

# QUIET

Sleep is essential for optimal brain, immune, and physical function. In patients admitted to the ICU, sleep disruption is common due to the effect of both acute illness and the ICU environment. Patients in the ICU rate sleep disruption as a major stressor. Furthermore, sleep disruption has been associated with the development of delirium, an acute confusional state, which itself is a risk factor for increased mortality and serious morbidity in critically ill patients.

Ear plugs are a safe, cheap and are potentially an easy strategy to improve sleep in the ICU by decreasing the amount of noise patients experience.

The aim of this study is to determine the feasibility of ear plug placement as a strategy for improving sleep in patients admitted to the ICU.

## Who Will be Studied?

A total of 40 participants will be recruited from the Intensive Care Unit at St John of God Hospital Subiaco. To enroll in the study each participant must meet all the inclusion criteria and no exclusion criteria.

### Inclusion Criteria

- Listed for elective surgery with a plan for post-operative admission to the ICU while still receiving mechanical ventilation

### Exclusion Criteria

- Age <18 years
- Preexisting hearing difficulties requiring the use of a hearing aid
- Suspected or confirmed ruptured tympanic membrane
- Unable or unwilling to have ear plugs placed for sleep promotion whilst in ICU
- Treating surgeon deems enrollment is not in the best interest of the patient

## Study Treatment

Prior to surgery participants will be asked to undertake a test where you place earplugs in both ears and wear a set of headphones to assess how well the earplugs reduce noise. The test is designed to determine the extent to which earplugs reduce noise and will take four to five minutes to complete. Prior to surgery, participants will also be asked to complete a brief questionnaire to assess any pre-existing sleep problems. The questionnaire will take approximately two minutes to complete.

This study requires no other additional blood tests, x-rays or other imaging tests beyond the standard tests required by the medical team

Participants will be randomised, (like the toss of a coin) to *routine postoperative placement of ear plugs* in addition to standard care, **or** standard care alone *without postoperative placement of ear plugs* in the ICU. Earplugs are not currently available for ICU patients and earplugs will only be available within the trial.

Aside from the ear plugs, patient management will be otherwise unaffected and the treating clinicians will be free to provide whatever other care is deemed necessary.

## Consent

A study brochure and consent form will be provided to potentially eligible participants who have been booked for surgery including ICU admission. Eligible participants will then be approached during the preoperative period (in the outpatient clinic or inpatient ward) by a member of the treating team (primary surgical team, anaesthesia and intensive care) and enrolled if the patient provides informed consent.

Participants will have the right to withdraw consent to continue the study treatment at any time without this affecting their treatment or their relationship with the hospital staff.

## Information

The study has been designed by a collaborative group of Intensive Care researchers. Study data will be collected, analysed and published with full credit assigned to the collaborating Investigators, Research Co-ordinator and Institution (SJOHGC).

For more information about the **QUIET Study** at **St John of God Hospital Subiaco**, please contact:

### The ICU Research Officer:


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### The Principal Investigator:

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**via switch board on 9382 6111**


The  
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Study

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A Pilot Randomised Controlled  
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