

# BMJ Open Investigating the application of motion accelerometers as a sleep monitoring technique and the clinical burden of the intensive care environment on sleep quality: study protocol for a prospective observational study in Australia

Lori J Delaney,<sup>1,2</sup> Marian J Currie,<sup>1</sup> Hsin-Chia Carol Huang,<sup>2,3</sup> Edward Litton,<sup>4</sup> Bradley Wibrow,<sup>5</sup> Violeta Lopez,<sup>6</sup> Frank Van Haren<sup>7,8</sup>

**To cite:** Delaney LJ, Currie MJ, Huang H-CC, *et al.* Investigating the application of motion accelerometers as a sleep monitoring technique and the clinical burden of the intensive care environment on sleep quality: study protocol for a prospective observational study in Australia. *BMJ Open* 2018;8:e019704. doi:10.1136/bmjopen-2017-019704

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-019704>).

Received 21 September 2017  
Revised 10 November 2017  
Accepted 24 November 2017



For numbered affiliations see end of article.

## Correspondence to

Assistant Professor Lori J Delaney;  
[lori.delaney@canberra.edu.au](mailto:lori.delaney@canberra.edu.au)

## ABSTRACT

**Introduction** Sleep is a state of quiescence that facilitates the significant restorative processes that enhance individuals' physiological and psychological well-being. Patients admitted to the intensive care unit (ICU) experience substantial sleep disturbance. Despite the biological importance of sleep, sleep monitoring does not form part of standard clinical care for critically ill patients. There exists an unmet need to assess the feasibility and accuracy of a range of sleep assessment techniques that have the potential to allow widespread implementation of sleep monitoring in the ICU.

**Key measures** The coprimary outcome measures of this study are to: determine the accuracy and feasibility of motion accelerometer monitoring (ie, actigraphy) and subjective assessments of sleep (nursing-based observations and patient self-reports) to the gold standard of sleep monitoring (ie, polysomnography) in evaluating sleep continuity and disturbance. The secondary outcome measures of the study will include: (1) the association between sleep disturbance and environmental factors (eg, noise, light and clinical interactions) and (2) to describe the sleep architecture of intensive care patients.

**Methods and analysis** A prospective, single centre observational design with a within subjects' assessment of sleep monitoring techniques. The sample will comprise 80 adults (aged 18 years or more) inclusive of ventilated and non-ventilated patients, admitted to a tertiary ICU with a Richmond Agitation-Sedation Scale score between +2 (agitated) and -3 (moderate sedation) and an anticipated length of stay >24 hours. Patients' sleep quality, total sleep time and sleep fragmentations will be continuously monitored for 24 hours using polysomnography and actigraphy. Behavioural assessments (nursing observations) and patients' self-reports of sleep quality will be assessed during the 24-hour period using the Richards-Campbell Sleep Questionnaire, subjective sleepiness evaluated via the Karolinska Sleepiness Scale, along with a prehospital discharge survey regarding patients' perception of sleep quality and disturbing factors using the Little Sleep Questionnaire will be undertaken. Associations

between sleep disturbance, noise and light levels, and the frequency of clinical interactions will also be investigated. Sound and luminance levels will be recorded at 1 s epochs via Exttech SDL600 and SDL400 monitoring devices. Clinical interactions will be logged via the electronic patient record system Metavision which documents patient monitoring and clinical care.

**Ethics and dissemination** The relevant institutions have approved the study protocol and consent procedures. The findings of the study will contribute to the understanding of sleep disturbance, and the ability to implement sleep monitoring methods within ICUs. Understanding the contribution of a clinical environment on sleep disturbance may provide insight into the need to address clinical environmental issues that may positively influence patient outcomes, and could dispel notions that the environment is a primary factor in sleep disturbance. The research findings will be disseminated via presentations at national and international conferences, proceedings and published articles in peer-reviewed journals.

**Trial registration number** ACTRN12615000945527; Pre-results.

## INTRODUCTION

Sleep is widely acknowledged to be important for optimal physical and psychological performance and well-being.<sup>1-3</sup> Patients cared for in intensive care unit (ICU) experience substantial sleep disturbance,<sup>4-6</sup> for which the aetiology is likely multifactorial. Intrinsic factors associated with critical illnesses (eg, disruption of the circadian rhythm) and extrinsic environmental factors (eg, noise, light and clinical interactions) contribute to poor sleep among this patient cohort.<sup>7-10</sup>

Previous research has shown that the sleep architecture of patients admitted to the ICU is characterised by significant fragmentation and lack of deep sleep, with their sleep

architecture predominantly comprising non-rapid eye movement (ie, stages 1 and 2 of the sleep cycle). This may limit the restorative functions of sleep and exacerbate deranged circadian rhythms.<sup>1 11 12</sup> Previous studies have described the somatic, cognitive and physiological effects of sleep disturbance.<sup>13–16</sup> Neurocognitive disturbances have been reported to persist postdischarge and are associated with a permanent decline in working memory.<sup>17–20</sup>

For critically ill patients, alteration to circadian patterns is associated with a decrease in overall well-being and prolonged recovery from critical illness.<sup>21–23</sup> Further, poor sleep is considered a major stressor for patients, which is acknowledged by family members and clinical staff,<sup>24 25</sup> and is associated with an increased incidence of delirium.<sup>3 26</sup> Preventing and treating sleep disturbance in the ICU may reduce morbidity and mortality. However, understanding and monitoring the sleep patterns of ICU patients require the identification of accurate and feasible sleep monitoring techniques suitable for widespread implementation.

### Sleep monitoring

Polysomnography (PSG) is the gold standard of sleep monitoring and can provide objective information of the sleep architecture of patients both during ICU admission and subsequent to discharge.<sup>1 8 11 12 27</sup> However, its application to the ICU environments is limited due to the costs associated with monitoring, the technical skills required to interpret the results and the uncertainty in describing common PSG patterns observed in critically ill patients according to standard physiological sleep patterns.<sup>28–31</sup>

In contrast, the implementation of subjective behavioural assessment performed by clinical staff to assess patients sleep is an inexpensive process. However, few of the commonly employed sleep questionnaires have been validated for use within the ICU population, and there are concerns regarding the clinical accuracy of subjective assessments compared with biophysiological-based monitoring.<sup>32</sup> While, the implementation of questionnaires is inherently less complex, their clinical utility is questionable given that 50% of ICU patients do not have the mental acumen required to complete such questionnaires.<sup>33</sup> Despite these issues, research conducted by Litton *et al* indicated that nursing staff are confident in documenting the differences between sleep and sedation.<sup>34</sup> However, research also suggests nurses overestimate patients' total sleep time regardless of the method employed to document sleep (real time or morning after documentation), and has been found to correlate poorly with patients' perceptions of their sleep.<sup>4 12 29 35–37</sup> For example, research undertaken by Kamdar *et al*<sup>14</sup> investigating the nurse–patient reliability of the Richards-Campbell Sleep Questionnaire (RCSQ) found the nurses significantly overestimated sleep depth and sleep quality. Similar findings have been reported in studies which required five minutely nursing documentation of patients sleep status, whereby nurses significantly overestimated sleep compared with PSG.<sup>38</sup> In contrast,

Edwards and Schuring<sup>39</sup> who compared 15 minutely nursing-based assessment of patient's sleep–wake status compared with PSG identified nursing assessment as being correct 82% of the time. However, the authors noted issues attributed to missing data and the impact of confounding factors such as sedation on the assessment process. A primary limitation of this study was the brief documentation period (4 hours), which may not adequately reflect the extent of monitoring required to evaluate sleep sufficiently. More recently, it has been suggested that subjective and objective measures may be complementary to inform staff regarding patients sleep quality.<sup>39</sup> As a result, the evolution of new devices such as motion accelerometers may be a valuable adjunct to monitoring sleep in the ICU.

Presently, there is an unmet need for an inexpensive and accurate method to assess total sleep time and sleep fragmentation. Motion accelerometers, such as actigraphy (ACTG) are a non-invasive method employed to monitor human rest/activity cycles. ACTG represents a more feasible sleep monitoring method compared with PSG, as it is relatively cheap, easy to implement and discontinues and produces easy to interpret results. ACTG has been found to have a high level of agreement (ie, >90%) with PSG in healthy participants; however, limited research has been conducted on the reliability and accuracy of ACTG in ICU populations, and the research that has been undertaken has yielded conflicting results.<sup>40–42</sup>

### Extrinsic disruption to sleep: the clinical environment

The apportionment of the clinical environment to sleep disturbance has been reported subjectively by patients, and in studies using objective assessments such as noise (dB-A and dB-C) and light (lux) monitoring. However, the relative contributions of the specific elements of the clinical environment on sleep disturbance are uncertain. A review undertaken by Xie *et al* reported that the effect of noise on sleep contributed to between 17% and 57% of arousal and awakenings.<sup>43</sup> In contrast, Gabor *et al*<sup>8</sup> and Freedman *et al*<sup>4</sup> reported that only 11%–24% of sleep arousal was attributable to noise events, suggesting that these results may reflect an adaptive response to clinical environments.

The ability of the patient to adapt to the clinical environment has been questioned, and emerging research suggests that noise variability may be a significant factor for sleep disturbance rather than the ambient noise levels. Delaney *et al*<sup>44</sup> reported noise variability in the ICU environment to range between 9.9 and 44 dB(A) over 5 min intervals, with noise sources >70 dB(A) occurring 10 times per hour. Secondary to the unpredictability of the environment, it is unlikely that patients could become accustomed to the diverse and rapid noise variations. Efforts to implement behavioural-based interventions to reduce noise levels have demonstrated limited success, with studies reporting a reduction in the subjective perception of noise levels.<sup>44 45</sup> Although, these have not translated to a measurable reduction in noise levels, or an

ability to sustain the reported reductions.<sup>45</sup> Subsequently, there has been an emergence of research investigating environmental masking, such as the effects of earplugs and eye masks as methods to reduce patients' exposure to noise and light.<sup>46 47</sup>

Extrinsic disruptions in the form of clinical interactions are frequent among this patient cohort. Early observational studies<sup>48 49</sup> reported that patients are disturbed between 1 and 14 times per hour, with the longest period of uninterrupted sleep being 43 min. In contrast, studies conducted by Tamburri *et al*<sup>50</sup> and Celik *et al*<sup>51</sup> reported much higher patient to staff interactions, with both studies reporting between 40 and 60 interactions per night, and as high as 20–60 interactions per hour in mechanically ventilated patients. This has significant implications on patients' ability to sleep, with reports indicating that 50% of ICU patients recall being woken two to five times throughout the night, and once woken up expressed difficulty in falling asleep again.<sup>1 10 52</sup> The frequency of clinical interaction can adversely impact on total sleep time and contributes to sleep disturbance, and in turn leads to poor quality of sleep. However, minimal studies have been conducted that concurrently monitors the biophysiological component of sleep to identify if some or all interaction contributes to sleep disturbance.

### Intrinsic disruption to sleep: critical illness

Intrinsic factors associated with critical illnesses (rather than clinical environments) may be the leading causes of sleep disturbance.<sup>7 53 54</sup> The effects of extrinsic factors compared with intrinsic factors on sleep quality have not yet been fully elucidated; however, emerging neuroimmunological research suggests that sleep disturbance may have an adverse impact on immunological responses. In particular, the suppression of the adaptive immune response and the increased activity of proinflammatory cytokines exacerbating sleep fragmentation.<sup>55 56</sup>

Understanding the dynamics between extrinsic and intrinsic factors and their effect on sleep is complex, which is further compounded by a lack of congruence between patients' subjective reports and physiological measurements of sleep. Subjective studies indicate that ICU survivors perceived light exposure to be minimally disruptive to their ability to sleep,<sup>57</sup> although it appears to have a detrimental effects on circadian patterns. Melatonin plays an important role in regulating the sleep wake cycle, with research indicating the ICU patients demonstrate a suppression in endogenous melatonin secretions.<sup>58–60</sup> The role that melatonin plays in regulating circadian patterns continues to be of interest to researchers, with studies investigating optimal administration patterns and assessment of its biophysiological impact on sleep architecture.

### STUDY AIMS

The aims of this study are to:

1. Determine the accuracy and feasibility of motion accelerometer monitoring (ie, ACTG) and subjective

assessments of sleep (nursing-based observations and patient self-reports RCSQ) to the gold standard of sleep monitoring (ie, PSG) in evaluating sleep continuity and disturbance.

2. Identify the association between sleep disturbance environmental factors (eg, noise, light and clinical interactions).
3. Describe the sleep architecture of intensive care patients.

## METHODS AND ANALYSIS

### Study design and setting

The observational study will have a within-subject design. Specifically, concurrent sleep monitoring will be performed using ACTG, PSG, nurses' subjective assessments documented hourly and questionnaires (RCSQ, Karolinska Sleepiness Scale (KSS) and the Little Sleep Questionnaire (LSQ)) completed by patients. Further, the effects of the clinical environment (ie, noise, light and clinical interactions) as factors affecting sleep disturbance will be investigated. The information obtained from the environmental monitoring will be compared with the arousal and wakeful event findings recorded by the PSG to ascertain their effects on patients' sleep.

The study site is a 31-bed tertiary referral ICU at an Australian teaching hospital that provides combined ICU and high dependency care. The unit admits approximately 2000 patients per year, including medical and surgical, admissions for trauma, neurosurgical and cardiothoracic care. The unit is located on the second floor of the hospital and has an open plan design with large fixed casement windows, two open plan nursing stations, shared bed spaces separated by disposable polypropylene non-woven curtains, partially enclosed walls and four dedicated isolation bays.

### Participants

Adults (aged 18 years and above), requiring ICU level care beyond the next calendar day, who score between +2 (ie, agitated) and –3 (ie, moderate sedation) on the Richmond Agitation-Sedation Scale (RASS) will be eligible for inclusion in the study. Sleep monitoring will be commenced between 13:00 and 16:00 hours and conducted over a single 24-hour period, as patients' sleep frequently traverses both day and night. The exclusion criteria are summarised in [box 1](#).

### Demographics and clinical data

The following variables will be collected: gender age, Acute Physiology and Chronic Health Evaluation (APACHE II) score, and APACHE II diagnostic classification, continuous renal replacement therapy, type of respiratory support, length of ICU admission when sleep monitoring was commenced, the use of eye masks or ear plugs, the presence or absence of physical restraints, delirium score (confusion assessment method: ICU), ICU length of stay (LOS), hospital LOS and mortality (alive/deceased in ICU or hospital). Further, the use of



**Box 1 Exclusion criteria for study participation**

Patients will be excluded from this study if on initial assessment.

- ▶ Admitted to the intensive care unit primarily for a neurological condition.
- ▶ Treatment intent is palliative and/or not expected to survive for more than 24 hours.
- ▶ Confirmed or suspected drug overdose.
- ▶ Likely to be administered a neuromuscular blocking agent during the 24 hours study period.
- ▶ Likely to be administered a barbiturate during the 24-hour study period.
- ▶ History of cognitive impairment, for example, Alzheimer's disease.
- ▶ Have inadequate English language skills to allow completion of a sleep survey.
- ▶ Have facial or skull injuries that prohibit the placement of the polysomnography electrodes.
- ▶ Have injuries that preclude the placement of actigraphy.
- ▶ Spinal cord injury.
- ▶ Have clinically suspected encephalopathies (ie, septic, hepatic or uraemic encephalopathies).

analgesedation, antipsychotic and hypnotic medications, administration of melatonin, inotropes and vasopressors will be documented to assess the heterogeneity of the sample and enable the measurement of predictive factors.

**Sample size and power**

The sample size for the study was based on Cohen's<sup>61</sup> power primer, with an alpha value of 0.05 and a power of 80%, resulting in a minimum sample size of 67 patients to be recruited into the study in order to determine an absolute difference (moderate size effect; 0.3) between the sleep monitoring methods PSG and ACTG. To account for missing data such as incomplete monitoring and discharge prior to completion the sample size was increased by 20% to a total of 80 participants for the study.

**Sleep monitoring protocol and interventions****Actigraphy**

ACTG will be applied to a patient's wrist (similar to a wristwatch). ACTG is capable of sensing motion with the resultant forces of at least 0.01 g, and has a sampling rate of 32 Hz. An Actiwatch (by Phillips Respironics) will be applied to the wrist of each participant in the study on the side that has the least invasive devices (eg, intravenous cannulation, arterial line and sphygmomanometer). Recordings will be synchronised with the PSG to determine the reliability and accuracy of the device. ACTG data will be collected at 30 s epochs.

**Polysomnography**

The Embla PSG (VMedical) ambulatory monitoring device will be used to continuously monitor participants' PSG scores for a period of 24 hours. The data obtained from the PSG (Embla) will be downloaded to a secure digital data card manager so that the information can be transferred to a personal computer. A board-certified sleep scientist (Registered Polysomnographic

Technologist) experienced in PSG scoring will review the PSG data to ensure accuracy and consistency in the data analysis. To prevent any undue influence secondary to knowledge, ascertainment bias and limit the effect of the assessors' inclinations or attitudes towards the sleep measures, the sleep scientist reviewing the PSG data will be blinded.<sup>62</sup>

The international 10–20 electrode placement standards for portable PSG monitoring will be used to determine the positioning of the PSG electrodes; electroencephalogram electrode placement: C4/M1, C3/M2, F4/M1, F3/M2, O2/M1 and O1/M2. The electro-oculogram (EOG)-L (left) electrode will be positioned 1 cm lateral and below the left eye outer canthus, EOG-R (right) electrode 1 cm lateral and above the right eye outer canthus, EOG-C electrode positioned in the centre of the forehead. The electromyography of the submental (EMG), EMG+and EMG– electrodes positioned under the chin and approximately 3 cm apart.

**Subjective behavioural monitoring**

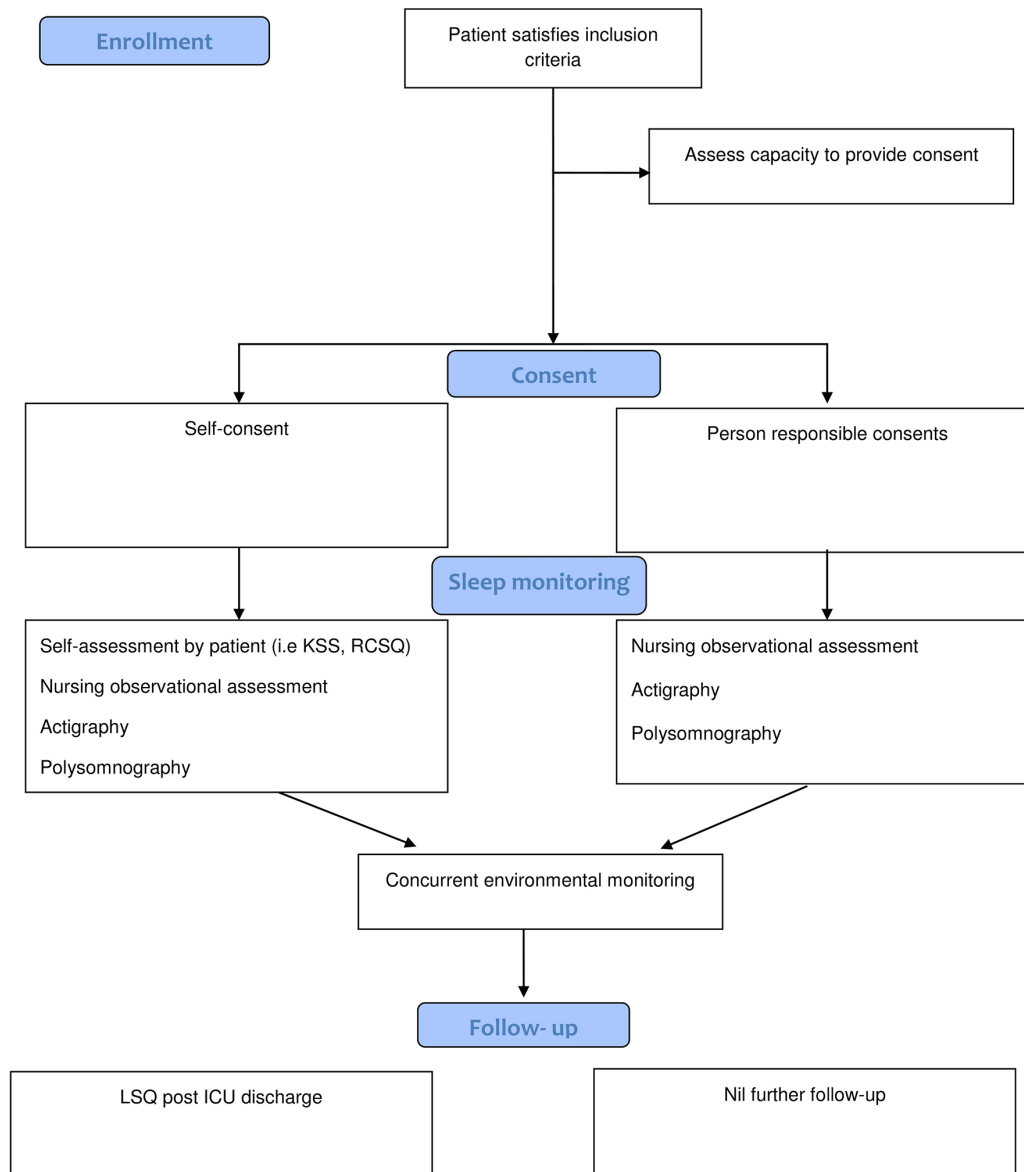
Subjective assessment of sleep will be based on the Edwards and Schuring's<sup>39</sup> method, with nursing staff required to manually record each hour the sleep status of the patient: awake, asleep for 15 min or less, asleep for 15–30 min, asleep for 30–45 min, or has been asleep for the hour (60 min). The nursing staff will be blinded to the PSG and ACTG data, and will not be able to base their assessments on this information. The subjective assessment will be integrated into the computerised electronic patient data system of MetaVision (iMDsoft), used in the ICU to document patients' clinical care.<sup>34</sup>

**Patient self-reports**

The research team will assess each patients' competency based on: (1) the feedback of clinical staff in relation to each patient's cognitive ability; (2) the patient's negative confusion and assessment method results across three subscales (ie, inattention, altered level of consciousness and disordered thinking) and (3) whether the patient has a RASS between –1 (drowsy, but sustained awakening) and +1 (restless, but not agitated) (figure 1). Patients deemed competent will be invited to complete the RCSQ and the KSS, with assistance from clinical staff if required. A follow-up questionnaire: LSQ will be undertaken within 7 days of the patients identified hospital discharge date. Where patients do not meet the competency-based criteria, patient self-reported sleep quality via the RCSQ, KSS and LQS will be omitted (refer to figure 1).

**The Richards-Campbell Sleep Questionnaire**

The RCSQ is a five-item questionnaire designed to evaluate ICU patients' quality of sleep and will be completed after each patient's night recording between 09:00 and 10:00. The RCSQ has previously been validated against PSG and comprises five subscales: (1) sleep depth, (2) sleep latency, (3) number of awakenings,



**Figure 1** Flow diagram of the monitoring procedure. ACTG, actigraphy; ICU, intensive care unit; KSS, Karolinska Sleepiness Scale; LSQ, Little Sleep Questionnaire; PSG, polysomnography; RCSQ, Richards-Campbell Sleep Questionnaire.

(4) efficiency and (5) sleep quality ( $\alpha=0.90$ ).<sup>63</sup> The RCSQ is recorded using a 100mm visual analogue scale. A mean score will be derived from the five subscales to provide an overall score reflecting patients' perceptions of their sleep quality. A higher score on the questionnaire indicates a better quality of sleep.

#### Karolinska Sleepiness Scale

The KSS is a self-reported nine-point Likert scale of subjective drowsiness at the point in time of testing to evaluate if this precipitates the patient's onset of sleep. The KSS has been widely used, particularly to describe changes over time in study participants, and will be completed on initiation of monitoring, between 21:00 and 22:00 hours and the following morning within 2 hours of awakening. A KSS score  $>7$  reflects a state of drowsiness under which an individual may be susceptible to involuntary microsleep

behaviours with episodic losses of awareness, followed by returns of awareness.<sup>64</sup>

#### Little Sleep Questionnaire

The LSQ was modelled on the ICU memory tool and developed for the use among ICU patient to explore the sleep experiences of patients, secondary to a lack sleep questionnaires addressing primary issues experienced by ICU patients.<sup>65</sup> This questionnaire explores patients' perceived quality and quantity of sleep at home prior to ICU admission, during their ICU stay and following discharge from the ICU; ICU-related factors contributing to poor sleep and possible changes in the ICU that could improve sleep. The survey will be excluded in instances where the patients' clinical condition or recovery precludes their ability to complete the LSQ. The LSQ will be conducted post the participants discharge from

the ICU and within 7 days of the participants' estimated hospital discharge date.

### Environmental monitoring protocol

Extech sound meter (SDL600: frequency range 31.5 Hz–8 kHz, decibel range 30–180 dB) and lux metres (Extech SDL460: luminance range of 0–1999 lux, accuracy:  $\pm 4\%$  +2 disability glare threshold) positioned at a height of 155 cm behind the head of patients' beds will be used to monitor noise and light. This positioning of the sound meter will allow the noise and light sources to which each patient is subjected to be monitored without interfering with or disrupting a patient's clinical care. These monitors will log noise and light level data at 1 s epochs over the 24-hour study period. Noise will be recorded on the A-weighted decibel (dB) scale that most closely reflects the sound and loudness perceived by the human ear. Whereas light levels will be recorded in lux, the standard unit of measurement in photometry and a measurement that is representative of the intensity of light perceived by the human eye.

Clinical interactions with patients will be recorded by the inpatient electronic data system, Metavision. This system documents patient care, including patients' vital signs, medication administration, titrations and clinical activities.

### Outcome measures and instruments

The primary outcome measure of the study is to determine the accuracy and feasibility of motion accelerometer monitoring (ie, ACTG) and subjective assessments of sleep (nursing-based observations and patient self-reports) compared with the gold standard of sleep monitoring (ie, PSG) in evaluating sleep continuity and disturbance.

Sleep onset will be defined in accordance with the American Academy of Sleep Medicine Manual for Scoring Sleep and Associated Events (V2.4) as the first epochs of any sleep stage.<sup>66</sup> Sleep features such as total sleep time, total wake time, wake after sleep onset, arousal index and sleep efficiency will be correlated to sleep data derived from ACTG. The sensitivity (percentage of ACTG data that agreed with sleep determined via PSG), specificity (percentage of ACTG data that agreed with awake determined using PSG) and accuracy (ability to detect both sleep and wake compared with PSG=number to sleep and wake epochs of PSG scored sleep and wake epochs) between PSG and ACTG findings will also be analysed.<sup>67</sup> PSG hypnograms will be used to depict sleep and sleep stages over time, along with reporting the percentage of total sleep time in sleep stages N1, N2, N3 and REM sleep.

Atypical sleep patterns are known to occur within the ICU patient cohort, which hampers the ability to interpret sleep staging based on traditional criteria. In cases where atypical PSG data is identified, these will be analysed based on Watson *et al*'s<sup>31</sup> revised ICU sleep scoring criteria.

### Box 2 Secondary outcome measures of the study

- ▶ Report the sleep architecture of intensive care patients.
- ▶ Compare the accuracy of polysomnography (PSG) compared with actigraphy, nursing assessment and patient self-reports.
- ▶ Determine the accuracy of patient self-reports of sleep quality compared with their biophysiological data.
- ▶ Determine the accuracy of nurses' observations of patients' total sleep times compared with PSG.
- ▶ Determine the effects of noise events (>70 dB (A)) on sleep stages.
- ▶ Determine the effects of exposures to artificial, nocturnal light during the sleep stages.
- ▶ Identify whether any clinical interactions are causal factors that arouse patients' from sleep.

Box 2 outlines the secondary outcome measures of the study, including the percentage of time that participants spend in each of the sleep stages as identified by PSG. In addition, to comparisons between the subjective sleep assessment conducted by clinical staff and the patient participants, and sleep disturbances associated with environmental factors will be performed.

### Statistical methods

The data analyses will involve descriptive and analytic statistics, calculated using the Statistical Package for Social Science (V.20). Descriptive statistics (ie, means, SD and ranges) will be used to describe and summarise the demographic and clinical features of the study cohort, and the categorical data will be presented in frequency tables (n, %). The reasons associated with missing data attribute to PSG and ACTG monitoring will be documented and included in the analysis to explore the clinical application of these monitoring techniques. In the instances where data is missing for nursing-based observations of patient sleep an imputation method of the last observation carried forward will be applied.<sup>68</sup> While, missing data pertaining to the measure of noise and light will be addressed via the multiple imputation (multiple regression) method, as a means to reduce the likelihood of type 1 error.

Inferential statistical procedures, including parametric and non-parametric statistical analyses, will be used to analyse any data that violates the principles for the normal distributions of nominal or ordinal data. Cohen's kappa coefficients ( $\kappa$ ) will be employed to determine the inter-rater agreement between PSG and ACTG in determining the mutually exclusive states of wakefulness and sleep. The values derived from the Cohen's kappa will be characterised as follows: a result of <0 will indicate no agreement, a result of 0–0.20, will indicate slight agreement, a result of 0.21–0.4 will indicate a fair level of agreement, a result of 0.61–0.80 will indicate substantial agreement and a result of 0.81–1 will be deemed to be an almost perfect agreement.<sup>69</sup>

Bland-Altman plots will be used to determine the clinical comparability of PSG and ACTG and their level of agreement will be used to determine patients' waking

and sleep states, as a high a level of correlation does not necessarily indicate agreement. The computations will be based on a 95% limit of agreement for each comparison. The level of agreement between nurses' observations and patients' self-reports of sleep will also be measured using the Bland-Altman plot to visually present the differences in patients (x-axis) and nurses' (y-axis) reports. The RCSQ scores will be classified across three domains: poor sleep (0–33), moderate sleep (34–66) and a good night's sleep (67–100). The sleep domains of overall sleep quality and number of awakenings, ICU LOS, and APACHE II scores will be investigated via the non-parametric Spearman's correlation coefficient. The Mann-Whitney test will be used to test the differences between groups based on diagnostic classifications.

The environmental data will be analysed against the PSG monitoring to determine the effects of noise events, light levels and clinical care on patients' sleep. A non-parametric analysis using Spearman's correlations ( $r$ ) will be conducted to ascertain the effect of these environmental factors on sleep quality. Categorical outcomes will be analysed using the  $X^2$  test or Fisher's exact test. The significance level will be set at 0.05 (two tailed).

### Ethics and consent

Patients admitted to the ICU for an anticipated admission period of 24 hours, with prehospital discharge follow-up for patients meeting the criteria to complete self-report will be identified by the ICU medical team and assessed by the chief investigator to determine whether they meet the study's eligibility criteria. Potential participants will be approached and asked to provide written consent to participate. A patient's severity of illness on admission may mean that some potential participants cannot consent. In such cases, the identified next of kin will be approached, provided information on the study and asked to provide or decline consent. In accordance with the relevant territory laws, patients who are under guardianship orders or subject to an Enduring Power of Attorney will be excluded from the study. In circumstances where family members have provided consent, once the patient is able, he/she will be provided with an opportunity to retrospectively withdraw from the study, or formally consent to participate in study.

### DISSEMINATION

Sleep is considered an important component of recovery and can minimise the neurocognitive complications associated with sleep deprivation. Previous studies have revealed a number of themes that continue to go unaddressed in critical care environments, including identifying a method to monitor sleep, understanding the underlying factors that contribute to sleep disturbances and developing interventions that reduce the impact of adverse effects of sleep disturbance on patients.<sup>4 8 11 14 22</sup> If the challenges faced in the field are to be successfully

overcome, research investigating sleep in the critical care needs to be ongoing and progressive.

This observational study will endeavour to ascertain the potential and ability of a motion accelerometer to accurately identify ICU patients' total sleep time and sleep fragmentation. Acquiring cost-effective and easily interpretable data on ICU patients' sleep and sleep disturbances will provide clinicians with important information on which they can base clinical management strategies to enhance patients' overall well-being and recovery. There are, however, limitations associated with the study, these include, it being a single centre study which may limit the generalisability of the findings, although it may provide the impetus for future multicentre studies. Further, PSG is deemed the gold standard of sleep monitoring, however, its ability to monitor sleep within the intensive care patient cohort presents challenges in regards to the data acquired. The impact of missing data will be investigated as outlined and may further highlight the issues and complexity of sleep monitoring among ICU patients and the clinical feasibility of PSG monitoring. Additionally, the results of this study will enhance understandings of how and to what extent environmental factors contribute to sleep disturbance and thus provide valuable information that can be used to inform the future designs and characteristics of ICUs. The findings derived from this study will be submitted to academic peer-reviewed journals for publication and presented at relevant international and national conferences. The transfer of knowledge obtained from this study will also be provided to the institution's healthcare policy makers and clinicians via seminars and study synopses to aid in the improvement of clinical care.

### Author affiliations

<sup>1</sup>Faculty of Nursing, University of Canberra, Canberra, Australia

<sup>2</sup>College of Health and Medicine; Australian National University, Canberra, Australia

<sup>3</sup>Chronic Diseases Management and Respiratory and Sleep Medicine, Canberra Hospital, Canberra, Australia

<sup>4</sup>Intensive Care Unit, St John of God Subiaco Hospital, Perth, Australia

<sup>5</sup>Intensive Care Medicine, Sir Charles Gairdner Hospital, Nedlands, Australia

<sup>6</sup>Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, Singapore, Singapore

<sup>7</sup>Intensive Care Unit, Canberra Hospital, Canberra, Australia

<sup>8</sup>University of Canberra, Australian National University, Canberra, Australia

**Contributors** LJD: development of research concept, contribution of original material, editing and approving the final manuscript. MJC: statistical analysis support, editing and approving the final manuscript. H-CCH: research supervision, contribution of original material and content and study design relating to polysomnography, editing of manuscript and approving the final manuscript. VL: research supervision, contribution of original material, editing and approving the final manuscript. EL: contribution of original material, critical review of protocol, editing of manuscript and approving the final manuscript. BW: contribution of original material, critical review of protocol and editing of manuscript and approving the final manuscript. FVH: research supervision, research design, contribution of original material, editing and approving the final manuscript.

**Funding** This work is supported by the Canberra Hospital Foundation (ACT, Australia), VMedical Australia Pty Ltd and the Intensive Care Foundation Research Grant.

**Competing interests** None declared.

**Patient consent** Obtained.



**Ethics approval** The healthcare institute and the university's Human Research and Ethics Committees have formally approved the study (Eth5.16.071 and 2016/449).

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Open Access** This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2018. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

## REFERENCES

- Tranmer JE, Minard J, Fox LA, et al. The sleep experience of medical and surgical patients. *Clin Nurs Res* 2003;12:159–73.
- Frieze RS, Bruns B, Sinton CM. Sleep deprivation after septic insult increases mortality independent of age. *J Trauma* 2009;66:50–4.
- Ely EW, Inouye SK, Bernard GR, et al. Delirium in mechanically ventilated patients: validity and reliability of the confusion assessment method for the intensive care unit (CAM-ICU). *JAMA* 2001;286:2703–10.
- Freedman NS, Gazendam J, Levan L, et al. Abnormal sleep/wake cycles and the effect of environmental noise on sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 2001;163:451–7.
- Richards KC, Bairnsfather L. A description of night sleep patterns in the critical care unit. *Heart Lung* 1988;17:35–42.
- Bihari S, Doug McEvoy R, Matheson E, et al. Factors affecting sleep quality of patients in intensive care unit. *J Clin Sleep Med* 2012;8:8.
- Mundigler G, Delle-Karth G, Koreny M, et al. Impaired circadian rhythm of melatonin secretion in sedated critically ill patients with severe sepsis. *Crit Care Med* 2002;30:536–40.
- Gabor JY, Cooper AB, Crombach SA, et al. Contribution of the intensive care unit environment to sleep disruption in mechanically ventilated patients and healthy subjects. *Am J Respir Crit Care Med* 2003;167:708–15.
- Aaron JN, Carlisle CC, Carskadon MA, et al. Environmental noise as a cause of sleep disruption in an intermediate respiratory care unit. *Sleep* 1996;19:707–10.
- Lee CY, Low LP, Twinn S. Older men's experiences of sleep in the hospital. *J Clin Nurs* 2007;16:336–43.
- Elliott R, McKinley S, Cistulli P, et al. Characterisation of sleep in intensive care using 24-hour polysomnography: an observational study. *Crit Care* 2013;17:R46.
- Frieze RS, Diaz-Arastia R, McBride D, et al. Quantity and quality of sleep in the surgical intensive care unit: are our patients sleeping? *J Trauma* 2007;63:1210–4.
- Delaney LJ, Van Haren F, Lopez V. Sleeping on a problem: the impact of sleep disturbance on intensive care patients - a clinical review. *Ann Intensive Care* 2015;5:1.
- Kamdar BB, Needham DM, Collop NA. Sleep deprivation in critical illness: its role in physical and psychological recovery. *J Intensive Care Med* 2012;27:97–111.
- Lautenbacher S, Kundermann B, Krieg JC. Sleep deprivation and pain perception. *Sleep Med Rev* 2006;10:357–69.
- Honkous VL. Sleep deprivation in critical care units. *Crit Care Nurs Q* 2003;26:179–91.
- Dubois MJ, Bergeron N, Dumont M, et al. Delirium in an intensive care unit: a study of risk factors. *Intensive Care Med* 2001;27:1297–304.
- Brummel NE, Girard TD. Preventing delirium in the intensive care unit. *Crit Care Clin* 2013;29:51–65.
- Richardson A, Crow W, Coghill E, et al. A comparison of sleep assessment tools by nurses and patients in critical care. *J Clin Nurs* 2007;16:1660–8.
- Burkhalter H, Sereika SM, Engberg S, et al. Validity of 2 sleep quality items to be used in a large cohort study of kidney transplant recipients. *Prog Transplant* 2011;21:27–35.
- Obayashi K, Saeki K, Iwamoto J, et al. Exposure to light at night and risk of depression in the elderly. *J Affect Disord* 2013;151:331–6.
- Bellapart J, Boots R. Potential use of melatonin in sleep and delirium in the critically ill. *Br J Anaesth* 2012;108:572–80.
- Hatta K, Kishi Y, Wada K, et al. Preventive effects of ramelteon on delirium: a randomized placebo-controlled trial. *JAMA Psychiatry* 2014;71:397–403.
- Rotondi AJ, Chelluri L, Sirio C, et al. Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. *Crit Care Med* 2002;30:746–52.
- Novaes MA, Knobel E, Bork AM, et al. Stressors in ICU: perception of the patient, relatives and health care team. *Intensive Care Med* 1999;25:1421–6.
- Ely EW, Gautam S, Margolin R, et al. The impact of delirium in the intensive care unit on hospital length of stay. *Intensive Care Med* 2001;27:1892–900.
- Richards KC, Bairnsfather L. A description of night sleep patterns in the critical care unit. *Heart Lung* 1988;17:35.
- Boesen HC, Andersen JH, Bendtsen AO, et al. Sleep and delirium in unsedated patients in the intensive care unit. *Acta Anaesthesiol Scand* 2016;60:59–68.
- Pisani MA, Frieze RS, Gehlbach BK, et al. Sleep in the intensive care unit. *Am J Respir Crit Care Med* 2015;191:731–8.
- Drouot X, Roche-Campo F, Thille AW, et al. A new classification for sleep analysis in critically ill patients. *Sleep Med* 2012;13:7–14.
- Watson PL, Pandharipande P, Gehlbach BK, et al. Atypical sleep in ventilated patients: empirical electroencephalography findings and the path toward revised ICU sleep scoring criteria. *Crit Care Med* 2013;41:1958–67.
- Bourne RS, Minelli C, Mills GH, et al. Clinical review: Sleep measurement in critical care patients: research and clinical implications. *Crit Care* 2007;11:226.
- Frisk U, Nordström G. Patients' sleep in an intensive care unit - patients' and nurses' perception. *Intensive Crit Care Nurs* 2003;19:342–9.
- Litton E, Elliott R, Thompson K, et al. Using clinically accessible tools to measure sound levels and sleep disruption in the ICU: a prospective multicenter observational study. *Crit Care Med* 2017;45:966–71.
- Delaney LJ, Haren FV, Currie M, et al. Sleep monitoring techniques within intensive care. *Int J Nurs Clin Pract* 2015;2:5.
- Sanders RD, Maze M. Contribution of sedative-hypnotic agents to delirium via modulation of the sleep pathway. *Can J Anaesth* 2011;58:149–56.
- Stuck A, Clark MJ, Connelly CD. Preventing intensive care unit delirium: a patient-centered approach to reducing sleep disruption. *Dimens Crit Care Nurs* 2011;30:315–20.
- Aurell J, Elmqvist D. Sleep in the surgical intensive care unit: continuous polygraphic recording of sleep in nine patients receiving postoperative care. *Br Med J* 1985;290:1029–32.
- Edwards GB, Schuring LM. Pilot study: validating staff nurses' observations of sleep and wake states among critically ill patients, using polysomnography. *Am J Crit Care* 1993;2:125–31.
- Cole RJ, Kripke DF, Gruen W, et al. Automatic sleep/wake identification from wrist activity. *Sleep* 1992;15:461–9.
- Sadeh A, Sharkey KM, Carskadon MA. Activity-based sleep-wake identification: an empirical test of methodological issues. *Sleep* 1994;17:201–7.
- Sadeh A, Hauri PJ, Kripke DF, et al. The role of actigraphy in the evaluation of sleep disorders. *Sleep* 1995;18:288–302.
- Xie H, Kang J, Mills GH. Clinical review: The impact of noise on patients' sleep and the effectiveness of noise reduction strategies in intensive care units. *Crit Care* 2009;13:208.
- Delaney LJ, Currie M, Huang H-CC, et al. The nocturnal acoustical intensity of the intensive care environment: an observational study. Australian National University, 2017.
- Konkani A, Oakley B, Penprase B. Reducing hospital ICU noise: a behavior-based approach. *J Healthc Eng* 2014;5:229–46.
- Yazdani AR, Zareie A, Hasanpour M, et al. The effect of earplugs and eye mask on patients' perceived sleep quality in intensive care unit. *Iran J Nurs Midwifery Res* 2014;19:673.
- Hu RF, Jiang XY, Zeng YM, et al. Effects of earplugs and eye masks on nocturnal sleep, melatonin and cortisol in a simulated intensive care unit environment. *Crit Care* 2010;14:R66.
- Walker BB. The postsurgery heart patient: amount of uninterrupted time for sleep and rest during the first, second, and third postoperative days in a teaching hospital. *Nurs Res* 1972;21:164–9.
- Woods NF. Patterns of sleep in postcardiotomy patients. *Nurs Res* 1972;21:347–51.
- Konburri LM, DiBrienza R, Zozula R, et al. Nocturnal care interactions with patients in critical care units. *Am J Crit Care* 2004;13:13.
- Celik S, Oztekin D, Akyolcu N, et al. Sleep disturbance: the patient care activities applied at the night shift in the intensive care unit. *J Clin Nurs* 2005;14:102–6.
- Redeker NS, Hedges C. Sleep during hospitalization and recovery after cardiac surgery. *J Cardiovasc Nurs* 2002;17:56–68.



53. Li SY, Wang TJ, Vivienne Wu SF, *et al.* Efficacy of controlling night-time noise and activities to improve patients' sleep quality in a surgical intensive care unit. *J Clin Nurs* 2011;20:396–407.
54. Durrington HJ, Farrow SN, Loudon AS, *et al.* The circadian clock and asthma. *Thorax* 2014;69:90–2.
55. Benedict C, Dimitrov S, Marshall L, *et al.* Sleep enhances serum interleukin-7 concentrations in humans. *Brain Behav Immun* 2007;21:1058–62.
56. Imeri L, Opp MR. How (and why) the immune system makes us sleep. *Nat Rev Neurosci* 2009;10:199–210.
57. Freedman NS, Kotzer N, Schwab RJ. Patient perception of sleep quality and etiology of sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 1999;159:1155–62.
58. Zeitzer JM, Dijk DJ, Kronauer R, *et al.* Sensitivity of the human circadian pacemaker to nocturnal light: melatonin phase resetting and suppression. *J Physiol* 2000;526:695–702.
59. Figueroa-Ramos MI, Arroyo-Novoa CM, Lee KA, *et al.* Sleep and delirium in ICU patients: a review of mechanisms and manifestations. *Intensive Care Med* 2009;35:781–95.
60. Shigeta H, Shigeta M, Nakazawa A, *et al.* Lifestyle, obesity, and insulin resistance. *Diabetes Care* 2001;24:608–08.
61. Cohen J. A power primer. *Psychol Bull* 1992;112:155–9.
62. Grimes DA, Schulz KF. Bias and causal associations in observational research. *Lancet* 2002;359:248–52.
63. Richards KC, O'Sullivan PS, Phillips RL. Measurement of sleep in critically ill patients. *J Nurs Meas* 2000;8:131–44.
64. Johns MW. A new perspective on sleepiness. *Sleep Biol Rhythms* 2010;8:170–9.
65. Little A, Ethier C, Ayas N, *et al.* A patient survey of sleep quality in the intensive care unit. *Minerva Anesthesiol* 2012;78:406–14.
66. Berry RB, Brooks R, Gamaldo CE, *et al.* The AASM manual for the scoring of sleep and associated events, version 2.2. *J Clin Sleep Med* 2015;11:1253–4.
67. Kushida CA, Chang A, Gadkary C, *et al.* Comparison of actigraphic, polysomnographic, and subjective assessment of sleep parameters in sleep-disordered patients. *Sleep Med* 2001;2:389–96.
68. Little RJ, D'Agostino R, Cohen ML, *et al.* The prevention and treatment of missing data in clinical trials. *N Engl J Med* 2012;367:1355–60.
69. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33:159.