of handling (Max Lite, Howard Leight). All study participants were undergoing MV on admission to the ICU. Participants assigned to receive earplugs had earplugs placed on admission to the ICU, according to a standard operating procedure (see Appendix). Once extubated, participants assigned to receive earplugs were offered earplug placement between the hours of 10 pm and 6 am for their first night in the ICU (see Appendix). For participants assigned to standard care alone, earplugs were not provided and the use of earplugs was considered a protocol violation.

Study outcomes

Our primary outcome was study feasibility, measured by meeting all four of the following criteria:

- $\leq 10\%$ of patients otherwise screened as eligible refusing to participate on the basis of concerns over the placement of earplugs
- $\geq 90\%$ of patients randomised to receive earplugs receiving them within 6 hours of ICU admission
- $\geq 90\%$ of patients randomised to receive earplugs receiving them on the first night in the ICU occurring immediately after extubation
- $\leq 10\%$ of patients randomised to not receive earplugs receiving earplugs at any time while admitted to the ICU.

Secondary outcomes included:

- proportion of time that earplugs were placed while the patient was undergoing MV
- proportion of time between 10 pm and 6 am during which the patient was not undergoing MV and earplugs were placed

- doses of propofol and fentanyl (the primary sedative and analgesic agents, respectively) during the period of intubation
- administration (per day) of a newly prescribed antipsychotic medication during the ICU stay (measured as a surrogate for hyperactive delirium)
- ICU and hospital length of stay
- ICU and hospital mortality.

All participants completed the Richards–Campbell Sleep Questionnaire (RCSQ) after their first full night during which they were not undergoing MV.¹²

Maximum sound levels were recorded every hour for patients while they were undergoing invasive MV and between 10 pm and 6 am for the first night after extubation, using a sound measuring app downloaded to a personal mobile device (see Appendix for details of the app and sound measurements). Indicative abated sound levels with earplugs in situ were calculated for a subgroup of 10 patients by subtracting their preoperative measured level of abatement (average of measurements from the two ears) from their hourly overnight recorded sound levels.

In addition to standard reporting of serious adverse events (SAEs), otitis externa, suspected or confirmed ruptured tympanic membrane and any other complications thought to be related to earplug placement were collected as specific SAEs. No data safety monitoring board was formed for the study, but all SAEs were to be reported to the HREC within 24 hours of notification to the study investigators.

Statistical analysis

We report continuous variables as means with standard deviations (SDs) or medians with interquartile ranges (IQRs). Between-group differences were analysed using the Student *t* test or the Wilcoxon rank-sum test for apparently normal and non-normally distributed data, respectively. Categorical variables are reported as proportions and were analysed using the χ^2 test or Fisher exact test, as appropriate. All analyses were conducted on an intention-to-treat basis. No imputation was made for missing data. Statistical significance was defined as a two-sided $P \leq 0.05$. We conducted all analyses with Stata, version 14 (StataCorp). No interim analyses were planned or conducted. We calculated the sample size beforehand, on the basis of defining the lower end of the 95% confidence interval (CI) around the point estimate of acceptable compliance with the allocated intervention as 80%. On the basis that 90% of participants would receive the intervention to which they were assigned, the lower limit of the 95% CI of a study of 40 participants was 80.9%. Study participation required prior informed consent and did not include follow-up beyond hospital discharge; therefore, loss to follow-up was neither expected nor accounted for.

Results

Between 28 October 2015 and 24 April 2016, we screened 57 and enrolled 40 participants. The derivation of the cohort is shown in Figure 1. All participants were admitted to the ICU undergoing MV after cardiac surgery. The demographic characteristics of the cohort are shown in Table 1.

Feasibility

Feasibility was judged to have been achieved on the basis of all four feasibility endpoints having been met (Table 2). Of the participants randomised to receive earplugs, 19/20 had earplugs placed within 6 hours of ICU admission and spent a mean of 7.5 hours (SD, 5.3 hours) with earplugs in situ while undergoing MV (76% of the total ventilated time). Earplugs were placed for 18/20 participants in the ICU during their first full night after extubation, for a mean of 6.2 hours (SD, 2.5 hours) overnight with earplugs in situ (78% of the total overnight time).

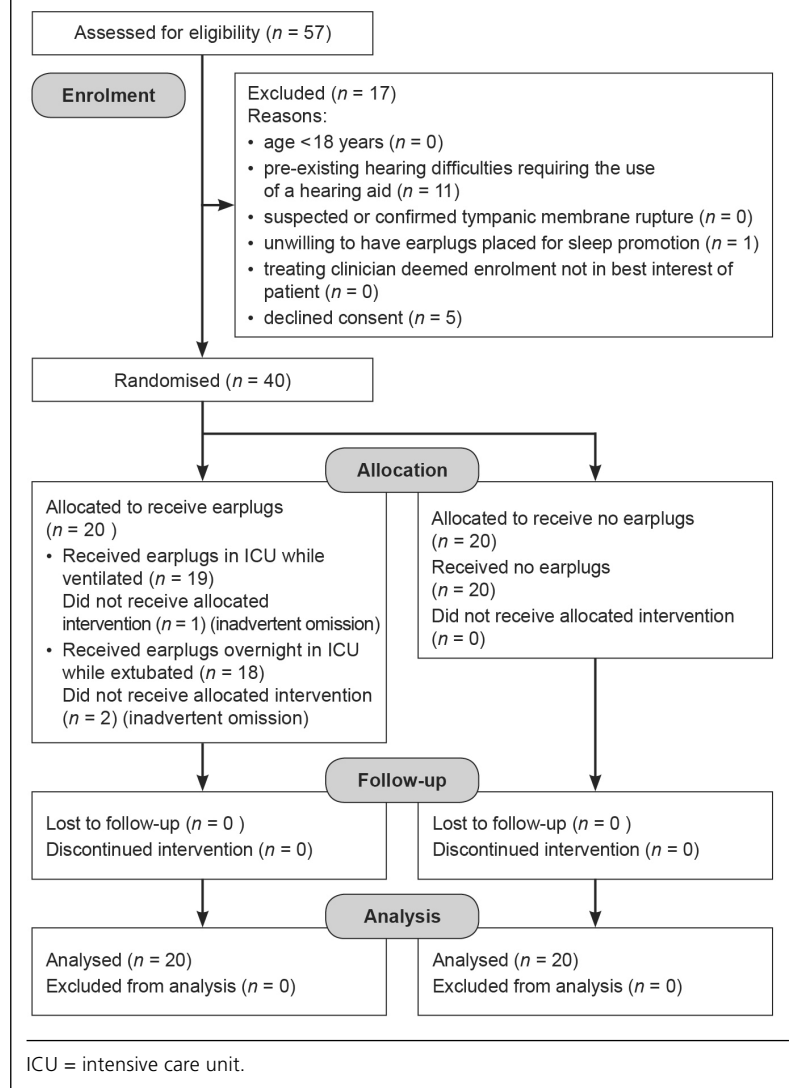
Sound levels, abatement, earplug comfort and ease of insertion

A record of overnight hourly sound levels for the first night after extubation in the ICU was available for 37 of 40 participants. The mean maximum sound level was 69 dB (SD, 7 dB; range, 59–86 dB). For the subgroup of 10 participants who underwent pre-operative testing of noise abatement associated with earplug placement, the median abatement for the right and left ears was 9 dB (IQR, 2–25 dB) and 12 dB (IQR, 0–23 dB), respectively. The maximum overnight hourly sound levels and inferred abated sound levels associated with earplug use are shown in Figure 2. Participant-rated earplug comfort, ease of insertion and reasons for earplugs not being used or being removed early are shown in Table 3.

Medication use, sleep scores and other secondary endpoints

There were no between-group differences in the total administered doses of propofol or fentanyl in the first 24 hours after admission to the ICU. No patients received antipsychotic medication in the ICU. The RCSQ sleep summary scores were 43 (IQR, 20–58) and 45 (IQR, 29–64) for the earplugs and no earplugs groups, respectively (median difference, 2; 95% CI, –21 to –25; $P = 0.58$) (Table 4).

Figure 1. Derivation of the participant cohort



Discussion

In this randomised trial, we found that earplug insertion in the ICU overnight, while undergoing MV and while breathing unassisted, was acceptable to a high proportion of patients screened for enrolment in the study. There was also high compliance with the protocol in delivery of the assignment arm procedure; measured noise abatement associated with earplug use was in a range that could improve sleep hygiene; and reported ease of insertion and comfort associated with the earplugs were high. Our results thus met our pre-defined criteria for feasibility.

Earplugs vary substantially in comfort and noise abatement.^{13,14} Training in optimal earplug placement is also a significant determinant of noise abatement.¹⁵ Previous studies in critically ill patients have used a range of earplugs and have generally not included a description of insertion technique or associated training, or a measurement of the

Table 1. Baseline characteristics of the participant cohort

Variable	Entire cohort (n = 40)	Earplugs (n = 20)	No earplugs (n = 20)	P
Median age, years (IQR)	69 (59–74)	70 (63–74)	66 (57–74)	0.417
Male sex, n (%)	31 (78%)	14 (70%)	17 (85%)	0.256
Mean height, m (SD)	1.74 (0.10)	1.71 (0.11)	1.76 (0.09)	0.164
Mean weight, kg (SD)	86 (20)	80 (19)	91 (19)	0.061
Admission diagnosis, n				
CABG	16	9	7	–
Valve surgery	18	9	9	–
Combined CABG + valve surgery	4	1	3	–
Other cardiac surgery	2	1	1	–
Comorbidities, n				
Sleep apnoea	2	2	0	–
Other sleep disorder	0	0	0	–
Short-term memory loss	0	0	0	–
Long-term use of earplugs	0	0	0	–
NYHA class, n				
1	14	8	6	–
2	16	7	9	–
3	10	5	5	–
4	0	0	0	–
Median APACHE II score (IQR)	14 (12–18)	16 (12–19)	14 (11–16)	0.148
Median ICU admission time, hours (IQR)	13:00 (12:00–16:00)	13:00 (12:00–16:00)	13:00 (12:00–16:00)	0.81

IQR = interquartile range. CABG = coronary artery bypass grafting. NYHA = New York Heart Association. APACHE = Acute Physiology and Chronic Health Evaluation. ICU = intensive care unit.

Table 2. Results for primary outcome

Feasibility criteria	Result, n (%)	Achieved feasibility
≤ 10% of otherwise eligible patients refused to participate on basis of concerns over placement of earplugs	1/41 (2%)	yes
≥ 90% of patients randomised to receive earplugs received earplugs within 6 hours of ICU admission	19/20 (95%)	yes
≥ 90% of patients randomised to receive earplugs received earplugs on first night in ICU after extubation	18/20 (90%)	yes
≤ 10% of patients randomised to not receive earplugs received earplugs at any time while admitted to ICU	0/20	yes

ICU = intensive care unit.

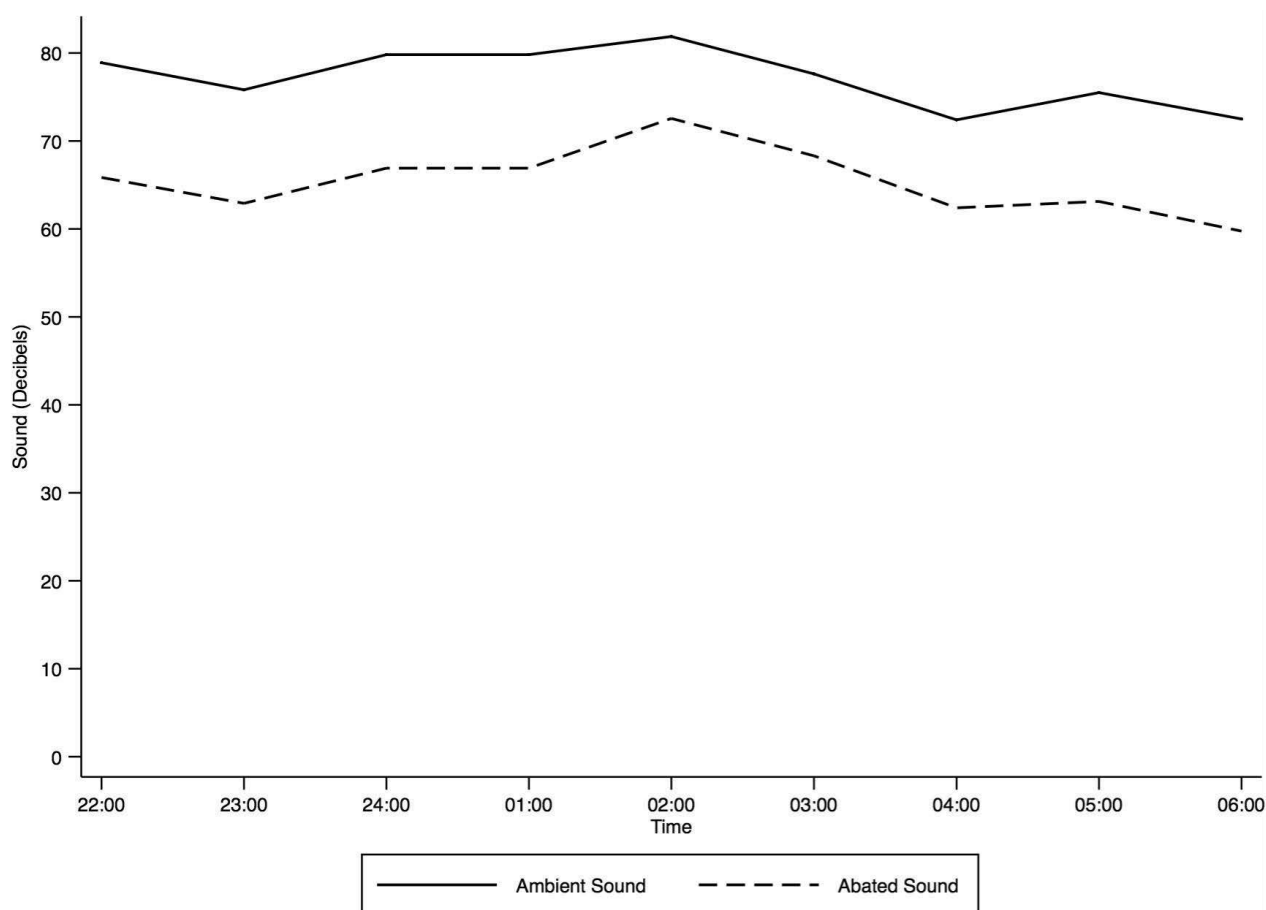
Table 3. Earplug sound abatement, comfort and ease of insertion

Variable	Pre-operative (n = 10)	ICU (n = 17)
Median sound abatement, right ear, dB (IQR) [range]	9 (2–25) [0–44]	na
Median sound abatement, left ear, dB (IQR) [range]	12 (0–23) [0–30]	na
Median participant-rated sound abatement,* dB (IQR)	7 (7–8)	na
Participant-rated earplug comfort, n (%)		
Intolerable	0	1 (6%)
Uncomfortable	2 (20%)	1 (6%)
Neither uncomfortable nor comfortable	6 (60%)	3 (18%)
Comfortable	2 (20%)	8 (47%)
Very comfortable	0	4 (24%)
Earplug ease of insertion,† n (%)		
Extremely difficult	0	1 (6%)
Difficult	1 (10%)	2 (12%)
Neither difficult nor easy	9 (90%)	5 (29%)
Easy	0	7 (41%)
Extremely easy	0	2 (12%)
Reason earplugs not used or removed, n (%)		
Clinician forgot	na	1 (10%)
Delirium	na	0
Participant declined insertion or ongoing use	na	5 (50%)
Ear trauma	na	0
Difficulty inserting	na	4 (40%)
Other	na	0

ICU = intensive care unit. IQR = interquartile range. na = not applicable. * 0 = no abatement; 10 = complete silence. † Rated pre-operatively by participants and in ICU by nurses.

proportion of time with earplugs in situ.^{16–19} Our results suggest that the choice of earplug and the adequacy of training in insertion are important aspects of a definitive trial of earplugs in the ICU.

Compared with our study, previous studies of use of earplugs in critical illness have included few, if any, patients undergoing MV.^{16–19} Given the ubiquitous nature of noise and sleep disruption in the ICU, this is a substantial limitation to the generalisability of the current evidence.¹⁰ The noise levels in our study exceeded World Health Organization recommendations and were consistent with the high noise levels found in other studies.^{20,21} In our study, perceived sound levels were reduced by about half with the use of earplugs (www.noisehelp.com). It is plausible that this level of abatement would result in clinical benefit, while, importantly, being insufficient to result in silence.

Figure 2. Overnight maximum ambient sound and indicative abated sound levels**Table 4. Results for secondary outcomes**

Variable	Earplugs (n = 20)	No earplugs (n = 20)	Median difference (95% CI)	P
Median propofol volume received in first 24 hours, g (IQR)	1.1 (0.7–1.9)	1.1 (0.9–1.9)	0 (–1 to 1)	0.756
Median fentanyl volume received in first 24 hours, µg (IQR)	290 (200–540)	330 (240–491)	40 (–147 to 226)	0.481
Median days receiving antipsychotic medication while in ICU	0	0	0	–
Median RCSQ total score* (IQR)	43 (20–58)	45 (29–64)	2 (–21 to 25)	0.580
Median RCSQ components score* (IQR)				
Deep sleep	29 (16–73)	45 (30–89)	na	0.110
Falling asleep	32 (11–57)	27 (9–61)	na	0.912
Number of awakenings	36 (12–66)	51 (27–85)	na	0.205
Proportion of time awake	46 (14–71)	44 (19–55)	na	0.837
Quality of sleep	39 (12–69)	63 (25–86)	na	0.067
Median duration of MV, hours (IQR)	7 (5–17)	6 (5–15)	1 (–6 to 8)	0.713
Median ICU length of stay, days (IQR)	4 (3–5)	3 (3–5)	1 (0–1)	0.251
Median hospital length of stay, days (IQR)	9 (8–14)	9 (7–11)	0 (–4 to 3)	0.376
ICU mortality, n	0	0	na	–
Hospital mortality, n	0	0	na	–
Serious adverse events, n	0	0	na	–

IQR = interquartile range. ICU = intensive care unit. RCSQ = Richards–Campbell Sleep Questionnaire. na = not applicable. MV = mechanical ventilation.
* 0 = worst sleep; 100 = best sleep.

Limitations

The trial was conducted exclusively in cardiothoracic patients in a single centre, and the generalisability of the findings is uncertain. However, given that protocol compliance was high in our non-university-affiliated private ICU, it is likely that tertiary institutions with substantial trial experience could achieve similar, if not better, results. For pragmatic reasons, the study was open label. In a definitive trial, blinding of some elements may be feasible. The study was underpowered to detect clinically important differences, and the CI around the point estimates included potentially clinically important benefit as well as harm. The inferred noise abatement was calculated from measurements made pre-operatively. It is possible that insertion of earplugs in the ICU environment may result in less abatement, although only a small minority of ICU nurses reported earplug insertion as being difficult or very difficult. Finally, earplugs were tested in isolation as a sleep hygiene intervention. It is plausible that initiation of earplug therapy would result in other changes related to sleep hygiene in the ICU, such as staff avoidance of unnecessary disturbance overnight.

Conclusion

A definitive study of earplugs as a noise-abatement strategy to improve outcomes in patients admitted to the ICU is feasible on the basis of participant acceptability of the intervention, protocol compliance, earplug-associated noise abatement, ease of insertion and comfort.

Competing interests

None declared.

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