SLEEP DURING AND AFTER CARDIOTHORACIC INTENSIVE CARE AND PSYCHOLOGICAL HEALTH DURING RECOVERY

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Certificate of authorship/originality

I certify that the work in this thesis has not been previously submitted for a degree nor has it been submitted as part of the requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help I have received in my research work and in the preparation of this thesis has been acknowledged. In addition, I certify that all the information sources and literature used are indicated in the thesis.

Signature of candidate

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Abstract

The research in this thesis investigated sleep and recovery in coronary artery bypass graft (CABG) patients during and after Intensive Care Unit (ICU) treatment. Intensive care patients and former ICU patients experience sleep disruption and poor sleep quality. Psychological distress, including depression, anxiety, stress and symptoms of posttraumatic stress disorder (PTSD), and diminished health-related quality of life (HRQOL) are common among former ICU patients. Few previous studies employed longitudinal analysis to explore continuity of problems related to sleep disruption and poor sleep quality, and whether patients who experience sleep problem in ICU continue to have sleep problems during recovery. Few studies have compared sleep between on-pump and off-pump open-heart surgery patients. The main reason for adult ICU admission in Australia is CABG surgery. Therefore cardiothoracic ICU patients were the focus of this study. The broad aim was to determine any association between sleep disruption in the cardiothoracic ICU and during recovery, and patients' psychological wellbeing and HRQOL during recovery.

One-hundred and one ICU patients who had undergone CABG surgery completed self-report questionnaires on their sleep quality in ICU, on the ward, and at two and six months after discharge; prehospital sleep state was retrospectively reported while in ICU. Perception of the ICU experience was assessed at two months after discharge, and psychological health and HRQOL six months after discharge using validated instruments.

Descriptive and multivariate statistical analyses revealed that patients had a mean age of 66.60±11.07 years, 78% were male and the median ICU stay was two days. In ICU, 76.0% of patients reported poor sleep quality, 71.9% in the ward, and 68.4% and 62.0% at two and six months after discharge; 11.9% of patients had poor sleep at all time points. Six months after hospital discharge there was a positive relationship between poor sleep quality and lower psychological wellbeing and lower HRQOL in bivariate analyses. In multivariate analysis, prehospitalisation insomnia ($p=0.004$), and mental ($p\leq0.0005$) and physical ($p\leq0.0005$) HRQOL were independently associated with sleep quality at six months after discharge, but not on-pump versus off-pump open heart surgical technique.

In conclusion, it has been shown in this thesis that the quality of sleep of a substantial proportion of postoperative CABG patients is often poor in ICU, in hospital and up to six months after hospital discharge. This was associated with physical and mental aspects of HRQOL six months after discharge, but not with whether surgery was performed on or off cardiopulmonary bypass.

1 Introduction and literature review

1.1 Introduction

Just over 120,000 critically ill people in Australia and New Zealand (ANZ) require treatment in an intensive care unit (ICU) each year. There were 122,753 admissions in 153 Australian and New Zealand (ANZ) adult intensive care units during the 2012/2013 financial year (Australian and New Zealand Intensive Care Society 2014).The top five reasons for admission in Australian adult ICUs in 2012/2013 were: coronary artery bypass graft (CABG) surgery (n=7,124; 6.3%); orthopaedic surgery (n=4,930; 4.4%); gastrointestinal (GI) surgery for neoplasm (n=4,792; 4.3%); valvular heart surgery (n=4,331; 3.9%); and drug overdose (n=4,092; 3.6%). In Australia CABG surgery was the top (n=7,124; 6.3%) reason for admission to ICU in New Zealand, CABG surgery (n=1,266, 11.4%) was the first reason for admission to ICU (Australian and New Zealand Intensive Care Society 2014). Approximately 74% of ICU patients were discharged to their home and another 9% were discharged to a chronic care facility. Patients needing ICU admission frequently require mechanical ventilation via artificial airway for breathing, multiple intravenous medications and fluids for haemodynamic support and continuous invasive monitoring and treatments. High activity and noise levels in the ICU are often inevitable. These factors may lead to the inability of patients to sleep as a result of disruptions. Despite the fact that these patients need restorative sleep, they are unlikely to experience it while in the ICU. Sleep disruption in the ICU may continue while in the hospital ward and at home, and may affect a patient's psychological well-being during recovery.

Sleep consists of two main stages which are non-rapid eye movement (NREM) and REM sleep (Kryger, Roth & Dement 2005). There are four stages in NREM sleep, with NREM stages 3 and 4 considered slow wave sleep (SWS). Normally, a sleep cycle progresses through NREM stages 1, 2, 3 and 4, and finally to the REM stage. Each sleep cycle is approximately 90 minutes long and there are four to six cycles during nocturnal sleep. Most people are awake less than 5% of the time. Despite the unknown function and mechanism of human sleep, it is universally understood to be vital for health and wellbeing; adequate and good quality sleep is considered imperative to brain and body functional restoration (Siegel 2005). Thus sleep disruption in ICU patients may affect their recovery from illness. The measurement of sleep in ICU patients is challenging due to the severity of illness and the high level of activity involved in their care and treatment. A number of objective and subjective methods for assessing sleep are available;

polysomnography (PSG) remains the gold standard. Limitations, such as altered cognitive level or the inability to communicate due to the presence of an artificial airway, may affect the reliability of self-report instruments. Each instrument has its strengths and weaknesses, hence several instruments may be administered to optimise the reliability of results.

It is well documented that patients experience abnormal sleep architecture resulting in none or little SWS and REM sleep while in ICU (Elliott, McKinley & Cistulli 2011; Elliott et al. 2013; Freedman et al. 2001; Friese 2008; Gabor et al. 2003; Hardin et al. 2006; Watson et al. 2013). Although, the duration of sleep maybe normal or reduced, up to 50% of total sleep time may occur during the daytime, and night time sleep is highly fragmented (Elliott et al. 2013; Gabor et al. 2003; Hardin et al. 2006). Poor quality sleep, frequent waking, and difficulty falling asleep have been reported by patients using subjective measurements. Sleep in the ICU may be affected by pathophysiological factors, such as the underlying disease process, pain, anxiety, stress and effects of medications. Environmental factors, such as excessive sound levels, frequent light exposure and diagnostic testing may be concomitant factors that disrupt the patients' sleep. After discharge from hospital, some patients continue to experience poor sleep quality and report compromised psychological well-being and diminished health related quality of life (HRQOL) (Eddleston, White & Guthrie 2000; Edell-Gustafsson, Hetta & Aren 1999; Lee et al. 2009; McKinley et al. 2012; McKinley et al. 2013; Myhren et al. 2010; Orwelius et al. 2008; van de Leur et al. 2004). The link between sleep problems in ICU and subsequent psychological recovery is still unclear despite the prevalence of these problems among ICU patients and recovering ICU patients (Kamdar, Needham & Collop 2012).

It is noted in the literature review that the majority of ICU sleep data were collected and analysed in more than one type of ICU setting, which affects the interpretation of study findings as there are often significant differences in management, clinical demography, routine and unit design between ICUs. The review of sleep, psychological health and HRQOL revealed that the cardiothoracic ICU patients, including coronary artery bypass graft (CABG) surgery patients, experience similar problems to that of patients treated in other types of ICU, but over different time frames. Numerous studies performed on the cardiac surgery population focused on mortality and other physical outcomes; such as bleeding, repeat revascularisation and returning to operating theatre rates. Sleep studies in this population were conducted without comparing the results for different surgical techniques; a potential confounder. A paucity of results was found for the comparison of sleep, psychological recovery and HRQOL in on-pump and off-pump patients. Thus the state of current knowledge concerning the potential effect of the different surgical technique is unsatisfactory. Cardiothoracic ICU patients may experience a

unique array of pathophysiological, neurocognitive and psychological factors, compared to patients treated in other types of ICU. A few rehabilitation programs for open-heart surgery patients have been found to be effective in the improvement of physical function (Jones et al. 2003; Monteleone et al. 2015; Wang et al. 2015). On the basis of this literature review, research studies focusing on cardiothoracic ICU patients, regarding sleep and psychological recovery are lacking. More research is necessary and may provide important information to more fully understand the effect of sleep during recovery in cardiothoracic ICU patients. Accordingly, this study was designed to examine this proposition. Therefore the broad aim of the current study was to determine the association between sleep disruptions of patients in the cardiothoracic ICU and during recovery, and their psychological wellbeing during recovery.

As CABG surgery is the top reason for ICU admission according to the Australian and New Zealand Intensive Care Society 2014 database, potential knowledge that may be gained from the study, could improve recovery and rehabilitation for this patient group, leading to improvements in recovery and quality of life. Lastly, the proposed research will inform future research in sleep and psychological health during and after treatment in the cardiothoracic ICU, including future rehabilitation.

1.2 Stages and architecture of normal sleep

The basic need for sleep in healthy adult humans is between seven to eight hours per day and consists of two main states: NREM and REM sleep (Kryger, Roth & Dement 2005; Richards, O'Sullivan & Phillips 2000). Non-rapid eye movement sleep is divided into stages 1 to 4 and is associated with minimal mental activity. The depth of sleep and arousal thresholds increase as the NREM stages progress. Rapid eye movement sleep is determined by a burst of rapid eye movement, muscle twitches and cardiorespiratory irregularity. The brain is highly activated during REM sleep and vivid dreaming is commonly reported. During a sleep episode, these two states alternately cycle in a period of approximately 90 minutes, and approximately four to six cycles occur during nocturnal sleep. Non-rapid eye movement comprises 75-80% of total sleep time and REM comprises 20-25% of total sleep time. Most healthy adults begin their sleep with NREM stage 1, then progress deeper through stages 2, 3 and 4, and finally enter the REM sleep (Kryger, Roth & Dement 2005). Stages 3 and 4 comprise SWS which predominates in the first third of the night, and is linked to the need to sleep (so called ‘sleep pressure’). Rapid eye movement sleep occurs in the last third of the night and is associated with the circadian rhythm of body temperature. Wakefulness accounts for less than 5% of the total nocturnal sleep time.

Most studies examining sleep have used the scoring system which was published by Rechtschaffen and Kale (R and K) in 1968 (Rechtschaffen & Kales 1968). The American Academy of Sleep Medicine (AASM) has developed a more recent manual for scoring sleep and associated events (Iber et al. 2007). The terminology recommended by AASM for the stages of sleep are stage W (Wakefulness); N1 (NREM 1); N2 (NREM 2); N3 (NREM 3 and 4) and R (REM). Stage N3 represents slow-wave sleep (SWS) which replaces stages 3 and 4 of NREM sleep in the R and K criteria. There has been some controversy reported regarding the new approach to categorising human sleep. Therefore, although it is increasingly used, the manual has not yet become the universal standard for characterising human sleep. The stages and architecture of normal sleep in a healthy young adult human are provided in Table 1.

Table 1. The stages and architecture of normal sleep

Characteristics	**Percentage of total sleep time**
NREM[a]	75% to 80%
Stage 1	2% to 5%
Stage 2	45% to 55%
Stage 3	3% to 8% of
Stage 4	10% to 15 %
REM[b]	20% to 25%

The information in the table is summarised from Kryger, Roth and Dement (2005). [a]Non-rapid eye movement, [b]Rapid eye movement

Multiple factors may modify sleep stage distribution, such as age, prior sleep history, circadian rhythm, medications and body temperature (Kryger, Roth & Dement 2005). A recent meta-analysis of quantitative sleep studies reported that the percentage of SWS was negatively correlated with age in adults; older people have less SWS (Vecsey et al. 2015). Total sleep time (TST), sleep efficiency, percentage of REM sleep and REM latency, significantly decreased with age, whereas sleep latency, percentage of stage 1 and 2 sleep, and the proportion of time awake after sleep onset significantly increased with age.

1.3 Sleep function

Despite the fact that the exact function of sleep is unclear, it is known that the human body requires an adequate amount and quality of sleep to maintain healthy function. To improve the understanding of sleep function sleep research has been predominately conducted on animals (there are ethical concerns associated with causing harm to participants by deliberately depriving or disrupting their sleep). Observational and cohort studies are more common in human sleep studies. Available research in both humans and animals suggests that good sleep plays a crucial role in restoring the physical and psychological well-being of individuals (Lower, Bonsack & Guion 2003; Nicolas et al. 2008; Siegel 2005). Effects of partial sleep stage deprivation and disruption have been investigated to enable an understanding of sleep function. As a result theories have been suggested for the function of NREM and REM sleep. For example, energy conservation and nervous system recuperation are suggested to occur during NREM sleep. Also the loss of NREM sleep has been associated with immunosuppression, slow tissue repair, tolerance to lower pain tolerance, and increased susceptibility to infection (Lower, Bonsack & Guion 2003; Patel et al. 2008; Salas & Gamaldo 2008; Siegel 2005). While NREM sleep, stages 3 and 4 or SWS appear to affect the ability to physically heal, REM sleep appears to have a positive impact on an individual's emotional and psychological recovery. The absence of REM sleep is related to psychological disturbances, such as confusion, irritability, hallucinations and impaired memory (Lower, Bonsack & Guion 2003; Nicolas et al. 2008; Siegel 2005; Vecsey et al. 2015). The effects of sleep on adverse health outcomes in critically ill patients remains unclear. However, negative effects are evident for long-term sleep loss in animals, such as skin lesions, changes in body temperature, increased food intake, abnormal secretions of inflammation and bone metabolism-related factors, and even death (Everson & Crowley 2004; Geng et al. 2015). In healthy adult humans, a variety of effects related to restricting sleep have been reported, for example lapses of attention, slowed working memory, reduced cognitive performance, and depressed mood (Banks & Dinges 2007). The negative impacts of sleep loss on physical and emotional wellbeing suggest the significant role and function of sleep in preserving health; the most accepted theory of the function of sleep is for the restoration of the brain and body (Siegel 2005).

1.4 Patients' sleep measurements in the intensive care unit

Patients' sleep in the ICU can be assessed by both subjective and objective methods. Subjective sleep methods are often chosen because they are simple and easy to use; for example questionnaires and sleep diaries. On the other hand, objective sleep measurements, such as PSG, can provide more detail about sleep architecture or the stages of sleep, and the number of times patients wake. Polysomnography remains the gold standard for a sleep quality study (Kryger, Roth & Dement 2005). In ICU, the use of PSG is typically an abbreviated form of the more extensive version used in the sleep laboratory but still includes electroencephalography (EEG), electro-oculography (EOG) and electromyography (EMG) (Kryger, Roth & Dement 2005). Each method has limitations for assessing patients' sleep in the ICU. In order to acquire more valuable detail related to patients' sleep, some research has used objective and subjective methods concurrently. Below is a brief summary of available instruments for each method. The details of instruments selected for the current study and discussion of rationale are provided in the methods chapter.

The subjective sleep measures available are patients' self-reported questionnaires and nurses' observations. Patient self-reported questionnaires that have been validated using PSG, include the Verran/Snyder-Halpern Sleep Scale (VSH) and the Richards-Campbell Sleep Questionnaire (RCSQ). The VSH sleep scale consists of 14 visual analogue scales (VAS) and provides information about three dimensions of sleep: disturbance, effectiveness and supplementation (Beecroft et al. 2008). It has convergent validity ($r=0.39$) only when PSG awakenings of more than four minutes are scored (Fontaine 1989). The RCSQ is a self-report questionnaire, comprising five visual analogue scales (VAS). It has five 100mm VAS: sleep depth, latency, awakenings, time awake, and quality of sleep. The correlation between RCSQ and the PSG sleep efficiency index (SEI) was 0.58 ($P<0.001$) during its development (Richards, O'Sullivan & Phillips 2000). Another self-report instrument which was developed for sleep assessment in the ICU is the Sleep in Intensive Care Questionnaire (SICQ) (Freedman, Kotzer & Schwab 1999). The seven-item Likert scale questionnaire provides information about sleep disruptions secondary to interruptions by health care personnel and diagnostic testing, ICU sleep quality, daytime sleepiness and sleep disruptions associated with environmental factors.

Nurses' assessment of patients' sleep is cost effective and can be incorporated into routine nursing care, although the reported accuracy varies. Edwards & Schuring (1993) found that a nurse's perception of a patient's sleep, in comparison to PSG, was correct 81.9% of the time. No statistically significant difference between nurse and patient perceptions of the patients' sleep in the ICU was found ($P=0.125$) in another study (Frisk & Nordstrom 2003).

Conversely, more recent studies reported 44% agreement between nurses' perception of patients' sleep and patients' sleep perceptions (Nicolas et al. 2008) and nurses tended to overestimate patients' total sleep time (Aurell & Elmqvist 1985; Nicolas et al. 2008).

Objective measurements of sleep are PSG, bispectral index (BIS) and actigraphy. Polysomnography remains the only gold standard of sleep measurement because it is the only method to categorise individual sleep stages using the R and K criteria (Bourne et al. 2007). Notwithstanding the advantages of PSG, the procedure is intensive requiring the presence of a skilled technician and the equipment is costly. Polysomnography requires a trained professional to use and interpret the recording. It is also more expensive and may even interfere with the quantity and quality of sleep (Richards 1987) as the electrodes and recording equipment themselves may disrupt sleep (Richards, O'Sullivan & Phillips 2000).

Bispectral (BIS) index is used to measure the depth of consciousness and sedation in the operating theatre (OT) during anaesthetic, ICU and other clinical settings. The BIS values correlate with depth of analgesia; a score of 100 represents an 'awake' clinical state, whereas zero represents EEG silence. One study performed with ICU patients, confirmed the results found by PSG (Nicholson, Patel & Sleigh 2001). However other studies have found that there was a significant overlap of values for any given sleep stage (Nieuwenhuijs et al. 2002; Sleigh et al. 1999). Furthermore, neurological abnormalities, such as traumatic brain injury, dementia, delirium, patients' restraint and residual effects of sedative agents, were found to affect BIS values and potentially providing an inaccurate indication of sleep characteristics (Bourne et al. 2007; Ely EW et al. 2004; Renna, Handy & Shah 2003). The advantage of the BIS index is that a skilled technician is not required to ensure good recording or to replace the electrodes when they are accidently removed by the patient. However, the practicality and reliability of the BIS index remains an issue. Electrical interference, movements and increased electromyography (EMG) activity in non-sedated patients affect the signal quality. The BIS algorithm development was primarily based on depth of sedation in patients undergoing general anaesthesia. Differences and similarities between sleep and sedation EEG states must be investigated before BIS can be used for the purpose of sleep measurement.

An actigraph is a non-invasive device used to monitor activity and the sleep wake cycle over time. The small unit is worn on the wrist to record movements that can be used to estimate sleep parameters (Ancoli-Israel et al. 2003). Actigraphy has been well studied in the evaluation of sleep in patients with depression and dementia. It is not widely used in ICU clinical studies where patients' movements are limited by medication, weakness and

treatments. Overall agreement between actigraphy and PSG was less than 65% (Beecroft et al. 2008).

1.5 Patients' sleep in the intensive care unit

Findings using objective sleep measurement

Numerous studies in ICU using 24-hour and overnight PSG measurements have reported abnormal sleep for patients admitted to ICU for many diagnoses (Aurell & Elmqvist 1985; Broughton & Baron 1978; Cooper et al. 2000; Edell-Gustafsson, Hetta & Aren 1999; Fontaine 1989; Hilton 1976; Orr & Stahl 1977; Richards & Bairnsfather 1988; Rosenberg et al. 1994). The common characteristics of their sleep were increased daytime sleep, and increased frequency of arousal and awakening equally during the day and night. More recent studies and relevant reviews support the finding that ICU patients experience unique sleep disturbances, sleep fragmentation, prolonged sleep latency, decreased sleep efficacy, frequent arousals leading to decreased and virtually absent SWS and REM sleep (Elliott, McKinley & Cistulli 2011; Elliott et al. 2013; Freedman et al. 2001; Friese 2008; Gabor et al. 2003; Hardin et al. 2006; Watson et al. 2013; Weinhouse & Schwab 2006). Even though the average total sleep time appears favourable for health (approximately eight hours), the sleep was highly fragmented, severely disrupted and had abnormal architecture (Cooper et al. 2000; Elliott et al. 2013; Friese et al. 2007; Hardin et al. 2006). More than 41-50 % of the total sleep time in ICU patients has been found to occur during the daytime (Elliott et al. 2013; Gabor et al. 2003; Hardin et al. 2006). Mean arousals and awakenings varied from 10-56/hour (Beecroft et al. 2008; Cooper et al. 2000; Edell-Gustafsson, Hetta & Aren 1999; Elliott et al. 2013; Gabor et al. 2003). The average sleep period over 24 hours was 41±28 minutes with each period averaging 15±9 minutes. Median duration of sleep without waking was as short as three minutes (Elliott et al. 2013). Although some ICUs have made changes to improve patient sleep, more recent studies continue to reveal a commonality in sleep problems among ICU patients. To summarise, sleep for ICU patients is abnormal when measured using PSG (Table 2).

Table 2. Summary of reported abnormalities in the ICU

Parameter	Deviation from norm
NREM[a] Sleep	
Stage 1	Increased
Stage 2	Increased
Stage 3 (SWS[b])	Decreased
Stage 4 (SWS)	Decreased
REM sleep	Decreased
TST[c]	Unchanged or decreased
Sleep latency	Unchanged or increased
Sleep efficiency	Decreased
Sleep fragmentation	Increased
Daytime sleep	Increased
Duration of sleep without waking	Decreased

[a]Non-rapid eye movement, [b]Slow wave sleep, [c]Total sleep time

Findings using subjective sleep measurement

Significant sleep problems have also been reported in studies using subjective sleep measures. Patients perceived their sleep in the ICU as poor quality, with frequent waking, difficulty going back to sleep after waking and daytime sleepiness (Elliott, McKinley & Cistulli 2011; Elliott et al. 2013; Freedman, Kotzer & Schwab 1999; Friese 2008; McKinley et al. 2013; Ritmala-Castren et al. 2014). These findings corresponds with studies involving post-operative patients and previous research studies performed on critically ill patients (Aurell & Elmqvist 1985; Cooper et al. 2000; Fontaine 1989; Hilton 1976; Richards & Bairnsfather 1988; Rosenberg-Adamsen et al. 1996). Patients perceived their sleep in the ICU as being significantly poorer than their sleep at home (Freedman, Kotzer & Schwab 1999; Friese et al. 2007; Richards & Bairnsfather 1988). This perception was found similar across different ICUs and over time. In addition some studies reported that patients' ratings of their sleep varied widely (total sleep score from 0-97 mm, mean 45.5 mm) on the Richards-Campbell Sleep Questionnaire (RCSQ)(Frisk & Nordstrom 2003). Some patients stated that they did not sleep

at all and others stated that they slept very well. Subjective sleep quality reports are summarised in Table 3.

Table 3. Subjective sleep measurement report summary

Description	Reports
Quality of sleep	Poor
Number of awakenings	Frequent
Falling asleep	Difficult
Going back to sleep	Difficult
Daytime sleepiness	Increased
Compared with quality of sleep at home	Poorer

Common factors affecting sleep quality

Multiple possible factors have been shown to affect patients' sleep. Patients reported that their quality of sleep in ICU was less than they experience at home (McKinley et al. 2013). Studies have found that various factors including noise, light, pain, patient care and treatment activity, circadian rhythm disruption, mechanical ventilation, medications and inherent the effect of critical illness, contribute to sleep disruption in the ICU (Evans & French 1995; Freedman, Kotzer & Schwab 1999; Hardin 2009; Hilton 1976; Olson et al. 2001; Simpson, Lee & Cameron 1996; Topf, Bookman & Arand 1996). More recent studies revealed similar results despite improvements in ICU design, technology and the training of health care personnel (Bihari et al. 2012; Elliott et al. 2013; Elliott, McKinley & Eager 2010; Le et al. 2012; Zhang et al. 2013). High sound levels (particularly staff communication) and patient-care activities were responsible for 40% of the sources of sleep disruption (Hardin 2009). Similar findings were revealed in a more recent study conducted in Australia (Elliott et al. 2013). Furthermore, surgical procedures, unwanted side-effects, such as post-operative delirium, and anaesthetic drugs, may affect the sleeping patterns of patients who have undergone major surgery (Aurell & Elmqvist 1985; Edell-Gustafsson et al. 1997; Krachman, D'Alonzo & Criner 1995). Some of the common factors known to affect sleep quality in ICU patients are summarised in Table 4.

Table 4. Common factors affecting ICU sleep quality

Environmental factors	Pathological and pathophysiological factors
Excessive noise level	Loss of physical activity
Continuous patient care activity	Severity of illness
Frequent light exposure	Mechanical ventilation
Temperature	Pain
Smell	Thirst
Unfamiliarity with the environment	Effects of medications
Diagnostic testing	Anxiety and stress
Administration of medications	Sleep disorders

1.6 Problems experienced by former ICU patients

Research has revealed that ICU patients may continue to experience sleep problems after being discharged home (Eddleston, White & Guthrie 2000; Edell-Gustafsson, Hetta & Aren 1999; Lee et al. 2009; McKinley et al. 2012; McKinley et al. 2013; Orwelius et al. 2008). Sleep problems may jeopardise their health both physiologically and psychologically. After recovery from critical illness, patients are presented with a problem which could cause ill health if left undetected or untreated. This has the potential to greatly impact survivors, their family, their quality of life, and the cost for the public health system and communities. The continued experience of poor sleep quality after treatment in ICU has been reported to occur from one to 12 months after hospital discharge (Eddleston, White & Guthrie 2000; Edell-Gustafsson, Hetta & Aren 1999; Lee et al. 2009; McKinley et al. 2012; McKinley et al. 2013; Orwelius et al. 2008).

Psychological problems experienced by patients after an ICU stay are prevalent. Some of the problems that patients have reported after hospital discharge were recollections of discomfort, impaired memory, anxiety, depression and post-traumatic stress symptoms, all of which can continue up to 12 months (McKinley et al. 2012; McKinley et al. 2013; Myhren et al. 2010; van de Leur et al. 2004). Research has found that patient's perception of the intensive care experience was associated with stress, anxiety, depression and poor QOL during their recovery (Rattray et al. 2010; Rattray & Hull 2008; Schelling et al. 2003). Extensive reviews and studies on HRQOL and psychological problems revealed that ICU patients experience severe

post-traumatic stress symptoms, and high levels of anxiety and depression after hospital discharge (Davydow, Desai, et al. 2008; Davydow, Gifford, et al. 2008; Griffiths et al. 2007; Jackson, Mitchell & Hopkins 2015; Kamdar, Needham & Collop 2012; Karnatovskaia et al. 2015; Myhren et al. 2009; Sukantarat et al. 2007). Decreased physical function and cognitive impairment were also commonly reported by critical-illness survivors. The collection of signs and symptoms including impairment of mental health, cognition and physical functioning after critical illness has been called post-intensive-care syndrome (PICS) (Needham et al. 2012). Intensive care-related PTSD symptoms, anxiety and depression are prevalent after a stay in ICU during recovery from critical illness (Kamdar, Needham & Collop 2012). In summary, patients experience poor sleep quality in ICU and psychological health after hospital discharge. Identifying the relationship between patients' sleep quality during ICU admission and their psychological outcomes during recovery is challenging because of the multiple factors and ICU-related stressors that affect both psychological health and sleep. Therefore, it has not yet been clearly elucidated whether patients' sleep disruption in ICU contributes to reduced post-ICU psychological well-being. Problems commonly reported by recovering ICU patients are shown in Table 5.

Table 5. Summary of problems experienced by recovering ICU patients

Physical, social and cognitive problems	**Psychological problems**
Sleep disturbances	Depression
Decreased physical function	Anxiety
Impaired memory, attention and concentration	Stress
Executive dysfunction	Post-traumatic Stress Disorder

Following treatment in ICU, patients are discharged to a hospital ward under the care of the ward consultant and where their treatment and care is no longer the responsibility of the critical care team. Once patients are mobile or their condition is manageable in the community, they are discharged to a carer, home or another facility. The course of ICU patients' recovery is of increasing interest to researchers. Persisting illness, reduced physical and social functioning, neurocognitive deficits and compromised HRQL are some of the problems former patients contend with along with sleep and psychological problems (Angus & Carlet 2003; Dowdy et al. 2005; Eddleston, White & Guthrie 2000; Hofhuis et al. 2008). A

number of studies have addressed these longer term problems with a view to improving outcomes after treatment in ICU. Interventional and randomised controlled trial studies have been conducted, with the aims of improving cognitive, physical and functional problems experienced by recovering ICU patients (Brummel et al. 2014; Brummel et al. 2012; Denehy et al. 2013; Elliott et al. 2006; Elliott, McKinley & Cistulli 2011; O'Neill et al. 2014).

1.7 Cardiothoracic ICU patients

Surgical management

The usual pattern of care and treatment of patients undergoing open-heart surgery involves the patient attending a pre-admission clinic at the out-patient department, prior to surgery. Investigations, such as chest X-ray, electrocardiogram and blood tests are performed during this appointment. Generally patients are admitted to the cardiothoracic step-down unit one day prior to surgery. Orientation to the cardiothoracic ICU and step-down units are provided. Patients also have an opportunity to view a video explaining the preoperative procedure, and details about the postoperative period such as haemodynamic and cardiac monitoring, the continuous assessment and treatment, deep breathing exercises and services provided by the hospital. Preoperative and postoperative management, including possible complications, is explained to each patient by their surgeon and written informed consent is obtained. Physiotherapists are involved in evaluating pulmonary function and providing postoperative exercise education. An anaesthetist performs a health assessment one day prior to the surgery. Following open-heart surgery, patients usually stay in the cardiothoracic ICU for 24-48 hours, depending on their condition and progress. They are transferred to the cardiothoracic step-down unit for further postoperative management once stable. In addition to the intensive and invasive monitoring and treatment during their cardiothoracic ICU stay, open-heart surgery patients are challenged with unique physiological and psychological changes postoperatively. As cardiac surgery is the top admission reason for Australian adult ICUs, exploring the problems experienced by these patients is imperative, so that the knowledge may enhance the improvement of health services.

Surgical techniques and physical outcomes

Cardiothoracic surgery involves the heart and chest or both. Open-heart surgery describes the surgical procedure in which the chest is opened (usually via a sternotomy) and surgery is performed on muscles, valves, and arteries of the heart. The CABG surgery has been the intervention of choice for coronary revascularisation in high-risk patients and patients in

whom cardiac catheterisation and stenting is not possible. A cardiopulmonary bypass (CPB) pump may be used to bypass the heart and lungs (on-pump surgery). Blood returning to the heart is diverted through a CBP pump before returning to the arterial circulation. On-pump coronary artery bypass (ONCAB) grafting involves the use of CPB which performs the work of the heart and lungs. The alternative is off-pump coronary artery bypass (OPCAB) grafting which involves minimising aortic manipulation and avoiding aortic cannulation and cross-clamp time. It is performed on the beating heart and in theory may reduce mortality and morbidity in high-risk patients. The technique selected for cardiothoracic surgery is based on the preference of the individual surgeon and assessment of the patient's characteristics and risk factors.

Comparing outcomes of OPCAB and ONCAB surgery is challenging because of differences in research study design, duration of follow-up, the surgeon's experience and hospital protocol. Some early postoperative physical advantages of OPCAB were revealed; for example lower risks of stroke and blood transfusion requirements, shorter average length of hospital stay, lower risks of respiratory failures, less renal failure requiring dialysis, fewer sternal wound infections, and reduced mortality and morbidity rates in high risk patients (Al-Ruzzeh et al. 2001; Calafiore et al. 2003; Dhurandhar et al. 2015; Hannan et al. 2007; Lamy et al. 2012; Puskas et al. 2009; Racz et al. 2004; Sa et al. 2012; Sabik et al. 2004). However OPCAB has also been associated with long-term higher rates of repeat revascularisation, cardiac-related deaths and major cardiac events (Bishawi et al. 2013; Hannan et al. 2007; Racz et al. 2004).

Long-term outcomes that have been shown to be comparable for the two techniques, are neuropsychological function, quality of life and survival rates at five and ten years post-surgery (Calafiore et al. 2003; Puskas et al. 2009; Sarin et al. 2011; Shroyer et al. 2009; Usta et al. 2013). A more recent large-scale multicentre randomised trial of off-pump (n=1,104) versus on-pump (n=1,099) surgery on quality of life was conducted on 2,203 nonemergency CABG patients (Bishawi et al. 2013). At three months and one year after surgery, the results confirmed previous study findings that there was no clinically relevant difference between groups in any quality of life measures. In summary, research suggests that OPCAB surgery has more clinical short-term advantages than ONCAB surgery. The disadvantages of OPCAB surgery in having incomplete revascularisation, converting to ONCAB surgery and less graft patency, may outweigh those advantages, when longer-term outcomes are considered. Subsequently, the OPCAB surgery may result in higher general hospital costs when later complications are taken into account. There is debate as to whether OPCAB surgery should be continued in practise. Unless research demonstrates that ONCAB surgery results are comparable or show

more short- and long-term benefits than the OPCAB surgical technique, this surgery will continue to be performed.

Sleep, cognitive and psychological outcomes during recovery

Sleep disturbances are commonly found in cardiothoracic ICU patients which is similar to the experience of patients in other ICU settings. Most sleep studies performed in this population are dated and the follow-up time varied between studies. Following open-heart surgery, extensive sleep disturbances and fragmentation with minimal or no REM sleep and SWS on objective sleep measures has been observed (Edell-Gustafsson, Hetta & Aren 1999; Edell-Gustafsson et al. 1997; Orr & Stahl 1977; Redeker et al. 1996). Poorer sleep quality was reported during the early post-operative periods after CABG surgery than at other times during recovery (Edell-Gustafsson, Hetta & Aren 1999; Orr & Stahl 1977; Yilmaz & Iskesen 2007). Sleep problems may extend to one week or six months before returning to preoperative sleep quality, while in older patients it could take longer. The characteristics of sleep during recovery at home included reduced or normal total sleep time, frequent waking and poor self-reported sleep quality (Edell-Gustafsson et al. 1997; Knapp-Spooner & Yarcheski 1992; Redeker & Hedges 2002; Redeker et al. 1996; Redeker, Ruggiero & Hedges 2004b). As much as 50% of total daily sleep time in ICU took place during the day which is similar to patients treated in other ICU settings (Redeker et al. 1996). Patients in cardiothoracic ICU have also reported a high level of sleepiness which could be explained by temporary deterioration of circulation in the centre of the brain stem and hypothalamus, the areas that control sleeping and waking (Yilmaz & Iskesen 2007).

Although poor quality sleep has been reported by cardiothoracic ICU patients, there is a paucity of published research comparing patients' sleep quality between ONCAB and OPCAB surgery. One study involved a secondary analysis of 48 ONCAB and 81 OPCAB surgery patients using actigraphy, PSQI and sleep diaries to assess their sleep on the second night after transfer to the cardiac surgery step-down unit (Hedges & Redeker 2008). Although it was used after the transfer to the step-down unit, PSQI provides information about sleep for the month before. This study revealed that patients who had OPCAB surgery had fewer awakenings objectively ($p=0.02$) and subjectively ($p=0.04$) (the analysis controlled for sex and age). In their sleep diary, OPCAB surgery patients reported better sleep quality ($p<0.05$). Future longitudinal studies in larger samples of patients are required to compare sleep quality in these populations, which may yield generalisable findings for sleep quality in patients receiving on-pump versus off-

pump CABG surgery. Potentially, rehabilitation services could be designed to suit each group to optimise their recovery.

Patients who undergo cardiac surgery have a slight risk of developing neurocognitive impairment postoperatively, otherwise known as postperfusion syndrome (colloquially referred to as 'pump head'). Off-pump coronary artery bypass surgery was developed partly to avoid this complication but research has demonstrated that there is no lasting neurocognitive dysfunction associated with CPB (Edwards & Huang 2010; Peterson 2009; Selnes et al. 2007). Disturbances in cognitive function, memory formation, emotional state and general performance were reported to occur in 60-80% of patients immediately after surgery but this usually disappears with time in the majority of cases (Mills & Prough 1991; Toner et al. 1997) suggesting that medication in particular anaesthetic agents and sedatives rather than the 'pump' is responsible. Also patients who undergo coronary artery disease frequently have a high prevalence of cerebrovascular disease, another concomitant contributing to cognitive function disturbances (Goto et al. 2001). In addition it is possible that the neurocognitive effects relate to existing health status (a strong possibility since certain subgroups appear to be at higher risk for example the elderly and severely ill) or the neurocognitive dysfunction may relate to the surgery itself (Edwards & Huang 2010).

It has long been known that, most patients' physical function improves after open-heart surgery (Heller et al. 1974). According to the Institute of Medicine, the Patient Centered Outcomes Research Institute, and many other leading national health organisations, the impact of medical interventions on patients' HRQOL should be emphasised (Spertus 2008). Recent research and related reviews have revealed evidence of declined psychological health after open-heart surgery (Fraguas Junior et al. 2000; Rafanelli, Roncuzzi & Milaneschi 2006; Tully & Baker 2012). Up to 50% of these patients reported symptoms of depression. Sleep disturbances during and after the operation were experienced by these patients, but whether surgery contributes or worsens psychological well-being, is not yet known. Therefore the relationship between patients' sleep, psychological outcomes and HRQOL in patients who underwent CABG was explored in the current study. In addition, the findings in relation to patient self-reported sleep quality, psychological outcomes and HRQOL between ONCAB and OPCAB surgery groups were studied.

1.8 Summary of findings in the literature

Normal healthy sleep comprises NREM stages 1, 2, 3 and 4 and REM sleep according to the Rechtschaffen and Kale scoring system. More recent terminology recommended by AASM are stage W (Wakefulness), N1 (NREM 1), N2 (NREM 2), N3 (NREM 3 and 4) and R (REM). Normal healthy adults begin and progress through deeper sleep in this order to achieve the basic need of seven to eight hours per day. Although, the function of sleep remains unclear, theories of sleep function have been developed from observational research using partial sleep deprivation (most were conducted on animals due to ethical concerns about causing harm to participants during total sleep deprivation / disruption). A summary of theories suggest that NREM sleep promotes physical well-being and recovery and REM sleep promotes emotional and psychological well-being and recovery. Negative effects from long-term sleep loss are evident which emphasises the crucial function of sleep in restoring the brain and body.

Assessment of patient's sleep in the ICU can be performed objectively and subjectively; PSG remains the gold standard. Each method and instrument has its advantages and disadvantages which can be minimised by using more than one instrument. Assessing sleep quality in the ICU can be challenging because of biological and environmental factors, such as severity of illness, medications and higher levels of activity. Commonalities in sleep problems found in ICU patients are: abnormal sleep architecture (including reduced SWS and REM sleep), increased sleep fragmentation and daytime sleep, and unchanged or decreased TST. Evidence of poor sleep quality, frequent waking and difficulty falling asleep has been widely reported. There are a number of factors known to affect sleep in patients treated in ICU, for example elevated sound levels, light, pain, patient care and treatment activity, and mechanical ventilation. Poor sleep quality may continue for up to 12 months after hospital discharge in this population. Reports of poor psychological health, including symptoms of stress, anxiety, depression and PTSD symptoms, are well documented in ICU survivors, which may compromise their HRQOL.

This study aimed to explore the sleep and psychological recovery of patients treated in a cardiothoracic ICU. There are factors specifically experienced by cardiothoracic ICU patients, such as undergoing surgery using a CPB pump that may affect their sleep and psychological recovery. It is well documented that this population, like other types of ICU patients, experience poor sleep quality and decreased psychological health outcomes after surgery. However, information comparing the sleep quality experienced by patients who undergo ONCAB and those who undergo OPCAB surgery is limited. Furthermore, there is no published study performed on cardiothoracic ICU patients that has investigated the relationship between

post-operative sleep quality, psychological recovery and HRQOL. These problems have been reported in this population and theoretically may be related to each other. This research may provide more insight about ICU patients' sleep quality and psychological outcomes. Short-term and long-term follow up was performed to assess patients' sleep after discharge to determine the continuity of sleep problems. Their psychological wellbeing and quality of life were assessed. The relationships between sleep problems and psychological outcomes and HRQOL were explored. The differences in sleep and psychological recovery between patients who have on-pump and off-pump CABG surgery were also determined.

1.9 Outline of the thesis

Cardiothoracic ICU patients experience poor quality of sleep, decreased psychological wellbeing and compromised HRQOL. Despite the well-established knowledge of this, the paucity of longitudinal studies combining sleep, psychological recovery and HRQOL in this population has potentially prevented the advancement of knowledge and our understanding of the course of recovery. The comparison between surgery techniques on a patient's sleep, psychological recovery and HRQOL may assist in the innovation of rehabilitation services. Chapter one provides an overview of the stages and architecture of normal sleep, the function of sleep and patients' sleep measurements in the ICU. Sleep problems, common factors affecting sleep quality and problems experienced by ICU survivors are identified. Information on cardiothoracic ICU patients with respect to surgical technique, surgery management, and sleep is presented and, cognitive and psychological outcomes are provided.

In chapter two, the research methods are outlined to include the study aims, the process of data collection and the procedures used for data analysis. Chapter three presents the results of the study, describing the characteristics of the study sample and results with respect to the research questions. Chapter four discusses the interpretation of the results and how they integrate with previous work, strengths and limitations of the research, and explores the implications of the results on future avenues of research.

2 Method

2.1 Introduction

This chapter will describe the study aims and methodology of my research. Details of the study setting, research question, sample, instruments, data collection and ethical considerations are included. To assist readers in understanding the research process of this study, data analysis is described in relation to the order of the study's specific aims. The Cronbach's alpha scores from the questionaries used in the study are presented in the instrument section.

2.2 Research question and study aims

Research question

What is the relationship between sleep disruptions of patients in the cardiothoracic intensive care unit (ICU) and during recovery, and their psychological wellbeing during recovery?

Study aims

The broad aim of the current study was to determine the association between sleep disruptions of patients in the cardiothoracic intensive care unit (ICU) and during recovery, and their psychological wellbeing during recovery.

The following specific aims were addressed in the research:

- Assessment of self-reported patients' sleep quality in the ICU, on the hospital ward and at home two and six months after hospital discharge.
- Determination of whether patients who experience sleep disruption in the ICU, continue to experience poor sleep quality while recovering after ICU discharge.
- Determination of the relationship between patients' sleep disruption and their psychological wellbeing during recovery.
- Determination of the differences in sleep quality and psychological wellbeing between patients who have 'on-pump' and 'off-pump' open heart surgery.

2.3 Study design

A prospective observational study was conducted to address the study aims. This study was designed to assess patients' sleep and their psychological wellbeing during recovery at various times, including while the patient was in the ICU/high dependency unit (HDU), the hospital ward, and again at two and six months after hospital discharge. Data were collected from cardiothoracic ICU patients who had open heart surgery; for example, coronary artery bypass graft (CABG), heart valve replacement/repair and correction of congenital heart defects. Patients completed self-report questionnaires regarding their sleep in the ICU, in the hospital ward after leaving ICU and after hospital discharge. At two and six months after hospital discharge, patients completed further self-report questionnaires on their psychological health and health-related quality of life (HRQOL). The 'on-pump' and 'off-pump' patients were compared with regard to sleep and psychological wellbeing, including HRQOL.

2.4 Definitions of key terms

Intensive care unit (ICU): A designated unit of the hospital which is specially staffed and equipped to provide observation, care and treatment of patients with actual or potential life-threatening illnesses, injuries or complications.

Cardiothoracic ICU: An ICU which is specifically designed for the care of patients after cardiac and thoracic surgery.

High dependency unit (HDU): A transitional unit for patients who require close observation, treatment and nursing care that cannot be provided on a hospital ward, but whose care is not at a critical enough level to warrant treatment in ICU. The ICU and HDU in the setting of this study were combined and will be referred to as ICU in this thesis.

Cardiopulmonary bypass (CPB): A technique that temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and oxygen content of the body while the heart is stopped. The CPB pump is referred to as a 'heart-lung machine' or the 'pump'.

'On-pump' open heart surgery: Surgery that is performed while the patient is connected to the cardiopulmonary bypass machine.

'Off-pump' open heart surgery: Surgery that is performed without putting the patient on the cardiopulmonary bypass machine.

2.5 Study setting

The study was conducted in a 600-bed metropolitan hospital in Sydney, Australia. The intensive care department delivered statewide tertiary referral services for neurosurgical, spinal, burns and trauma cases in three specialised units: cardiothoracic, neurosurgical and general. The study setting was a cardiothoracic ICU and hospital ward that the patients were transferred to after discharge from the cardiothoracic ICU within the tertiary referral facility. The ICU and HDU in the setting of this study were combined and referred to as ICU. The admission and management of all ICU patients was the responsibility of an accredited ICU staff specialist. The registered nurse (RN) and patient ratio was dependent on the level of acuity of the patient. For mechanically-ventilated patients, the nurse-to-patient ratio was one-to-one while the ratio for high dependency patients was usually one-to-two. Although the majority of patient care was the responsibility of the RN, multidisciplinary team members, including a dietitian, a physiotherapist, a pharmacist, social workers and support staff, also contributed to patient care and treatment. The ICU was a closed unit where admitting physicians were required to admit patients to the intensive care service. The ICU staff specialists were responsible for all medical decision-making while the patients were in the ICU. Other disciplines or specialists were able to consult regarding patient care during the ICU stay. There were no time restrictions for visitors, but a guideline of two visitors per patient was followed. The bed spaces were separated by curtains. The equipment at the patient's bed space included a heart monitor, a mechanical ventilator, intravenous (IV) pumps and a suction unit. Some patients may require other equipment such as intra-aortic balloon pump (IABP) and continuous renal replacement therapy (CRRT).

The hospital ward differed from the ICU. Patients were accommodated in four-bed spaces with shared toilet and bathroom facilities. Occasionally patients were accommodated in single rooms if there was suspicion or confirmation of colonisation or infection of multi-resistant micro-organisms. The RN to patient ratio was one-to-four on the hospital ward. Two to four visitors per patient at a time were permitted and there were restricted visiting hours (10:00 to 20:00 hours).

2.6 Sample

Data were collected from cardiothoracic ICU patients. The patients were normally transferred from the operating theatre to ICU after surgery. The anaesthetic effects were not fully reversed and patients required mechanical ventilation. Patients were on continuous advanced cardiac, haemodynamic and oxygenation monitoring, sedation and analgesia. After open heart surgery without complication, patients generally stayed in the cardiothoracic ICU for 24-48 hours, depending on their condition. After two to three days, patients were transferred to a hospital cardiothoracic ward for further post-operative management. If there were no complications, patients were discharged within seven days of surgery.

Patients were assessed for eligibility to participate in this study while in the ICU by the research student between two to three days per week. The information about the patients' reason for admission to ICU and health condition was obtained from the bedside 24 hours ICU observation chart and the patients' file. If clarification or more information was needed the bedside nursing staff or team leader was questioned. Participants were approached when they were assessed to have sufficient cognitive capacity to provide informed consent. Patients were invited to participate at a time convenient to both the patient and nurse, to minimise the impact on patient care and treatment. Informed consent gained after the patient or next of kin was satisfied with the information provided in the participant information sheet including clarification with the research student, and agreement to participate. Detail about data collection in the ICU, hospital ward and after discharge from hospital after informed consent were obtained is provided in section 2.8. In the main study, patient screening, gaining informed consent and data collection were completed mainly by research officers and supervisors. The patient inclusion criteria were:

- Age > 17 years
- ICU/HDU length of stay ≥ two nights
- Ability to give informed consent to participate in the research
- Ability to complete study questionnaires in English
- Adequate vision and hearing to complete the study questionnaires
- Medically cleared for discharge from ICU
- No cognitive impairment

Patients were excluded if they had:

- A history or suspicion of a pre-existing sleep disorder, e.g. obstructive sleep apnoea
- Significant treatment limitations, or considered palliative
- Psychiatric illness requiring treatment with medication
- Evidence of brain injury on radiological imaging
- Any likelihood of having an extended stay in hospital and/or a rehabilitation facility
- A history or suspicion of dementia
- A known or suspected infection with multiresistant organisms

Cognitive capacity assessment

Cardiothoracic surgery patients were sedated and mechanically ventilated on arrival to ICU. Low dose sedation medication was administered continuously until the patients were sufficiently recovered from anaesthesia to be assessed for readiness to extubate (remove the endotracheal tube). A continuous intravenous infusion of opioid analgesic was used to manage postoperative pain. The infusion was substituted with oral medication when the pain was managed to a level that allowed deep breathing and coughing. The cognitive capacity of patients to participate was assessed using the following procedure (Fan et al. 2008):

- The nurse was questioned about patient cognition and ability to give informed consent
- Each patient was requested to state or mouth their name
- Each patient was requested to identify the correct colour when one of three coloured papers was shown to them

Cognitive capacity of patients was considered intact if they could perform these tasks.

Sample size and statistical power

A sample size calculation was not performed a priori; the sample size was set in order to meet the requirements to successfully complete research competencies for the masters by research curriculum. All patients at the study site were assessed for eligibility and cognitive capacity during the time period approved by the Human Research Ethics Committee (HREC) and the student candidature's research plan for data collection: two to three days per week from 5 May, 2012 to 9 September, 2012. There were 68 patients who satisfied the inclusion criteria in 51 days of screening. A further 65 patients 'data were extracted from the mainstudy. As a result, there were 101 patients included in the study: 25 OPCAB and 75 ONCAB patients.

2.7 Study instruments

Patient demographics

Relevant demographic data and clinical information were collected on enrolment while patients were in the ICU/HDU. The data collection sheet was used to collect details and baseline information; for example, severity of illness, pain intensity, anxiety level, age and gender. This sheet was stored separately from the patient information form. The following instruments were used for demographic data collection in the current study.

The Acute Physiology and Chronic Health Evaluation III (APACHE III). The APACHE III prognostic system is used to predict hospital mortality for critically-hospitalised adults (Knaus et al. 1991). The scores range from zero to 299. Higher scores indicate higher severity of illness. The data were collected and scores calculated by designated specifically trained hospital staff in the current study site. The patients' scores in the current study were extracted from the ICU database in which the scores were calculated.

Sequential Organ Failure Assessment (SOFA) score. This scoring system is used in the ICU to determine the extent of patients' organ function or rate of failure (Vincent et al. 1998). The instrument comprises six different scores, one each for the respiratory, cardiovascular, hepatic, coagulation, renal and neurological systems. The scores range from zero to 20. The higher score indicates a higher level of organ system dysfunction.

Richmond Agitation Sedation Scale (RASS). This scale was developed as a collaborative work between critical care physicians, nurses, and pharmacists to provide an assessment of sedation level. It comprises a 10-point scale. The highest (+4) score represents patients who are combative, violent and of immediate danger to staff. The lowest score (-5) represents patients who have no response to voice or physical stimulation. Zero represents alert and calm patients. The instrument had a high inter-rater reliability (r=0.92-0.98) (kappa=0.64-0.82) among different types of ICUs, sedated and non-sedated patients and patients with or without mechanical ventilators (Sessler et al. 2002). It had high validity (r=0.93) when tested against a visual analogue scale. Patients' RASS scores in the current study were obtained from the 24 hour ICU observation chart, bedside nurse or researcher assessment.

Pain intensity. Each patient was asked to rate their pain using the numerical rating scale. The scale ranges from zero to 10. Zero indicates the absence of pain, while 10 indicates the most intense pain possible.

Anxiety level. Each patient was asked to choose the face that best described how anxious they felt on the Faces Anxiety Scale(McKinley, Coote & Stein-Parbury 2003). The Faces Anxiety Scale comprises five faces representing different levels of anxiety. It was developed for

use in the ICU and criterion validity shown in relation to the Spielberger State-Trait Anxiety Inventory ($r=0.7$, $p<0.0005$)(McKinley & Madronio 2008).

Glasgow Coma Scale (GCS). This is a neurological scale used to assess the status of the central nervous system. The scale is composed of three tests: eye, verbal and motor responses. The sum of the three scores, as well as their separate values, are considered. The lowest possible GCS (the sum) is three, indicating deep coma or death. The highest is 15, indicating a fully conscious person(Teasdale, Knill-Jones & van der Sande 1978).

Self-report questionnaires were used for the current study. The time at which they were provided and the variables measured in the study are provided in Table 6. Specific details for each instrument are described in the text.

Table 6. Instruments and time lines

Instrument	Measurement	Time provided
Numerical Pain Scale	Intensity of pain	ICU/HDU on enrolment
Faces Anxiety Scale	Level of anxiety	
Richards-Campbell Sleep Questionnaire (RCSQ)	Sleep quality	
Insomnia Severity Index (ISI)	Sleep quality and insomnia severity	
Sleep in the Intensive Care Unit Questionnaire (SICQ)-question 1	Sleep quality prior to hospitalisation	
Richards-Campbell Sleep Questionnaire (RCSQ)	Sleep quality	Hospital ward
Sleep in the Intensive Care Unit Questionnaire (SICQ)	Sleep quality and sleep disturbances in ICU	
Pittsburgh Sleep Quality Index (PSQI)	Sleep quality and sleep disturbances at home	Two months after hospital discharge
Intensive Care Experience Questionnaire (ICEQ)	Perception of ICU experiences	
Pittsburgh Sleep Quality Index (PSQI)	Sleep quality and sleep disturbances at home during the previous month	Six months after hospital discharge
Depression Anxiety Stress Scales (DASS-21)	Symptoms of depression, anxiety and stress	
Post-traumatic Stress Disorder (PTSD) Checklist for Specific Event (PCL-S)	PTSD symptoms	
Medical Outcomes Trust Short Form-36 (SF-36) health survey–Version 2	Physical and mental components of health related quality of life	

2.7.1 The Insomnia Severity Index (ISI)

The ISI is a questionnaire used for the measurement of insomnia severity, satisfaction with current sleep patterns, the effects of insomnia on daily function, effects on quality of life and level of distress associated with sleep difficulties. Each item is rated on a Likert scale, which ranges from zero (not at all) to four (extreme) during the time frame of the previous two weeks. Adding scores for all seven items gives a total score ranging from zero to 28. Higher scores indicate more severe insomnia. A total score of 15 or more is suggestive of clinical insomnia. The ISI requires less than five minutes to complete and less than one minute to calculate the total score. The questionnaire was administered in the ICU/HDU on enrolment. The ISI was compared with sleep diary data by (Morin 1993; Morin et al. 2011), in which concurrent validity was shown to be adequate (r=0.65) (Bastien, Vallieres & Morin 2001). The studies showed that the ISI had adequate internal consistency and good concurrent validity (n=145 sleep disorder clinic patients and n=78 patients in a randomised-controlled trial of behavioural and pharmacological therapies for insomnia). The ISI is a valuable screening instrument for insomnia that compares well with clinician interviews, using the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), diagnostic criteria for insomnia. The ISI had very good internal consistency in the current study (Cronbach's alpha=0.89).

2.7.2 The Richards-Campbell Sleep Questionnaire (RCSQ)

The RCSQ is a self-report instrument, comprising visual analogue scales (VAS). This instrument has five sleep domains: depth, latency, awakenings, percentage time awake and quality of sleep (Richards, O'Sullivan & Phillips 2000). There is a VAS for each domain. The VAS requires patients to mark an 'X' on each line measuring 100mm (zero is the poorest quality sleep and 100 is the optimum quality sleep). The length is measured from the low end (left side) to the mark in millimetres. The total scale for RCSQ is the sum of the total distance in millimetres divided by five. The instrument was provided after patients spent at least one night in the hospital ward.

Pilot testing of the RCSQ was completed in nine patients at a medical critical care unit with polysomnography (PSG), with a total of 14 nights' sleep (Richards & Bairnsfather 1988). The correlations with PSG were not large for two of the visual analogue scales: number of awakenings and percentage of time awake. The RCSQ was further validated in a study comprising 70 male patients in a medical critical care unit. The Cronbach's alpha was 0.90 and the correlation between the total RCSQ score and the PSG sleep efficiency index (SEI) was 0.58 ($p<0.001$) (Richards, O'Sullivan & Phillips 2000). The RCSQ total score was shown to predict 33% of the variance of the SEI. Although the RCSQ is reliable and validated for use in the acute

hospital setting, cut-off points for good and bad (poor) sleep have not yet been identified. Furthermore, norms for a healthy 'good' sleeper have not yet been established. The Cronbach's alpha values were 0.91 and 0.89 when the questionnaires were responded to in the ICU and hospital ward in this study.

2.7.3 Sleep in the Intensive Care Unit Questionnaire (SICQ)

The SICQ was developed to assess the quality of sleep and the factors that contributed to sleep disruption in ICU patients (Freedman, Kotzer & Schwab 1999). The instrument assesses patients' perception of the quality of their sleep at home and in the ICU, degree of daytime sleepiness during their ICU stay, and degree of disruption by activities and noises, using a Likert scale from one (poor) to 10 (excellent). There are also two open-ended questions. Although this instrument has not been validated with PSG, it is a useful brief method of comparing sleep quality prior to hospitalisation with current sleep quality, an obvious advantage for the ICU patient (Bourne et al. 2007). Internal consistency checks are not valid for SICQ because this is a descriptive questionnaire and not intended to be a psychometric scale.

2.7.4 The Pittsburgh Sleep Quality Index (PSQI)

The PSQI is a self-rating questionnaire that enables the assessment of sleep quality and sleep disturbance. It measures subjective sleep in seven areas (quality, latency, duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications and daytime dysfunction) over the previous months using the Likert scale from zero to three (Buysse et al. 1989; Smyth 2008). The instrument comprises 19 items which generate seven component scores. The sum of these components is the PSQI global score which ranges from zero to 21. Higher scores indicate poor sleep quality. The cut point score is five. The questionnaire takes five to ten minutes to complete and five minutes to score. It was provided at two and six months after hospital discharge.

During the development of the PSQI, the questionnaire was provided to healthy people (n=52), depressive disorder patients (n=54) and sleep-disorder patients (n=62), to assess its clinical and clinimetric properties (Buysse et al. 1989). The questionnaire had high internal consistency in seven component scores (Cronbach's alpha=0.83). A PSQI global score cut-off at five indicated a diagnostic sensitivity of 89.6% and specificity of 86.5% (kappa=0.75, $p<0.001$) to differentiate good and poor sleepers. The PSQI is highly recommended for use in psychiatric clinical practice and research because of its high validity and reliability (Smyth 2008). The

questionnaire had acceptable internal consistency in seven component scores at two (Cronbach's alpha=0.77) and six (Cronbach's alpha=0.81) months in the current study.

2.7.5 The Intensive Care Experience Questionnaire (ICEQ)

The ICEQ comprises 24 items that assess four dimensions of the intensive care experience: awareness of surroundings (nine items and scores nine to 45), frightening experiences (six items and scores six to 35), recollection of experiences (five items and scores five to 25) and satisfaction with care (four items and scores four to 20) (Rattray, Johnston & Wildsmith 2004). There are two Likert-type answer formats, ranging from strongly agree to strongly disagree and frequency ranging from, all of the time to never. Each of the items is scored one to five. There are also three open-ended questions: best, worst and anything the patients would like to note about their intensive care experience. High scores indicate greater awareness, more frightening experiences and greater satisfaction with care. For the 'recall of experience' component, low scores are suggestive of unclear recollection of the ICU experience and a desire to recall more of what happened. In the current study the questionnaire was completed and returned by mail two months after hospital discharge.

In the development of the ICEQ, Cronbach's alpha statistic for each component was acceptable: awareness of surroundings (Cronbach's alpha=0.93), frightening experiences (Cronbach's alpha=0.78), recall of experiences (Cronbach's alpha=0.73) and satisfaction with care (Cronbach's alpha=0.71) (Rattray, Johnston & Wildsmith 2004). The Hospital Anxiety Depression Scales (HADS) and Impact of Event Scale (IES) were used to assess the concurrent and predictive quality of the ICEQ components. Moderate correlations were evident for frightening experiences, and the HADS anxiety score at hospital discharge, and at six and 12 months after discharge from hospital ($r=0.444$-0.483, $p<0.01$). Moderate to high correlations (0.413-0.6, $p<0.01$) were evident for frightening experiences and IES (avoidance and intrusion) at hospital discharge, and at six and 12 months after discharge from hospital. Further studies revealed that the ICEQ had satisfactory reliability and validity for the identification of the subjective intensive care experience of short- and long-term ICU treatment (Rattray et al. 2010; Rattray, Johnston & Wildsmith 2005). Additionally, subjective intensive care experience appeared to be related to both short- and long-term emotional outcomes. Cronbach's alpha statistic in the current study for each component was 0.84 (awareness of surroundings), 0.74 (frightening experiences), 0.77 (recall of experiences) and 0.57 (satisfaction with care).

2.7.6 The Depression Anxiety Stress Scales instrument (DASS-21)

The DASS-21 is used to measure dimensions of depression, anxiety and stress (Henry & Crawford 2005). It contains three scales, comprising seven Likert scale items ranging from zero (not at all) to three (very or most of the time) (Shea, Tennant & Pallant 2009). Each item of DASS-21 (the short-form version) was taken from the original 42-item DASS (three of 14-item scales). Doubling the scores on each item in DASS-21 yields similar subscale and global values from the original version of the instrument (Henry & Crawford 2005). The DASS-21 has been validated in various studies. The internal consistency of the individual DASS-21 scales was good to excellent: depression (Cronbach's alpha=0.88), anxiety (Cronbach's alpha=0.82), stress (Cronbach's alpha=0.90) and total scales (Cronbach's alpha=0.93) (Henry & Crawford 2005). Furthermore, the DASS-21 has been shown to have adequate construct validity and to be more acceptable for use by patients with a limited level of attention (Henry & Crawford 2005). The questionnaire was completed at six months after hospital discharge to measure patients' symptoms of depression, anxiety and stress over the past week in the current study. The reliability for the individual DASS-21 scales in the current study was good to excellent: depression (Cronbach's alpha=0.91), anxiety (Cronbach's alpha=0.73) and stress (Cronbach's alpha=0.91).

2.7.7 The Post-traumatic Stress Disorder Checklist for Specific Event (PCL-S)

The PCL-S is a brief self-report questionnaire for assessing the 17 symptoms of PTSD based on DSM-III-R diagnostic criteria, one of the gold standards for diagnosing PTSD. There are three versions of the PCL: the military (PCL-M), the civilian (PCL-C) and the specific event (PCL-S). Items in the PCL-M refer to a stressful military experience. The PCL-C is not linked to a specific event; but rather the questions refer to a stressful experience from the past. The PCL-S is developed for any specific traumatic event; patients nominate the event and questions refer to the stressful experience. Although the three versions are slightly different, the scoring is the same.

The PCL was shown to be valid and reliable for use in screening for PTSD symptoms in clinical practice and research according to DSM-IV criteria (Ventureyra et al. 2002). A test-retest reliability of 0.96 was reported. The correlation between the PCL total score and Clinician Administered PTSD Scale's (CAPS) total score (based on DSM-IV criteria) was high ($r=0.93$, $p<0.0001$), and internal consistency coefficient (Cronbach's alpha=0.94) was excellent. A cut-off score of 44 for PCL had demonstrated high sensitivity (0.94), specificity (0.86) and overall diagnostic efficacy (0.90) with motor vehicle accident (MVA) survivors. The PCL-S was used in the current study to assess the effect of the cardiothoracic ICU experience. It was

administered at six months after hospital discharge. The patients were asked to indicate how much they had been affected by the specific stressful life experience in the past month on a five-point severity scale; re-experiencing (items one to five), avoidance behaviour or numbing (items six to 12), and physiological hyperarousal (items 13-17). The questionnaire can be completed in five to seven minutes. The internal consistency for the PCL-S total score and for each of the three subscales was measured by Cronbach's alpha in the current study. Cronbach's alpha was 0.91 for the PCL-S total score, 0.87 for re-experiencing, 0.84 for avoidance and 0.78 for hyperarousal.

2.7.8 The Medical Outcomes Trust Short Form-36 (SF-36)

The health survey-version 2 was used in the current study to measure patients' physical and mental health related quality of life (HRQOL). The SF-36 has been identified as well-suited for measuring quality of life in research conducted during patient recovery from critical illness (Angus & Carlet 2003). The questionnaire contains 36 questions; each question has five-levels of response. The SF-36 is well-regarded internationally to measure health-related quality of life and has been validated in many countries and settings (Ware 2000). It can be completed in five to 10 minutes. The eight subscales of the SF-36 are used to derive physical and mental component scores, analysed and reported in the thesis The lowest possible Physical Component Summary (PCS) (zero) score is indicative of significant limitations in the ability to self-care, including physical, social, and role functions, severe body pain, and frequent tiredness. The highest PCS score (100) indicates the absence of any physical limitations. The lowest score for the Mental Component Summary (MCS) (zero) suggests emotional problems leading to frequent psychological distress and social and role disabilities. The highest possible MCS (100) is indicative of positive affect and absence of psychological distress, with no limitations in usual social/role activities. In the current study the instrument was completed at six months after hospital discharge to measure patients' health related quality of life.

The instrument's reliability has been tested using both internal consistency and test-retest methods. The Cronbach's alpha and correlation coefficient values had been reported to exceed 0.70 in more than 25 studies (Ware 2000). The correlation of SF-36 scales with many general health concepts and with many specific symptoms and problems, has been substantial (r=0.40 or greater). Cronbach's alpha statistic in the current study for each scale was 0.94 (physical functioning), 0.95 (role-physical), 0.91 (body pain), 0.85 (general health), 0.85 (vitality), 0.87 (social function), 0.91 (role-emotion) and 0.84 (mental health). The reliability of PCS (Cronbach's alpha=0.84) and MCS (Cronbach's alpha=0.85) were good.

2.8 Data collection

2.8.1 Data collection in the ICU

After informed consent was obtained, study participants were assigned a unique study number. Confidentiality and privacy of patients was protected by storing patient identifiers in a locked cabinet inside a secure office. Electronic data related to the study were password-protected. Each patient's date of birth, current address and contact details including the next of kin details, were confirmed before the patient was discharged from hospital. Demographic data were collected from each patient's 24-hour ICU observation chart with any other relevant documents. Sedation score, pain site and intensity, anxiety level and GCS were assessed and recorded. Patients were asked to rate the overall quality of their sleep at home (SICQ-first question). The ISI (sleep and satisfaction in the past two weeks) and RCSQ (last night of sleep in the ICU) were also administered just after enrolment in the ICU. If the questions were read to the patients, the researcher documented the answers according to the patients' responses. If the patients preferred, they self-completed and then the questionnaire was collected later. Patients were informed that the researcher would follow them up on the hospital ward approximately one day later.

2.8.2 Data collection in hospital ward

Each patient's location was tracked on the hospital electronic records database. After one or two night's sleep in the hospital ward, each patient was requested to confirm their consent to participate in the study. They were then asked to complete the RSCQ and all the questions of the SICQ. If they preferred the questions to be read to them, the researcher obliged and the answers were documented by the researcher. Once the questionnaires were completed, which usually took five to 10 minutes, the patients were again informed that they would be followed up after hospital discharge and requested to complete more questionnaires.

2.8.3 Data collection after discharge from hospital

Each patient's location and date of hospital discharge was tracked using the hospital electronic records' database. Follow-up occurred at two and six months after discharge from the hospital. A cover letter, the PSQI, the ICEQ and a self-addressed prepaid postage envelope were mailed to each patient's address two weeks prior to the two month follow-up date. A telephone call to each patient was made at two weeks after the questionnaires were mailed, to confirm that they had received them and to ask if any clarification was needed. A standardised telephone transcript was used. The participants were asked to confirm their

intention to remain in the study and were invited to answer the questions over the telephone. If the questions were read to the patients over the phone, the researcher documented the responses. If any patients had health concerns during the telephone conversation, they were advised to see their general practitioner. If the patients preferred, they self-completed and then returned the questionnaire by mail later. If the questionnaires were not returned after two weeks, another set of questionnaires was posted. A maximum of two attempts were made to contact the patient. The same process was followed at six months for the PSQI, DASS-21, PCL-S and SF-36 instruments.

2.9 Data analysis

Data entry

Demographic and questionnaire data were entered into a password-protected Microsoft Office Excel® (Microsoft, California, 2007) spreadsheet by the researcher. Data were transferred into SPSS Statistics Standard Grad Pack 21.0 (IBM, Ireland, 2013) for analysis. The answers to open-ended questions were typed and saved as Microsoft Office Word® (Microsoft, California, 2007) documents. Visual checks for inaccuracies in the data were performed by inspecting for values outside of a predetermined range. The responses for all questionnaires were checked within the database for every 10th patient. Data screening and cleaning were performed using methods suggested in the SPSS Survival Manual; for example, checking for errors, finding and correcting any errors in the data file (Pallant 2007).

Missing data

All returned questionnaires were checked for missing responses. Patients were contacted to obtain answers for any missing values. Patients who failed to return questionnaires and were unable to be followed up, were treated as having missing data. After attempts to obtain valid data had failed, the missing data were replaced or omitted according to the instrument developer's instructions. For example, the global PSQI score cannot be computed if the data are incomplete. The ICEQ missing values were substituted by the scale mean or median. The data were not replaced if the participants omitted the responses intentionally because the question or item was not applicable to them; for example, 'the middle of ICU stay' (SICQ) did not apply to patients who spent two nights or less in the ICU.

Data analysis

The demographic and questionnaire data were analysed using descriptive statistics in order to describe the data. Frequencies and percentages were reported for categorical variables, such as sex and marital status. Continuous data were checked for the characteristics

of distribution using histograms. If the data were normally distributed, the mean and standard deviation were reported. Where data distribution was skewed, such as the length of stay and APACHE III score, the median and interquartile ranges were reported.

Inferential statistics were used; univariate analyses were performed to characterise the patients and explore differences between patient groups; for example, 'off-pump' and 'on-pump' open heart surgery. The Chi-Square test for independence was used to compare the categorical data. Normally distributed continuous data were compared using parametric statistics, such as the Independent-sample t-test. Non-normally distributed continuous data were compared using a non-parametric technique, such as the Mann-Whitney U Test. Furthermore, multivariate analysis was performed to explore factors related to poor and good sleep quality reported on PSQI at six months after discharge. Standard multiple regression was used which involved all of the independent variables being entered into the equation at once. The PSQI scores at six months were used as the dependent variable. Independent variables were determined by selecting normally distributed continuous variables that were related ($p<0.05$) to sleep quality at six months from bivariate analysis (prehospital symptoms of insomnia, physical and mental HRQOL at six months), and/or had sound theoretical reason for analysis (on and off-pump surgical techniques). The results indicated how well this set of variables was able to predict patients' sleep quality at six months. The probability value (p) of less than 0.05 was considered statistically significant.

2.10 Ethical considerations

The Human Research Ethics Committee (HREC) approval from Northern Sydney Central Coast Area Health Service (NSCCAHS), and ratification by the HREC of the University of Technology, Sydney (UTS) were received prior to the commencement of the study. The study and participant information were explained to the patient if they met the inclusion criteria. An opportunity for questions and discussion was provided. Informed consent was obtained when the patient indicated that they were satisfied with the information provided. The patient's next of kin or proxy was invited to sign the consent form if the patient agreed to participate but was unable to sign. A copy of the participant information sheet (including a revocation of consent form) and the signed consent form were given to the patient. Another copy was filed in the patient's health care records. The original copy was locked in a cupboard inside a secure office. Patient information and data collection forms (appendix B) were stored separately in the same locked cupboard (different draw requiring a different key) inside the same office. Based on the paper work in appendix B, the patient identifiers were on the same form as the

patient data creating a risk. The confidentiality and privacy were assured by limiting access to only the researcher (myself) and the principal supervisor at the time (Professor Sharon McKinley).

There were minimal anticipated risks of harm to patients as a result of participating in the study, particularly as there were no changes to treatment and no interventions. Nonetheless, a range of psychological outcomes were being assessed; this had the potential to arouse or reveal psychological distress. In the event of evidence of distress in the responses to the study questionnaires, the patients would have been contacted and, if they wished, referred to the ICU social worker. If the patients had become distressed or did not wish to continue answering questionnaire, the interview would have been stopped/paused, and patients would have been reassured. If they were at home, their next of kin would have been notified. The patients were made aware that they could withdraw from participating in the study whenever they wished. In the event of any medical problems reported by participants or revealed by the researcher, the patients would have been referred to their general practitioner (GP) as appropriate. There was no evidence of distress identified and no referral to the ICU social worker or GP was required for patients who participated in the current study.

3 Results

3.1 Introduction

This chapter describes the demographic and clinical characteristics of the patients who participated in the study. The flow chart showing the recruitment and retention of study participants is depicted in Figure 1. Descriptive statistics are provided for participant characteristics. The association between sleep disruption for patients in the cardiothoracic intensive care unit (ICU) and during recovery, and their psychological wellbeing during recovery, are presented in this chapter. Each of the study aims are addressed and presented. The first aim was to assess patients' self-reported sleep quality in the ICU, on the hospital ward and at two and six months after hospital discharge. The second aim was to determine whether patients who experience sleep disruption in the ICU continue to experience poor sleep quality while recovering after ICU discharge. The third aim was to determine the relationship between patients' sleep disruption and their psychological wellbeing during recovery. The last aim was to determine the differences in sleep quality and psychological wellbeing between patients who had on-pump and off-pump open-heart surgery.

Patients' sleep quality in the ICU, while they were on the hospital ward and at home two and six months after hospital discharge, are presented as scores and according to cut points. Sleep quality over time was explored, that is whether patients who experienced sleep disruption in the ICU continued to have poor quality sleep during recovery. In addition, objective and subjective data relating to the patients' ICU experiences are presented. Patients' psychological wellbeing/status and quality of life at six months after hospital discharge, are reported as descriptive statistics. The relationships between patients' sleep disruption and their psychological wellbeing during recovery were explored. Data on ICU experiences and psychological outcomes were compared for patients who reported poor and good quality sleep in the ICU. The relationship between sleep quality at six months after hospital discharge and factors known to affect sleep quality were explored. Differences in sleep quality, quality of life and psychological wellbeing of patients who had on-pump and off-pump open-heart surgery, are presented.

3.2 Participants

The study was a sub-study of a larger questionnaire (main) study exploring sleep in ICU patients. There were two data sets; one data set was collected by the researcher and the second data set was extracted from the larger study. Data collected by the researcher included only cardiothoracic patients while the main study included three specialised ICUs (cardiothoracic, neurosurgical and general). Both data sets were collected within the timeframe approved by the same HREC and shared the same study design, methods, sample inclusion and exclusion criteria, study setting and instruments. Based on the same data collection conditions, it was appropriate to extract cardiothoracic ICU patients' data from the main study and incorporate this with data collected by the researcher to explore sleep and psychological health in this particular group.

Seventy-seven patients were screened between 5 May, 2012 and 9 September, 2012. Screening was performed for 51 days resulting in 68 patients who met the study inclusion criteria. Of these patients, 14 were excluded for reasons such as history/evidence of sleep disorder (n=4), insufficient understanding of English (n=4) and inadequate hearing or sight to complete the study instruments (n=1). Fifty-four patients were eligible but 18 of these patients were not enrolled (five were discharged before enrolment and 13 declined). As a result, 36 additional patients were enrolled in the study and completed the questionnaires in the ICU/HDU. A further 65 cardiothoracic surgery patients' data were extracted from the main study (n=222), using Australian and New Zealand Intensive Care Society modified-Acute Physiological and Chronic Health Evaluation (APACHE) (ANZICS 2004) diagnostic subcodes. Consequently, the total number of participants was 101. Four participants were lost to follow-up during their hospital ward stay and 95% (n=96) remained in the study. At two months after discharge 76 patients (75%) and, subsequently, 71 patients at six months (70%), returned the questionnaires. Details on screening and enrolment are presented in Figure 1.

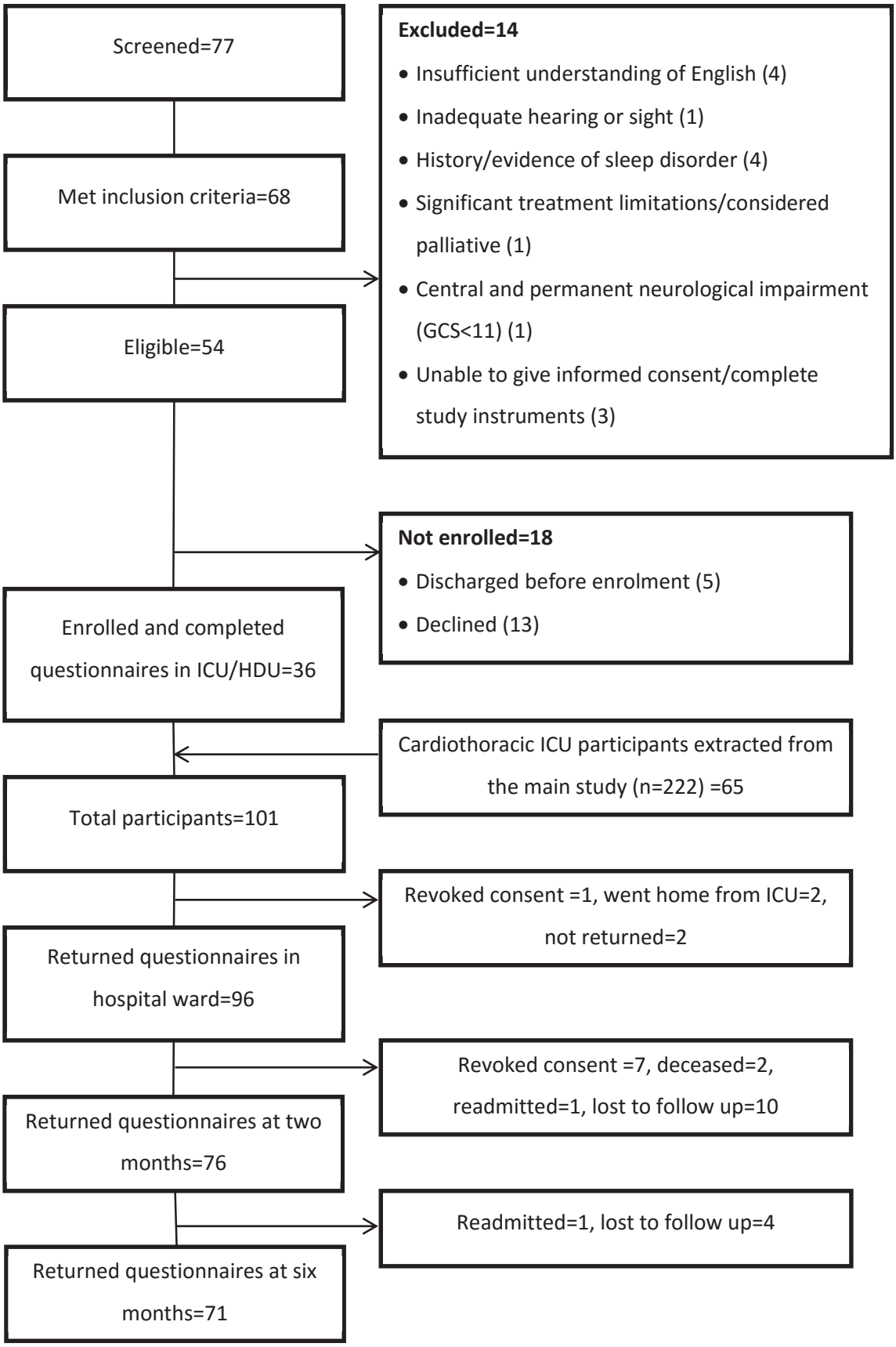

Figure 1. Flow chart showing the recruitment and retention of study participants.

3.3 Participant characteristics

The mean age of participants was 66.60±11.07 years with an average body mass index (BMI) of 27.30±4.32kg/M². The ratio of males (n=79, 78.20%) to females (n=22, 21.80%) was 3.6:1. On enrolment, patients were requested to state their anxiety level using the Faces Anxiety Scale (McKinley, Coote & Stein-Parbury 2003). The mean anxiety level score was 2.28±1.11. The data for one patient who received cardiopulmonary bypass (CPB) could not be extracted from the medical record because they discontinued their enrolment and were not asked if their data up to that time point could be used. The majority of patients had on-pump surgery (n=75, 75%) and a quarter of patients (n=25, 25%) underwent off-pump surgery. Almost all patients were alert, calm and cooperative (sedation score (RASS) of zero) on enrolment. The median pain intensity score on enrolment was 2.00. Median ICU length of stay was 2.00 (IQR: 2.00-4.00) days and the median hospital length of stay was 12.00 (IQR: 8.50-15.00) days. Demographic characteristics of participants are reported in Table 7.

Table 7. Selected demographic and clinical characteristics of patients on enrolment (n=101)

		N	%
Gender			
Male		79	78.20
Female		22	21.80
Cardiopulmonary bypass pump[a]			
On-pump		75	75.00
Off-pump		25	25.00
Sedation score on enrolment (RASS)[b]			
-1		1	1.00
0		99	98.00
1		1	1.00
	N	**Mean**	**SD[c]**
Age (years)	101	66.60	11.07
BMI (kg/M²)[d]	101	27.30	4.32
Anxiety level on enrolment (1-5)	101	2.28	1.11
	N	**Median**	**IQR (25-75%)[e]**
Pain severity on enrolment (0-10)	101	2.00	0.00-4.00
Length of mechanical ventilation (days)	101	1.00	0.50-1.00
ICU length of stay (days)	101	2.00	2.00-4.00
Hospital length of stay (days)	101	12.00	8.50-15.00

[a] Missing one patient (discontinued), [b] Richmond Agitation Sedation Scale, [c] SD=standard deviation, [d] BMI=body mass index, [e] Interquartile range

3.4 Subjective sleep outcomes

3.4.1 Subjective sleep outcome scores

Patients' subjective sleep quality before hospitalisation was assessed on enrolment using the Insomnia Severity Index (ISI) (Bastien, Vallieres & Morin 2001), and the first question of the Sleep in the Intensive Care Unit Questionnaire (SICQ) (Freedman, Kotzer & Schwab 1999). The mean ISI score was 7.85±7.66. The quality of sleep in the ICU (4.41±2.40) was lower than the self-reported quality of sleep at home (6.81±2.52). Patients reported higher quality sleep while they were on the hospital ward (51.84±25.23mm) compared to when they were in the ICU (42.76±29.10mm). The sleep quality mean score reported on the Pittsburgh Sleep Quality Index (PSQI) at two months was 8.18±4.23 and the sleep quality mean score at six months was 7.92±4.64 after hospital discharge. Subjective sleep outcome scores are presented in Table 8.

Table 8. Subjective sleep outcome scores

	N	Mean	SD	Min-Max
Total ISI (0-28)[a]	101	7.85	7.66	0-28
Quality of sleep at home (SICQ) (1-10)[b]				
Reported in ICU[c]	101	6.81	2.52	1-10
Reported in ward	96	6.95	2.39	1-10
Overall quality of sleep in ICU (SICQ) (1-10)[b]	96	4.41	2.40	1-10
Mean total RCSQ (0-100 mm)[b]				
In ICU	100	42.76	29.10	0-100
In ward	96	51.84	25.23	0-100
Total PSQI after hospital discharge(0-21)[a]				
Two months	76	8.18	4.23	1-20
Six months	71	7.92	4.64	1-21

[a] Lower scores are better, [b] Higher scores are better, [c] A cut point of 70/100mm on the RSCQ was used to categorise good and poor sleep, based on an average score of prehospital sleep quality of 7/10 on the SICQ

3.4.2 Subjective sleep outcome categorised by cut points

More than nineteen percent of patients (n=20) reported having symptoms of clinical insomnia prehospital (ISI≥15). Seventy-six percent of patients (n=76) reported poor sleep in the ICU (RCSQ<70mm) and 72 percent reported poor sleep in the hospital ward (n=69). Over 55 percent of patients reported poor sleep in both the ICU and hospital ward (n=53). The percentage of patients who reported poor sleep at two months was 68% and 62% at six months. Seven percent (n=7) of patients reported poor sleep quality at all five data collection time points; prior to hospitalisation, in the ICU, on the hospital ward, and at two and six months after hospital discharge. Almost 12 percent (n=12) of patients reported poor sleep quality in the ICU, ward, two months and six months after hospital discharge. Subjective sleep data categorised by cut points are presented in Table 9.

Table 9. Subjective sleep data categorised by cut points

	N	%
Insomnia Severity Index (ISI≥15)		
No or subclinical insomnia	81	80.20
Clinical insomnia-moderate or severe	20	19.80
Richards-Campbell Sleep Questionnaire (RCSQ) in ICU[a]		
Poor (RCSQ <70 mm)	76	76.00
Good (RCSQ ≥70 mm)	24	24.00
RCSQ in ward		
Poor (RCSQ<70 mm)	69	71.90
Good (RCSQ≥70 mm)	27	28.10
RCSQ in ICU and ward		
Poor in ICU and ward	53	52.50
Poor in ICU or ward	34	35.40
Good in ICU and ward	9	9.40
Pittsburgh Sleep Quality Index (PSQI) at two months		
Poor (PSQI>5)	52	68.40
Good (PSQI≤5)	24	31.60
PSQI at 6 months		
Poor (PSQI>5)	44	62.00
Good (PSQI≤5)	27	38.00
PSQI at two and six months		
Poor at two and six months	39	50.00
Poor at two or six months	21	26.90
Good at two and six months	18	23.10
Sleep quality over time		
Poor-home, ICU, ward, two months and six months after hospital discharge	7	6.90
Poor-ICU, ward, two months and six months after hospital discharge	12	11.90
Poor after hospital discharge only	12	11.90

[a]A cut point of 70/100 mm on the RCSQ used to categorise good and poor sleep, based on an average score of prehospital sleep quality of 7/10 on the SICQ.

3.5 Intensive Care Experience

The patients' experience of their treatment in the ICU was assessed at two months after hospital discharge using the Intensive Care Experience Questionnaire (ICEQ). The mean-scores for the four domains of ICEQ are presented in Table 10.

Table 10. Domain IECQ score

Domain	N	Mean	SD	Min-Max
Awareness of surroundings (9-45)[a]	78	35.00	8.80	5-45
Frightening experiences (6-30)[b]	78	12.20	4.70	1-28
Recall of experiences (5-25)[a]	78	17.00	4.50	6-25
Satisfaction with care (4-20)[a]	78	14.70	3.50	3-20

[a] Higher scores are better, [b] Lower scores are better

3.6 Psychological outcomes

The Depression Anxiety Stress Scales (DASS-21), Post-traumatic Stress Disorder Checklist for Specific Event (PCL-S) and Medical Outcomes Trust Short Form-36 Health Survey-Version 2 (SF-36) were mailed to the patients at six months after hospital discharge. The median depression and stress scores were six while the median state anxiety score was four. The mean score for PCL-S was 26.10±9.40. Quality of life (SF-36) was reported in two summary measures: Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. The mean MCS score was 48.90±9.40 and the mean PCS score was 44.03±10.50. Quality of life outcomes at six months after hospital discharge are presented in Table 11.

Table 11. Depression, anxiety, stress, posttraumatic stress symptoms and HRQOL at six months after discharge fromhospital

	N	Median	IQR[a] (25-75%)	
DASS[b]-21-Depression (0-42)	71	6.00	0.00-14.50	
DASS-21- Anxiety (0-42)	71	4.00	0.00-10.00	
DASS -21-Stress (0-42)	71	6.00	0.00-14.00	
	N	**Mean**	**SD**	**Min-Max**
Posttraumatic stress symptoms (PCL-S[c]) (17-85)	71	26.10	9.40	17.00-57.00
Quality of life (SF-36[d])				
PCS[e] (0-100)	71	44.03	10.50	14.20-61.50
MCS[f] (0-100)	71	48.90	9.40	25.30-65.20

[a] IQR=interquartile range, [b] DASS=Depression Anxiety Stress Scale, [C] PCL-S=Posttraumatic Stress Disorder Checklist for Specific Event, [d] SF-36=Form-36 Health Survey-Version 2, [e] PCS=physical component summary, [f] MCS=mental component summary

3.7 A comparison of the experience of treatment in the ICU and psychological wellbeing during recovery for patients who reported poor and good quality sleep in the cardiothoracic ICU

There were no statistically significant differences in ICEQ scores, posttraumatic stress symptoms, stress, anxiety, depression and quality of life during recovery surgery between patients who reported poor and good quality sleep when they were in the cardiothoracic ICU. The proportion of on-pump patients who reported poor quality sleep in the ICU was not significantly different from the proportion of off-pump patients who reported poor quality sleep in the ICU. The comparisons of those variables are presented in Table 12.

Table 12. The experience of treatment in the ICU and psychological wellbeing during recovery for patients who reported poor and good quality sleep in the cardiothoracic ICU

		RCSQ total<70 mm – poor sleep quality	**RCSQ total≥70 mm – good sleep quality**	**N**	***P***
ICEQ Awareness of surroundings	Median	37.00	39.00	78	0.26[b]
	IQR[a]	31.00-41.00	36.00-41.00		
ICEQ[e] Frightening experiences	Mean±SD[d]	12.32±5.00	11.79±3.92	78	0.67[c]
ICEQ Recall of experiences	Mean±SD	16.88±4.74	17.37±3.67	78	0.68[c]
ICEQ Satisfaction with care	Mean±SD	14.54±3.82	15.16±2.32	78	0.40[c]
DASS[f]-21-Depression	Median	6.00	8.00	71	0.24 [b]
	IQR	0.00-14.00	4.00-16.00		
DASS-21-Anxiety	Median	4.00	6.00	71	0.97 [b]
	IQR	0.50-10.00	0.00-10.00		
DASS-21-Stress	Median	6.00	6.00	71	0.68 [b]
	IQR	0.00-14.00	2.00-12.00		
PCL-S[g] total	Median	24.00	22.00	71	0.45 [b]
	IQR	19.25-31.75	18.00-29.00		
SF-36[h] PCS[i]	Mean±SD	43.67±9.65	45.03±12.70	71	0.63[c]
SF-36 MCS[j]	Mean±SD	48.95±9.32	49.07±9.90	71	0.96[c]
CPB[k] pump (%)	On-pump	56 (74.70)	18 (24.30)	74	1.00[l]
	Off-pump	19 (76.00)	6 (24.00)	25	

[a] IQR=interquartile range, [b] Mann-Whitney U Test, [c] Independent-sample t-test, [d] SD=standard deviation, [e] IECQ=Intensive Care Experience Questionnaire, [f] DASS=Depression Anxiety Stress Scales, [g] PCL-S=Posttraumatic Stress Disorder Checklist for Specific Event, [h] SF-36=Form-36 Health Survey-Version 2, [i] PCS=physical component summary, [j] MCS=mental component summary, [k] CPB=cardiopulmonary bypass, [l] Chi-square test

3.8 Factors related to patients' sleep quality at six months

Patients' sleep quality at six months was assessed using the PSQI and the cut off score was five; higher scores indicate poor sleep quality. Bivariate comparisons between factors related to patients' sleep quality and total PSQI at six months are displayed in Table 13. There was a statistically significant difference for gender at six months; more men than women reported good quality sleep (p=0.02). Almost eighty-nine percent (n=16) of female patients reported poor quality sleep at six months. Patients who reported poor sleep quality at six months reported higher median ISI (higher scores indicate more severe insomnia) total score (p=0.02). These patients also had higher median scores for the DASS-21 subscales (stress, anxiety and depression), total PCL-S score and total PSQI at two months (p<0.01): more stress, anxiety, depression and symptoms of PTSD, and poorer sleep at two months. Moreover, patients who reported good sleep quality at six months had a higher ICEQ component 'better awareness of surroundings' median score (p=0.03). They also reported higher physical component summary (PCS) and mental component summary (MCS) mean scores for the SF-36 (p<0.0005). This indicates that better physical and mental functioning relate to higher sleep quality at six months.

Factors found in bivariate comparisons to be related (p<0.05) to sleep quality were used as independent variables in multiple variables analyses with PSQI scores at six months as the dependent variable (Table 14). The specific model, which includes on or off-CPB pump surgery, prehospital symptoms of insomnia, physical and mental HRQOL at six months (higher scores indicate better functioning), was significant (p<0.01) and explained 55% of the variance in the PSQI scores at six months (R=0.547). The on and off-pump surgical techniques were included in the analysis for theoretical reasons, because it has been proposed that it makes a difference to early post-op recovery. Poorer sleep quality at six months was independently associated with greater prehospital symptoms of insomnia and lower physical and mental HRQOL at six months, but not with on-pump surgery using cardiopulmonary bypass.

Table 13. Factors related to patient's sleep quality at six months (bivariate comparisons)

		PSQI total>5-poor sleep quality	**PSQI total≤5-good sleep quality**	**N**	***P***
Gender (%)	Female	16(88.90)	2(11.10)	18	0.02 [a]
	Male	28(52.80)	25(47.20)	53	
Age, years	Mean±SD[b]	65.95±9.97	66.44±10.81	71	0.85[c]
BMI[d],kg/M²	Mean±SD	27.81±4.89	27.68±3.57	71	0.91[c]
CPB[e] pump (%)	On-pump	34(63.00)	20(37.00)	54	0.98[a]
	Off-pump	10(58.80)	7(41.20)	17	
ISI[f] total score	Median	6.00	2.00	71	0.02[h]
	IQR[g]	2.25-14.75	0.00-9.00		
SICQ[i] Q1 in ICU home sleep	Median	7.00	8.00	71	0.11[h]
	IQR	5.00-8.00	6.00-10.00		
SICQ Q2 ICU sleep quality	Median	4.00	5.00	68	0.67[h]
	IQR	2.00-6.00	2.00-7.00		
RCSQ[j], ICU total, mm	Median	39.30	36.80	71	0.89[h]
	IQR	20.90-39.30	15.00-74.20		
RCSQ, ward total, mm	Mean±SD	53.84±25.03	55.28±22.91	68	0.82[c]
ICEQ[k] Awareness of surroundings	Median	37.00	40.00	68	0.03[h]
	IQR	33.00-39.00	36.00-42.00		
ICEQ Frightening experiences	Mean±SD	12.39±4.53	11.52±3.82	68	0.03[h]
ICEQ Recall of experiences	Mean±SD	16.93±4.20	18.11±4.35	68	0.27[c]
ICEQ Satisfaction with care	Mean±SD	14.78±3.72	14.93±3.39	68	0.87[c]
DASS-21-[l]Depression	Median	10.00	2.00	71	<0.0005[h]
	IQR	2.00-18.00	0.00-8.00		
DASS-21-Anxiety	Median	7.00	2.00	71	<0.0005[h]
	IQR	4.00-12.00	0.00-2.00		
DASS-21-Stress	Median	10.00	2.00	71	<0.0005[h]
	IQR	4.00-18.00	0.00-6.00		

		PSQI total>5-poor sleep quality	PSQI total≤5-good sleep quality	N	*P*
PCL-S[m] total	Median	26.50	21.00	71	<0.0005[h]
	IQR	21.00-35.75	17.00-24.00		
Total PSQI[n]-two months	Median	10.00	4.00	68	<0.0005[h]
	IQR	7.00-12.00	3.00-6.00		
SF-36[o] PCS[p]	Mean±SD	40.40±9.03	49.94±10.09	71	<0.0005[c]
SF-36 MCS[q]	Mean±SD	45.66±9.76	54.40±5.63	71	<0.0005[c]

[a] Chi-square test, [b] SD=standard deviation, [c] Independent-sample t-test, [d] BMI=body mass index, [e] CPB=cardiopulmonary bypass, [f] ISI=Insomnia severity index, [g] IQR=interquartile range, [h] Mann-Whitney U Test, [i] SICQ=Sleep in the Intensive Care Unit Questionnaire, [j] RCSQ=Richards-Campbell Sleep Questionnaire, [k] ICEQ=Intensive care Experience Questionnaire, [l] DASS=Depression Anxiety Stress Scale, [m] PCL-S=Posttraumatic Stress Disorder Checklist for Specific Event, [n] PSQI=Pittsburgh Sleep Quality Index, [o] SF-36=Medical Outcomes Study Short Form-36 Health Survey-Version 2, [p] PCS=physical component summary, [q] MCS=mental component summary

Table 14. Independent associations with sleep quality[a] six months after discharge from hospital

	N	B	Std. Error of B	Beta[b]	P	95% Confidence Interval for B
On-or off-pump	71	1.314	0.917	0.123	0.156	-0.516–3.144
ISI[c] total score	71	0.148	0.050	0.244	0.004	0.048–0.247
SF-36 PCS[d]	71	-0.188	0.038	-0.424	<0.0005	-0.265– -0.111
Sf-36 MCS[e]	71	-0.230	0.042	-0.466	<0.0005	-0.314– -0.146

Adjusted R square=0.547, [a] Dependent variable=total PSQI at six months, [b] Standardised coefficient, [c] ISI=insomnia severity index, [d] PCS=physical component summary, [d] MCS=mental component summary

Table 15. Sleep quality, the experience of treatment in the ICU and psychological outcomes during recovery for patients who had on-pump and off-pump open-heart surgery

		On-pump	Off-pump	N	P
RCSQ[a] ,ICU total, mm	Median	41.40	36.80	99	0.99[b]
	IQR[c]	18.20-69.20	21.30-65.90		
RCSQ, ward total, mm	Mean±SD[d]	51.64±24.29	51.44±28.81	95	0.97[e]
IECQ[f] Awareness of surroundings	Median	37.00	38.00	78	0.86 [b]
	IQR	33.00-41.00	32.00-41.00		
IECQ Frightening experiences	Mean±SD	12.22±5.02	12.11±3.86	78	0.93[e]
IECQ Recall of experiences	Mean±SD	16.68±4.64	18.00±3.87	78	0.27[e]
IECQ Satisfaction with care	Mean±SD	14.75±3.57	14.53±3.41	78	0.81[e]
DASS[g]-21-Depression	Median	6.00	0.00	71	0.04[b]
	IQR	2.00-15.00	0.00-13.00		
DASS-21-Anxiety	Median	6.00	2.00	71	0.43[b]
	IQR	2.00-8.50	0.00-11.00		
DASS-21-Stress	Median	8.00	4.00	71	0.07[b]
	IQR	2.00-14.00	0.00-8.00		
PCL-S[h] total	Median	24.00	19.00	71	0.02[b]
	IQR	21.00-32.00	17.00-26.00		
SF-36[i] PCS[j]	Mean±SD	42.23±10.79	49.61±7.14	71	0.01[e]
SF-36 MCS[k]	Mean±SD	47.79±9.18	52.78±9.38	71	0.06[e]

[a] RCSQ= Richards-Campbell Sleep Questionnaire, [b] Mann-Whitney U Test, [c] IQR=interquartile range, [d] SD=standard deviation, [e] Independent-sample t-test, [f] ICEQ=Intensive care Experience Questionnaire, [g] DASS=Depression Anxiety Stress Scales, [h] PCL-S=Posttraumatic Stress Disorder Checklist for Specific Event, [I] SF-36=Form-36 Health Survey-Version 2, [j] PCS=physical component summary, [k] MCS=mental component summary

3.9 Comparison of sleep quality, the experience of treatment in the ICU and psychological outcomes during recovery for patients who had on-pump and off-pump open-heart surgery.

Sleep quality, experience of treatment in the ICU, psychological and quality of life outcomes for patients who had on-pump and off-pump open-heart surgery are presented in Table 15. There were statistically significant differences in DASS depression scale scores (p=0.04), PCL-S score (p=0.02) and the SF-36 physical component summary score (p=0.01) between patients who had on-pump open-heart surgery and those who had off-pump open-heart surgery. According to the results in Table 15, the on-pump patients reported a higher median DASS depression score (6.00) (more depression symptoms) than the median (0.00) for off-pump patients. Furthermore, the median PCL-S score was also higher (more PTSD symptoms). On the other hand, patients who had off-pump surgery reported a higher (better) mean physical SF-36 component summary score.

3.10 Summary of main findings

The majority of participants were male and the mean age was 66.60 years. The mean BMI was 27.30kg/M^2. Most of the patients were calm and cooperative at the time of enrolment. The median pain intensity score was two (IQR: 0.00-4.00) and the median duration of mechanical ventilation was one day (IQR: 0.50-1.00). The median ICU stay was two days (IQR: 2.00-4.00) and hospital length of stay was 12 days (IQR: 8.50-15.00).

Self-reported mean quality of sleep (RCSQ) when patients were in the ICU, was 42.76±29.10 mm and 51.84±25.23 mm while in the hospital ward. Mean sleep quality (PSQI) at two months was 8.18±4.23 and 7.92±4.64 at six months after hospital discharge. The percentage of patients with poor sleep quality decreased over time from the ICU, hospital ward, and two and six months after hospital discharge. Moreover, the results indicated that approximately one-sixth of patients (16%) who experienced poor sleep in the ICU continued to experience poor sleep during recovery. There were no statistically significant differences in the experience of treatment in the ICU and psychological outcomes between patients who reported poor and good sleep quality while in the ICU. There was no association between CPB pump status during open-heart surgery and sleep quality in the cardiothoracic ICU. More female than male patients reported poor quality of sleep at six months after hospital discharge. Some patients who experienced poorer sleep at six months after hospital discharge reported higher ISI total scores prehospitalisation. Moreover, patients in the poorer sleep group at six months reported higher stress, anxiety, depression and PTSD symptoms during

recovery. Many patients who reported poor sleep at six months also reported higher PSQI total scores (worse sleep) at two months after hospital discharge. Conversely, patients who reported good sleep at six months after hospital discharge were likely to report higher awareness of their surroundings while they were in the ICU and higher quality of life at six months, as reflected in both the physical and mental component summary scores.

Factors associated with sleep quality including on-or off-CPB pump surgery, prehospital symptoms of insomnia, and physical and mental HRQOL explained 55 per cent of the variance in the PSQI score (self-reported sleep quality) at six months. Of these four variables, having on-or off-pump open-heart surgery was not independently associated with sleep quality at six months. Mental HRQOL at six months made the highest independent contribution, followed by physical HRQOL and prehospital symptoms of insomnia, respectively.

The patients who had on-pump surgery reported higher DASS depression scale scores during recovery. Those who had off-pump surgery reported better quality of life at six months after hospital discharge (that is higher scores for the SF-36 physical and mental component scores). Patients who had on-pump surgery reported higher PTSD symptoms than those who had off-pump surgery ($p=0.02$).

4 Discussion and conclusion

4.1 Introduction

The current study was an observational study of patients' sleep in the cardiothoracic ICU, in the hospital ward and their sleep and psychological health at two and six months after hospital discharge. The study was a sub-study focusing on the cardiothoracic ICU patients while the previously conducted main study had the same research process and approval from HREC; however, it also included the general ICU setting. Potential participants were identified and invited to participate in the study while in ICU. Willing participants completed self-report questionnaires in ICU, the hospital ward and at two and six months after discharge. The response rates were satisfactory, 95%, 76% and 70% on the ward, and two and six months respectively. The study findings provide an understanding of patients' sleep in ICU, the hospital ward, and at two and six months after discharge. Their ICU treatment experience and psychological wellbeing during recovery are also described. Furthermore, the differences in clinical, psychological and HRQOL outcomes in OPCAB and ONCAB patients were investigated. In this chapter, a summary of the major findings of the study are summarized and discussed in relation to previous published research reports. The strengths and limitations of this study are acknowledged. Recommendations for clinical practice and future research are outlined. The Conclusion from study completes the chapter and the thesis.

4.2 Summary of the outcomes of the literature review

In this thesis, ICU patients' sleep, psychological wellbeing and quality of life literature were reviewed. It was found that ICU patients experience sleep disruption and poor sleep quality during and after ICU treatment. However, it was unclear whether patients who experience sleep disruption in ICU continue to experience the problem in the hospital ward and at home during recovery. Psychological distress and diminished HRQOL were experienced among ICU survivors. The review of cardiothoracic ICU literature on patients' sleep showed similar results, except that these patient experiences included the worst reports of sleep quality predominantly during the immediate post-operative period. The clinical, psychological and HRQOL outcomes in OPCAB and ONCAB surgery patients were also reviewed. It was concluded that short-term clinical outcomes were better in patients who had OPCAB surgery, but long-term outcomes were better for patients who had ONCAB surgery. Although sleep disruption and psychological distress were found in cardiothoracic ICU patients, there was a scarcity of studies that compared patients who underwent OPCAB or OPCAB surgery for these

outcomes. Long-term HRQOL in both patients groups was comparable. There was also a paucity of studies examining patients' sleep, psychological wellbeing and HRQOL. The broad aim of the current study was addressed to determine the association between sleep disruption of patients in the cardiothoracic ICU and during recovery, and their psychological wellbeing during recovery.

The following specific aims were addressed in the research:

- Assessment of self-reported patients' sleep quality in the ICU, on the hospital ward and at home two and six months after hospital discharge.
- Determination of whether patients who experience sleep disruption in the ICU, continue to experience poor sleep quality while recovering after ICU discharge.
- Determination of the relationship between patients' sleep disruption and their psychological wellbeing during recovery.
- Determination of the differences in sleep quality and psychological wellbeing between patients who have 'on-pump' and 'off-pump' open heart surgery.

4.3 Summary of major findings

Quality of sleep in ICU

The study showed that the majority of participants were male and the mean age was 66.60 years. The mean BMI was 27.30 kg/M². Most patients were calm and cooperative at the time of enrolment. The median pain intensity score was two and the median duration of mechanical ventilation was one day. The median ICU stay was two days and hospital length of stay was 12 days. The sample characteristics suggested the participants were overweight (World Health Organisation 2006), and had a short duration of mechanical ventilation and treatment in ICU. Patients were screened after they spent two or more nights in ICU, were declared appropriate for ward transfer and had the cognitive capacity to understand the implications of agreeing to participate and provide informed consent, and complete the study instruments.

This study showed that cardiothoracic ICU patients' self-reported mean sleep quality (RCSQ) in ICU was 42.76/100 mm and 51.84/100 mm while in the hospital ward. This indicated poor sleep quality using the cut point of 70 mm on the RCSQ. The finding was lower compared to a previous published study using the RCSQ. The study was conducted in the same hospital but included ICU patients who had other diagnoses as well as those who had undergone cardiothoracic surgery (n=222) (McKinley et al. 2013). The mean RCSQ total score in ICU was

47.20 mm and 54.30 while in the ward. In another study at this study site but with different patients, the median total RCSQ score was reported at 57.50 mm (Elliott et al. 2013). In a study utilising RCSQ and the agreement of nurse and patient sleep assessment, the mean total RCSQ score reported by patients was 51.42 mm (Nicolas et al. 2008). The average RCSQ score in ICU in this study was also lower than those reported in other recent international studies of 54.5 mm (Kamdar et al. 2013; Li et al. 2011). Furthermore, sleep quality in ICU measured using question two in the SICQ was 4.41/10 (mean) which is similar to the value reported when the SICQ was developed (Freedman, Kotzer & Schwab 1999). Another study (Elliott et al. 2013) reported the mean sleep quality rating in the ICU on the SICQ at 4.51, while Garbor et al. (2003) reported 5.50. It appeared that the quality of cardiothoracic ICU patients' sleep while in ICU (RCSQ and SICQ) was poor and similar to reports in the international health care literature. The findings of this study were comparable to the findings of a previous study on patterns of sleep pattern disturbance after cardiac surgery (Nicolas et al. 2008; Redeker, Ruggiero & Hedges 2004a), which demonstrate that cardiac surgery patients have poor sleep quality during the early post-operative period while in ICU.

The lower mean RCSQ total score in this study, in contrast to some others, might be the result of significant changes in sedation regimens over the past few years. Typical clinical practice formerly included heavily sedating patients while they were treated in ICU. However more recently lighter levels of sedation are used more frequently together with non-pharmacological interventions to reduce anxiety and agitation (Hager et al. 2013; Tingsvik et al. 2013). Sedation regimens have changed from continuous infusion to maintaining target sedation levels agreed by the clinical team. Additionally, daily interruption of sedation to avoid the accumulation of sedative medications may also have changed the ICU patients' experience. Although these changes in practice were aimed at sedation levels they may have contributed to greater wakefulness (Hager et al. 2013) and thereby the lower RCSQ total score observed in this study, compared to the results in previous studies.

There are many potential consequences of sleep disturbance in the ICU and they are far reaching. For example, chronic sleep deprivation is associated with increased cardiovascular morbidity and mortality (Hoevenaar-Blom et al. 2011). The cohort study conducted in Germany on men and women without cardiovascular disease history revealed that the relative risk of cardiovascular disease and coronary artery disease was more than 60% higher among individuals who slept less than six hours, especially those with poor sleep quality. Treating hypertension is necessary to reduce cardiovascular risk (World Health Organization (WHO) 2013). Apart from medication and changing life style, parasympathetic

activity, which is highest at night and contributes to lowering blood pressure, is important in blood pressure control (Smolensky et al. 2007). Given that cardiac ICU patients are experiencing poor nighttime sleep quality, they may not benefit from the positive effects of blood pressure control from increased parasympathetic activity. Despite this evidence, it is not established that poor sleep quality in ICU contributes to cardiovascular mortality.

Quality of sleep at home

Patients' self-reported quality of sleep at home after discharge using the PSQI (Buysse et al. 1989) demonstrated that there were significant signs in the sample of poor sleep at two and six months after discharge from hospital. The suggested cut off score for poor quality sleep is a global score of five (Buysse et al. 1989). Approximately 69% percent of the sample reported poor quality sleep at two months and 62% at six months after discharge. The mean global scores at two months were 8.18 and at six months 7.92. In previous published studies (same hospital but a mixture of types of ICU patients), one study reported a mean PSQI global score of 7.71 two months after hospital discharge (Elliott et al. 2013), while another study reported 7.90 at two months and 7.40 at six months after discharge (McKinley et al. 2013). In a study using PSG, it appeared that CABG surgery patients' sleep improved and returned to almost preoperative values one month after surgery (Edell-Gustafsson, Hetta & Aren 1999). The results from the same study using the Nottingham Health Profile (NHP) found a contrasting result with self-report sleep scores becoming worse at one month. However, the sleep score on the NHP significantly improved at six months after discharge. In another study, women (44%) and men (25%) reported sleep disturbance at three months after discharge from ICU but this improved by six months to 28% of women and 18% of men (Eddleston, White & Guthrie 2000). In view of previous evidence suggesting temporary sleep disturbance in the majority of former ICU patients, the results of the current study showed that many cardiothoracic ICU patients' poor sleep quality persisted at two and six months after discharge. The potential reasons may be ongoing health problems, stress, depression, anxiety, PTSD or the lack of support. Further harm could eventuate for these patients. For example a systemic review including 474,684 participants showed that chronic sleep deprivation may have contributed to a higher risk of developing and dying from coronary artery disease (Cappuccio et al. 2011). Thus former cardiothoracic ICU patients who continued to have poor sleep while at home may be at risk of having further cardiovascular events, one of many potential consequences of sleep disturbance.

In this study, retrospective reports of sleep at home prior to the hospitalisation were also explored to identify any pre-existing sleep problems. Almost 20% of the sample reported moderate to severe clinical insomnia using the ISI, 68% of the sample reported poor sleep after hospital at two months and 62% at six months. This finding was similar the results reported by McKinley et al (2013). The prevalence of insomnia in the community ranged from 10 to20% and insomnia was found to be associated with depression (Buysse 2013). In the current study, the prehospital ISI scores were different between patients with poor and good sleep at six months after hospital. The median ISI score was six, in the patients who had poor sleep, and two in patients who hadgood sleep at six months after hospital discharge (p=0.02). An independent association between ISI score and sleep quality at six months was found to be statistically significant. This finding concurs with those of McKinley et al. (2013); prehospital sleep quality should be included in sleep assessment conducted in ICU. The predictive ability of sleep before hospital admission relative to sleep quality at home at six months suggested that the evaluation of sleep quality prior to hospitalisation may assist in identifying and treating patients who are at highest risk of poor sleep quality after hospitalisation.

Quality of sleep over time

More than half of the sample reported poor sleep in ICU and on the ward. More than two-thirds of the sample reported poor sleep (PSQI) at two months and over 60% at six months after hospital. Half of the sample reported poor sleep at both post-hospital time points. Poor sleep was reported by 12% of the sample at all time points: in ICU, on the hospital ward, and at two and six months after hospitalisation. In comparison to the only previous published study that reported this result (McKinley et al. 2013), the percentage of patients with poor sleep quality in the current study were similar but slightly higher. McKinley et al. (2013) reported these data for general, cardiothoracic and neurological ICU patients (n=222) in the same hospital. The average overall quality of sleep was seven out of 10 at home, and almost 70% reported poor sleep quality in ICU, 68% in ward, and 52% in both ICU and ward (McKinley et al. 2013). More than 60% of patients reported poor sleep at two months and 57% at six months after hospital discharge, with 40% reporting poor sleep at both post-hospital time points (McKinley et al. 2013). In addition, only 10% of patients reported poor sleep at all time points. The results from the current and previous published (McKinley et al. 2013) studies, suggested that 10-12% of patients experienced poor sleep quality during ICU admission and recovery. Looking at the retrospective report of prehospital

sleep quality, both studies revealed that 7% of patients had poor sleep before, during and after hospital. In summary, some patients who had poor sleep quality in ICU continued to have poor sleep quality at home, while a small number of patients had pre-existing poor quality sleep and continued to have poor sleep through the course of hospitalisation and recovery. Therefore it is worthwhile assessing patients for sleep disturbance or insomnia prior to hospitalisation in critical care sleep research to identify patients at risk of poor sleep. Treating these patients' sleep conditions may reduce the prevalence of sleep disturbances during and after hospitalisation.

Intensive care experience

The patients' perception of treatment in ICU was assessed at two months after hospital using the ICEQ (Rattray, Johnston & Wildsmith 2004). The mean score of each domain was similar to those in published in the previous study (McKinley et al. 2013). In comparison to two reports from the developer, the mean score in the current study was better for awareness of surroundings (35.00), frightening experiences (12.20) and recall of experience (17.20), and similar for satisfaction with care. The mean score for each domain in the report of the developer in 2004 and 2010 was 23.20 and 30.20 for awareness of surroundings, 20.40 and 15.70 for frightening experiences, 13.20 and 14.20 for recall of experiences, and 51.10 and 15.40 for satisfaction with care (Rattray et al. 2010; Rattray, Johnston & Wildsmith 2004). The questionnaire was completed just prior to ICU discharge in the developer's studies, while it was completed at two months after discharge in the current study. Also differences in practice, such as sedation and ventilation regimens, routine of care and treatment, and patient's severity illness between countries (Australia and United Kingdom) may partly explain the differences in results. Moreover, during the preadmission clinic appointment and the orientation to the unit on the day before surgery, the cardiothoracic ICU patients in the current study may have been better informed and prepared for the expected treatment and possible events, resulting in better perception of experiences. Poor sleep at six months after hospital was associated with a lower mean score for awareness of surroundings and higher mean score for frightening experiences in this study. Thus sleep quality at six months may be influenced by the patients' level of awareness and frightening experiences during ICU treatment. Preparation of patients during preadmission or prior to surgery, informing patients of the treatment they are receiving each time and

reassuring them and their family may help to increase awareness, reduce frightening experiences during ICU treatment and be associated with better sleep quality at home after hospital discharge.

Psychological health

Psychological health during recovery at six months was assessed using DASS-21 and PCL-S. The DASS-21 was administered to assess patients' psychological distress during recovery (Lovibond & Lovibond 1995). The mean scores on the depression, anxiety and stress scales in this study were similar to those in a non-clinical sample (Henry & Crawford 2005), but a little lower than those in former ICU patients in the main study (general, cardiothoracic and neurological ICUs) (McKinley et al. 2013). The posttraumatic stress symptoms were assessed using the PCL-S. The mean PCL-S score in the study was lower than the cut point suggested for the PCL instrument (Blanchard et al. 1996), but similar to those in main study (McKinley et al. 2013). Psychological distress and PTSD are commonly reported by former ICU patients (Chahraoui et al. 2015; Davydow, Desai, et al. 2008; Davydow et al. 2009; Davydow, Gifford, et al. 2008; Griffiths et al. 2007; Rattray et al. 2010). A contemporary and practical review of CABG patients experiences also showed that between 30% and 40% of these patients are affected by depression (Tully & Baker 2012). The review also suggested that CABG patients have a higher prevalence of depression than community samples. However, the similarity in the mean depression, anxiety and stress scales of DASS-21, between this study sample and the norms, may reflect the upturn in mood associated with improvement in physical condition from revascularisation (McKhann et al. 1997). Also, the study sample was admitted to ICU for a short time after surgery and discharge from hospital was seen as a sign of clinical improvement which may allow patients more independence and satisfaction. However, some patients may develop new depressive symptoms over the course of recovery (Peterson et al. 2002). Higher mean scores of depression, anxiety, stress and PTSD symptoms were also associated with poor sleep quality at six month in bivariate analysis of this study, which was consistent with the report of the previous published main study (McKinley et al. 2013). This may indicate that if patients' sleep quality is improved during recovery, their psychological health may also improve.

Health related quality of life

The finding for physical and mental component summary scores was similar to previous studies in former ICU patients (Cuthbertson et al. 2009; Elliott et al. 2011; McKinley et al. 2013). Lower mean scores in both PCS and MCS were found to be associated with poor sleep quality at six months after discharge in the current study, which concurred with the findings of the main study (McKinley et al. (2013). Further exploration using multivariate analysis showed an independent association between PCS and MCS and sleep quality at six months after hospital; another finding of the main study(McKinley et al. 2013). These results were comparable with another study which showed that post-ICU insomnia (12 months) was independently associated with worse mental HRQOL and physical function (Parsons et al. 2015). Furthermore, greater sleep complaints prior to CABG surgery were found to be associated with greater physical symptoms, poorer physical HRQOL and greater sensory pain after surgery (Poole et al. 2014). These findings confirm outcomes in the current study, prehospital sleep quality may predict sleep quality during and after hospitalisation and may be related to the psychological health and HRQOL in CABG patients during recovery.

Surgical techniques

There was no difference found in patients' subjective quality of sleep in ICU between patients having on-pump and off-pump CABG surgery, which confirmed the findings of a previous study (Hedges & Redeker 2008). Hedges and Redeker (2008) found that the use of off-pump CABG surgery may improve objective sleep continuity during the early postoperative period. In multivariate analysis, the specific model specified in the current study, which included on or off-CPB pump surgery, prehospital symptoms of insomnia, physical and mental HRQOL at six months, was statistically significant and explained 55% of the variance in the PSQI score at six months. However, the use of CPB was not independently associated with sleep quality at six months after discharge. This finding was the opposite to the researcher's postulation that OPCAB patients might recovery differently. There was no difference between ONCAB and OPCAB patients with regards to long-term sleep. The difference in group sizes (ONCAB, n=75 and OPCAB, n=25) in a fairly small sample may have resulted in statistical error. Another possible explanation is that the physical effects from both surgical techniques may be equalised by the time the patients were followed up. The results might be more generalisable if the groups were larger and equal.

4.4 Strengths and limitations of the study

The strengths of this study which warrant consideration include the design, instruments and sample. This is a repeated measures study design in which data were collected at different time points. The design allowed longitudinal analysis and the ability to monitor how patients changed over time. Using instruments that are valid and reliable to measure outcomes and variables of interest is a crucial component of research quality. Key indicators of the quality of a measuring instrument are the reliability and validity of the measures. The instruments used in this study were validated and shown to be reliable in previous studies. The sample in this study was selected from a cardiothoracic ICU population. The sample size was satisfactory (n=101) and the cognitive capacity at the time patients were approached was optimal. The patients were approached in ICU after they had been cleared for transfer to the ward and their cognitive capacity was assessed prior to providing the study information.

There are some limitations to this study that include the potential for reporting bias from self-report questionnaires and patient retention in the study. The completion of questionnaires during hospitalisation may have been affected by the activity, care and treatments the patients were receiving. The timing was optimised by the accommodations made by the researchers of the patients' needs and nurses' workload. However, at times patients stated that they were fatigued and displayed signs of decreased levels of concentration but nevertheless willingly completed the questionnaires. As a result, the questionnaire may not have always been thoroughly read and understood by patients. This may affect the reliability of the results. Patients' response rates varied for each questionnaire and was particularly low for some, for example the ICEQ. Some patients said (or may have perceived) that some ICEQ items were too sensitive at the time and brought back bad memories of the ICU experience. In addition some patients found the wording of the ICEQ too difficult to understand or answer. These factors could have frustrated patients and lead to incomplete responses. In some questionnaires, for example the IECQ, domain scores cannot be calculated if there are unanswered items. The response rate was optimised by offering and providing clarification and emphasizing the importance of completing all questions in each questionnaire. A telephone call to follow up after the questionnaires were mailed to the patients was made. Reasons for not wishing to continue participating in the study were fatigue, readmission to hospital, deterioration in health and too many other commitments after return to work.

Other potential limitations to this study include recruitment site, number of times data were collected at each time point and the unequal group sizes for the subgroups. Recruiting from a single site study may result in the recruitment of patients with specific clinical and demographic characteristics which are not generalisable to other metropolitan hospitals. In addition, the measurement of sleep once at each time point may have been influenced by other temporary intrinsic (such as urinary retention) and extrinsic (such as sharing a room with a confused patient) Factors. Sequenced data collection at each time point may have provided a better idea of average sleep quality. The group size between ONCAB and OPCAB patients was unequal which could have resulted in statistical error. Prevention of this could have been attempted by extending the recruitment period to preferentially recruit equal numbers of OPCAB patients; however, based on the time limitation to complete the master of nursing by research program, this was not possible.

4.5 Recommendations for clinical practice

The findings of the current study may be used to contribute to the understanding of patients' sleep in intensive care unit (ICU) and during recovery. The knowledge of sleep problems and its continuity may contribute to the development of care, treatment and rehabilitation for patients to enhance better sleep during and after hospitalisation. For example, implementation of sleep promotion in ICU through multifaceted interventions focused on multifactorial minimisation of nighttime sleep disruptions and maintenance of sleep-wake cycles. Music therapy and pharmacological measures such as the administration of exogenous melatonin may help to promote sleep in the ICU. Patients may benefit from rehabilitation programs that include screening and focusing on sleep quality to optimise the overall quality of life outcomes. Referral for further investigation by sleep experts may also be indicated if posthospital sleep problems persist.

Importantly a small number of patients, who first experienced poor sleep quality in ICU, continued to experience poor sleep in the ward and during recovery at home. A small proportion of patients with moderate to severe insomnia prehospitalisation, continued to have poor sleep quality in ICU, on the ward and at home. These problems require attention and further investigations in order to improve outcomes. Assessing patients' sleep quality prior to hospitalisation, especially for elective surgery, may help identify and treat those high risk patients. An important finding also indicated that mental and physical health related quality of life (HRQOL) were independently associated with patients' sleep at six months after hospital discharge. To improve HRQOL, patients' sleep may need to be improved first, or vice versa; the

direction of the relationship is not fully understood. During recovery from CABG surgery, improving physical function alone may not be effective, strategies to improve patients' sleep result in greater benefit in terms of HRQOL which is an important surgical outcome.

The results of the current study may also be used to further inform care providers, patients, and their families about patients' potential problems during hospitalisation and during recovery. The care providers may be more conscious and aware of the patients' experiences. The patients may be less stressed knowing the experiences of sleep disruption and psychological distress are common during and after ICU treatment. Moreover, in the event of persisting symptoms of poor sleep and psychological distress during recovery, patients may be more aware and seek help from professionals. The patient's family may be more supportive and seek advice to assist during their recovery. Another important finding that could influence future practice is that low awareness level and high frightening experiences in ICU appear to be related to poor sleep at six months. Many nursing and medical practices during ICU treatment may promote better sleep quality during recovery; for example, utilising sedation scales to guide the administration of sedative medication to achieve individualised target levels, daily interruption of sedation, reorientating and frequently reassuring patients before during and after treatment procedures, providing a clock visible to the patient and patient diaries.

4.6 Recommendations for future research

Several recommendations have emerged from this study that require further investigation. These are related to confirmation and investigation of patients who continue to have poor sleep in ICU and during recovery. Further investigation may reveal factors affecting this, for example gender and age differences, and the medications used in the group who continue to have poor sleep during recovery. Also, prehospitalisation sleep quality assessment should be included in future ICU investigations into the assessment and improvement of patients' sleep. In this study, higher prehospital insomnia scores related to poor sleep quality during recovery. For example, by incorporating baseline sleep before CABG surgery, some high risk patients could be identified. Long-term investigation of the effect of an ICU based sleep promoting intervention should include follow up to identify any differences in sleep quality during recovery.

The impact of medical interventions on patients' HRQOL has been identified as an example of patient-centred outcomes of health status that are clinically meaningful in their own right (Spertus 2008), which leads to the next area of future research recommendations.

Further exploration is needed into the strategies to improve patients' sleep, ICU experiences and psychological health which potentially improve their HRQOL. Those strategies may include implementing sleep promotion protocols in ICU that include interventions such as aromatherapy, medication therapy, appropriate light levels and sound attenuation protocols, as well as minimising procedures, nursing care and treatments at nighttime.

4.7 Conclusion

This thesis reported the results of an observational study of patients who had been treated in a cardiothoracic ICU. The purpose of research was to investigate patients' sleep quality in the ICU, on the hospital ward and at home two and six months after hospital discharge. Patients' ICU experiences, psychological wellbeing and HRQOL were explored. Differences in sleep quality and psychological health between OPCAB and ONCAB were also investigated. Many ICU patients experienced poor sleep quality before, during and after ICU treatments. A small portion of patients who first experienced sleep disruption in the ICU, continue to experience poor sleep quality while recovering after ICU discharge. The findings suggest that poor sleep quality may be identified in some patients prior to CABG surgery. Additionally, patients in ICU, in the hospital ward and after discharge from hospital are at risk of negative consequences related to poor sleep quality.

There is an association between sleep disruption of patients in the cardiothoracic ICU and during recovery, and their psychological wellbeing during recovery. While bivariate analysis results indicated that sleep quality at six months after discharge related to multiple factors, prehospital insomnia, perception of ICU experiences, the state of depression, anxiety and stress, symptoms of PTSD, sleep quality at two months and HRQOL. Specifically in comparison of ONCAB and OFCAB surgery, off-pump open-heat surgery was related to fewer symptoms of depression, fewer symptoms of PTSD, and higher physical component HRQOL summary scores. This could be the result of a shorter operation time, less medication use and less interference to the normal function of the heart required during OPCAB surgery; patients who have OPCAB patients may also have fewer comorbidities and lower risk of poor outcomes after surgery.

In multivariate analysis, after checking assumptions were met, only prehospital symptoms of insomnia, physical and mental HRQOL at six months and surgical technique were included. The specific model explained 55% of the variance in the sleep quality at six months. Poorer sleep quality at six months was independently associated with greater insomnia scores prior to hospitalization and lower HRQOL in both mental and physical components, but no independent association was found with sleep quality and ONCAB versus OPCAB surgery.

In summary, it has been shown in this thesis that the quality of sleep of a substantial proportion of postoperative CABG patients is often poor in ICU, in hospital and up to six months after hospital discharge. This is associated with physical and mental aspects of health-related quality of life six months after discharge, but not with whether surgery was performed on or off cardiopulmonary bypass.

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APPENDIX A: Participant information statement and consent form

UNIVERSITY OF TECHNOLOGY SYDNEY

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

RESEARCH STUDY:

SLEEP DURING AND AFTER CRITICAL ILLNESS AND PSYCHOLOGICAL HEALTH IN RECOVERY

Invitation

You are invited to participate in a research project into the sleep of people who are critically ill and need treatment in an intensive care or high dependency unit (ICU/HDU). The study will investigate patients' sleep while they are in the ICU/HDU, then on the hospital ward after transfer from ICU/HDU and later at home, and the relationship of sleep to psychological recovery after critical care.

The study is being conducted by:

- Sharon McKinley, Professor of Critical Care Nursing, Northern Sydney Central Coast Area Health Service and the University of Technology, Sydney (telephone: 02 9926 8281)
- Kylie Leach, Clinical Nurse Consultant, Northern Beaches Intensive Care Service
- Doug Elliot, Professor of Nursing, University of Technology, Sydney
- Mary Fien, Research Officer, Northern Sydney Central Coast Area Health Service and the University of Technology, Sydney
- Rosalind Elliott, PhD Student, University of Technology, Sydney

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The project is a multicentre collaborative study coordinated by Professor Sharon McKinley.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **'What is the purpose of this study?'**
   The purposes of this study are:
   I. to investigate patients' sleep while they are in ICU or HDU, while they are in the hospital wards after ICU/HDU and after hospital discharge;
   II. to investigate relationships between sleep at each time point and sleep and recovery after 2-6 months.

2. **'Why have I been invited to participate in this study?'**
   You are eligible to participate in this study because you have been in the Intensive Care Unit or High Dependency Unit for at least 2 days.

3. **'What if I don't want to take part in this study, or if I want to withdraw later?'**
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. **'What does this study involve?'**
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. This study will be conducted over 6 months. If you agree to participate in this study, your participation will involve:
    - answering two short questionnaires on your sleep while in ICU/HDU;
    - answering two short questionnaires about your sleep when you have been in the hospital ward for 1-2 nights afterwards. These questionnaires will take approximately 15-30 minutes of your time;
    - you will be contacted 2 months after you are discharged from hospital and asked to complete a questionnaire on your sleep at that time and a questionnaire on your experience as an ICU/HDU patient;
    - you will be contacted again at 6 months after you are discharged from hospital and asked to complete a questionnaire about your sleep and questionnaires about your psychological health during recovery.

    We will post the questionnaires to you for completion at home. You can choose whether to complete them and post them back to us, or whether you would prefer us to go through them with you and take your answers over the phone. These questionnaires will take approximately 30-45 minutes of your time.
    In addition, the researchers would like to have access to your medical record to obtain information about your illness that is relevant to the study.

5. **'How is this study being paid for?'**
The study is being supported by a grant from the Australian College of Critical Care Nurses. All of the money from the grant is deposited in an account managed by the University of Technology, Sydney. No money is paid directly to individual researchers.

6. **'Are there risks to me in taking part in this study?'**
No adverse effects or risks are foreseen as a result of this project.

7. **'What happens if I suffer injury or complications as a result of the study?'**
It is extremely unlikely that you will suffer any injuries or complications as a result of this study. However, if you believe that the study has affected your health in any way you should contact the study investigators as soon as possible, who will assist you in arranging appropriate medical treatment. In addition, you may call the Hospital Research Office (telephone: 02 9926 8106 and quote [HREC project number: 1002-045M]).

8. **'Will I benefit from the study?'**
This study aims to further knowledge and may improve the future care and treatment of patients in the ICU. However, the results obtained from the study may or may not be of direct benefit to your care and management.

9. **'Will taking part in this study cost me anything, and will I be paid?**
Participation in this study will not cost you anything. There is no payment for participating in this study.

10. **'How will my confidentiality be protected?'**
Only those named on Page 1 will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, except as required by law. Only the researchers named above will have access to your details and results that will be held securely at Royal North Shore Hospital.

11. **'What happens with the results?'**
If you give us your permission by signing the consent document, we plan to publish the results in health care journals and at national and international conferences. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

12. **'What happens to my treatment when the study is finished?'**
If your responses to the questionnaires suggest that you may have serious problems with your sleep or that you are not recovering as well as expected, we will contact you to ask how you are feeling. If you wish, we will discuss with you the options for you to consult an appropriate health professional. Other than this, your treatment will be unaffected by involvement in this study.

13. **'What should I do if I want to discuss this study further before I decide?'**
When you have read this information, one of the researchers listed on Page 1 will discuss it with you and answer any questions you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on 9926 8281.

14. **'Who should I contact if I have concerns about the conduct of this study?'**
This study has been approved by the Hawkesbury HREC of Northern Sydney Central Coast Health (NSCCH) and the HREC of University of Technology, Sydney. If you have concerns or complaints about the conduct of this study you should contact the Hospital Research Office (telephone: 02 9926 8106 and quote [HREC project number: 1002-045M]) or the University Ethics Officer (02 9514 9615), who are nominated to receive complaints from research participants.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

UNIVERSITY OF TECHNOLOGY SYDNEY

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH

CONSENT FORM

SLEEP DURING AND AFTER CRITICAL ILLNESS AND PSYCHOLOGICAL HEALTH IN RECOVERY

1. I,.....
of.....
agree to participate as a subject in the study described in the participant information statement ***(attached to this form).***

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the University of Technology, Sydney and the Northern Sydney Central Coast Area Health Service or the health care personnel involved in my care and treatment.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Professor Sharon McKinley on telephone 02 9926 8281, who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to Royal North Shore Hospital Research Office (telephone: 02 9926 8106) or the University Ethics Officer (telephone: 02 9514 9615).

Signature of participant (***or person responsible):***	**Please PRINT name**	**Date** __/__/__
Signature of investigator:	**Please PRINT name**	**Date** __/__/__
Signature of witness (***bedside nurse***)**:**	**Please PRINT name**	**Date** __/__/__

UNIVERSITY OF TECHNOLOGY SYDNEY

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH

REVOCATION OF CONSENT

SLEEP DURING AND AFTER CRITICAL ILLNESS AND PSYCHOLOGICAL HEALTH IN RECOVERY

I hereby wish to **WITHDRAW** my consent to participate in the study named above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the University of Technology, Sydney or the Northern Sydney Central Coast Area Health Service or the health care personnel involved in my care and treatment.

Signature Date

Please PRINT Name

This Revocation of Consent should be forwarded to:

Professor Sharon McKinley
Critical Care Professorial Office
Level 6, Main building
Royal North Shore Hospital
St Leonards
NSW 2065
Australia

APPENDIX B: Patient information and data collection forms

Study ID No.			
	Data entered		
	Date	Form(s)	Initials
	Date	Form(s)	Initials
	Date	Form(s)	Initials

Phone numbers				
Person closest to patient				
G.P.				
Follow-up on the ward				
Follow-up at home				
Other information				
Comments				

Instruments completed

Instrument	Date
Insomnia Severity Index (on enrolment)	
Richards-Campbell Sleep Questionnaire (RCSQ) (ICU)	
Richards-Campbell Sleep Questionnaire (RCSQ) (ward)	
Sleep in Intensive care Questionnaire (SICQ) (ward)	
Pittsburgh Sleep Quality Index (PSQI) (2 months)	
Intensive Care Experience Questionnaire (ICEQ) (2 months)	
Pittsburgh Sleep Quality Index (PSQI) (6 months)	
Post-traumatic Stress Disorder – specific event (PCL-S) (6 months)	
Depression, Anxiety, Stress and Symptoms – short version (DASS-21) (6 months)	
Medical Outcomes Trust Short Form-36 (SF-36)	

Patient details on enrolment and baseline status

DOB		**Age (years)**		**Sex**	M / F
Wgt (kg)		**Height (cms)**		**BMI (wt/ht^2)**	
Patient location on enrolment:					
APACHE III diagnostic code on ICU admission					
APACHE II severity of illness score (1st 24 hours ICU)					
APACHE III severity of illness score (1st 24 hours ICU)					
SOFA score on enrolment					
Type of ventilation on enrolment					

Reason for admission/ ongoing clinical problems	
Past medical history	
Relevant medications on enrolment and pre-admission	

RASS				
Pain intensity				
Pain site(s)				
Anxiety level				
GCS				
SICQ 1st Q: Rate the overall quality of your sleep at home. Use a scale of 1 to 10 (1 is poor, 10 is excellent)				

Details on discharge/death

Hospital length of stay (days)		**Date of hospital admission:** **Date of hospital discharge:**
ICU length of stay (days)		**Date of ICU admission:** **Date of ICU discharge:**
Duration of mechanical ventilation (days)		
Status on ICU discharge	**Dead**	**Alive**
Treatment limitations during ICU stay	**Yes**	**No**

APPENDIX C: Insomnia Severity Index (ISI)

ICU sleep and recovery: Insomnia Severity Index **During enrolment**

Date: __/__/____ **Study ID. _____**

Please take the time to recall the details of your sleep at home and answer the following questions.

1. Please rate the current (i.e last 2 weeks at home) **SEVERITY** of your insomnia problem(s).

	None	Mild	Moderate	Severe	Very Severe
Difficulty falling asleep:	0	1	2	3	4
Difficulty staying asleep:	0	1	2	3	4
Problem waking up too early:	0	1	2	3	4

2. How **SATISFIED**/dissatisfied are you with your current sleep pattern at home?

Very Satisfied				Very Dissatisfied
0	1	2	3	4

3. To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning at home (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc)?

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

4. How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life at home?

Not at all Noticeable	Barely	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

5. How **WORRIED**/distressed are you about your current sleep problem at home?

Not at all	A little	Somewhat	Much	Very Much
0	1	2	3	4

ICU sleep and recovery: Insomnia Severity Index

During enrolment

Date: __/__/____

Study ID. _____

Guidelines for Scoring Insomnia Severity Scale

Add scores for all 7 items (1a + 1b + 1c + 2 + 3 + 4 + 5) = _____

Total score ranges from 0-28

0-7 = no significant insomnia

8-14 = sub-threshold insomnia

15-21 = clinical insomnia (moderate severity)

22-28 = clinical insomnia (severe)

Insomnia severity index (copyright Charles M Morin, 1993)

Then note whether:

- symptoms of insomnia have been present for > 1 month
- frequency of symptoms > 3 times per week
- daytime dysfunction present/reported Yes No
- dissatisfaction with sleep quality reported Yes No

APPENDIX D: Richards-Campbell Sleep Questionnaire (RCSQ)

ICU sleep and recovery: Richards-Campbell Sleep Questionnaire
Date: __/__/____

ICU on enrolment

Study ID. .....

Each of these questions is answered by placing an "X" on the answer line. Place your "X" anywhere on the line that you feel best describes your sleep last night.

1. My sleep last night was:

Deep Sleep — Light Sleep

2. Last night, the first time I got to sleep, I:

Fell asleep immediately — Just never could fall asleep almost

3. Last night, I was:

Awake very little — Awake all night long

4. Last night, when I woke up or was awakened, I:

Got back to sleep immediately — Couldn't get back to sleep

5. I would describe my sleep last night as:

A good night's sleep — A bad night's sleep

Thank you for your assistance.

Critical Care Nursing Professorial Office 02 9926 8281

(version 1, 05/11/2009)

APPENDIX E: Sleep in the Intensive Care Unit Questionnaire (SICQ)

ICU sleep and recovery:
Sleep in the Intensive Care Unit (ICU) Questionnaire
Date: __/__/_____

Ward after night 1

Study ID. .....

Please answer the following questions about your sleep while in the intensive care unit.

1. Rate the overall quality of your sleep at <u>home.</u>
Use a scale of 1 to 10 (1 is poor, 10 is excellent)

1 2 3 4 5 6 7 8 9 10

2. Rate the overall quality of your sleep in the <u>ICU</u>
Use a scale of 1 to 10 (1 is poor, 10 is excellent)

1 2 3 4 5 6 7 8 9 10

3. Rate the overall quality of your sleep in ICU on the following days
(1 is no sleep, 10 is excellent)

- **On the first night in the ICU**
  1 2 3 4 5 6 7 8 9 10
- **During the middle of your ICU stay**
  1 2 3 4 5 6 7 8 9 10
- **At the end of your ICU stay**
  1 2 3 4 5 6 7 8 9 10

4. Rate the overall degree of daytime sleepiness during your ICU stay (1 is unable to stay awake, 10 is fully alert and awake)

1 2 3 4 5 6 7 8 9 10

5. Rate the overall degree of daytime sleepiness during your ICU stay on the following days (1 is unable to stay awake, 10 is fully alert and awake)

- **On first day in the ICU**
  1 2 3 4 5 6 7 8 9 10
- **During the middle of your ICU stay**
  1 2 3 4 5 6 7 8 9 10
- **At the end of your ICU stay**
  1 2 3 4 5 6 7 8 9 10

Please turn page

6. Rate how disruptive the following activities were to your sleep during your ICU stay (Use a scale of 1 to 10, 1 is no disruption, 10 is significant disruption)

- **Noise**
  1 2 3 4 5 6 7 8 9 10
- **Light**
  1 2 3 4 5 6 7 8 9 10
- **Nursing interventions (e.g. baths)**
  1 2 3 4 5 6 7 8 9 10
- **Diagnostic testing (e.g. chest x-rays)**
  1 2 3 4 5 6 7 8 9 10
- **Vital signs (blood pressure, pulse, temperature)**
  1 2 3 4 5 6 7 8 9 10
- **Blood samples**
  1 2 3 4 5 6 7 8 9 10
- **Administration of medications**
  1 2 3 4 5 6 7 8 9 10

7. Rate how disruptive the following noises were to your sleep during your ICU stay (Use a scale of 1 to 10, 1 is no disruption, 10 is significant disruption)

- **Heart rate monitor alarm**
  1 2 3 4 5 6 7 8 9 10
- **Ventilator alarm**
  1 2 3 4 5 6 7 8 9 10
- **Oxygen finger probe**
  1 2 3 4 5 6 7 8 9 10
- **Talking**
  1 2 3 4 5 6 7 8 9 10
- **IV pump alarm**
  1 2 3 4 5 6 7 8 9 10
- **Suctioning**
  1 2 3 4 5 6 7 8 9 10
- **Nebulizer**
  1 2 3 4 5 6 7 8 9 10
- **Doctor's pagers**
  1 2 3 4 5 6 7 8 9 10
- **Television**
  1 2 3 4 5 6 7 8 9 10
- **Telephone**
  1 2 3 4 5 6 7 8 9 10

Thank you for completing this form

APPENDIX F: Pittsburgh Sleep Quality Index (PSQI)

ICU Sleep and recovery - Pittsburgh sleep quality index (PSQI)

Study ID. ..... Date: __/__/____ **At home 2 months post discharge**

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month ONLY. Your answers should indicate the most accurate reply for the *majority of* days and nights in the past month.
Please answer *all* questions.

1. **During the past month, when have you usually gone to bed at night?**
   USUAL BED TIME _____
2. **During the past month, how long (in minutes) has it usually taken you to fall asleep each night?**
   NUMBER OF MINUTES _____
3. **During the past month, when have you usually risen out of bed in the morning?**
   USUAL GETTING UP TIME _____
4. **During the past month, how many hours of *actual sleep* did you get at night? (This may be different to the number of hours you spend in bed)**
   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, mark the one best response. Please answer *all* questions.

5. **During the past month, how often have you had trouble sleeping because you.....**

a) Cannot get to sleep within 30 minutes

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

b) Wake up in the middle of the night or early morning

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

c) Have to get up to use the bathroom

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

d) Cannot breathe comfortably

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

e) Cough or snore loudly

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

f) Feel too cold

Not during the past month		Less than once a week		Once or twice a week		Three or more times a week	

ICU Sleep and recovery - Pittsburgh sleep quality index (PSQI)

Study ID. ..... Date: __/__/_____ **At home 2 months post discharge**

Question 5 continued. During the past month, how often have you had trouble sleeping because you.....

g) Feel too hot

Not during the past month ☐ Less than once a week ☐ Once or twice a week ☐ Three or more times a week ☐

h) Had bad dreams

Not during the past month ☐ Less than once a week ☐ Once or twice a week ☐ Three or more times a week ☐

i) Have pain

Not during the past month ☐ Less than once a week ☐ Once or twice a week ☐ Three or more times a week ☐

j) Other reason(s), please describe

_____

_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month ☐ Less than once a week ☐ Once or twice a week ☐ Three or more times a week ☐

6. **During the past month, how would you rate your sleep quality overall?**

Very good ☐ Fairly good ☐ Fairly bad ☐ Very bad ☐

7. **During the past month, how often have you taken medicine (prescribed or 'over the counter') to help you sleep?**

Not during the past month ☐ Less than once a week ☐ Once or twice a week ☐ Three or more times a week ☐

8. **During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?**

Not during the past month ☐ Less than once a week ☐ Once or twice a week ☐ Three or more times a week ☐

9. **During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?**

No problem at all ☐ Only a very slight problem ☐ Somewhat of a problem ☐ A very big problem ☐

Thank you for completing this questionnaire.

APPENDIX G: Intensive Care Experience Questionnaire (ICEQ)

ICU Sleep and recovery: Intensive care experience (ICE) questionnaire

Study ID. ..... Date: __/__/_____ **At home post discharge**

This questionnaire is designed to find out what you felt and remember about your intensive care experience.

Please tick the box that best describes what you think about each of the statements below:

How much do you agree:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1. Most of my memories are blurred:					
2. I never knew whether it was day or night:					
3. I wish I remembered more about it:					
4. My care could have been better:					
5. I wish I had known more about what was happening to me:					
6. I thought I would die:					
7. It was always too noisy:					
8. I have no recollection of being in intensive care:					
9. I seemed to sleep too much:					
10. I was constantly disturbed:					
11. I thought my care was as good as it could have been:					
12. I was able to let people know what I wanted.					

PLEASE TURN THE PAGE.

ICU Sleep and recovery: Intensive care experience (ICE) questionnaire

Study ID. ..... Date: __/__/_____ **At home post discharge**

Please tick the box that best describes how often these happened:

	All of the time	Most of the time	Some of the time	Rarely	Never
13. I was aware of someone near to me:					
14. I knew what was happening to me:					
15. I felt in control:					
16. I knew where I was:					
17. I remember my relatives being with me:					
18. I saw strange things:					
19. I felt helpless:					
20. I seemed to be in pain:					
21. I felt scared:					
22. I recognised my relatives:					
23. I felt safe:					
24. I seemed to have bad dreams:					

Open questions

What was best about intensive care?

What was worst about intensive care?

Is there anything else you'd like to tell me about intensive care?

Thank you for completing this questionnaire.

APPENDIX H: Depression Anxiety Stress Scales instrument (DASS-21)

ICU Sleep and recovery: DASS-21 questionnaire

Study ID. ..... Date: __/__/_____ **(at home post discharge)**

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all

1 Applied to me to some degree, or some of the time

2 Applied to me to a considerable degree, or a good part of time

3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Critical Care Nursing Professorial Unit 02 9926 8281

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(Version 1, 05/11/09)

Appendix I: Post-traumatic Stress Disorder Checklist for Specific Event (PCL-S)

ICU Sleep and recovery - PTSD checklist (PCL-S)

Study ID. ..... Date: __/__/_____ **At home post discharge**

The event you experienced recently was a severe illness which led to your admission to intensive care. Instructions: Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the past month. Please answer all questions.

		Not at all	A little bit	Moderately	Quite a bit	Extremely
1	Repeated, disturbing *memories, thoughts*, or *images* of the stressful experience?	1	2	3	4	5
2	Repeated, disturbing *dreams* of the stressful experience?	1	2	3	4	5
3	Suddenly *acting* or *feeling* as if the stressful experience *were happening again* (as if you were reliving it)?	1	2	3	4	5
4	Feeling *very upset* when *something reminded you* of the stressful experience?	1	2	3	4	5
5	Having *physical reactions* (e.g., heart pounding, trouble breathing, sweating) when *something reminded you* of the stressful experience?	1	2	3	4	5
6	Avoiding *thinking about* or *talking about* the stressful experience or avoiding *having feelings* related to it?	1	2	3	4	5
7	Avoiding *activities* or *situations* because *they reminded you* of the stressful experience?	1	2	3	4	5
8	Trouble *remembering important parts* of the stressful experience?	1	2	3	4	5
9	*Loss of interest* in activities that you used to enjoy?	1	2	3	4	5
10	Feeling *distant* or *cut off* from other people?	1	2	3	4	5
11	Feeling *emotionally numb* or being unable to have loving feelings for those close to you?	1	2	3	4	5
12	Feeling as if your *future* will somehow be *cut short*?	1	2	3	4	5
13	Trouble *falling* or *staying* asleep?	1	2	3	4	5
14	Feeling *irritable* or having *angry outbursts*?	1	2	3	4	5
15	Having *difficulty concentrating*?	1	2	3	4	5
16	Being *"super-alert"* or watchful or on guard?	1	2	3	4	5
17	Feeling *jumpy* or easily startled?	1	2	3	4	5

Thank you for completing this questionnaire.

Critical Care Nursing Professorial Office 02 9926 8281

Page 1 of 1
(Version 1, 05/11/2009)

Appendix J: The Medical Outcomes Trust Short Form-36 (SF-36)

ICU Sleep and recovery – SF 36

Study ID. ..... Date: __/__/_____ At home post discharge

(SF-36v2 Acute)

Your Health and Well-Being

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one week ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one week ago	Somewhat better now than one week ago	About the same as one week ago	Somewhat worse now than one week ago	Much worse now than one week ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

ICU Sleep and recovery – SF 36

Study ID. ..... Date: __/__/_____ **At home post discharge**

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a kilometre	☐ 1	☐ 2	☐ 3
h Walking several hundred metres	☐ 1	☐ 2	☐ 3
i Walking one hundred metres	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Study ID. ..... Date: __/__/_____ At home post discharge

5. **During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **During the past week, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **How much bodily pain have you had during the past week?**

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

ICU Sleep and recovery – SF 36

Study ID. ..... Date: __/__/_____ **At home post discharge**

9. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

APPENDIX K: Human Research Ethics Committee approval

NORTHERN SYDNEY CENTRAL COAST NSW HEALTH

29 April, 2010

Professor S McKinley
Critical Care Nursing Professorial Unit, Level 6
Royal North Shore Hospital
St Leonards NSW 2065

Dear Professor S McKinley,

Re: **LEAD HREC MULTI-CENTRE APPLICATION APPROVAL**
NSW HEALTH ACCREDITED HREC: HARBOUR/HAWKESBURY
NORTHERN SYDNEY CENTRAL COAST HEALTH (NSCCH)
LOCAL REFERENCE: Protocol 1004-153M(SSA) **- S McKinley, K Leach, D Elliott, M Fien, R Elliot**
Sleep during and after critical illness and psychological health in recovery.
(AU RED Ref. SSA/10/HAWKE/47 & NEAF Ref. HREC/10/HAWKE/11)

Thank you for providing additional information as requested at the meeting on **the 7th April 2010** by the **HAWKESBURY** Human Research Ethics Committee (HREC) of Northern Sydney Central Coast Health (NSCCH). Please be advised that your study has now been approved. The documentation included in the approval is as follows:

- National Ethics Application Form Version 2.0 Lock Code AB/15505/1
- Master Version: Patient Information Sheet and Consent Form Critical Care Nursing Professional Office Version 2 dated 14/04/2010
- Appendix 1, Version 1 Sleep and Recovery Illness

It is noted that the approval covers the following NSW Health sites:

- Royal North Shore Hospital
- Manly Hospital
- Mona Vale Hospital

It is noted that the study has been assessed by the HREC for *ethical* and *scientific review* ONLY and that clearance on the Site Specific aspects of the trial (local sign-off's, legal documentation etc) MUST be obtained from the above listed sites prior to commencement of research. Each site has different requirements. NSW Area Health Service sites require submission and approval of a Site Specific Assessment (SSA), which can be completed at **www.ethicsform.org/au.** Please contact each site for advice on any local requirements.

*If you wish to add an additional site to the project within the area you will be required to complete a *'Site Specific Assessment Form'*, that can be accessed from www.ethicsform.org/au.

The HREC recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purpose of conducting this clinical trial.

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia*, and in line with NSCCH HREC policy, the Chief Investigator is responsible to ensure that:

Research Business Unit
Level 2 Building 51, Royal North Shore Hospital
St Leonards NSW 2065 Ph: (02) 9926 8106 Fax: (02) 9926 6179

NORTHERN SYDNEY
CENTRAL COAST
NSW HEALTH

29 April, 2010

Professor S McKinley
Critical Care Nursing Professorial Unit, Level 6
Royal North Shore Hospital
St Leonards NSW 2065

Dear Professor S McKinley,

Re: **Protocol 1002-045M**(Other) - **S McKinley, K Leach, D Elliott, M Fien, R Elliott**
Sleep during and after critical illness and psychological health in recovery.
(NEAF AURED REF: HREC/10/HAWKE/11)

I can confirm that the **HAWKESBURY** Human Research Ethics Committee is constituted and functions in full compliance with NHMRC Guidelines.

Currently there are nineteen (19) members of this Committee including:

- Laywomen
- Laymen
- 2 Ministers of Religion
- a Lawyer
- 5 Medical Graduates
- a Scientist with research experience
- a Clinical Trials Pharmacist
- an alternate Clinical Trials Pharmacist
- a Neuropsychologist
- a Psychologist
- Registered Nurses

We can confirm that none of the researchers involved in the study are members of the NSCCH HREC.

Yours sincerely,

Mrs Leonne Thompson
Ethics Officer
Hawkesbury Human Research Ethics Committee

Research Business Unit
Level 2 Building 51, Royal North Shore Hospital
St Leonards NSW 2065 Ph: (02) 9926 8106 Fax: (02) 9926 6179

Health
Northern Sydney
Local Health District

Health
Central Coast
Local Health District

14 February 2012

Professor Sharon McKinley
Critical Care Nursing Professorial Unit, Level 6
Royal North Shore Hospital
St Leonards 2065 NSW

Dear Professor McKinley,

Re: NATIONAL ETHICS APPLICATION FORM (NEAF) PROTOCOL- 1002-045M, (Other - CS)
AURED NEAF REF: *HREC/10/HAWKE/11*
STUDY INVESTIGATORS: *Professor Sharon McKinley,*
STUDY TITLE: ***Sleep during and after critical illness and psychological health in recovery.***

Thank you for sending the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC) email correspondence dated 16 January 2012 and 7 February 2012 for the above study.

The original approval letter dated 29 April 2010, for this study listed Critical Care Nursing Professional Office Version 1 (dated 05/11/2009) but did not stipulate the questionnaires listed below.

Please note that the following questionnaires were approved with the original submission:-

- ICU Sleep and Recovery: Richards-Campbell Sleep Questionnaire, Version 1, dated 5 November 2009.
- ICU Sleep and Recovery: Insomnia Severity Index, Version 1, dated 5 November 2009.
- ICU Sleep and Recovery: Sleep in the Intensive Care Unit (ICU) Questionnaire, Version 1, dated 5 November 2009.
- ICU Sleep and Recovery – Pittsburgh sleep quality index (PSQI), Version 1, dated 5 November 2009.
- ICU Sleep and Recovery: Intensive care experience (ICE) questionnaire, Version 1, dated 5 November 2009.
- ICU Sleep and Recovery: DASS-21 Questionnaire, Version 1, dated 5 November 2009.
- ICU Sleep and Recovery – PTSD checklist (PCL-S), Version 1, dated 5 November 2009.
- ICU Sleep and Recovery – SF 36, Version 1, dated 5 November 2009.

Yours sincerely,

Charmaine Israel
Ethics Officer
NSLHD HREC
Research Office
NORTHERN SYDNEY LOCAL HEALTH DISTRICT

Northern Sydney Local Health District
ABN 63 834 171 987

Research Office
Royal North Shore Hospital
Level 2, Building 51
St Leonards NSW 2065
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Health
Northern Sydney
Local Health District

Health
Central Coast
Local Health District

29 February 2012

Professor Sharon McKinley
Critical Care Nursing Professorial Unit, Level 6
Royal North Shore Hospital
St Leonards, 2065, NSW

Dear **Professor McKinley,**

Re: NEAF NOTIFICATION OF CHANGE IN PERSONNEL
PROTOCOL: 1002-045M, (Other - CS)
AURED NEAF REF: *HREC/10/HAWKE/11*
STUDY INVESTIGATORS: *Professor Sharon McKinley,*
STUDY TITLE: *Sleep during and after critical illness and psychological health in recovery.*

Thank you for sending the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC) notification dated **27 February 2012** to advise a change in personnel for the above mentioned research project.

The following Investigators have now been acknowledged as approved research personnel:

- Mr Michael Wood
- Ms Nittaya Caruana

Yours sincerely,

Leonne Thompson
Ethics Coordinator
NSLHD HREC
Research Office
NORTHERN SYDNEY LOCAL HEALTH DISTRICT

Northern Sydney Local Health District
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APPENDIX L: Cover letter to accompany questionnaires completed at home

NSW GOVERNMENT Health
Northern Sydney
Local Health Network

Date 2011

Name Address post code

Dear ,

Re: Sleep and recovery in critical illness study

When you were in the Intensive Care Unit (ICU) at Royal North Shore Hospital about 6 months ago you kindly agreed to participate in a project we are conducting in people such as yourself who have been very ill. People who have been in ICU are at risk of having disturbed sleep. The aim of the study is to assess sleep during and after critical illness and its links to psychological recovery.

You filled in some questionnaires for us about your sleep in the ICU, then again after one or two nights of being in the ward after ICU. You may recall that we informed you that the study also involves completing a final set of questionnaires 6 months after discharge from the Hospital. You are now due to complete the 6-month questionnaires.

Please find enclosed questionnaires which I would be most grateful if you could complete. I have enclosed a prepaid addressed envelope for you to return them when you have completed them. I will telephone you next week to offer clarification on any questions you may have queries about.

If you would prefer that we record your answers to the questions over the phone, we are happy to complete the questionnaires that way.

Thank you again for helping us study this important aspect of recovery. Please do not hesitate to contact me on 02 9926 8281 if you require further information.

Yours sincerely,

Sharon McKinley
Professor of Critical Care Nursing

University of Technology Sydney &
Northern Sydney Local Health Network

Critical Care Nursing Professorial Unit
Northern Sydney Local Health Network
ABN 63 834 171 987
Royal North Shore Hospital St Leonards NSW 2065
Telephone 02 9926 8281 Facsimile 02 9439 8418