Sleep quality and sleep disruptive factors in adult patients in the intensive care unit: Feasibility and acceptability of the daily use of self-report for sleep quality assessment in the ICU in Saudi Arabia

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“Sleep that knits up the ravelled sleeve of care. The death of each day's life, sore labour's bath Balm of hurt minds, great nature's second course, chief nourisher in life's feast” William Shakespeare, Macbeth.

Abstract

Background

Poor sleep quality is common in ICU patients, where various sleep disruptive factors are associated with poor sleep in ICUs. Sleep assessment on a daily basis in ICU patients is challenging yet important to enable nurses to recognise poor sleep and develop appropriate interventions and support to manage this. One such tool recommended in recent literature for undertaking daily sleep assessment is the Richards Campbell Sleep Questionnaire (RCSQ). However, there is little evidence of its feasibility and acceptability in daily use in ICU clinical practice and no evidence of its use in Arab speaking countries. Furthermore, data about patients' sleep quality and sleep disruptive factors in ICUs in Arabic speaking countries, particularly Saudi Arabia is limited.

Aim

The aim of the study reported on in this thesis was to develop and test the psychometric properties, and feasibility and acceptability of daily self-report assessment of sleep quality in an ICU setting in Saudi Arabia using an Arabic version of the RCSQ (the RCSQ-A). The study also aimed to report on sleep quality and sleep disruptive factors among ICU patients in Saudi Arabia.

Design and methods

The study was carried out in Saudi Arabia in a mixed medical and surgical ICU using a two-phase design. The first phase involved two steps: in the first step, the RCSQ was translated into Arabic, while the second step involved testing the internal consistency and reliability of the RCSQ-A in an initial pilot sample of 57 ICU patients. Content validity was also examined in a subsample of 30 ICU patients using a cognitive interviewing method.

The second phase was a prospective observational repeated measures study carried out over a three-month period. In this phase, 120 ICU patients were asked to rate their previous night's sleep quality on a daily basis using RCSQ-A

alongside a self-report of sleep disruptive factors using the modified Sleep in Intensive Care Questionnaire (SICQ) until their discharge from the ICU. Data regarding the feasibility and acceptability of repeated measurement using the RCSQ-A were collected. The correlations between self-reported sleep disruptive factors, patients' demographic and clinical variables, and patients' self-reported sleep quality were assessed.

Results

The Arabic version of the RCSQ (RCSQ-A) showed evidence of content validity and internal consistency with a Cronbach's alpha of 0.89 for self-report sleep quality assessment in an Arabic ICU patients. The RCSQ-A was shown to be feasible and acceptable to the ICU patients for daily self-report sleep assessment with self-completion requires external assistance to complete RCSQ-A. Sleep quality in the participants was generally poor; their sleep patterns were characterised by light sleep with frequent awakenings. Factors disrupting sleep were multiple and highly varied. Nevertheless, noise, talking and fear, were the highest-rated disruptive factors. In the multiple regression analysis , factors which significantly associated with patient sleep [exp(b), p-value] were previously receipt of Midazolam [-6.424, $p<0.0005$] and Propofol sedation [-3.600, $p<0.05$], noise [-1.033, $p<0.05$], daytime sleepiness [0.856 $p<0.05$], the presence of mechanical-ventilation [-1.218, $p<0.05$], and sex differences [1.836, $p<0.05$].

Conclusion

The results from this study highlight that the RCSQ-A is a feasible and acceptable measure for daily routine use for self-report sleep assessment in Saudi ICU clinical practice. Further research would be useful to contribute to the growing body of research addressing its effectiveness in middle eastern populations. The results highlight the importance of routinely inquiring about ICU patients' sleep quality and identifying individual sleep disruptive factors to develop individualised interventions to meet patient needs. This thesis can thus be viewed as a solid foundation for further research, which is required to strengthen, expand on, and confirm the findings contained herein.

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Thesis dedication

This work is dedicated to my son; Rakan who was my companion along my PhD journey. You have made me stronger, better and more fulfilled than I could have ever imagined. You were my inspiration to achieve greatness.

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Author's Declaration

I hereby declare that explicit reference is made to the contribution of other, that this thesis is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institutions.

Printed name: Ghaida Alsulami

Signature:

Publications arising from this work

Alsulami, G., Rice, A. M. & Kidd, L. 2019. Prospective repeated assessment of self-reported sleep quality and sleep disruptive factors in the intensive care unit: acceptability of daily assessment of sleep quality. *BMJ Open,* 9**,** e029957.

Alsulami, G. S., Rice, A. M., Kidd, L., O'Neill, A., Richards, K. C. & McPeake, J. 2019. An Arabic Translation, Reliability, Validity, and Feasibility of the Richards-Campbell Sleep Questionnaire for Sleep Quality Assessment in ICU: Prospective-Repeated Assessments. *J Nurs Meas,* 27**,** E153-e169.

Alsulami, G., Rice, A. M.& Kidd, L. 2019. A prospective repeated assessment of sleep quality and sleep disruptive factors in the intensive care unit: strategies to improve patients' sleep in the ICU in Saudi Arabia. *British Asscoation of Critical Care Nurses (BACCN), Edinbourgh, 16th &17th* September (oral presentation).

Abbreviation

AASM	American Academy of Sleep Medicine
APACHE II	Acute Physiology and Chronic Health Evaluation
BIS	Bispectral Index
CAM-ICU	Confusion Assessment Method for the ICU
CASM	Cognitive Aspects of Survey Methodology
CFA	Confirmatory Factor Analysis
DB	Decibel Scale
EEG	Electroencephalographic
EMG	Electromyogram
EOG	Electrooculogram
GH	Growth Hormone
GCS	Glasgow Coma Scale
ICU	Intensive Care Unit
NOC	Nurse Observation Checklist
NSF	National Sleep Foundations
Non-REM	Non-Rapid Eye Movement
PSG	Polysomnography
REM	Rapid Eye-Movement
RCSQ	Richards Campbell Sleep Questionnaire
RASS	Richmond Agitation Sedation Scale
ROC	Receiver Operating Characteristic
SP	Skin Potential
SCCM	Society of Critical Care Medicine
SEI	Sleep Efficiency Index
SICQ	Sleep in Intensive Care Questionnaire
SAPS-II	Simplified Acute Physiology Score
SMHSQ	St Mary's Hospital sleep questionnaire
SWS	Slow Wave Sleep
TST	Total Sleep Time
VAS	Visual Analogue Scale
VSH	Verran Snyder-Halpern
WHO	World Health Organisation
WASO	Wakefulness After Sleep Onset

Chapter 1 Introduction

This chapter provides a brief overview of the background and significance of the topic of the thesis, highlighting the overall aim, research questions, and purposes of the study. It also describes the phases undertaken to complete this study and presents the overall layout of the thesis.

1.1 Background

Sleep is a basic biological need for humans; it is as essential in its way to survival as water, food, and air. It enables the human body to regenerate itself as well as playing a vital role in cleaning the brain of the toxins that build up during waking hours (Besedovsky et al., 2012, National Sleep Foundation, 2017). It has, however, been reported widely in international research that patients treated in Intensive Care Units (ICUs) suffer from sleep fragmentation (multiple brief arousals throughout the night) and insufficient sleep overall, resulting in them achieving poor quality sleep (Aitken et al., 2017, Jeffs and Darbyshire, 2019, Pisani et al., 2015, Ritmala-Castren et al., 2014) . Many sleep disruptive factors, including both extrinsic factors related to the ICU environment and intrinsic or patient-related factors have been proposed as contributing to interrupted sleep in ICU patients. These include environmental sounds, light, and nursing activities as well as severity of illness, pain, fear, and medical treatment (Elliott et al., 2014, Bihari et al., 2012, Beltrami et al., 2015, Delaney et al., 2015).

It is generally understood that poor quality sleep has a significant impact upon the wellbeing of humans, and the impacts of sleep disruption may be even more severe in critically ill patients (Delaney et al., 2015; Pisani et al., 2015). Poor sleep quality among ICU patients is believed to contribute to multiple adverse

clinical outcomes , including impaired physical and cognitive function, increased mortality, and increased length of stays in hospital (Matthews, 2011, Pisani et al., 2015). In a global survey, 97% of ICU physicians and nurses (from a sample of 1,223), agreed that poor sleep in the ICU is also a risk factor for delirium (Kamdar et al., 2016). This growing awareness of the consequences of poor sleep for ICU patients has encouraged sleep promotion in ICUs, with the development of interventions for sleep promotion thus being of keen interest to researchers (Andrejak et al., 2013, Boyko et al., 2017, Hu et al., 2015, Patel et al., 2014).

One of the main barriers to sleep promotion in ICUs is the lack of a standardised tool to assess sleep (Jeffs and Darbyshire, 2019), however, which means that regular assessment of sleep quality is not part of the standard clinical care given to ICU patients. Evaluation of ICU patients' sleep can be challenging due to their general severity of illness and the high level of activity involved in care and treatment in that environment (Jeffs and Darbyshire, 2019, Pisani et al., 2015). Nevertheless, routine and regular evaluation of patients' sleep in ICU clinical practice is highly recommended, as regular assessment is important to early identification of disrupted sleep, which in turn can lead to identifying the causes of any problems (Jeffs and Darbyshire, 2019, Devlin et al., 2018, Hoey et al., 2014). This is necessary to allow implementation of the proper interventions to improve patients' sleep as well as to evaluate their effectiveness (Devlin et al., 2018, Hoey et al., 2014, Ritmala-Castren et al., 2014).

1.2 Thesis overview

This PhD thesis begins with an extensive literature review covering the main elements and concepts supporting the underlying topic. The process of developing this review included building up a knowledge of the existing research and debates regarding sleep characteristics, both in healthy humans in general and in ICU patients in particular. The review highlights evidence supporting the importance of assessing sleep based on patients' own perceptions of sleep in ICU clinical practice as a necessary first step for adequate sleep management. In particular, self-reporting of patients' sleep is the current recommended method of regular sleep assessment in ICU patients (Devlin et al., 2018, Jeffs and Darbyshire, 2019, Pisani et al., 2015, Ritmala-Castren et al., 2014).

Further, the review highlights the fact that the Richards Campbell Sleep Questionnaire (RCSQ) is one of the most promising tools for self-report sleep assessment in ICU patients (Jeffs and Darbyshire, 2019), with this being recommended in recently published clinical practice guidelines by the Society of Critical Care Medicine (SCCM) for the management of pain, agitation, delirium, and sleep disruption in ICUs (Devlin et al., 2018). As the questionnaire of choice for sleep assessment in research, it may thus also be useful for routine use in sleep assessment in ICU clinical practice (Devlin et al., 2018, Jeffs and Darbyshire, 2019, Menear et al., 2017). This fact guided a structured review of the literature with a focus on ICU-based sleep studies that have utilised RCSQ to examine the evidence with regard to RCSQ validity, reliability, feasibility, and acceptability for sleep assessment in ICU patients.

This structured review highlighted three main areas that required further work. First, despite widespread use of the RCSQ internationally and the existence of evidence of the validity and reliability of the RCSQ with regard to self-reported sleep assessments in ICU patients, as well as some initial evidence that RCSQ is a brief and simple tool (Aitken et al., 2017, Chen et al., 2018, Elliott et al., 2014, Frisk and Nordstrom, 2003, Kamdar et al., 2012, Krotsetis et al., 2017, Li et al., 2011, Murata et al., 2019, Naik et al., 2018) , evidence of the RCSQ's feasibility and acceptability in daily use in ICU clinical practice remains scant. In particular, none of the available studies reported data about patient acceptance of completing RCSQ on a daily basis during ICU stays. Feasibility and acceptability are important aspects of outcome measures, and should thus be considered prior to implementing any assessment tool in clinical practice (Sekhon et al., 2017, Fitzpatrick et al., 1998).

Second, despite the evidence that ICU patients experience poor sleep quality, and the common use of RCSQ, particularly in western countries (Aitken et al., 2017, Elliott et al., 2014, Frisk and Nordstrom, 2003, Kamdar et al., 2013, Krotsetis et al., 2017, Menear et al., 2017), no Arabic version of the RCSQ has been generally available. Thus, no data about RCSQ use in Middle Eastern countries existed. Third, there was a general lack of knowledge about patients' self-reported sleep quality and sleep disruptive factors in ICUs in Arabic speaking countries, particularly Saudi Arabia. Based on these identified gaps, the overall aim and the questions of this thesis thus emerged.

1.2.1 Overall aim

To develop and test the psychometric properties, feasibility, and acceptability of daily self-reported assessment of sleep quality in an ICU setting in Saudi Arabia using an Arabic version of the RCSQ (RCSQ-A) and to report on sleep quality and sleep disruptive factors among ICU patients in Saudi Arabia.

1.2.2 Research questions

To achieve the study's aim; the following questions were developed:

1. Can an Arabic version of the RCSQ (RCSQ-A) be developed for daily self-reported assessment of sleep quality in ICU settings in Saudi Arabia?
2. What is the content validity and internal consistency reliability of the resulting RCSQ-A in terms of daily self-reported assessment of sleep quality in ICU patients in Saudi Arabia?
3. What is the feasibility and acceptability of the RCSQ-A in terms of daily self-reported assessment of sleep quality in ICU patients in Saudi Arabia?
4. What is the self-reported quality of patients' sleep in an ICU setting in Saudi Arabia?
5. What factors related to patients' self-reported sleep quality arise in an ICU setting in Saudi Arabia?

1.2.3 Research purposes

The main overall purpose of this study was to contribute to the development of a reliable and valid Arabic version of the RCSQ (RCSQ-A) to enable assessment of self-reported sleep quality in ICU patients both in the current study and in future research and clinical practice in Arabic-speaking ICU settings, particularly in Middle Eastern countries. An additional purpose was to provide a clearer understanding of the feasibility and acceptability of self-report RCSQs in daily use in ICU clinical practice generally, and in Saudi ICU clinical practice in particular. This was intended to determine whether the RCSQ is a simple and

effective instrument for collecting sleep data based on patients' perceptions of their own sleep as well as to determine whether the RCSQ is an acceptable tool for ICU patients to complete on a daily basis during ICU stays. Such assessment was necessary in order to understand whether RCSQ could be implemented as a standard tool for sleep assessment in Arabic ICU clinical practice.

A further purpose of this study was to provide a comprehensive overview of the quality of ICU patients' sleep and sleep disruptive factors from the perspective of Saudi Arabian ICU populations. Existing data about patients' sleep quality and sleep disruptive factors in Saudi Arabian ICUs were very scant, and thus further assessment of sleep quality and sleep disruptive factors in these settings is important. In addition, such assessment is needed to inform recommendations for future research and ICU clinical practice in terms of evaluating and improving sleep quality in ICU patients, with any pressing needs identified.

1.2.4 Thesis overview

This thesis begins with an extensive review of the literature, offered in chapters two and three, which forms the basis of the thesis. Within this review of the literature, the current state of knowledge about sleep in ICU patients was synthesised, and multiple gaps in the current knowledge identified. Thus, the five key concepts of this study emerged, and these have informed the research questions and aims: these are sleep quality, sleep disruptive factors, and the feasibility and acceptability of measurement instruments, as seen in Figure 1-1. These concepts are thus discussed and explained in further detail in chapters two and three.

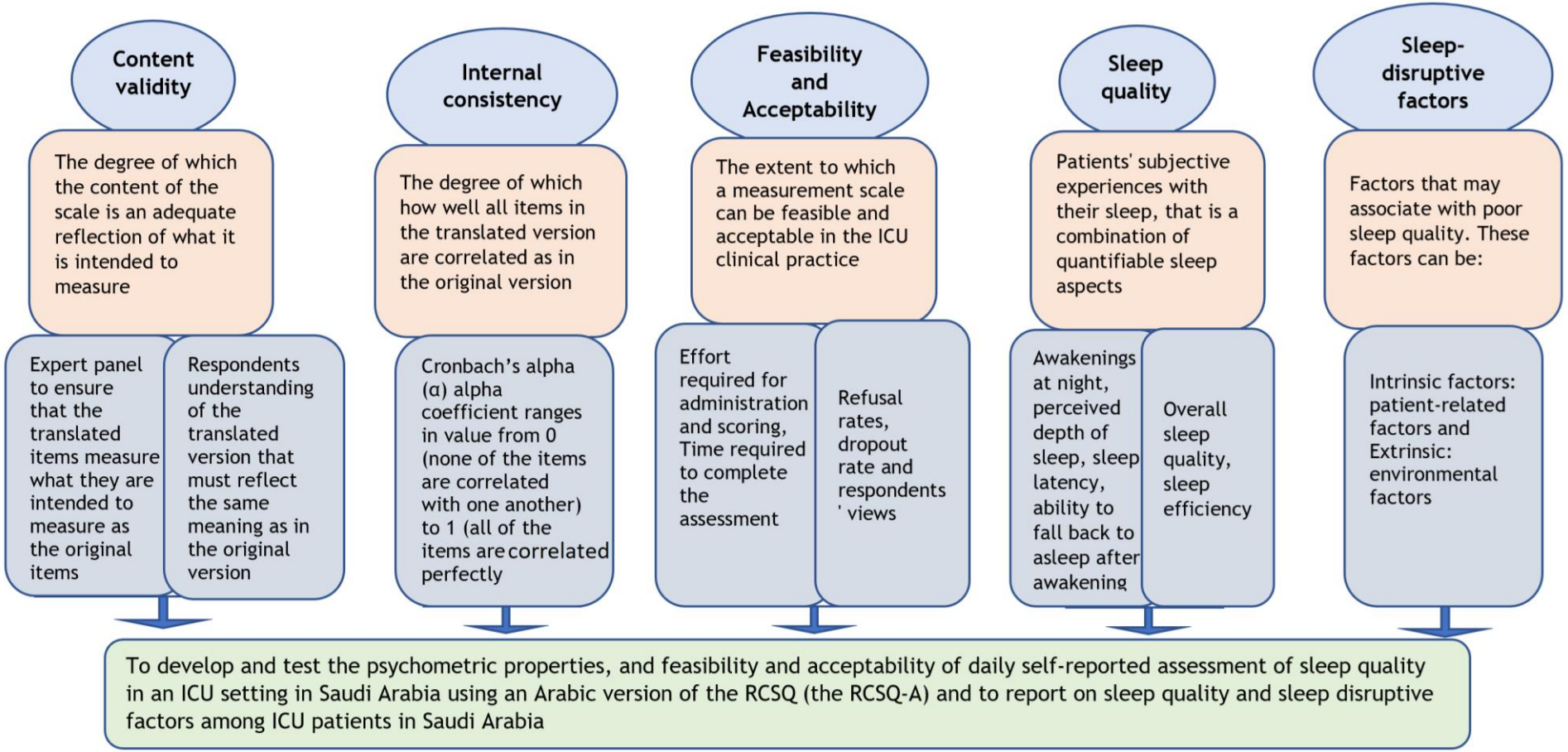

Figure 1-1 Basic concepts of the study

Thereafter, a quantitative, prospective observational design utilising a repeated measures study was utilised to address the identified questions and to fill the identified gaps, based on guidance developed from the literature review. Each process within this study, including the selection of research approach, design, and methods, was thus guided by the adopted conceptual definitions from the literature review. Further discussion of these concepts (Figure 1-1) and the ways in which they guided this study are thus presented in Chapter four.

This study was carried out in Saudi Arabia using a two-phase design. The first phase was carried out during March and April 2018, which addressed the aim of this study, which was to develop an Arabic version of the RCSQ (RCSQ-A). The completion of phase one was thus crucial for the next phase of the study to proceed. This phase therefore involved two steps: the first step was the RCSQ being translated into Arabic using the rigorous translation process recommended by the World Health Organisation (WHO) for tool translation and adaptation (World Health Organisation, 2017), while the second step involved the testing of the internal consistency and reliability of the RCSQ-A in an initial pilot sample of 57 ICU patients. Content validity was also examined in a subsample of 30 ICU patients during the pilot testing process, with a cognitive interviewing method used to assess participant understanding of the meaning of each item in the RCSQ-A (Reeve et al., 2011).

The second phase was a prospective observational repeated measures study carried out over a three-month period from May to August 2018. In this phase, 120 ICU patients rated their previous night sleep daily using the RCSQ-A each morning until the patient was due to be discharged from the ICU. After each RCSQ-A completion, patients were also asked about their perceptions of factors

disruptive to their sleep during the previous night using a self-report Sleep in Intensive Care Questionnaire (SICQ). Data regarding RCSQ-A feasibility and acceptability in ICU clinical practice were thus collected based on the repeated measures technique, and the correlations between self-reported sleep disruptive factors, patients' demographic and clinical variables, and patients' self-reported sleep quality were thus explored.

1.2.5 Thesis structure

This thesis is comprised of eight chapters, which are set out as follows:

Chapter one offers a brief introduction to the topic of the thesis, highlighting the questions and aims of the thesis, presenting an overview of the thesis, and discussing key concepts underlying the study. It also identifies the layout of the thesis overall.

Chapter two provides an overview of the characteristics of normal human sleep. It presents the functions of sleep and the effects of sleep deprivation and sleep disruption on people’s well-being, as well as discussing the specific case of critically ill patients. It then describes the current literature related to characteristics of sleep in ICU patients, including definitions of quality and quantity of sleep, and the identification of factors that may disrupt ICU patients' sleep. It also discusses a range of sleep measurement methods used in assessing ICU patients' sleep, noting the advantages and disadvantages of each.

Chapter three provides a structured review of studies that have utilised RCSQ in assessing sleep in ICUs patients. This chapter presents evidence with regard to RCSQ usefulness and effectiveness in terms of validity, reliability, feasibility, and acceptability in ICU clinical practice for evaluating patients' sleep quality.

This chapter also provides essential definitions of the basic aspects of the outcome measures, including psychometric properties, feasibility, and acceptability.

Chapter four reviews the basic concepts underlying this study by presenting and summarising the conceptual definitions adopted. It also presents the framework constructed from these concepts to support this study, which helped in developing an understanding of the nature of the data required to answer the research questions. It further examines the research approach adopted in this thesis, clarifying and justifying the research design and laying out the reasons for the adoption of the final research methods.

Chapter five details the materials and method used in the current study. It also presents the two distinct phases of the study, as well as offering a description of the ethical approval received, the study setting, and the participant recruitment and selection processes. This chapter also describes the instruments and data collection process and the data management, ethical considerations, and analysis methods applied, insofar as these relate to the study aim and questions.

Chapter six presents the results of this study, including the results of the pilot test in phase one with regard to content validity and internal consistency and reliability of the translated RCSQ-A. This chapter also presents the results of the quantitative observational repeated measures in phase two of the study, including the results regarding the feasibility and acceptability of the RCSQ-A, and the results of self-reported sleep quality and sleep disruptive factor assessment.

Chapter seven is the discussion chapter, which discusses the results of the current study in relation to the previous literature and highlights the strengths and limitations of the study. It also offers an overall summary of the study, including emergent recommendations for future research and clinical practice, as well as defining the current study's original contribution to knowledge in this field.

Chapter 2 Background to the literature

This chapter presents a narrative review of current understandings of the normal characteristics of human sleep in order to allow a full appreciation of sleep abnormalities in critically ill patients in ICUs. The chapter thus presents and discusses the function of sleep, and the effects of sleep deprivation and sleep disruption on human well-being generally, as well as more specifically examining the case of ICU patients. The chapter thus defines and discusses the concepts of quantity and quality of sleep, as well as summarising the current literature on factors that may disrupt ICU patients' sleep; as part of this, it discusses a range of sleep measurement methods that have been used in assessing ICUs patients' sleep, noting the advantages and disadvantages of each in terms of ICU use.

2.1 What is sleep

Human sleep is most simply defined as a lack of wakefulness or a behavioural state of unresponsiveness accompanied by postural recumbency, immobility, and closed eyelids (Fontaine, 1989). This simplistic definition was revised in the late 20th century when the complexity of the phenomenon began to be better appreciated, however, and sleep is now recognised as being a dynamic, highly organised physiologic state in which different parts of the brain undertake a range of diverse and complex processes (Avidan, 2017).

2.2 Normal sleep architecture

Sleep architecture refers to the basic structure of normal sleep patterns (Altevogt and Colten, 2006). Sleep is a complex process with two main phases: Rapid Eye-Movement (REM) sleep and Non-Rapid Eye Movement (non-

REM) sleep (Kryger et al., 2011). Each phase is identifiable by unique and characteristic patterns of eye movements, muscle tone, and brain waves, with the latter determined using electroencephalographic (EEG) recordings (Avidan, 2017, Kryger et al., 2011). Non-REM sleep constitutes the largest proportion of Total Sleep Time (TST) at 75 to 80%, with REM sleep making up the remaining 20 to 25% (Carskadon and Dement, 2005, Sateia, 2014). According to the original Rechtschaffen and Kales sleep scoring system (Rechtschaffen and Kakes, 1968), non-REM sleep consists of four stages. This sleep scoring system was updated in 2007 by the American Academy of Sleep Medicine (AASM) to reduce the four stages to three as follows: N1 (formerly stage 1), N2 (formerly stage 2), and N3 (formerly stages 3 and 4) (Iber and Iber, 2007). These stages are described further later in this section and in Figure 2-1.

Usually, sleep in healthy adults commences with an N1 stage, which is the lightest form of NREM; this is a transition state between wakefulness and sound sleep (Avidan, 2017, Iber and Iber, 2007, Kryger et al., 2011). Brainwaves in this early portion of sleep are made up of alpha waves (high amplitude patterns of electrical activity); however, EEG recordings show that, as the alpha stage progresses, there is an increase in theta wave activity, which is characterised by low-voltage (4 to 7 Hz) and higher amplitude brain waves (Avidan, 2017, Altevogt and Colten, 2006). The N1 stage thus progresses to the N2 stage, which is characterised by slower, higher amplitude waves in comparison to N1. Theta waves are increased in frequency this stage, and EEG recordings show sleep-spindles, which are rapid bursts of higher frequency brain waves, and K-complexes, very high amplitude patterns of brain activity that may in some cases occur in response to environmental stimuli (Altevogt and Colten, 2006, Avidan, 2017). This is followed by N3, or Slow Wave Sleep (SWS), which is the deepest

stage of sleep (Carskadon and Dement, 2005). During N3, there is high threshold for arousal and it is harder to rouse an individual in this stage than in N2 or N1 (Carskadon and Dement, 2005, Iber and Iber, 2007). Consequently, this stage is regarded as being the most restorative, and thus key to cell regeneration and energy consolidation (Moorcroft, 2013). N3 gives way to the restful REM periods of sleep; the threshold for awakening is lower in REM than in the preceding N3 stage, however (Carskadon and Dement, 2005, Moorcroft, 2013).

During REM sleep, the brain is highly active, showing "saw-tooth" theta waves on EEGs; it is during this stage that dreams typically occur, and muscle tension is minimal (Avidan, 2017, Iber and Iber, 2007). Alternating between NREM and REM states creates a sleep cycle, which is generally repeated 5 or 6 times a night (Iber and Iber, 2007, Kryger et al., 2011). The duration of sleep cycles varies, with the first being the shortest at 70 to 100 minutes (Avidan, 2017, Moorcroft, 2013). Subsequent cycles are longer, lasting between 90 and 120 minutes. The repetition of sleep cycles generally amounts to 7 to 9 hours of TST in normal adults (Ohayon et al., 2017).

The sleep efficiency index (SEI) is an alternative method of evaluating the amount of sleep attained; it is a measure of the ratio of TST compared to the total amount of time spent awake in bed (Ohayon et al., 2004). In a healthy adult, SEI is usually 85 to 90% (Ohayon et al., 2017), and normally, the proportion of N3 in each cycle decreases towards the morning, while the proportion of REM sleep in successive sleep cycles increases (Avidan, 2017, Moorcroft, 2013). Figure 2-1 below summarises the sequences of different sleep stages throughout each sleep-night.

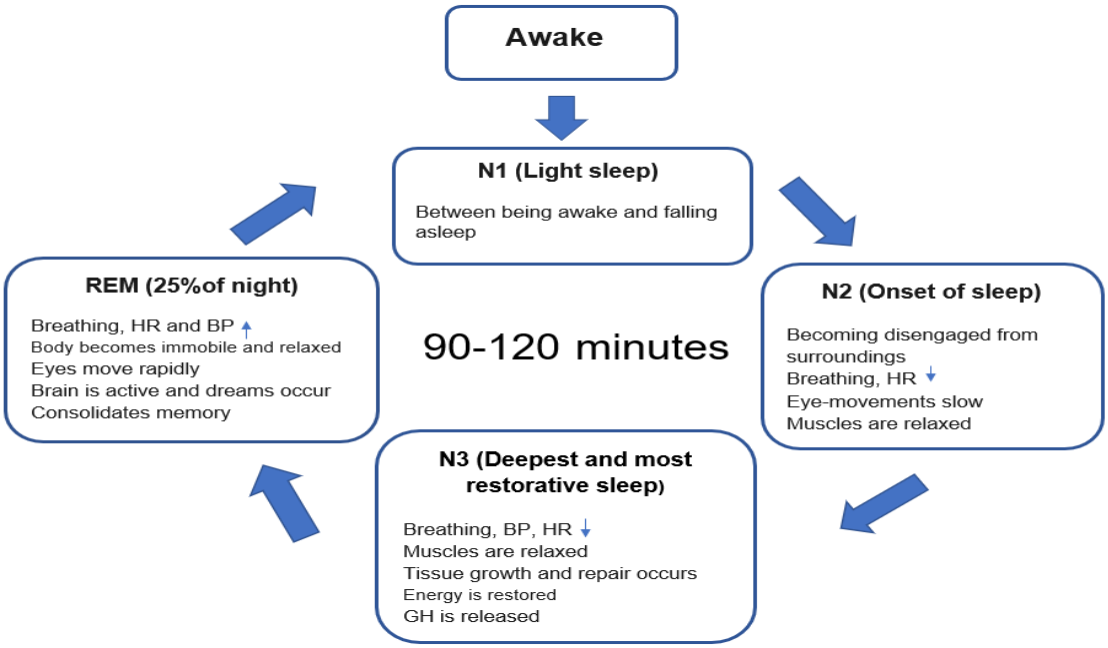

Figure 2-1 Sleep stages (National Sleep Foundation, 2017)

Every stage of sleep occurs in a predictable sequence, and the sequence must be complete and proceed in order to produce normal and restful sleep. When these conditions are not met, sleep becomes disturbed. Berger (2009) and Altman et al. (2017) define sleep disturbance as any perceived or actual alterations in night-time sleep such that sleep becomes insufficient for normal daily function. These alterations include common complaints or symptoms such as finding it hard to fall asleep or to remain asleep, frequent awakenings during the night with an inability to return to sleep, non-restorative sleep, and excessive daytime sleepiness (Matthews, 2011).

In a healthy person, sleep latency, which is the time taken to fall asleep, is 20 minutes or less (Ohayon et al., 2017). Once a healthy person has fallen asleep, there are likely to be few awakenings between sleep cycles and little time spent awake. Wakefulness After Sleep Onset (WASO) should be less than 40 minutes

during the night. (Ohayon et al., 2017). Table 2-1 summarises the sleep domains and the characteristics of normal sleep in healthy adults.

Table 2-1 Sleep domains and characteristics of normal sleep in normal adults

Sleep domains	Definition	Normal characteristics
Total Sleep Time (TST)	The amount of actual sleep time from sleep onset to final awakening.	Seven to nine hours
Sleep Efficiency Index (SEI)	An alternative method of evaluating the amount of sleep; the ratio of TST compared to the total amount of time spent awake in bed	≥85 to 90%
Sleep latency	The time it takes to fall asleep	< 20 minutes
Wakefulness After Sleep Onset (WASO)	The amount of time spent awake between sleep onset and final waking in the morning	Time awake 20 to 40 minutes during night
Nocturnal Awakenings	Frequency of awakenings per night	Few, less than 5% of TST
Arousals	Any abrupt change from deep sleep to a mixture of very light sleep and/or partial wakefulness.	10-22 arousals per hour
N1 sleep stage	A transition state between wakefulness and sound sleep	2 to 5% of TST
N2 sleep stage	The onset of light sleep	45 to 55% of TST
N3 or Slow wave sleep (SWS) sleep stage	Deep sleep (most restorative sleep)	13 to 23% of TST
REM sleep stage	Restful sleep (dreaming stage)	20 to 25% of TST
Number/patterns of sleep cycles	Alternation of all sleep stages forming a sleep cycle	Five to six cycles per night, both organised and in sequence

N1, N2, N3=None-rapid eye movement different sleep stages. REM=Rapid eye movement sleep stage (Kryger et al., 2011, Ohayon et al., 2004).

2.3 Sleep quality versus quantity

The two basic components of sleep are quantity and quality. Although these components of sleep overlap to some extent, there is a qualitative difference between them. Sleep quantity refers to the amount of sleep or TST (Ohayon et al., 2017), and the amount of night-time sleep that an individual requires varies with age, decreasing as the individual gets older (Hirshkowitz et al., 2015, Ohayon et al., 2004, Schmidt et al., 2012). The National Sleep Foundations (NSF)

has produced updated recommendations that detail minimum and maximum ranges of sleep duration for different ages, as seen in Figure 2-2.

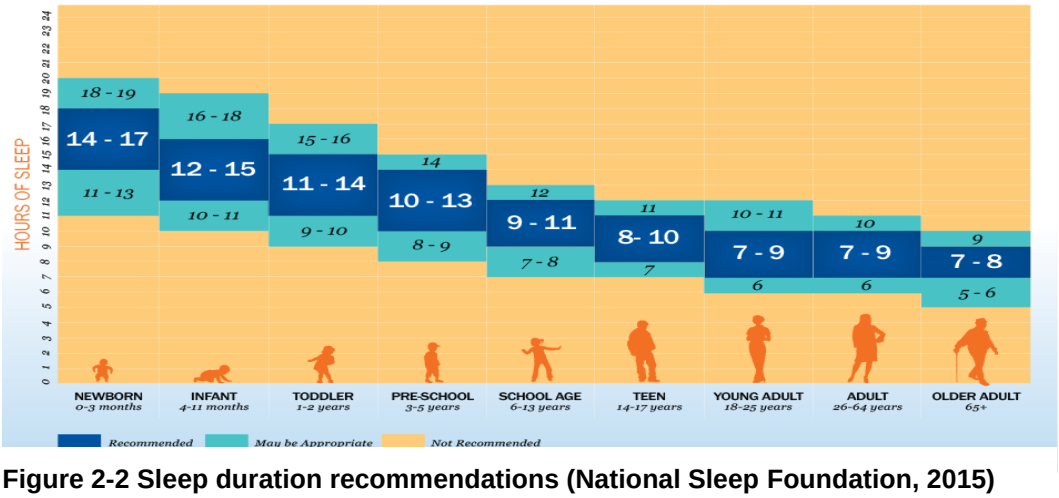

Figure 2-2 Sleep duration recommendations (National Sleep Foundation, 2015)

The recommended sleep duration for adults aged 18 to 64 years is 7 to 9 hours, with 7 to 8 hours recommended for adults aged 65+ years (Hirshkowitz et al., 2015, National Sleep Foundation, 2015). However, the actual amount of sleep required by a person is very individual. To feel healthy and well rested, some adults need as little 6 hours of sleep per night, while others need 10 or 11 hours (Hirshkowitz et al., 2015, National Sleep Foundation, 2015).

To accommodate the individual variability in sleep duration, the NSF added a new range, “may be appropriate” to its definition, and as each person is different, it is important to focus on whether the individual feels alert and restful after sleep (indicating good sleep quality), rather than focusing solely on sleep duration (Ohayon et al., 2017). The quality of sleep is extremely important and should be taken into account when assessing individual sleep, rather than relying only on the amount of sleep recorded (Buysse, 2014, Pelayo, 2017).

Webster's dictionary offers a simple definition of "quality" as "how good or bad something is' (Webster, 2018). Incorporating this simple definition into the NSF definition of quality of sleep, as used in this study, sleep quality refers to individuals' subjective experiences of and satisfaction with their sleep (Ohayon et al., 2017). However, the NSF also offers an alternative means of defining sleep quality by breaking it down into specific quantifiable sleep components. Using this approach, sleep quality is defined as the combination of the quantifiable constituent aspects or processes considered to be valuable; these include awakenings at night, sleep latency and ability to fall back to asleep after awaking up, the perceived depth of sleep, and general sleep satisfaction.

Indicators of poor sleep quality have also been set out by the NSF. The NSF characterises poor sleep quality in adults as the presence of one or more of the following symptoms: taking 30 minutes or more to fall asleep (prolonged sleep latency), reduced sleep efficiency, waking more than once during the night (fragmented sleep), light sleep, inability or difficulty in getting back to sleep after waking up in the night, and feeling unwell due to bad sleep (Ohayon et al., 2017).

2.4 Function of sleep and potential consequences of sleep disruption

Whilst the precise function of sleep has yet to be determined, it is recognised that, to varying degrees, almost every organism requires sleep of some sort, which highlights its importance. Most human sleep studies are observational and cohort studies (Friese et al., 2009, Maragno-Correa et al., 2013, Yin et al., 2017). Studies into the effects of disrupted sleep and partial sleep deprivation

have also been undertaken with the aim of building an understanding of the function of sleep.

Conducting studies to evaluate the impact of prolonged sleep disturbances and deprivation poses several ethical concerns due to the effects of inadequate sleep upon human health; it is inappropriate to expose study participants deliberately to harmful situations, and thus, animal models tend to be used to for experimental sleep research that deliberately deprives or disrupts sleep (Pittaras et al., 2018, Yin et al., 2017). This means that conclusions about the function of sleep and the impacts of disrupted or insufficient sleep in humans, are largely extrapolated from animal studies. In light of the evidence gathered this way, a number of theories have been advanced by sleep scientists to explain the functions and importance of sleep (Adam, 1980, Benington and Heller, 1995, Berger and Phillips, 1995, Xie et al., 2013). The complexity of sleep mechanisms suggests that it is unlikely that its utility can be explained by a single theory; rather, it is more likely that it could be explained by two or more of the proposed explanations (Frank, 2006).

The most commonly cited theories on sleep function are that it repairs and restores cognitive and bodily functions and conserves energy (Benington and Heller, 1995, Berger and Phillips, 1995). Despite the difficulties of researching sleep disruption and deprivation in humans, numerous epidemiological studies have provided considerable evidence that sleep plays a vital role in restoring physical and psychological health (Dashti et al., 2015, Guyon et al., 2014, Ibarra-Coronado et al., 2015, Liu and Chen, 2019, Maragno-Correa et al., 2013). The evidence relating to disrupted sleep can broadly be categorised in terms of

metabolic consequences, cognitive consequences, immunological consequences, and consequences for the cardiovascular and respiratory systems.

2.4.1 Cognitive consequences

Numerous epidemiological studies indicate that, as well as restoring body and brain function, sleep is required to clear accumulations of neurotoxic proteins from the brain; left to accumulate, these contribute to neurodegenerative disorders (Tarasoff-Conway et al., 2015, National Institutes of Health, 2013). In one study, levels of the toxic peptide Amyloid-ß (AB) were found to rise in healthy people deprived of sleep for just one night, and increased AB is associated with Alzheimer's Disease (Shokri-Kojori et al., 2018). It has thus been postulated that repeated sleep disturbance inhibits the repair and maturation of brain cells, especially hypothalamic cells, giving rise to cognitive and behavioural changes (Spira et al., 2013).

Delirium, which is a common phenomenon in ICU patients, is recognised as an independent predictor for adverse patient outcomes ranging from extended duration of hospital stay to enduring cognitive decline and increased mortality (Delaney et al., 2015, Kamdar et al., 2012). It has been hypothesized that sleep deprivation and delirium in ICUs are related (Figueroa-Ramos et al., 2009, Kamdar et al., 2012, Kamdar et al., 2015).

Certainly, there are a number of parallels between the cognitive consequences of insufficient sleep and delirium (Figueroa-Ramos et al., 2009, Kamdar et al., 2012, Pisani et al., 2015). Depressed mood, reduced cognitive performance, slips in attention, and slowed working memory are among the effects of restricted sleep experienced by healthy adults (Cho et al., 2008).

Nonetheless, a direct causal relationship between sleep deprivation and ICU delirium or vice versa has not been demonstrated definitively, and one prospective repeated assessment study that included 223 ICU patients demonstrated no association between the quality of daily perceived sleep and the transition to delirium (Kamdar et al., 2015). However, Trompeo et al. (2011) conducted an observational study that found that the numbers of days with delirium were greater in those patients who experienced very low quantities of REM sleep, which supports the idea of an association between sleep and delirium.

Van Rompaey et al. (2012) carried out a randomised control trial (RCT) in Belgium that recruited an intervention group of 69 adult ICU patients who were given earplugs overnight and a control group of 67 adult ICU patients who had no earplugs during the night. The focus of the study was early onset delirium, and patients were observed over a maximum of five nights. The study found that higher reported sleep quality was associated with lower incidence of delirium in the intervention group (Van Rompaey et al., 2012). However, while this suggests a probable relationship between sleep deprivation and delirium occurrence in ICU environments, this link has yet to be proven.

2.4.2 Immune consequences

Epidemiological evidence indicates that healthy individuals experiencing reduced sleep quality and quantity exhibit impaired immune function, thus becoming more vulnerable to bacterial, parasitic, and viral infections (Ibarra-Coronado et al., 2015, National Sleep Foundation, 2017). Multiple studies also report that inadequate sleep affects recovery from illness (Ibarra-Coronado et al., 2015, Kecklund and Axelsson, 2016, Watson et al., 2017). In a recent study involving

eleven pairs of homozygous twins with different patterns of sleep, in the twin who slept less than their sibling, immune function was found to be reduced (Watson et al., 2017).

Although evidence has largely been obtained from research in healthy people or animal studies, taken together, the overall outcomes make it clear that sleep deprivation has a disruptive effect upon the stability of the immune system. Based on the available evidence, therefore, it is not unreasonable to conclude that sleep deprivation may have even more severe adverse effects in critically ill patients, thus negatively influencing their recoveries (Delaney et al., 2015, Pisani et al., 2015).

2.4.3 Metabolic consequences

The repair and restoration theory of sleep postulates that sleep is fundamental to maintaining the health and proper function of both the mind and body, based on the fact that, during sleep, metabolic waste is eliminated and damaged cells are repaired (Adam, 1980). This theory receives strong support from an examination of the functions of the various hormones secreted during sleep and wakefulness; the functions of most sleep-related hormones, such as growth hormone (GH), are anabolic, whereas waking-related hormones, such as cortisol, are catabolic (Guyon et al., 2014, Weitzman et al., 1974). The significance of this for ICU patients is considerable, as excess catabolic hormones can aggravate underlying co-morbidities and promote the risk of secondary complications (Delaney et al., 2015, Pisani et al., 2015). For example, increases in patient morbidity and mortality are associated with volatile glucose regulation (Schmid et al., 2007).

2.4.4 Consequences for cardiovascular and respiratory systems

The association between chronic sleep deprivation and increased cardiovascular morbidity and mortality is well documented. Various results from cross-sectional and longitudinal epidemiological studies have shown higher blood pressure and hypertension associated with shortened durations of sleep (Lu et al., 2015, Yin et al., 2017). For example, the conclusion of a large systematic review and meta-analysis of 34 observational studies was that the risk of myocardial infarction was increased in shift workers (Vyas et al., 2012). In spite of this evidence, however, it has yet to be determined whether sleep deprivation in ICU patients contributes to cardiovascular morbidity.

Studies conducted on healthy individuals show that respiratory changes occur following even short periods of sleep deprivation (Spengler and Shea, 2000). A prospective cohort study was conducted by Roche Campo et al. (2010) in France to determine whether sleep quality helped to predict non-invasive ventilation (NIV) outcomes in patients with acute hypercapnic respiratory failure. The study involved 27 hypercapnic patients in a medical ICU who required non-invasive ventilation for >48 hrs. The results demonstrated that NIV was more likely to fail in those ICU patients who had larger quantities of daytime sleep and reduced REM at night (Roche Campo et al., 2010). Such data suggest that poor sleep quality may affect the respiratory function of ICU patients and complicate the process of weaning patients off mechanical ventilation. However, insufficient research has been done to determine the full effects of poor sleep quality on respiratory function in ICU patients.

It is generally clear that poor sleep quality has significant impacts that extend to multiple domains of physical and psychological functioning. However, most

research highlights differences in individuals' vulnerability to these adverse effects of poor sleep and to their abilities to recover from these effects (Worley, 2018). The extent to which an individual suffers from the effects of poor sleep quality is also influenced by the duration and frequency of the disruptive intervals; the impact of fragmented sleep becomes more significant as the duration between disruptive events becomes shorter (Elliott et al., 2011).

The initial literature thus clarifies the importance of sleep to all human beings, as its disruption has a significant impact upon the wellbeing of healthy individuals. It is not then a large step to surmise that the impact of any disruption is significantly exacerbated in ICU patients.

2.5 Sleep architecture in ICU patients

Sleep in ICU patients has been studied for over 30 years (Aurell and Elmqvist, 1985, Boyko et al., 2019, Hilton, 1976), and it is well documented that sleep abnormalities, including sleep disruption and altered sleep architecture, are common in ICU patients. Many studies have been carried out to measure sleep quality and quantity in ICU patients using PSG (Cabello et al., 2008, Elliott et al., 2013, Freedman et al., 2001, Gabor et al., 2003, Trompeo et al., 2011). Existing evidence suggests that ICU patients generally experience poor sleep quality, often experiencing prolonged sleep latency and severe sleep fragmentation with frequent arousal and awakening (Delaney et al., 2015, Pisani et al., 2015). Their sleep architecture is generally disrupted, with a predominance of light sleep stages N1 and N2 and decreases in the most restorative sleep stages, SWS and REM (Pisani et al., 2015).

In addition, increased daytime sleepiness is a frequent and common problem among ICU patients, with half of all TST occurring during daytime hours (Freedman et al., 2001). Patients in ICUs in general are not quantitively sleep deprived, however; their mean TST frequently does not differ markedly from the normal range of sleep duration, being about 7 to 9 hours, although wide individual variations are commonly reported with regard to TST (Elliott et al., 2011, Boyko et al., 2017). A summary of sleep architecture in ICU patients based on existing research is offered in Table 2-2.

Table 2-2 Summary of sleep architecture in ICU patients

Sleep aspects	**Description**
TST/SEI Patterns of sleep cycles	Normal/reduced/prolonged (wide variation) Sleep cycles are not organized (50% of sleep time occurs during day.
Awakenings/arousals	Frequent/severe
N1 and N2 stage	Disproportionately large
N3 and REM stage	Reduced

TST=total sleep time; SEI=sleep efficiency index; N1, N2, N3=None-rapid eye movement sleep stages. REM=Rapid eye movement sleep stage. (Beecroft et al., 2008, Boyko et al., 2019, Cooper et al., 2000, Elliott et al., 2013, Freedman et al., 2001)

An observational study employing PSG was conducted in Australia to evaluate sleep quality and quantity in ICU patients generally (Elliott et al., 2013). Sleep measurement using PSG was performed over a 24-hour period for 57 patients, with a mean age of 60 ±20 years, and a mean severity of illness Acute Physiology and Chronic Health Evaluation (APACHE-II) score of 18±8.23. Twenty-eight patients were mechanically ventilated during the PSG recording.

The researchers found that ICU patients' sleep was highly fragmented, with mean arousal indices of 27 per hour. Over 90% of patients' sleep was in the light

sleep stages, N1 and N2, with scant SWS and REM sleep recorded. TST was, on average, below the normal range of duration in adults, but it was close to normal, with a mean duration of 5±3h. However, daytime sleepiness comprised around 41% of all TST.

Similar findings were reported in three observational polysomnography studies that aimed to measure sleep in ICU patients using PSG. Research carried out by Trompeo et al. (2011) in Italy included 29 mechanically ventilated patients in the surgical ICU, with a mean age of 66±11.2 and high mean of severity of illness APACHE-II score of 38.9±11; the majority of participants were male (72%). Beecroft et al. (2008) conducted a study in Canada that included twelve medical and surgical ICU patients, with a mean age of 68±13 and a low severity of illness APACHE-II score of 11±3.8; again, the majority of participants were male (78%). Freedman et al. (2001) conducted a similar study in the USA that included 22 medical ICU patients with a mean age of 61±16 and a high mean of severity of illness score (APACHE-II) of 57±28; in their study, however, 45% of patients were female.

It is interesting to note the similarities across these findings since they employed different parameters in their measurement of sleep. PSG was performed over 24-hour period to assess patients' sleep quantity and quality in two studies (Beecroft et al., 2008, Trompeo et al., 2011) and over a 48 hour period in the other (Freedman et al., 2001). Overall, the findings regarding patients' sleep architecture were similar those in Elliott et al. (2013) although exact values for the sleep stages values varied between the studies. For instance, Freedman et al. (2001) reported the average amount of SWS was 9% of TST and REM sleep was

<5% of TST, while the average values of SWS and REM sleep were recorded as being negligible, less than 1%, in (Beecroft et al., 2008).

The average proportion of REM recorded by Trompeo et al. (2011) was 11%, a slightly higher figure than that determined by Beecroft et al. (2008),Freedman et al. (2001) and Elliott et al. (2013). Similarly, variation in the Mean TST was also reported across the studies. The mean TST was close to normal duration of 5±3 h in Trompeo et al. (2011), similar to that found by (Elliott et al., 2013), while it was within normal duration at 8.8±5 h in Freedman et al. (2001) and below 5±2 h in (Beecroft et al., 2008).

The differences in the results of the sleep data between studies can be accounted for by variations in demographic and clinical characteristics between study samples. Additionally, although slight differences in the mean value of sleep results occurred, all studies' results indicated that, while ICU patients were not necessarily sleep deprived, they did have very poor sleep quality, with the majority of their TST spent in light sleep (N1 and N2), and were thus heavily deprived of deep sleep (SWS and REM sleep). Additionally, although these sleep studies using a valid a standard gold for sleep measurement PSG offer comprehensive data on ICU patients' sleep architecture, their duration of sleep measurement was limited to short periods of assessment, with none exceeding a forty-eight-hour period.

Small sample sizes are also a notable limitation in these studies, with samples ranging from 12 to 57 participants (Beecroft et al., 2008, Elliott et al., 2013). Short periods of sleep measurement and small sample sizes in these studies occur due to many challenges encountered by researchers seeking to use PSG

with ICU patients, which include technical difficulties, high costs, and the fact that the study mode is both time-consuming and disagreeable and burdensome to ICU patients.

In Elliott et al. (2013), PSG data was not analysed for four of the initial patients, being analysed for only 53 patients; this was due to three patients asking for removal of the electrodes of the PSG, as they found them to limit mobility and even to impede sleep, and to difficulty in interpreting the PSG data for one patient, whose EEG waveform was affected by alpha intrusion (alpha wave activity superimposed on delta waves), which made analysis impossible.

Similarly, PSG data was not analysed for five *patients in Freedman et al. (2001) due to excessive electrical artefacts on their PSGs. Trompeo et al. (2011) reported that five* patients declined to participate in PSG testing, viewing the PSG monitoring as a potential impediment to their treatment. Difficulty in setting up the PSG device during the study, as this required a trained technician for application to patients, was also reported in both Elliott et al. (2013) and (Beecroft et al., 2008).

In addition, findings obtained by using PSG are limited to understanding the physiological characteristics of the patient's sleep; they do not give information on patients' quality of sleep from the patients' own perspectives. Patient's own experience of sleep is an essential aspect of evaluating patient's sleep quality. In particular, the concept of sleep quality (previously described in section 2.3) refers to the individual experience of sleep or how rested individuals feel upon awakening (National Sleep Foundation, 2017, Ohayon et al., 2017). The value of this aspect of sleep quality is most clearly demonstrated when individuals report

that sleep has been neither sufficient nor restorative despite the presence of normal PSG readings (Edinger et al., 2000, Harvey et al., 2008).

Overall, using the PSG in an ICU clinical setting is impractical. Thus, whilst the PSG is a valid tool for determining the measurement of sleep quality and quantity, its feasibility and acceptability to patients in the ICU environment is somewhat reduced, making it an impractical tool for routine use in ICU environments.

2.6 Sleep disrupting factors in ICUs

Multiple sleep-disrupting factors, including both extrinsic (related to the ICU environment) and intrinsic (patient-related) factors have been identified as having the potential to affect the sleep of patients in ICU settings. The term “sleep-disrupting factors” thus refers to anything that may keep a patient awake or interrupt their sleep patterns (Pisani et al., 2015, Simons et al., 2018). Extrinsic factors may include noise, light, and patient care activities, and these may combine negatively with intrinsic factors such as a patient's usual sleep pattern, the type and severity of their underlying illness, ongoing or prior treatments, age, sex, and psychology (propensity to stress and fear), all of which have been hypothesised as causal factors for sleep disturbance in ICU patients.

However, ICU-based sleep studies have generally differed when reporting the key factors affecting patients' sleep in ICUs, possibly due to differences in research methodologies, study designs, assessment methods, identification of patients or healthcare providers, and individual ICU settings. The sheer multitude of factors that contribute to sleep disturbances, and the variations in reporting these factors between ICU sleep studies, indicates that sleep

disrupting factors are not identical between ICU clinical settings, which highlights the importance of assessing sleep disrupting factors in a given ICU clinical practice prior developing any interventions for sleep management, especially in ICU settings in hospitals not previously studied. Whilst sections 2.6.1 and 2.6.2 are not intended to cover all of the research that has been undertaken in this area, in terms of background context, they do provide an overview of a variety of extrinsic and intrinsic sleep disrupting factors that have been identified in sleep studies in ICUs as potentially being disruptive to sleep. These are also summarised in Figure 2-3.

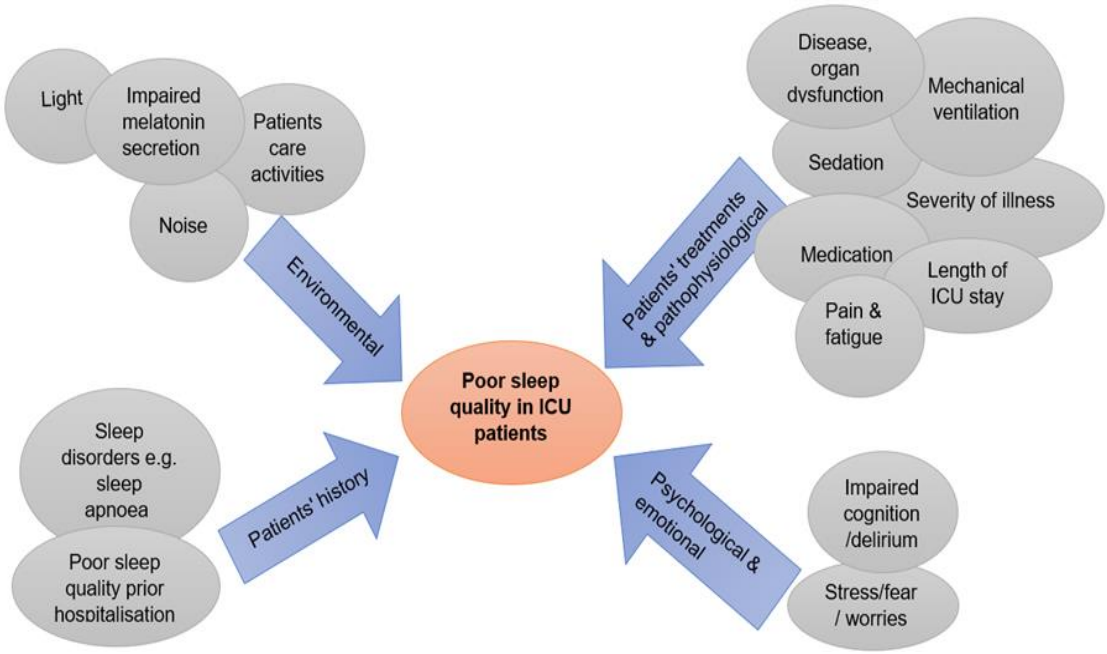

Figure 2-3 Factors related to sleep disruption in ICU patients

2.6.1 Extrinsic sleep disrupting factors (environmental)

Noise has been seen to play a significant role in sleep disruption in ICU patients. As any disturbing or undesirable sound can be termed noise (Birdja and Özcan, 2019), it is thus a subjective perception; nevertheless, any such unwanted

sounds may cause physiological or psychological stress (Birdja and Özcan, 2019). The WHO recommends that sound levels in hospitals should not exceed 35 dB during the day and 30 dB at night (Berglund et al., 1999). In ICU settings, however, sound levels frequently surpass these recommended levels, with day and night-time levels both frequently exceeding 50 dB (Darbyshire and Young, 2013, Qutub and El-Said, 2009, Simons et al., 2018). Qutub and El-Said (2009) measured sound levels in medical ICUs in Saudi Arabia over 24-h periods using a calibrated sound level meter. Their findings demonstrated that the sound levels were high during both day and night and that there was little difference between the average daytime sound measure of 59.7 dB and the night-time sound level of 58.8 dB.

The reported sources of noise in ICUs are numerous, and include staff conversations, ringing telephones, monitor alarms, intravenous pumps, ventilators, and additional equipment (Bihari et al., 2012, Freedman et al., 1999, Stewart et al., 2017). A cross-sectional study conducted in Australia by Delaney et al. (2017) in which noise levels were recorded overnight for three nights in the general ICU using sound monitors found that the average noise level was 52.85 dB; staff conversations were identified as the most common source of noise in that instance, accounting for 35% of all noise (Delaney et al., 2017).

Most of the evidence suggests that noise is associated with sleep disruption in ICU patients (Demoule et al., 2017, Gabor et al., 2003, Scotto et al., 2009). Demoule et al. (2017) carried out an RCT in a general ICU in France to determine the impact of ear plugs on sleep architecture in general ICU patients. Patients' sleep was measured using polysomnography (PSG) (described in detail in section

2.7.1) over a one-night period. The study enrolled 64 patients; of these, 32 were in the intervention group and wore ear plugs during the night, while 32 were in the control group and did not. The study revealed that the proportion of SWS in the 23 patients who tolerated wearing earplugs all night was significantly larger than for 28 of the patients in the control group (21% vs. 11%, p = 0.09). The mean of the item 3 (wakefulness at night) was also smaller in the intervention group than the control group (21 vs. 31, p = 0.02), suggesting that noise may well adversely associated with patients' sleep in the ICU.

However, noise is not always identified as a major factor in sleep disruption in ICU patients (Freedman et al.,2001; Cabello et al.,2008; Gabor et al.,2003). According to the results of other polysomnographic studies correlating PSG data to environmental noise monitoring, such as Freedman et al. (2001), noise contributes directly to only 11.5% of arousals and 17% of awakenings. Likewise, in similar studies, (Cabello et al., 2008) and Gabor et al. (2003) reported that just 24% and 20% of awakenings could be attributed to noise, respectively. These data indicate that noise is not responsible for the majority of sleep disturbances in ICU patients, suggesting other factors must be involved in interrupting the sleep of ICU patients.

Abnormal light exposure is well known to be a sleep-disrupting factor. Access to natural light during the day is important in order to maintain a normal circadian rhythm (Kamdar et al., 2012); to successfully suppress melatonin secretion, 100 to 500 lux is needed, with normal indoor light being about 180 lux (Kamdar et al., 2012). Thus, nocturnal light levels between 100 to 500 lux can affect melatonin secretion, while nocturnal levels between 300 to 500 lux also disrupt the circadian pacemaker (Kamdar et al., 2012). There are multiple sources of

light a typically well-lit ICU environment, including corridor lights, night lights, equipment lights, bed lights, sink lights, televisions, light from the windows, and staff using torches (Dunn et al., 2010). In the ICU environment, mean light levels at night have thus been recorded as ranging from 55.3 to 1,400 lux, with levels in the day ranging from 2.4 to 145 lux (Beltrami et al., 2015, Elliott et al., 2013, Pisani et al., 2015). These measurements highlight two facets to the problem, with a pattern of low light levels by day and high levels by night in the ICU. The evidence thus suggests that low daylight levels play a significant role in sleep disruption in ICU patients. Elliott et al. (2013) performed a study that recruited 43 patients in general and cardiothoracic ICUs in which light levels were recorded throughout a 24 h period, with PSG data collected during the same period for sleep measurement. The study found that median night-time light levels were appropriate (<2 lux), but that the median daytime light levels were insufficient for normal circadian rhythms to be established (74 lux). Thus, Elliott et al. (2013) suggested that the cause of high daytime sleepiness among study participants, with 41% of the patients' TST occurring during the day, was because patients were likely to have high melatonin levels during the day, contributing to daytime sleep.

Many nocturnal nursing care activities have also been identified as factors that contribute to sleep disruption in the ICU; these include taking vital sign measurements, taking blood samples, bathing patients, changing bed linen, and catheter management (Bihari et al., 2012, Ugras and Oztekin, 2007, Zhang et al., 2013). A cross-sectional study carried out in Turkey by Celik et al. (2005) aimed to determine the frequency and types of nursing activities in a surgical ICU during the night shift (from 19.00 to 07.00). The study included 30 sedated

and 30 non-sedated mechanically ventilated patients. Data regarding nursing care activities were gathered by means of retrospective examination of nursing chart notes. This study found that nursing care activities, including eye care, change dressing, catheter change, and suctioning were usually performed between midnight and 5 a.m., and that these resulted in each patient's sleep being interrupted on average of 51 times each night. This strongly suggests that nursing care activities contribute to patients lacking time to obtain the necessary amount of sleep overnight in the ICU.

A cross-sectional study of the impact of patient care activities on sleep disruption in male ICU patients (n=7) conducted by Gabor et al. (2003) in the USA, however, identified much lower numbers of patient and staff interactions than Celik et al. (2005), with just seven interactions per patient per night. Patients in that study identified alarms and staff conversations as the most disruptive environmental factors, suggesting that the nursing activities themselves were not a major sleep disturbance factor in that case (Gabor et al., 2003). The differences in the prevalence of care activities seen between studies and their contributions to sleep disruption in ICU patients can arguably be accounted for by differences in ICU designs and practices in terms of nursing activities and workloads. Additionally, differences in the results of these specific studies maybe related to sample differences, as Gabor et al. (2003) only recruited seven male patients.

2.6.2 Intrinsic sleep disrupting factors

2.6.2.1 Patient history

Many factors that exist prior to patient admission to the ICU have been suggested as potentially causing sleep disruption. These factors include pre-

existing sleep pathologies such as sleep apnoea, poor quality sleep as a norm, and the regular use of sleep aid medication at home (Bihari et al., 2012, Stewart et al., 2017, Matthews, 2011). In ICU-based sleep studies, many researchers thus tend to exclude patients with pre-existing sleep pathologies or patients who regularly take sleep aid medication at home, in order to isolate the influence of ICU factors on the quality of patients' sleep (Aitken et al., 2017, Elliott et al., 2014, Freedman et al., 1999, Frisk and Nordstrom, 2003, Kamdar et al., 2012, Krotsetis et al., 2017). Certainly, an understanding of patients' sleep quality at home is required in any ICU-based sleep study to help determine whether the ICU environment plays a role in sleep disruption in ICU patients (Kamdar et al., 2013, Patel et al., 2014). A study conducted by Freedman et al. (1999) in North America retrospectively assessed the sleep quality of ICU patients and the factors that contributed to sleep disruption, utilising the SICQ questionnaire as described in section 2.7.2. The patients were asked to evaluate their sleep quality at home and in the ICU on a scale of 1 to 10 (1=poor, 10=excellent) on discharge from the ICU. The findings revealed that respondents' perceived mean sleep quality in the ICU was significantly poorer than at home for all participants ($p= 0.0001$).

Similar findings were reported in another retrospective study using a similar tool that evaluated sleep quality among 100 medical ICU patients and to identify factors that disrupted patients' sleep over the course of ICU stays (Bihari et al., 2012). Bihari et al. (2012) found that patients' mean perceived quality of sleep was significantly poorer in the ICU than at home (7.03 ± 2.2 vs 4.0 ± 1.7, $p< 0.001$), indicating that there are specific factors within the ICU environment that cause changes in, and disruption of, patients' sleep.

Both Bihari et al. (2012) and Freedman et al. (1999) are supported by the results of a similar study in Australia by Elliott et al. (2014), assessed 45 patients' sleep quality and the factors disrupting their sleep in a medical ICU. Those patients were also asked to rate their sleep quality at home and after they were transferred from the ICU to a hospital ward using the SICQ. The results demonstrated that sleep quality in the ICU was perceived as being significantly poorer than that at home (SICQ: 7.06 ± 2.52 vs 4.50 ± 2.14, $P \leq .05$).
In contrast, however, another retrospective study in Australia carried out in medical and surgical ICUs by Stewart et al. (2017) (n=56) showed that only 55% of participants experienced worse sleep quality in the ICU as compared to at home, with 44% of patients rating their sleep in the ICU as better or unchanged. These results contradict the findings of several earlier studies (Freedman et al.,1999; Bihari et al., 2012; Elliot et al., 2014) that suggested that patients' perceived sleep quality as being poorer in the ICU than at home.

This difference in results may be related to sample structure, as Stewart et al. (2016) recruited patients known to have sleep disorders and psychological problems prior to hospitalisation among their sample; thus, 8.5% of their respondents took sleeping tablets in the ICU and 16.8% took anti-psychotic drugs. As patients with sleep disorders and psychological problems prior to hospitalisation are likely to also have had reduced quality of sleep prior to hospitalisation, the ICU environment may not have been notably additionally detrimental to their sleep quality; this may thus have affected the study results in terms of understanding the role of the ICU environment in affecting sleep quality for ICU patients more generally.

2.6.2.2 Patient demographics, illnesses, and treatment characteristics

Multiple interrelated factors contribute to sleep disturbances in ICUs, many of which are related to patients' treatments and demographic characteristics. These include diagnosis, pain, severity of illness, mechanical ventilation requirements, medications, length of ICU stay, age, and sex.

Critically ill patients usually suffer from a combination or group of health conditions or diseases that may affect multiple organ systems such as the respiratory system, cardiovascular system, gastrointestinal system, or neurological system (Kamdar et al., 2012). It is thus difficult to study the effects of a specific health condition or disease on sleep quality in ICU patients in isolation, even where such effects in healthy individuals are well documented. Severity of illness has also been suggested as playing a significant role in sleep disruption in the ICU (Pisani et al., 2015), yet there is very little evidence for this claim.

types of patients usually seen in the ICU in Saudi Arabia and discuss how this compares to the types of patients usually seen in the UK. Use the classifications of levels of care as seen in the UK (Intensive Care Society) for this comparison.

It is notable that the classification system of ICU patients, which is used to inform the level of care given to patients, is not uniformly adopted and varies among different countries. For example, in the UK, ICU patients are classified into four levels ranging from 0 to 3, each of which indicates the required level of care (Masterson and Baudouin, 2015). Level 0 is applied to patients whose needs can be met through normal ward care in an acute hospital; Level 1 critical care is for patients who are at risk of their condition deteriorating or those recently

relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team; Level 2 critical care is usually delivered in high dependency units (HDUs) and applied to patients requiring more detailed observation or intervention, including support for a single failing organ system, post-operative care and those 'stepping down' from higher levels of care. Finally, Level 3 critical care is for patients who require advanced respiratory support alone or basic respiratory support together with the support of at least two organ systems; this level includes all complex patients who require support for multi-organ failure and is provided in 'intensive care units' (ICUs) or 'intensive treatment/therapy units' (ITUs) (Masterson and Baudouin, 2015). However, the classification system used in UK ICUs is not applied in the Saudi ICU system, which instead classifies patients based on standard measures of severity of illness such as Acute Physiology and Chronic Health (APACHE II) scores to stratify patients risk as well as to estimate the peak of intensity of organ support that could be provided to demonstrate the level of clinical care delivered during an ICU (Arabi and Al Shimemeri, 2006). Saudi Arabian ICUs therefore treat patients with diverse severity of illness and different required levels of care within the same ICU settings. Despite the differences in classification of ICU patients, both UK ICUs and Saudi ICUs use APACHE-II scores to indicate the severity of illness, which is also the standard measure used internationally (Prin and Wunsch, 2012). Therefore, ICU-based sleep studies rely mainly on reporting the standard measure APACHE-II scores that give a view on the categories or type of ICU patients included in the studies (Aitken et al., 2017, Cooper et al., 2000, Elliott et al., 2014, Freedman et al., 2001, Gabor et al., 2003, Kamdar et al., 2013).

Gabor et al. (2003) compared ICU patients' sleep with that of healthy volunteers exposed to the same medical and surgical environment. Sleep was measured using PSG for a 24-hour period for seven patients and six healthy adults. All patients were mechanically ventilated and had a mean age of 56.7±19.2, a mean APACHE-II score of 65.7±19.2, and a mean length of ICU stay of 48.3±40.2. All patients received analgesics as needed for pain management and they were all alert and conscious, with Glasgow Coma Scale (GCS) scores of no less than 13. The study revealed that healthy individuals slept relatively well in this potentially disruptive environment, with the percentage of deep sleep SWS being significantly higher in the healthy adults than in the ICU patients (7.3± 2.7 vs 2.7±3.3; $p>0.05$). The researchers therefore hypothesised that the differences in sleep quality between healthy adults and ICU patients were due to the effects of severity of illness in the ICU patients (Gabor et al., 2003).

However, this conclusion is not supported by the results from an earlier study by Freedman et al. (2001) who characterised sleep-wake patterns over 48 hours for 22 medical ICU patients using PSG to assess the effect of severity of illness on patients' sleep. The study also assessed the effect of the presence of mechanical ventilation, length of ICU stays, age, and gender on patients' sleep quality. The sample comprised of 12 males and 10 females, with the mean age being 61±16, mean APACHE-II score being 57±6, and mean duration of ICU stay being 18±20 days. Twenty patients were mechanically ventilated, and fourteen patients were not sedated at all, with the remaining eight patients receiving intermittent intravenous doses of opioid analgesic (Fentanyl) as needed. All patients were alert and conscious, with GCS of 14 or greater upon entry to the study.

All patients exhibited poor sleep quality with highly fragmented sleep. Although the patients generally had high severity of illness, their APACHE-II scores did not correlate significantly with sleep quality ($p>0.05$), and there were also no significant correlations between sleep quality and age, gender, or duration of ICU stay ($p>0.05$). These results suggest that age, gender, severity of illness, and length of stay may not be important contributors to sleep alteration in the ICU environment.

Freedman et al. (2001) further reported that environmental noise was only responsible for 17% of awakenings and 11.5% of arousals; the cause of the majority (71.5%) of arousals in study participants was postulated by researchers as being patient-ventilator dyssynchrony (a mismatch between the demands of the patients' respiratory systems and their ventilators) along with the clinical interventions such as suctioning and the administration of treatments frequently required when mechanical ventilation is used. The researchers also suggested that other environmental factors, such as nurses' interventions and light, and patient-specific factors such as medication and pain, were responsible for many sleep disturbances.

An observational study by Cooper et al. (2000) in Canada measured sleep over a 24-hour period in medical and surgical ICU patients using PSG. Twenty mechanically ventilated patients were included, with a mean age of 62±15 years, and a mean APACHE-II score of 10±5; 60% of the sample was male. Patients were conscious, with GCS scores of 13 or greater, and the length of average ICU stay was 10±7 days. This study supported the results developed by

Freedman et al. (2001), suggesting that mechanically ventilated patients manifested poor sleep quality and that their sleep was severely fragmented.

However, Cooper et al. (2000) did not address the hypothesis that severity of illness may be responsible for disrupted sleep due to measuring patients' sleep only at one point in the ICU stay, which made the researchers unable to identify whether sleep quality changed as the severity of illness reduced. The researchers thus recommended that further sleep studies employing daily basis assessments of patients' sleep, along with in-depth evaluations of sleep-disrupting factors in the ICU, were needed.

The self-reported study by Bihari et al. (2012) was carried out in Australia to evaluate sleep quality in medical ICU patients and to investigate factors that affect sleep quality in the ICU using multiple regression analysis. A broader range of intrinsic factors that could potentially affect patients sleep were thus studied in Bihari et al. (2012) as compared to those examined in Freedman et al. (2001) and Cooper et al. (2003); these included severity of illness, mechanical ventilation, length of ICU stay, sedation, pain, age, and sex.

Data from patients regarding self-reported sleep quality and self-reported sleep disrupting factors were collected on discharge from the ICU using SICQ. The study included 100 patients with a mean age of 63.2±16.7 years, and a mean APACHE-II score of 18.1±7.5. The mean duration of stay in the ICU was 6.7±6.5 days and all patients were conscious and oriented, with GCS scores ≥14. The mean score for patient sleep quality was 4.0±1.7, and the mean daytime sleepiness score among subjects during their ICU stays was 5.0±1.4, indicating that patients experienced poor sleep quality during their stays in the ICU and experienced daytime sleepiness consistent with a lack of sleep overnight.

Bihari et al. (2012) found that neither length of stay in the ICU nor severity of illness significantly affected patients' sleep ($p > 0.05$), consistent with Freedman et al' s (2001) results. However, in contrast to Freedman et al (2001) , which suggested that factors such as age and sex did not affect patients sleep, Bihari et al. (2012) demonstrated that age and sex had significant effects on patients' sleep ($p>0.01$), with female patients experiencing better sleep than male patients and older patients sleeping better in the ICU than younger patients. The absence of a relationship between age and sleep quality in Freedman et al. (2001) may be because that none of that study's sample was younger than 40 years old, preventing such a relationship from emerging.

Bihari et al. (2012) also identified that neither mechanical ventilation nor sedatives such as Benzodiazepine (Midazolam) significantly affected patients sleep quality ($p=0.21$, $p=0.08$, respectively). However, studies differ in terms of the ways in which sleep is measured; Freedman et al. (2001) and Cooper et al. (2003) assessed sleep using PSG devices, delivering one-point assessments, while Bihari et al. (2012) used retrospective self-report assessments, in which recall bias may present a confounding problem.

A number of medications frequently used in ICUs may interfere with patients' sleep as a side effect (Table 2-3), and these medications can cause changes in both the quantity and quality of patients' sleep (Harvard Health Publishing, 2010, Song et al., 2018, Trompeo et al., 2011). Whilst these medication effects are well documented in the general population, it remains challenging to establish their interactions and influence upon sleep in ICU patients (Delaney et al., 2015,

Elliott et al., 2011, Kamdar et al., 2012). Sedatives and analgesics are often used to promote comfort during mechanical ventilation in patients requiring respiratory support (Altman et al., 2017); however, sedatives such as benzodiazepines are associated with superficial sleep due to their actions supressing SWS and REM sleep (Pandharipande and Ely, 2006, Pisani et al., 2015).

In addition, patients using benzodiazepines for an extended period have the potential to develop significantly altered sleep architecture and delirium in cases of abrupt withdrawal of benzodiazepines, while propofol, which is used primarily for deep sedation, has been shown to suppress REM sleep, and is thus associated with poor sleep quality in ICU patients (Janhsen et al., 2015, Trompeo et al., 2011). Dexmedetomidine (Precedex) is a sedative, anxiolytic, and analgesic drug that has been suggested to be associated with less delirium incidence than benzodiazepines and to promote better sleep architecture than either benzodiazepines or propofol (Pandharipande et al., 2010, Wu et al., 2016). However, its specific effects on sleep when administered at night to ICU patients requiring sedation have not yet been assessed.

Table 2-3 Effects of common ICU medications on sleep

Medications	**Effect on sleep**
Sedation Benzodiazepine (Midazolam)	↑TST, ↓SWS, ↓ REM

Propofol Dexmedetomidine (precedex)	↑TST, ↓ SWS, ↓REM, ↓ W ↑TST, ↑ SWS, ↓REM
Opioid Analgesic Fentanyl Morphine	 ↑TST, ↓N3, ↓REM, ↑W ↓TST, ↓N3, ↓REM, ↑W
Cardiovascular β-blockers Dopamine Norepinephrine/Epinephrine	 ↑W, ↓REM, nightmares ↓N3, ↓REM ↓N3, ↓REM
Corticosteroids	↑W, ↓ SWS, ↓REM

TST, total sleep time; SWS, slow wave sleep; REM, rapid eye movement; W, wakefulness after sleep onset; ↑, increase; ↓, decrease. (Kamdar et al.,2012; Delany et al.,2015).

In the Australian study by Elliot et al. (2014), the effects of sedation, analgesic, mechanical ventilation, and severity of illness on medical and surgical ICU patients' sleep quality were assessed. Forty-five patients' sleep was measured using PSG for 24-hour period, and a regression model was used to study the effects of sleep disrupting factors within this PSG sleep data. The mean age of patients was 60±20 years, and mean APACHE-II scores of 18±8.23 were recorded, with around half of the patients being on mechanical ventilation (54%) during sleep recording. Only lightly sedated patients were included, though 53% of the sample had benzodiazepine (Midazolam) or propofol sedation during sleep recording and 60% of the patients received an opioid analgesic (morphine).

All patients were interactive and calm, with Richmond Agitation Sedation Scale (RASS) scores of 0 or -1. The results demonstrated that all patients had poor sleep quality, with highly fragmented sleep and apparent reductions in SWS and REM sleep to varying degrees. Elliot et al. (2014) identified that mean arousal indices were significantly decreased in those patients receiving Midazolam or Propofol sedation (30.00 vs. 22.00; p=0.019), while the presence of mechanical ventilation during sleep monitoring was positively associated with PSG sleep data

(p=0.004), indicating that patients' sleep may be improved in the presence of mechanical ventilation or when sedative medications are administered. These results of the effects of mechanical ventilation and sedation on patients' sleep quality contradict most of the literature, which instead indicates that the presence of mechanical ventilation is an impediment to sleep in ICU patients and that sedatives adversely affect patients' sleep. Elliot et al. (2014) measured sleep only for one 24-hour period at a single point of patients' ICU stays; thus, they did not develop an understanding of whether patients' sleep changed after discontinuing sedatives or after removing mechanical ventilation. The benefits of administration of sedatives at night for ICU patients in terms of reducing arousal quantity and improving sleep quality have thus not been studied sufficiently.

A randomised crossover study was carried out by Kondili et al. (2012) in Greece to assess the effect of propofol administration on sleep quality in medical ICU patients. Two nights of sleep were measured using PSG for 20 mechanically ventilated patients, with and without propofol infusion. The results demonstrated that, with or without propofol, all patients demonstrated abnormal sleep architecture, characterised by sleep fragmentation, a predominance of light sleep (N1 and N2 stages), and reduced SWS. However, compared to those without propofol, the researchers noted that patients with propofol experienced a significant decrease in REM sleep (p = 0.04). The researchers therefore concluded that propofol further worsens poor sleep quality by supressing the REM stage of sleep architecture.

A randomised double blinded trial was carried out in India by Engelmann et al. (2014) to compare the effect of propofol and a benzodiazepine on ICU patients'

sleep quantity and quality. A total of 66 patients in a surgical ICU were enrolled in the study (benzodiazepine *n* = 32, propofol *n* = 34), and the mean age of patients was 60.06±12.0. Propofol was injected continuously (2 mg/kg/h), with benzodiazepine given as a bolus dose (0.015 mg/kg). Both sedatives were administered at night from 11 pm to 6 am. In the daytime, after the study, when patients were fully conscious, the patients were asked to judge several aspects of their sleep quality on a numerical scale by completing a sleep diary. The results identified that the maximum wakefulness at night reported by the propofol group was significantly lower than that reported by the benzodiazepine group (6 vs 30; p >0.001) ; however, both groups reported poor quality sleep in terms of falling asleep, and total sleep duration was low for both groups (Engelmann et al., 2014).

Studies therefore differ in terms of the effects of sedatives on the quality and quantity of ICU patients' sleep. Engelmann et al. (2014) suggested that the benefit of propofol lies in decreasing the state of wakefulness compared with benzodiazepine, though Elliot et al. (2014) suggested benefits to both propofol and benzodiazepine in terms of lowering arousal indices, and Kondili et al. (2012) demonstrated the negative role played by propofol in sleep disruption in terms of supressing REM sleep. The adverse effects of sedatives, especially Midazolam and Propofol, in terms of suppressing SWS and REM sleep and increasing incidence of delirium are, however, widely understood; they are thus not recommended for the purposes of sleep promotion in ICU patients by the SCCM (Devlin et al., 2018).

2.6.2.3 Psychological factors

Psychological factors that disrupt ICU patients' sleep may include fear, worry or stress due to unfamiliarity with the ICU environment; the inability to speak; or their illness; these factors have thus been the focus of multiple studies. The evidence suggests that emotional and psychological distress are indeed likely to contribute to disturbed sleep patterns in ICU patients (Ding et al., 2017, Matthews, 2011, Pisani et al., 2015). An exploratory qualitative study was carried out by Ding et al. (2017) in the USA to examine patients' perception of factors affecting sleep in the ICU based on semi-structured interviews with 14 medical ICU patients after transfer from the ICU to the medical ward. The mean age of patients was 60±15 years, and the mean length of ICU stay was 4.1±5.2 days; the majority of patients were male (64%), and half of the sample (50%) had received mechanical ventilation during their ICU admission.

This study found that 21% of patients identified noise factors and nurses' activities as stressors that affected night-time sleep. More than half of the patients, 54%, also reported affective psychological factors, especially emotional factors and cognitive factors. The patients overall expressed the idea that uncertainty and worry about health conditions affected sleep negatively.

Similarly, an earlier cross sectional study carried out in China by Zhang et al. (2013) that included 152 patients sought to identify their perceptions of factors affecting sleep in a thoracic surgery ICU. That study found that half of all patients reported having worries regarding their illnesses, and many also cited being unable to communicate as an influential factor negatively affecting sleep.

2.7 Sleep assessment methods in the ICU

The existing evidence on sleep abnormalities in ICU patients from the literature supports the view that sleep disruption in ICU patients is multifactorial, whilst highlighting that these factors vary widely between both individual patients and ICU settings. This demonstrates the importance of identifying and assessing which particular factors may influence an individual patient's sleep in a given situation when assessing patients' sleep, especially in areas of hospitals not previously studied. The evidence reviewed so far also highlights the available range of approaches for assessing sleep quality in ICU patients, which are considered further in this section.

Assessment is the first critical step in the full nursing care process, as it enables nurses both to develop appropriate interventions and evaluate the effectiveness of these in practice (Munroe et al., 2013). Regular assessment is also crucial in the early identification of any sleep problems that ICU patients may have, allowing identification of the causes of such problems and the implementation of proper interventions to improve patients' sleep (Hoey et al., 2014). Patients' sleep in the ICU can be assessed by either subjective or objective measurements; this section therefore discusses both subjective and objective measurements available for measuring sleep in ICU patients, offering an estimation of the strengths and weaknesses inherent in each approach. Table 2-4 summarises the most common objective and subjective sleep measurements used for sleep assessment in the ICU.

Table 2-4 Summary of common methods used in sleep studies for sleep assessment in ICU patients

	Description	Advantages	Disadvantages	Examples of ICU sleep studies have used the measure
Objective measures				
Polysomnography (PSG)	Gold standard Inter-rater reliability in critical care =0.79 to 083.	Provides the most detailed on sleep architectures. Able to diagnose disorders of sleep. Measures sleep quantity and quality.	Expensive Discomfort reported in ICU patients Requires analysis and interpretation Not feasible for routine	Freedman et al. (2001) Gabor et al. (2003) Kondili et al. (2012) Elliott *et al. (2013)* Boyko et al. (2019)
Actigraphy	Small electronic device typically worn on a patient's wrist, like a wristwatch or, less commonly, around the ankle. It includes an accelerometer that records movements, according to changes in acceleration levels and presents the data in numerical form. The data is read into a computer and translated into sleep-wake patterns for subsequent analysis.	Cost-effective. Non-intrusive. Provides data for extended periods. Easy to use in ICU clinical practice.	Only measures activity, with no data on other sleep aspects. Tends to overestimate the TST of ICU patients' sleep. Depends mainly on patient movement in recording sleep duration. Continuous bed rest ad the resulting muscle weakness in ICU patients and device removal are threats to validity and reliability. Not validated versus PSG in critical care patients.	Beecroft et al. (2008) Bourne et al. (2008) Mistraletti et al. (2009) Chen et al. (2012)

Bispectral Index (BIS)	Commercial device to assess the depth of sedation or anaesthetic agents. It has also the potential to measure the depth of sleep. It consists of a monitor, a sensor and a digital signal converter. The sensor is attached to the patient's forehead thereby permitting electrical signals to be transmitted to the digital signal converter.	Enables cost-effective Can be used easily by non-specialist. Easily applied.	Prone to electrical interference. Prone to patient dislodgment. Needs to be downloaded to a computer for complete evaluation. Not practical for routine use in ICUs. Not validated versus PSG in ICU patients.	Nicholson et al. (2001) Bourne et al. (2008) Shilo et al. (2000)
Skin Potentials (SP)	Monitors and estimates TST based on negative voltage variations on the skin as regulated by the autonomic nervous system	Can differentiate between the patient being asleep or awake. Can be used easily by non-specialist.	Cannot identify different sleep stages. Scant research on its use amongst ICU patients. Not validated versus PSG in ICU patients.	Shiihara et al. (2001)
Subjective measures				
Richards Campbell Sleep Questionnaire (RCSQ)	Five-item VAS. Domains: sleep depth, falling asleep, a state of wakefulness, percentage of time awake, and overall sleep quality.	Correlated with PSG SEI in ICU patients (r=0.58) High reliability (Cronbach's alpha) score of 0.90 Demonstrates good to high internal consistency across numerous translations (Cronbach's alpha coefficient scores of 0.88 to 0.92). Not expensive Short items.	Cannot be used with cognitively impaired patients (sedated, delirious, neurological injury).	Aitken et al. (2017) Bourne et al. (2007) Elliott et al. (2013) Frisk and Nordstrom (2003) Hu et al. (2015) Kamdar et al. (2013) Menear et al. (2017) Murata et al. (2019) Richards et al. (2000)
Verran and Snyder-Halpern (VSH) Sleep Scale	Fifteen-item VAS. Domains: sleep disturbance, sleep depth, falling asleep, a state of wakefulness	Valid and reliable in hospitalised patients.	Not validated versus PSG in critical care patients. Not reliable for sleep assessment in ICU patients. Long items.	Fontaine (1989) Scotto et al. (2009) Su et al. (2013)

Sleep in Intensive Care Unit Questionnaire (SICQ)	27-item Likert scale instrument under the headings sleep quality (five items), daytime sleepiness (four items), and factors that may contribute to sleep disturbances (18 items). Sleep items relate to overall sleep quality (poor-excellent): no other aspects of sleep quality are covered.	Most of the SICQ covers patient perceptions of a variety of factors known to affect sleep quality in the ICU. Offers a useful method of gaining the patient's perspective on specific potential sleep disruptive factors.	Not validated versus PSG in critical care patients. Sleep assessment suffers from recall bias.	Bihari et al. (2012) Freedman et al. (1999) Elliott et al. (2014) Hu et al. (2015) Li et al. (2011)
Nurse Observation Checklist' (NOC)	Four-point checklist: (awake, asleep, unable to determine, and no time to observe).	Nurse observations correspond only partially with patients' perceptions	Difficulties are encountered by nurses undertaking the assessment because of the need to be close to the patient resulting in awaking the patient during sleep. Risk of observer bias. Nurses tend to overestimate patients' sleep. Lack of commitment by nurses to observing the patient's sleep. Nurses' documentation of patients' sleep is not systematic and not comprehensive of sleep aspects.	Edwards and Schuring (1993) Ibrahim et al. (2006), Olson et al. (2001)

2.7.1 Objective measures for sleep assessment in ICU

Objective measures of sleep as a term refers to techniques that provide details about patients' sleep architecture or stages of sleep (Krystal and Edinger, 2008). Existing evidence shows that applying objective sleep measures repeatedly in critical care environments is not generally feasible or practical, due to limitations and challenges inherent in objective measures such as actigraphy or the BIS, or even the PSG that represents the gold standard for sleep assessment (Table 2.4) (Beltrami et al., 2015, Elliott et al., 2011, Jeffs and Darbyshire, 2019). In addition, findings obtained by using objective measures are limited to the physiological characteristics of the patient's sleep; they do not give information on patients' quality of sleep from the patients' perspective, despite a patient's own experience of sleep being an essential aspect of evaluating sleep quality (Aitken et al., 2017, Ohayon et al., 2017). The value of this aspect of sleep quality is most clearly demonstrated by individuals reporting that sleep has been neither sufficient nor restorative despite the presence of normal PSG readings (Edinger et al., 2000, Harvey et al., 2008).

Understanding of the physiological characteristics of ICU patients' sleep in ICU-based sleep studies has generally been achieved through the use of the gold standard of sleep evaluation, PSG (Table 2.4) (Elliott et al., 2013, Freedman et al., 2001, Gabor et al., 2003, Hilton, 1976, Trompeo et al., 2011). However, although sleep studies using PSG offer comprehensive data on ICU patients' sleep architecture, their duration of sleep measurement is limited to short periods of assessment, with none exceeding a forty-eight-hour period. Thus, researchers have been unable to ascertain whether patient' sleep quantity and quality varies

or improves during the period spent in the ICU (Beecroft et al., 2008, Elliott et al., 2013, Freedman et al., 2001).

Small sample sizes are also a notable limitation in these studies, with samples ranging from 12 to 57 participants (Beecroft et al., 2008, Elliott et al., 2013). The short periods of sleep measurement and small sample sizes in these studies occur due to many challenges faced by researchers seeking to use PSG with ICU patients, which include technical difficulties, high costs, and the fact that the study mode is both time-consuming for researchers and disagreeable and burdensome to ICU patients (Beecroft et al., 2008, Elliott et al., 2013, Trompeo et al., 2011).

A study by Elliott et al. (2013) in Australia evaluating sleep in patients in general ICU used sleep measurement using PSG over a 24-hour period for 57 patients. PSG data was not analysed for four of the patients, however, as three patients asking for removal of the electrodes used for PSG as they found them to limit mobility and even to impede sleep, and there was difficulty in interpreting the PSG data for one patient, whose EEG waveform was affected by alpha intrusion (alpha wave activity superimposed on delta waves), which made analysis impossible.

Similarly, PSG data was not analysed for five of the initial patients in a study conducted in the USA on 22 medical ICU patients by Freedman et al. (2001) due to excessive electrical artefacts on their PSGs. A further study carried out by Trompeo et al. (2011) in Italy included 29 surgical ICU patients, with the authors reporting that five patients declined to participate in PSG testing due to them viewing the PSG monitoring as a potential impediment to their treatment.

While other less intrusive objective techniques such as actigraphy or the BIS have been used in ICU-based sleep studies (Table 2-4), they show no evidence of validity as compared with the use of PSG devices in terms of evaluating sleep in ICU patients. In addition, further challenges and limitations in terms of their use in ICU patients have been demonstrated. Two cross-sectional studies, conducted in the Netherlands (van der Kooi-Pol et al., 2013) and Brazil (Hamze et al., 2015), aimed to understand whether actigraphy was a valid and reliable method for sleep assessment in ICU patients. These authors, however, found that actigraphy overestimated sleep time or led to false readings of wakefulness in a range of ICU patients, highlighting that it is not suitable for use in ICU populations at present.

The BIS has also demonstrated problems in terms of practical application in ICUs. A study conducted in Australia by Bourne et al. (2008) involving 12 patients in general ICU assessed nocturnal sleep using BIS over a single night. The authors were unable to access sleep stags data due to the limitations of BIS, which only provides data on sleep quantity. They further reported problems with this practical application of BIS due to it being subject to electrical interference: BIS data were not analysed for four patients due to movement and electrode detachment during sleep evaluation, which adversely affected the final results (Bourne et al.,2008). There is thus no evidence of BIS validity as compared with PSG in terms of sleep assessment in ICU patients, and thus, currently, BIS has no clinical role in an ICU context.

There is scant research about the use of SP amongst ICU patients, though Shiihara et al. (2001) monitored sleep-wake patterns in ICU patients in Japan over a nine-day period using an SP device, concluding that the SP device could

discriminate between states of being awake and asleep in ICU patients. However, no information was provided about the number of participants included in this study, and in addition, no information was provided regarding the sleep data obtained. There is thus no evidence of SP validity as compared with PSG use in ICU patient sleep assessment, and the role of SP with regard to sleep assessment in ICU patients cannot be verified.

Overall, the PSG remains the gold standard for objectively measuring sleep in ICU patients, and its use has allowed the development of an established understanding of the architecture of sleep in ICU patients (Elliott et al., 2013, Freedman et al., 2001, Trompeo et al., 2011) as described in section 2.5.

Overall, several challenges in using objective measures in ICU settings were reported, making their validity, reliability, feasibility and acceptability in the ICU environment somewhat limited, and identifying them as impractical tools for routine use in ICU environments. Alternative subjective measures to facilitate simple routine assessment of patients' sleep in ICUs and to enable researchers to study and improve sleep management in ICU environments have thus been sought. These subjective measures are discussed in the following section.

2.7.2 Subjective measures for sleep assessment in ICU

Subjective measures of sleep, unlike objective measures, are based on an individual's perception of sleep, whether via self-reporting or observatory evaluation of sleep by an external party. Subjective measures have become more commonly used as substitutes for objective methods of sleep assessment in ICU settings due to the significant limitations to using objective measures described previously 2.7.1.

Self-reporting of sleep is a measure that relies on the individual's reporting of their own sleep quality and quantity, including their feelings of being rested upon awakening, while nurses' observation of patient sleep only involves direct observations of a patient's apparent sleep state, combined with the completion of a questionnaire that does not include patient participation. Although self-reporting has several well-known challenges, especially for individuals with low attention spans or impaired cognition, generally, the patient is best-placed to judge their own sleep quality and quantity (Devlin et al., 2018, National Sleep Foundation, 2015, Ohayon et al., 2017).

A patient's perception of sleep is a necessary element for identifying sleep problems and thus developing interventions and evaluating their effectiveness (Hoey et al., 2014). Nurses' observation of patients' sleep may be the only option when the patient is unable to self-report (Devlin et al., 2018), though a well-known disadvantage of such observation measures is that the lack of patient participation increases the risk of observer bias (Devlin et al., 2018, Elliott et al., 2011, Ritmala-Castren et al., 2014).

Many structured sleep questionnaires have been used in ICU sleep studies for both patient self-reporting of sleep and nurse observations of patient sleep, including the Verran Snyder-Halpern (VSH) Sleep Scale (Snyder-Halpern and Verran, 1987), the Sleep in Intensive Care Questionnaire (SICQ) (Freedman et al., 1999); the Nurse Observation Checklist (NOC) (Edwards and Schuring, 1993); and the Richards Campbell Sleep Questionnaire (RCSQ) (Richards et al., 2000). Among these sleep assessment tools, the most valid, simple, and widely used questionnaire in ICU sleep studies involving sleep assessment in ICU patients is

the RCSQ (Elliott et al., 2011, Hoey et al., 2014, Jeffs and Darbyshire, 2019): this is thus seen as a promising tool that may facilitate daily routine sleep assessment in ICU environments (Elliott et al., 2011, Hoey et al., 2014, Menear et al., 2017, Nicolas et al., 2008). This section provides a brief background to the most common subjective measures that used in ICUs sleep studies, as well as discussing their validity and potential to assess sleep in ICU patients (Table 2.4).

2.7.2.1 Verran Snyder-Halpern (VSH) Sleep Scale

The self-report VSH sleep scale was developed by Snyder-Halpern and Verran (1987) to assess sleep in healthy adults. It is comprised of ten items that subjectively evaluate awakening, sleep latency, and sleep depth, and Snyder-Halpern and Verran (1987) established the tool's validity and reliability by comparing the VSH results for a sample of 69 subjects from a healthy population against two other self-reporting methods: the Baekeland and Hoy (1971) and the St Mary's Hospital Sleep Questionnaire (Ellis et al., 1981). The authors found satisfactory reliability (theta = 0.82) and performed a factor analysis of the scale to derive two factors, disturbance and effectiveness. The results led the study's authors to add four new items to the scale, bringing it to a total of 14 items, each of which are applied to a 0 to 100 mm Visual Analogue Scale (VAS). The VSH sleep scale is not an appropriate tool for sleep assessment in ICU patients, however, due to the multiplicity of items (14), which mean that it takes 10 to 15 minutes to complete (Snyder-Halpern and Verran, 1987). This may create too great a burden for many ICU patients; additionally, the scale shows no evidence of validity when compared with PSG data from ICU patients (Fontaine, 1989).

An observational comparison of the VSH scale with PSG data aimed at determining the reliability and validity of the VSH scale with regard to sleep assessment in ICU patients was carried out in USA by Fontaine (1989). The study involved 20 patients in trauma ICU. No correlation was found between PSG data and VSH variables in relation to sleep latency, mid-sleep awakenings, or wakefulness after sleep onset. Fontaine (1989) suggested that the disparity between the PSG data and the VSH sleep score could be explained partly by patients misinterpreting one of the VAS scale items, experiencing a distorted sense of time, or having poor recall of being awake for short periods. No further studies about VSH validity as compared to PSG in ICU patients have been published.

2.7.2.2 Sleep in Intensive Care Unit Questionnaire (SICQ)

The SICQ was developed specifically for use in the ICU context by Freedman et al. (1999) with the aim of examining quality of sleep from a patient perspective and identifying the factors that contributed to sleep disruption in intensive care. The SICQ is comprised of 27 items, with five items under the heading of sleep quality, four under daytime sleepiness and 18 under factors that contribute to sleep disturbance. Participants are required to (1) rate their overall quality of sleep in the ICU retrospectively using a 10-point scale ranging from 1 (poor) to 10 (excellent), (2) rate their sleep at home prior to their ICU admission, (3) average their sleep rating across their whole ICU admission; and (4) rate their sleep on the first day, at the midpoint, and at the end of their ICU stay. All the items on the SICQ that relate to quality of sleep focus only on overall sleep quality (ranging from poor to excellent), with no discussion of other aspects of sleep quality (Freedman et al., 1999).

Freedman et al. (1999) recruited 203 patients (121 males and 82 females) from a cardiac ICU, medical ICU, and surgical ICU on their day of discharge from the unit. Patients were asked to complete the SICQ to determine their perceptions of sleep quality and daytime sleepiness over the full course of their ICU stays and to determine the perceived effects of environmental factors on sleep disturbances in the ICU. The findings revealed that, overall, sleep quality among ICU patients was poor; their sleep quality was significantly poorer than their baseline sleep at home ($p = 0.0001$). However, these findings regarding patients' sleep quality were not sufficiently comprehensive to aid understanding of the quality of ICU patients' sleep as they were limited to overall sleep quality, with no data gathered about other aspects of sleep quality.

Freedman et al. (1999) also mentioned the risk of recall bias as a potentially confounding problem in their sleep assessment. In addition, the SICQ has not been validated against PSG for sleep assessment in ICU patients, and thus, the SICQ is not currently an adequate tool for assessing the quality of sleep of ICU patients. However, despite the SICQ's limitations in relation to sleep quality assessment, it nonetheless offers a useful method of gaining a patient's perspective on specific factors that may potentially be disruptive to sleep (Freedman et al., 1999), as the other main section of the SICQ includes two questions about patient perceptions of a variety of factors known to affect sleep quality in the ICU, scored on a Likert scale of between one and ten (1= no disruption, to 10 = significant disruption). The first question evaluates sleep disruption by health care personnel activities, such as taking vital signs, and the second question evaluates disruption caused by specific environmental noises such as alarms (Freedman et al., 1999).

Freedman et al. (1999) found that this part of the questionnaire was effective in identifying a variety of sleep disruptive factors from a patient perspective; the study results also clearly demonstrated that environmental causes of sleep disruption in ICU are multifactorial. Furthermore, as the nature of the ICU environment varies across different healthcare providers, regions, and countries such that there is inevitably variation in terms of patients, equipment, and design of the individual units, factors that affect sleep are thus unique in each ICU. The SICQ can therefore be useful in identifying factors that cause sleep disruptions from a patient perspective in a specific environment, and it can be supplemented or altered to fit patients' cultural backgrounds and the environment of a specific ICU (Elliott et al., 2014, Li et al., 2011, Bihari et al., 2012, Freedman et al., 1999).

2.7.2.3 Nurse Observation Checklist (NOC)

The NOC was developed by Edwards and Schuring (1993) for sleep assessment in ICUs from a nursing perspective. It is comprised of a four-point checklist that marks patients' status as awake, asleep, unable to determine, and no time to observe. Edwards and Schuring (1993) conducted an observational study to validate staff nurses' observations of patients' sleep using NOC among ICU patients as compared to a standard PSG. The study, conducted in the USA, included 21 patients in a medical ICU, with 15 nurses participating in the study. During sleep monitoring, the nurses were blinded to the PSG, and each staff nurse observed a single patient at night every 15 minutes for four hours, with PSG recording occurring from 0100 to 0500 hours.

A total of 340 observations were made, with an average of 17 observations per patient. The authors reported that nurses' observations using NOC showed good validity compared with PSG, as nurses' observations were correct 81.9% of the time. However, no specific criteria were given for the assignment of wake/sleep states, and, in addition, 8.5% of nurse observations were “no time to observe”, while 11% of the observations were “could not tell” (Edwards and Schuring, 1993). This indicates that nurses' observations using NOC lack practicality with regard to routine use in the ICU, and that its use at discrete times (every 15 minutes) is arguably not feasible in a busy ICU environment, making multiple missing datapoints likely (Bourne et al., 2007, Ritmala-Castren et al., 2014).

2.7.2.4 Richards Campbell Sleep Questionnaire (RCSQ)

The RCSQ was originally developed to allow critically ill patients to report on their previous night’s sleep in the ICU environment. Richards et al. (2000) believed that it was important to develop a brief, easily administered tool as an alternative to PSG that could provide a highly reliable and valid description of sleep. RCSQ was constructed as a five-item VAS (Richards et al., 2000), and each VAS in the RCSQ represents a different aspect of sleep: sleep depth, falling asleep, wakefulness, sleep latency, and the overall quality of sleep. These five aspects of sleep quality in RCSQ are aligned with the adopted definition of sleep quality by the NSF in this thesis (National sleep foundation,2015) that has previously discussed in section 2.3.

Each VAS in RCSQ ranges from 0 (the poor quality) to 100 (excellent quality), and the sleep scores are identified by measurement in millimetres from the low end

of the scale to wherever the patient makes their mark. The total RCSQ score is the mean of the five VAS scores (Richards et al., 2000).

The VAS format was chosen by Richards et al. (2000) as it has several advantages for critically ill patients. For those who lack the physical stamina to complete a long test, a VAS is suitable because it only needs the participant to make a single mark. A VAS can also be used for patients who are being mechanically ventilated and are thus not able to write lengthy responses or respond verbally to questions (Richards et al. (2000).

Richards et al. (2000) conducted a pilot test in the medical ICU on nine non-mechanically ventilated male patients; PSG recordings over a total of 14 nights were used to examine the RCSQ's criterion validity, based on the extent to which the RCSQ scale correlated with the gold standard PSG device readings. The study showed that the item on the RCSQ regarding light sleep/deep sleep strongly correlated with the PSG sleep characteristics for stage 4 NREM (r= 0.59) and stage 3 (r = 0.56). The item "A good night's sleep/A bad night's sleep" also showed a strong correlation with the lighter sleep stage of N2 (r=0.64) and REM (r=0.55). The item "Fell asleep immediately/Never could fall asleep" was strongly associated with latency to sleep onset, although this result was not strongly statistically significant (r = -0.51, p=0.07). These correlation results between PSG sleep characteristics and the perception of sleep as measured by the RCSQ generally suggest that the five-item RCSQ demonstrates validity against the PSG in terms of capturing the main domains of sleep quality.

Richards et al. (2000) further validated RCSQ against PSG in a more extensive investigation involving 70 male, non-mechanically ventilated, medical ICU patients. They examined the dimensions of RCSQ by performing factor analysis, grouping similar variables into dimensions to identify the construct “sleep”. This factor analysis resulted in a single factor of sleep efficiency emerging where the total RCSQ score explained 33% of the variance in the SEI (Richards et al., 2000); there was then a moderate correlation between total RCSQ score and SEI as measured by PSG ($r = 0.58$, $p < 0.001$). This suggests that RCSQ has promise as a method of estimating sleep quantity (SEI). Based on this validation, the authors developed a regression equation formula to calculate the SEI: 46.88 + (0.39 X RCSQ) = sleep efficiency index.

Furthermore, all five items on the RCSQ had substantive factor loadings, and a robust univariate factor (Richards et al., 2000), suggesting that RCSQ offers a unidimensional scale in which the total score can represent the overall construct of sleep (Richards et al., 2000). In addition, the Cronbach’s α coefficient for the RCSQ, which is a measure of internal consistency or reliability that reflects how closely related a set of items is as a group, was 0.90, indicating good inter-relatedness between RCSQ items. The RCSQ is thus currently considered to be the most suitable tool for assessing patients' sleep in the ICU.

A critical review by Jeffs and Darbyshire (2019) appraised several subjective tools used to assess sleep in the ICU based on a systematic search of papers published between 2005 and 2015 that identified studies that used subjective methods of assessing sleep in ICU patients. The review included 23 studies, with total sample size of 2,031 ICU patients, in which a total of 13 different

questionnaires were used to assess sleep in ICU patients; five studies utilised the RCSQ, four studies utilised the SICQ, two studies utilised the nurse observation tool, two studies utilised the VSH scale and ten studies utilised non-validated questionnaires designed specifically for each study.

Jeffs and Darbyshire (2019) critically appraised each sleep assessment questionnaire based upon the data reported about each questionnaire's validity (accuracy in measuring what is intended) and reliability (consistency). The review concluded that, of all the questionnaires used for sleep assessment in ICUs, the RCSQ is the most valid and reliable tool for assessing sleep in ICU patients. None of the other tools, such as SICQ, NOC, and VSH, were adequately validated against the gold standard PSG for the purpose of sleep assessment in ICUs (Jeffs and Darbyshire, 2019).

The review also suggested that the reason for developing new questionnaires to assess sleep in the ICU in some studies was the desire to identify factors influencing sleep in addition to making an overall assessment of sleep quality. Jeffs and Darbyshire (2019) thus recommended that, rather than developing new questionnaires for sleep assessment from a limited evidence base, RCSQ be used for subjective sleep assessment in conjunction with another questionnaire to identify the factors influencing that sleep (Jeffs and Darbyshire, 2019). However, Jeffs and Darbyshire's search strategy only included papers published between 2007 and 2015, while the review generated evidence on RCSQ psychometric properties and feasibility from only five studies (Frisk and Nordstrom, 2003, Kamdar et al., 2012, Nicolas et al., 2008, Patel et al., 2014, Richards et al., 2000). This warrants an updated review of published papers on

the use of questionnaire-based sleep assessment methods, specifically the RCSQ, to determine its psychometric properties and feasibility and acceptability from a number.

Although sleep assessment using self-reporting methods such as RCSQ is limited to patients with sufficient cognitive abilities, it is recommended by the SCCM (Devlin et al., 2018). In recently published clinical practice guidelines for the management of pain, agitation, delirium and sleep disruption in ICUs, the SCCM also stressed the importance of routinely enquiring about ICU patients' perception of their sleep using a valid tool such as RCSQ as a necessary first step for adequate sleep management (Devlin et al., 2018).

However, for a self-assessment tool to ensure that ICU patients' sleep is consistently assessed in the ICU to an extent that can support efficient evaluation for research and clinical practice, it must demonstrate sufficient evidence of all aspects of outcomes measures including feasibility , acceptability, and psychometric properties (validity and reliability) (Fitzpatrick et al., 1998, Roach, 2006). All of these outcome measures are important and should be considered prior to implementing an assessment tool in clinical practice (Roach, 2006). Therefore, further work focusing on ICU sleep studies utilising RCSQ was required in order to further support the current evidence on RCSQ's feasibility, acceptability, and psychometric properties.

2.8 Summary

This chapter introduced the concept of sleep, including the domains of sleep and the essential concepts underlying the current study into sleep quality, as understanding sleep is a necessary foundation for identifying the right assessment measures to evaluate it. This chapter also reviewed the literature related to normal sleep structure in healthy humans and its significance to their well-being, as well as examining the alterations to this sleep structure seen in ICU patients.

There is evidence that ICU patients experience poor and non-restorative sleep in terms of quality, although their total sleep quantity may be within normal bounds. This is because their sleep is characterised by frequent disruptions and a reduction in deep sleep phase frequency and duration. In addition, increased daytime sleepiness is a frequent and common problem among ICU patients. Several factors have been identified as potentially responsible for disrupted sleep in ICU patients, which may be related to the ICU environment or to the patients' own treatments or health. Variation between study results offers evidence of the need to routinely assess and enquire about patients' sleep, along with evaluating sleep-disrupting factors in the ICU clinical practice.

Measures of sleep assessment, including both objective and subjective measures, were thus also described and discussed in this chapter. All of the currently available methods have limitations; in particular, most objective measures have significant limitations which impede their use and effectiveness in regular sleep assessment in ICU clinical practice. Subjective measures are thus frequently proposed as alternatives for sleep assessment in ICUs, and the RCSQ has been

identified as the most promising current tool for sleep assessment in ICU patients. It is thus now recommended as the questionnaire of choice for self-reported sleep assessment in research as well as in ICU clinical practice.

The next chapter therefore offers a structured review of the literature describing and reviewing evidence of the RCSQ's feasibility, acceptability, and psychometric properties. The chapter also provides a comprehensive overview of quality of sleep from patients' perspectives based on the use of RCSQ, as well as exploring sleep disrupting factors that may be assessed during such sleep assessments.

Chapter 3 A structured review of the literature on the psychometric properties, feasibility, and acceptability of the RCSQ in ICU settings

As described in the previous chapter, RCSQ has been recommended as a tool for sleep assessment in ICU patients in both research and ICU clinical practice. However, further understanding of its psychometric properties, feasibility, and acceptability for sleep assessment in ICU patients, as well as an examination of countries it has been used in is important. Hence, this structured review of the literature focuses on ICU sleep studies that have utilised RCSQ, based on a search utilising the explicit application of systematic methods.

By undertaking a structured review of the literature, more focussed knowledge of a topic can be gathered that identifies any gaps in, relationships between, and inconsistencies in the literature by critically evaluating, synthesising, and integrating the findings from all directly relevant studies on the topic (Coughlan and Cronin, 2016). The purpose of undertaking a structured review as reported on in this chapter was to collate all individual studies matching pre-specified eligibility criteria (Coughlan and Cronin, 2016, Grove et al., 2012) in order to identify all ICU based studies that have used the RCSQ. The aims of this review were threefold:

1. To provide evidence of the validity, reliability, feasibility, and acceptability of using RCSQ among patients (self-reporting) or nurses (observational reporting) in ICU settings.

2. To provide a comprehensive overview of sleep quality and sleep disrupting factors in ICU settings, as identified through the use of the RCSQ.

3. To identify any limitations of, and gaps in, the evidence base in this area that could be used to inform the design and aim of the current study.

The chapter thus begins with a set of definitions of basic aspects of the outcome measures: psychometric properties, feasibility, and acceptability; an understanding of these is critical for determining the effectiveness of any measure addressing clinical outcomes (Coster, 2013, Fitzpatrick et al., 1998, Roach, 2006). After these definitions, a summary of the search strategy, including the screening and selection processes for relevant studies, is provided. The chapter then offers a synthesis of the relevant emergent studies before concluding with a summary that outlines the aims and purpose of the current study.

3.1 Basic concepts underlying outcome measures

The term “outcome measure” refers to any health measurement tool used to assess patient health or illness and the effectiveness of relevant treatment interventions, including whether the patient has demonstrated a response to a particular intervention (Fitzpatrick et al., 1998, Roach, 2006).

Evaluation criteria for outcome measures thus include psychometric properties, used to assess the scale’s accuracy (validity and reliability), feasibility, and acceptability, all of which are important to determining clinical usefulness. The following definitions of these criteria for outcome measures were thus applied in this review to act as a guide to abstracting information on the RCSQ's psychometric properties, feasibility, and acceptability from the identified studies in order to determine its usefulness in assessing sleep in ICU patients, as

well as to identify any limitations of or gaps in the evidence base in this area that could be used to inform the design and aim of the current study.

3.1.1 Reliability

Reliability refers to the consistency of a measurement scale, which can be evaluated in three aspects: internal consistency, equivalence, and stability. Internal consistency (homogeneity) is an assessment of how well all items in an outcome measure are correlated and thus measure the same underlying construct (in this case, sleep) (Roach, 2006). It is a widely used method of testing for reliability as it is economical and can identify errors in the sampling of items. It can be measured by several different procedures, including the split-half technique, Cronbach's alpha (α) (or coefficient alpha), and the Kuder–Richardson formula 20 (KR-20) (Roach, 2006, Bryman, 2012).

Cronbach's alpha is the most popular test of internal consistency; this essentially estimates the average level of agreement between the items in a scale. The resulting alpha coefficient ranges in value from 0 (none of the items are correlated with one another) to 1 (all of the items are perfectly correlated with one another) (McGoey et al., 2010). A general rule of thumb is that a Cronbach's alpha of 0.70 and above offers good reliability, though 0.80 and above is better and 0.90 and above is 'best' (Streiner, 2003, Tavakol and Dennick, 2011). A low Cronbach's alpha value (anything less than 0.70) indicates poor inter-relatedness between items in a measurement scale, suggesting that these be discarded or at least revised (Tavakol and Dennick, 2011).

A test of internal consistency is not only important in the questionnaire development process; it should also be considered in the process of translating a valid existing measurement scale, most particularly after a final version of the translated tool is produced, in order to ensure that items in the translated version remain intercorrelated, and that the final translated version maintains conceptual equivalence (Sousa and Rojjanasrirat, 2011).

Equivalence (inter-rater agreement) measures the correlation of scores between two or more raters based administering the same scale to the same participants (Bryman, 2012). The most important point to be considered in undertaking inter-rater reliability testing is that participating raters should be adequately trained to administer and score the measures to prevent measurement errors that may adversely affect reliability (Fitzpatrick et al., 1998, McGoey et al., 2010).

Stability refers to the recurrent administration of the same scale to the same sample in the same circumstances in order to measure the extent to which the scores remain similar (test-retest reliability) (Fitzpatrick et al., 1998, McGoey et al., 2010). Test-retest reliability needs to allow sufficient elapsed length of time between assessments (between 2 and 14 days) to ensure that participants are unlikely to recall their previous answers (McGoey et al., 2010).

3.1.2 Validity

Validity is an assessment of the accuracy of the outcome measure, that is, does it measure what it is supposed to measure (McGoey et al., 2010). There are several different approaches to testing validity, including criterion validity, construct validity, face validity, and content validity. Criterion validity assesses

the extent to which a measurement scale correlates with a selected “gold standard” (Bryman, 2012, Fitzpatrick et al., 1998). In this case, therefore, PSG is the gold standard for sleep assessment, so a high correlation with this gives a good indication that a measurement scale is measuring what it intends to measure.

Construct validity is another important part of scale development. It refers to the “completeness” of a tool, and how adequately it assesses the construct (in this case, sleep) (McGoey et al., 2010). To achieve construct validity, the measurement scale should be carefully developed based on relevant existing knowledge of the underlying concept. The RCSQ has the goal of measuring sleep quality in ICU patients in this study, so it would be expected that this would include elements that measure various aspects of sleep. A commonly used method to investigate construct validity is Confirmatory Factor Analysis (CFA), which is used in the development or construction phase to capture the variance in variables, to identify whether any relationships between the variables and their underlying construct exist, and to reduce the overall number of unobserved variables by examining commonalities within the data (Babyak and Green, 2010).

Content validity is the degree of which the content of the scale is an adequate reflection of what it is intended to measure (Fitzpatrick et al., 1998, McGoey et al., 2010). It is an essential aspect that should be considered in the process of translation and adaptation of an original measurement scale in order to ensure that the concepts of the items in the translated scale provide an adequate reflection of the performance of the items in the original version of the measurement scale (Sousa and Rojjanasrirat, 2011). Content validity for the

translated version of a scale can be evaluated by expert panel in the underlying concept's field (in this case, sleep) and context (in this case, ICUs). In addition, it should be evaluated by the target population (in this case, ICU patients) in order to see what this population thinks each scale item refers to. This approach is crucial to ensuring that the translated items retain the same meaning as the original items and that the items thus measure what they are intended to measure (Sousa and Rojjanasrirat, 2011, World Health Organisation, 2017).

Face validity is a similarly subjective measure that can be evaluated either by an expert panel or the target respondents, which assesses whether a measurement scale is both relevant and clear; this is thus more related to the subjects acceptance of the text (McGoey et al., 2010). In all cases, the measurement tool must be understandable and perceived as relevant by the subjects to ensure co-operation and motivation (Fitzpatrick et al., 1998, McGoey et al., 2010).

3.1.3 Feasibility

Feasibility refers to how easily a measurement scale can be produced and applied in clinical practice, specifically with regard to ease of administration and scoring by patients, clinical staff or researchers (Bowen et al., 2009, Fitzpatrick et al., 1998). According to Fitzpatrick et al. (1998), the indicators of a feasible tool in clinical practice or research include the time needed to complete the assessment by respondents and the respondents' burden as assessed through refusal rates, missing responses, and drop-out rates. In addition, simplicity, in terms of requiring minimal time and effort from patients, staff, or researchers for effective use, being easy to interpret, being cost-effective, and being resource efficient, all without disrupting clinical care are

important in relation to using and applying the RCSQ in ICU clinical practice. These factors have thus been abstracted from the relevant studies included in this review where these were reported.

3.1.4 Acceptability

In addition to feasibility of use for evaluators and patients, it is also crucial that any assessment tool is acceptable to them in order to minimise avoidable distress being offered to patients who must already cope with health problems; this also permits evaluators to obtain higher response rates to questionnaires, making the results more generalisable and less prone to bias (Fitzpatrick et al., 1998, Sekhon et al., 2017). Acceptability refers to the extent to which a measurement scale is acceptable to the participants (Fitzpatrick et al., 1998). In assessing ICU patients' sleep quality using the self-report RCSQ, it is thus important to determine whether using the RCSQ in routine practice is acceptable to ICU patients, as well as to the nurses, prior to implementing it within the daily routines in the ICU.

Sekhon et al. (2017) stated that successful implementation of new measures depends on the acceptability of the proposed measures to participants. They defined acceptability as a multi-faceted construct reflecting the extent to which people participating in new proposed measures consider them to be appropriate, based on their cognitive and emotional responses (Sekhon et al., 2017).

Sekhon et al. (2017) suggested that indicators of acceptability that should be considered when assessing acceptability for a specific measurement scale must include potential participants' willingness and readiness to engage in the assessment, negatively reflected in the number of eligible participants who were

invited to participate in the study but decided to decline. In addition, Fitzpatrick et al. (1998) argued that a direct assessment of patients' views about the proposed assessment tool should be made by asking respondents whether they find any questionnaire items difficult, annoying, or distressing.

3.2 Search strategy

Multiple databases, including CINHAL, PubMed, Embase, MEDLINE, and PsychINFO were searched. The Cochrane Library and Web of Science were also searched separately. The first search for relevant studies was carried out in 2017, and this incorporate publications from 2000 through to September 2017; the search was repeated at regular intervals during that year in order to identify new relevant studies that might fulfil the review purposes. The start search date was chosen because this was when the final version of RCSQ was published (Richards et al., 2000), thus allowing the review to capture all of the most relevant RCSQ-based studies in critically ill patients. The same database search strategy was repeated and updated in August 2019 to incorporate publications from 2017 through to 2019, to capture the most recent articles and ensure that the review was up to date prior to thesis submission.

The search keywords (Table 3-1) were kept broad, and all full-text articles were scanned and reviewed manually as necessary to prevent erroneous exclusion of studies evaluating sleep using RCSQ alongside other assessment measures, such as those where the "RCSQ" term was absent from both the abstract and keywords. The keywords were augmented using truncation (*), wildcards, and the adjacent operator (adj), as well as the Medicine Subject Headings (MeSH) specific to each database. The keywords used for all of the databases were related to the topic, and these were categorised into four specific groups: sleep,

sleep assessment, sleep-disrupting factors, and critical care, as presented in Table 3-1. Each group represents a range of terminology employed in that search, for which synonyms were also applied; the search was then narrowed by combining terms using the Boolean logical operators "AND" and "OR" (Hart, 2018). The reference lists for the relevant papers were also scrutinised manually in order to minimise the risk of missing relevant studies, and the "related article" and "cited by" tools in the PubMed Central database and Google Scholar were also utilised to maximise the capture of relevant data.

Table 3-1 Keywords used in searches

Group	Keywords
Sleep	"Sleep quality", "sleep quantity, "disturb*", "sleep disruption", "sleep deprivation", "sleep wake disorders", "sleep disorders", "poor sleep".
Critical Care	"ICU", "intensive*", "care", "critical care", "patients", "critical illness", "critically ill", "mechanically "ventilated", "acute" , "CCU" .
Assessment	"Self-report", "evaluat*, "measure*", "assess*", "observ*" "questionnaire", tools", "monitor", "instruments", "Richards Campbell Sleep Questionnaire", "RCSQ", "nurs*", "perception" , "views ", "feasibility, "acceptability", "validity", "reliability".

3.3 Inclusion and exclusion criteria

Both quantitative studies, whether observational or experimental, and qualitative studies were included where these used RCSQ in ICUs in order to examine the psychometric properties, feasibility, or acceptability of the RCSQ or if they utilised the RCSQ in ICUs with adult patients aged 18 years or over for the

purposes of assessing patients' self-reported sleep quality or to facilitate nurses' observations of patients' sleep quality.

Articles were excluded where they were not published in English, or where they assessed patients' sleep using RCSQ in wards in hospitals other than the ICU or following hospital discharge. Studies that included both sleep assessment in ICU and following ICU discharge, however, where the data gathered during patient stays in the ICU were reported separately, were included. Reviews, guidelines, case reports, books, conference abstracts or posters, and opinion articles not including any original data were excluded.

3.4 Search results

Figure 3-1 presents the results of the literature search carried out in 2017 that incorporated publications from 2000 through October 2017, and Figure 3-2 presents the results of the updated search carried out in August 2019 that incorporated publications from 2017 through to 2019. This version (Figure 3-2) presents the includes the previously identified studies to present the full results of an updated literature search, following the guidelines by Cochrane Collaboration work by Stovold et al. (2014).

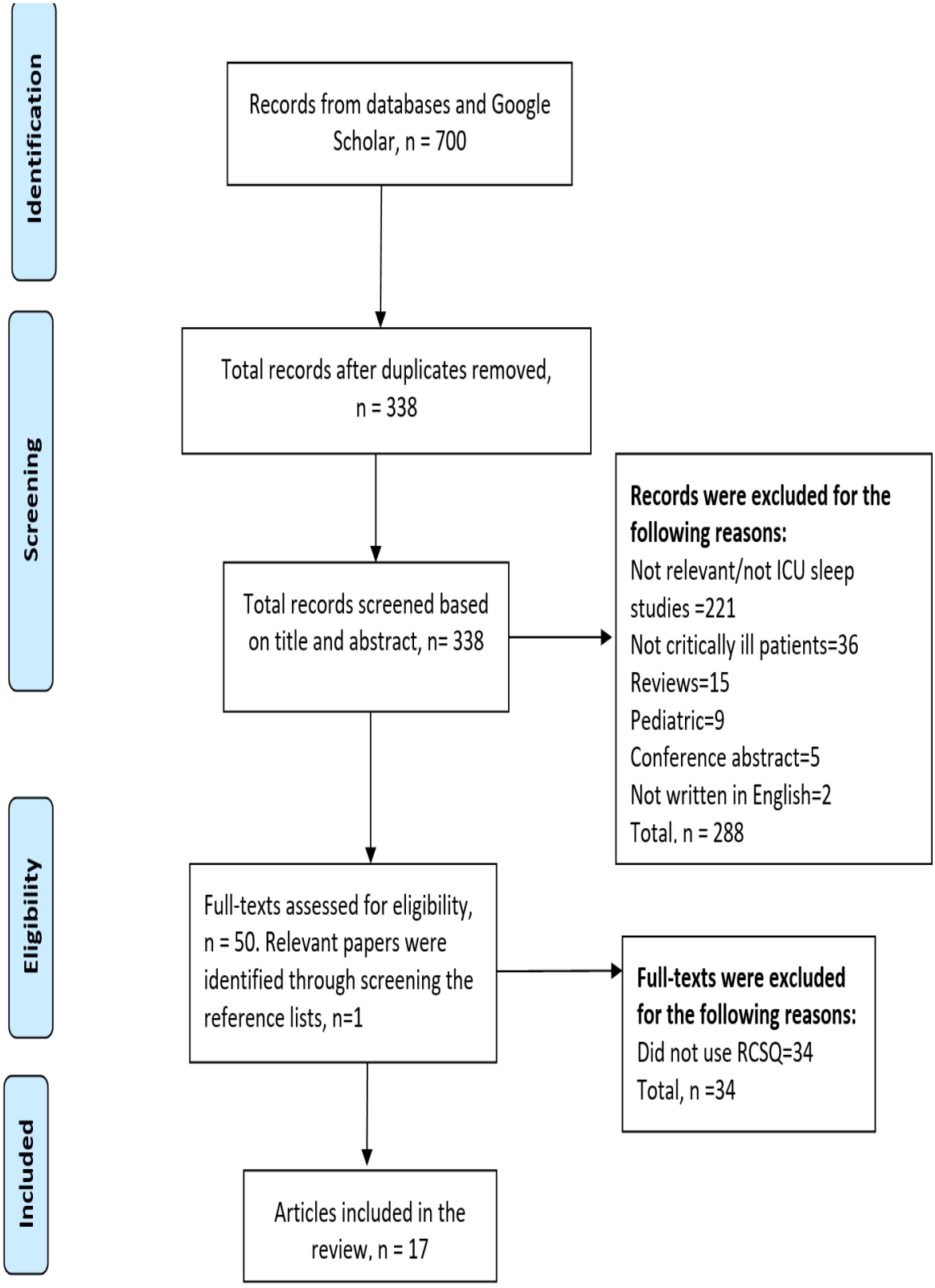

Figure 3-1 PRISMA flowchart of identification and screening process, (Moher et al., 2009)

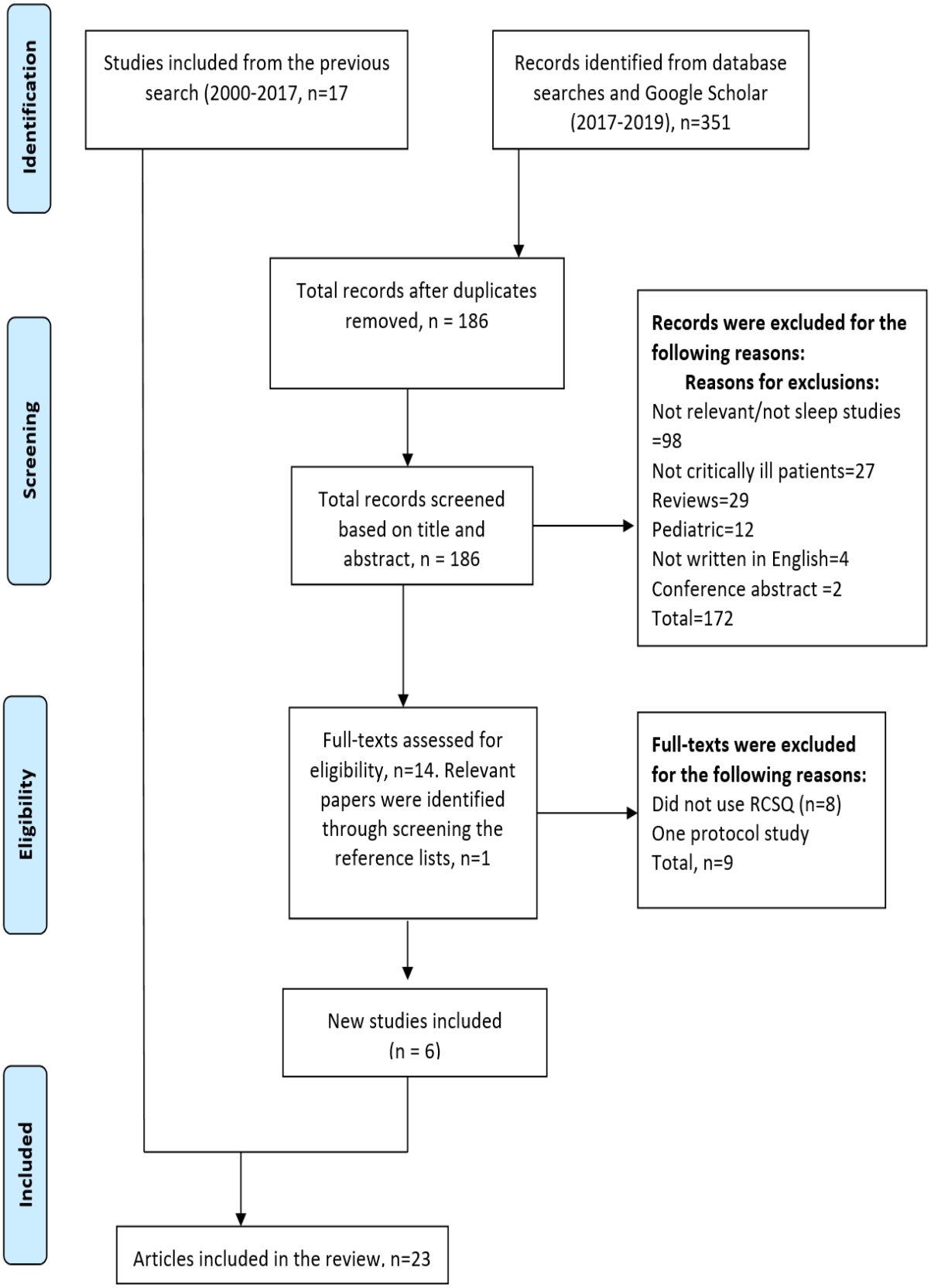

Figure 3-2 Updated PRISMA flow chart flowchart of identification and screening process,(Stovold et al., 2014)

The search results in October 2017 (Figure 3-1) were managed as follows: a total of 700 initial records were identified; these records were then transferred to the Endnote reference manger tool, where 362 duplicate articles were removed. The titles and abstracts of the remaining 338 articles were screened to identify relevant sleep studies in adult ICU patients, which resulted in 288 non-relevant articles being removed. The 50 full-text articles remaining were examined for further eligibility, and one further relevant article was identified through screening of the reference lists. Thirty-four studies were later excluded based on a review of their full texts (Figure 3-1), yielding a total of 17 full-text articles to be included in this review. An additional six new relevant studies were added to this review based on the results of the updated literature search in August 2019 (Figure 3-2) (Stovold et al., 2014).

Table 3.2. and Table 3.3 summarise the 23 articles included in this review of previous studies, which helped to build an understanding of the usefulness of RCSQ as used for sleep quality assessment, whether by patients self-reporting on their sleep quality or by nurses observing patients' sleep in ICU clinical practice, in terms of validity, reliability, feasibility, and acceptability. The review also helped to develop an understanding of sleep quality from a patient perspective, as well as allowing identification of the gaps in the research that required further investigation. In addition, it allowed development of an overview of the key methods and contradictory findings within existing studies, allowing their limitations and recommendations to be examined; these were used to help design the current study and to justify the findings of this thesis.

Specific key information types were extracted from each article, as provided in Table 3.2. and Table 3.3: study location/country; ICU setting; sample characteristics; key methods including study design, aims, and method of RCSQ administration to the patient (researcher or nurse); the results of the sleep quality assessment; and data about sleep disruptive factors. In addition, all reported information regarding the RCSQ's validity, reliability, feasibility, and acceptability were extracted and evaluated, based on the definitions of these concepts offered in section 3.1

Table 3-2 Characteristics of ICU based sleep studies used RCSQ

Author, country, ICU-setting and design	key methods and purpose of using RCSQ	Participants	Reported sleep disruptive factors	Sleep aspects mean/SD or (range)					
				Sleep depth	**Falling asleep**	**Number of awakening**	**Returning to sleep**	**Overall sleep quality**	**Overall RCSQ score/SEI**
1 Aitken et al.,2017 Australia, Surgical and medical ICU Prospective observational Repeated assessment	Patients asked to report on their sleep quality using RCSQ for 18-night. Examined the relationship between patients' self-report and their documented sleep by nurses. Patients asked open-ended questio n to determine those factors they perceive as disruptive to their sleep.	151 patients; mean age: 60 (46-71); sex: M (59%); F (41%); APACHE II: 15 (10-20); Patients were oriented ; RASS: NR; Ventilatory status: NR	Multiple factors reported by the patients; noise, light, care activities, fear, worry.	44 (16-64)	45 (22-70)	47 (24-72)	48 (20-73)	48 (16-72)	46(26-65) SEI: 65%
2 Bourne et al.,2008 Australia General ICU Experimental RCTs	Examined the effect of exogenous melatonin on nocturnal sleep using BIS. Assessed patients sleep using RCSQ and nurses' observation. Evaluated agreement between RCSQ, direct nurses' observation	24 patients; Mean age: 58.7 ± 12.5; sex: M (58.3%); F (41.7%); APACHE II :intervention group 17.3 ± 3.8 and control group of 16.8 ± 3.4. Patients were oriented; SAS score: < 4 Ventilatory status: MV	Not assessed	NR	NR	NR	NR	NR	SEI Intervention: 50% Control:41%
3 Chen et al.,2018 China Medical, surgical and emergency-ICUs Observational-Cross-sectional	Assessed patients sleep using the Chinese version of RCSQ-C. (Not specified how many nights the assessment). Evaluated patient-nurse agreement of the RCSQ-C.	150 patients; mean age: 64.74± 16.16; sex: M (36%); F (64/%);APACHE II: 26.04±22; Patients were oriented; ventilatory status: 143 not ventilated, and 7 patients were on MV.	Not assessed	40.44	46.04	46.40	45.67	45.33	44.76 SEI: NR

4 Elliot et al.,2013 5 Elliot et al.,2014 Australia General ICU Observational cross-sectional	Assessed sleep quality using PSG and RCSQ for one night. Identified factors using SICQ at patients discharge from the ICU.	53 patients; mean age: 60.13 ± 20.02; sex: M (68%); F (32%); APACHE II: 18.70 ± 8.23**;** patients were oriented; 32 patients received opioids analgesic; RASS: (0, -1)**.** Ventilatory status: 28 patients were on MV during the PSG; however, did not specify whether the patients were on MV during RCSQ assessment	Patient self-reports: SICQ item, scale 0-10 Patients rated noise and light as the most sleep disruptive in ICU; Noise: 5.70 ± 2.75; light: 5.15 ± 2.61; care interventions: 5.05 ± 2.44	NR	NR	NR	NR	NR	51.36±24.42
6 Faraklas et al.,2013 USA Burn ICU; Experimental nonrandomised, uncontrolled trial of a quiet time: pre-post design.	Examined the influence of "quiet time" on patients' sleep, patients sleep was assessed using RCSQ (Not specified how many nights the assessment).	130 patients; mean age: 41 (27–58); sex: M (58.3%); F (41.7%);severity of illness: NR; patients were oriented; Ventilatory status: not intubated.	Not assessed	Pre:60 Post:60	Pre:60 Post:80	Pre:50 Post:50	Pre:60 post:80	Pre:70 Post:70	Pre: NR Post: NR
7 Frisk et al.,2003 Sweden General ICU; Observational cross-sectional	Assessed self-report patients' sleep and nurses' observation using RCSQ for two-night assessment. Evaluated patient-nurse agreement of the RCSQ	31 patients; mean age:59 (19-85); sex: NR; severity of illness NR; patients were oriented; 12 patients (39%) were given some form of hypnotic during the night. Ventilatory status: NR	Patients who haven't received hypnotics had slept better than who received hypnotics (p = 0.037). No significant difference between patients who were treated for 4 days or longer and those treated for a shorted period (38.6 vs 47.9; *p*= 0.493). Most common factors reported by patients were discomfort (e.g. pain, worry).	40.2	48.1	52.8	47.4	39.0	45.5 (0-97)

8 Hansen et al. (2018) Danish Medical and surgical ICU; RCTs	Assessed the effects of music on patients sleep quality using RCSQ,	37 patients; mean age 63(17); sex: M (54%); F (46%); severity of illness NR; patients were oriented; Ventilatory status: Not intubated	Not assessed	Control: 42(28) Exp:64(29)	Control: 64(38) Exp:75(37)	Control: 36(32) Exp:74(29)	Control: 58(46) Exp:67(43)	Control: 48(36) Exp:80(29)	Control: 50(27) Exp:71(27)
9 Hu et al.,2015 China Cardiac-surgical ICU; RCTs	Examined the effects of ear plug and eye masks with relaxing music on patients sleep. Patients sleep assessed using RCSQ for one-two nights	45 patients; mean age 56.8± 11.2; sex: M (64%); F (36%); APACHE-II: 20±31. Patients were oriented; Ventilatory status: NR.	Patient perceptions of nighttime noise (40.2 vs 25.0; P <0.05)	Contrl:26.7 Exp:55.5	Contrl:32.7 Exp:60.4	Control: 25.3 Exp:51.2	Control: 21.7 Exp:63.4	Control: 23.7 Exp: 54.4	Control: NR Exp:NR
10 Krotsetis et al.,2017; German General/cardiac surgical/trauma ICUs; Observational cross-sectional	Translated RCSQ into German and evaluated patients sleep for one-night assessment. Patients asked open-ended question to determine those factors they perceive as disruptive to their sleep.	51 patients; mean age 63± 14.7; sex: M (67%); F (33%); severity of illness NR; Patients were oriented Ventilatory status: 6 patients were on MV.	Anxiety, fear are most cited factors.	38.04±35.7	50.53±37	52.65±30.7	52.69±32.4	50.20±32.5	47.00±27.57 (0-95)
11 Kamdar et al.,2013; USA Medical ICU; Experimental None controlled pre-post design 12 Kamdar et al.,2012; USA Secondary analysis of prospective observational, pre-post design	Examined the effect of quality improvement interventions on patients sleep using RCSQ for multiple night assessment. Identified factors using SICQ Assessed patients sleep using RCSQ for 137 patient-days ; and nurses observation using RCSQ a 92 paired patient-nurse assessment. Assessed patient-nurse interrater agreement of RCSQ.	300 patients; pre n=122; post n=178; mean age: 54 (43-63); sex: M (39%); F (61%);SOFA score: 6.0 (4.0-9.0); Patients were oriented; pre 78 patients were on MV. post: 83 were on MV Sub-analysis of 33 patients; mean age :54(43-63); SOFA score: 6.0 (4.0-9.0); Patients were oriented.	Home sleep quality: Patients who reported poor sleep quality at home, had worse RCSQ in ICU. Patient self-reports: SICQ item, patients rated noise and light as the most sleep disruptive in ICU; Noise: 7 (3-10); light : 8 (5-10); nurses activities 9 (2-10) ; daytime sleepiness 6 (5-9).	NR 48 ± 35	NR 60±36	NR 60±33	NR 61±34	NR 59±33	Pre: 54.5 Post: 53.2 (p=0.46) 57±28

13 Lewandowska et al. (2019) North Poland General ICU; Observational cross-sectional	Patients asked to report on their sleep quality using RCSQ for one-night assessment. Identified factors using SICQ at patients discharge from the ICU.	83 patients; mean age: 91 ±16.46; sex: M (63%); F (37%); severity of illness NR; Patients were oriented; ventilatory status : NR	Patient self-reports: SICQ item, scale 0-10 Patients rated nurses activities as the most sleep disruptive.	40.82±2.7	40.39±2.29	40.53±2.17	40.53±2.24	40.65±2.24	NR
14 Li et al.,2011 Taiwan Surgical ICU; Experimental None controlled pre-post design	Assessed the efficacy of sleep care guidelines for controlling night-time noise on patients sleep using RCSQ for one-night assessment.	55 patients, mean age 50± 2.5; APACHE-II 12.3±1.9; sex: M (67.3%); F (32.7%);35 patients received analgesic during assessment; ventilatory status: all patients were not on MV	Patients' perception of noise 73.8 vs63 (p=0.046) Sleep quality in the ICU was significantly better (p=0.027).	Contrl:50.7 Exp:64.4	Control: 54.1 Exp:65	Control: 51.1 Exp:64.8	Control: 54.4 Exp:65.5	Control: 51.3 Exp:65.2	Control: 52.3 Exp :72.2 SEI:69.3±10. 2 72.2±7.5
15 Menear et al.,2017 Australia General ICU; observational study-repeated assessment	Assess patients sleep quality for multiple days using RCSQ (Not specified how many nights the assessment). Assessed feasibility of RCSQ. Patients asked open-ended question to determine those factors they perceive as disruptive to their sleep.	50 patients; mean age 62.6±16.9); sex: M (76%); F (24%);APACHE II: 12.5 ±6.3; 24 (48%); patients received opioid analgesic. (lightly sedated patients); RASS score (-1 and 1; 7 (14%); Ventilatory status: patients were on MV	Noise and discomfort were most cited factors by patients.	39.9	46.8	46.0	55.9	50.7	47.9 ±24.4
16 McKinley et al.,2013 Australia General ICU; observational study design cross-sectional	Assessed patients sleep one-time at three period during ICU, hospital ward, and after hospital discharge.	222 patients; mean age: 57.2±17.2; sex: M (58.3%); F (41.7%);APACHEII: NR; RASS score (-1 and 1); Ventilatory status: NR	Not assessed	NR	NR	NR	NR	NR	47.2 (SD 28.1)
17 Murata et al.,2019 Japan General ICU; Observational; Cross-sectional	Assessed patients sleep using the Japanese version of RCSQ for one-night assessment	45 patients; mean age: 69.1 ±8.8; sex: M (69%); F (31%); APACHE II: 12.4 ±4.3); Ventilatory status: non-intubated	Not assessed	43.16±21.5	46.43±26.9	30.28±20.4	48.00±25.6	44.11±20.6	42.39 ±19.51

18 Nicolas et al.,2008 Spain Surgical ICU; Observational; Cross-sectional	Compared patients' perception of sleep using RCSQ for One-two nights; with nursing records and assessed patient-nurse agreement	104 patients; mean age: 57.72 ±14.81; sex: M (73%); F (27%);severity of illness: NR; 69 patients received non-opioid analgesics 35 patients received opioid analgesic; Ventilatory status: non-intubated	Noise was the most often cited factor. Pain: patients who received non-opioid analgesic reported poor sleep that those who received opioid (p=0.003).	50.46	55.74	42.08	56.15	52.66	51.42 ±12.7
19 Naik et al.,2018 India Medical l ICU; Observational; Cross-sectional	Assessed patients' sleep using RCSQ for one-night; patients asked open-ended question to determine those factors they perceive as disruptive to their sleep.	35 patients; mean age: 36.8 ±12.7; sex: M (56%); F (44%);APACHE II: 11.5 ±5.8; Ventilatory status: NR	Nurses care activities was the most often cited factors by patients as a disturbing factor	50	54	46	53	54	51±94
20 Patel et al.,2014 UK General ICU; Experimental None controlled pre-post design	Examined the effect of implementation of a bundle of non-pharmacological interventions on patients sleep using RCSQ for multiple night assessment (Not specified how many nights the assessment)	Baseline:(n=167) Intervention stage:(n=177); mean age 60.0 ±13.7; sex: M (51%); F (49%);APACHE II: 15.0±7.60; Ventilatory status: ventilated and non-ventilated patients	Patient self-reports: SICQ item, scale 0-10 Daytime sleepiness was rated high by patients before intervention reduced sig (6 vs 3; p=0.042); Noise:(7 vs 2, p < 0.001; light (5.5 vs 1; p = 0.011) and nursing interventions (4 vs 1; p = 0.043)	Pre:25 Post: 50	Pre:65 Post: 80	Pre:30 Post: 75	Pre:35 Post: 84	Pre:28 Post: 78	Pre:35 Post: 75 p<0.05 SEI Pre: 60.8 Post: 75.9
21 Richards et al.,2000 USA Medical ICU; observational, cross-section	Assessed RCSQ validity against PSG. Assessed patients' sleep using RCSQ for one-night assessment.	70 patients; mean age 65.81; severity of illness: stable status; sex: M (100%);ventilatory status: non-intubated	Not assessed	43.90	65.57	65.53	62.33	63.63	60.19 SEI: 60.19

22 Ritmala et al.,2017 Finland Medical and surgical ICU; Observational; cross-sectional	Compared patient's perception of sleep using RCSQ for one-nights; with nursing records and assessed patient-nurse agreement	114 patients; mean age: 59±14; sex: M (63%); F (37%); APACHE II:16±06; Patients were alert and oriented. N=95 (84%) received opioid analgesic; Ventilatory status: non-intubated	Not assessed	35 (15-75)	74 (38-97)	48 (27-80)	75 (25-98)	50 (30-70)	SEI: 57% 50 (30-70)
23 Simons et al.,2018 Netherlands Five-general ICUs; Cross-sectional observational design	Assessed patients sleep quality using RCSQ	64 patients; mean age 63.9 ±11.7; sex: M (68%); F (32%); APACHE II: 21.1± 7.1; 11 (17.2%) received opioid analgesic; N= 20 (31%); Ventilatory status: all patients were on MV	Noise factor significantly affected patients sleep; had a negative impact on sleep quality, whereas female patients ($\beta = 1.25$, $p < 0.01$) had positive correlation with patients sleep	54±25	60±30	58±26	53±30	57±29	56±24

Table 3-3 RCSQ's validity, reliability and acceptability as reported in the ICU based sleep studies

Author, country	Reliability	Validity	Interpretability	Feasibility and Acceptability				
1 Aitken et al.,2017 Australia	Inter-rater reliability/agreement : Moderate association between nurses' documentation and patients' self-report of sleep quality on RCSQ. But nurses overestimated patients' sleep	NR	Cut-off scores RCSQ below 50, interpreted as poor. SEI = 46.88 + [0.39*Overall RCSQ]; SEI > 85% indicates good sleep quality	**Assessment completed by**	**Assistance given on RCSQ**	**Dropout rates/ missing data/**	**Number of completed RCSQ/ Time needed to complete the RCSQ**	**Other information on feasibility and acceptability**
				Self-report (Researcher asked patients to complete RCSQ between 0700 and 1200). Observation/nurses' notes (maximum one observation per day)	NR	Not clear 17 patients were eligible but declined participation. Of 174 enrolled, 23 patients dropped out; three declined consent; 20 unclear reasons for withdrawal. 151 patients enrolled and completed RCSQ. Dropout rate (13%)	365 RCSQs completed by patients. 285 observation by nurses. Time needed to complete RCSQ: NR	50% of patients were able to report on their night-time sleep on two or more occasions, up to a maximum of 18 nights. It was feasible for researcher to ask patients to self-assess their sleep regularly using a brief structured RCSQ
2 Bourne et al.,2008 Australia	Inter-rater reliability/agreement : –0.56 (95% CI, –0.66 to –0.46) and 0.57 (95% CI, 0.47 to 0.67. Indicated agreement was poor between patient self-report and nurse assessment	NR	NR	Self-report (Researcher asked patients to complete RCSQ. Nurses direct observation /hourly observation (not specify how many observations were made by nurses	NR	Eligible: NR Of 24 enrolled, 17 patients dropped out. Due to the presence of delirium (n=16) and one patient was unable to complete RCSQ	NR	Direct and indirect nursing care activities will obviously affect the reliability of results. Due to frequent awakenings in these patients

3 Chen et al.,2018 China	Internal consistency of the Chinese version: 0.92. The alpha coefficients did not increase when any of the items were deleted Inter-rater agreement of the 44 patient-nurse measurement pairs. The ICC for agreement between nurses' observation and patients' self-report for all RCSQ-C items were range (0.31-0.61), indicated that the nurses' mean scores were higher than patients' mean score (nurses tend to overestimate patients' perceived sleep quality	Details of translation process was provided. Content validity (CVI) A panel of five members rated the relevance and adequacy of each item of RCSQ-C in measuring perceived sleep. Each item rated using -point Likert scale. The average CVI for all items was 0.84. Construct Person correlation coefficients with the SMHSQ as the 'valid sleep assessment questionnaire in healthy people' 0.866 for (sleep depth; 0.776 for (sleep latency), 0.504 for (awakenings) and for 0.856(sleep quality). The correlation between the total score was 0.771. Except for returning to sleep item, all correlation coefficients were significant at the 0.01 level. Construct (Structural) A principal component of factor analysis resulted in a single factor that explained 76.59% of the total variance	Cut-off scores: (0-25) very poor; (26-50) poor; (51-75) good); (76-100) very good The mean RCSQ-C score of 150 patients was 49.34 (SD 24.64). All components of the RCSQ-C with the highest quartile were higher than those of the lowest quartile (P<0.001). Indicated that RCSQ-C could discriminate poor and good sleeper	Self-report/ Researcher asked patients to complete RCSQ (between 0700 and 1200) Observation/nurses completed RCSQ for 44 patients); (not specify period/frequency of nurses' observation)	Questions were read to each participants and explanations were given by the researcher. Researchers marked RCSQ according to the patient's oral or gesture expression. Instructions were given to the nurses on RCSQ-completion	Eligible patients: NR. All finally enrolled 150 patients completed RCSQ on multiple days. Drop-out=0%	NR	The brevity of RCSQ-C indicate that it is suitable instrument. It could be used as routine evaluation instrument in ICU

4 Elliot et al.,2013 5 Elliot et al.,2014 Australia	NR	NR	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/NR method of RCSQ administration	NR	Of 266 eligible = 209 declined , 74; discharged before = 135*).*Of 57; 3 patients dropped out; one patient died and three due to difficulty in PSG) Drop-out=5%	NR	NR
6 Faraklas et al.,2013 USA	NR	NR	Cut-off scores: NR. High scores indicate good-quality sleep	Self-report/NR method of RCSQ administration	NR	All eligible enrolled n=130 patients in the final analysis completed RCSQ. Drop-out=0%	NR	NR
7 Frisk et al.,2003 Swedish	RCSQ was translated into Swedish. Internal consistency of the Swedish version: 0.92 Inter-rater reliability agreement: a high degree of correlation between nurses and patients (r=0.869; P=0.000)	NR	Cut-off scores: (0-25) very poor; (26-50) poo; (51-75) good); (76-100) very good	Self-report/ Researcher asked patients to complete RCSQ. Observation/ nurses completed RCSQ (not specify period/frequency of nurses' observation)	NR	Of 33 eligible, n=2 patients refused participation. Finally, n=31 enrolled and completed RCSQ. Drop-out=0%	NR	Nurses completed the RCSQ for 13 patients. No report on how many RCSQs completed by nurses . RCSQ was shown to be simple for patients and nurses to complete
8 Hansen et al. (2018) Denmark	NR	NR	Cut-off scores: NR High scores indicate good-quality sleep.	Self-report/ Researcher asked patients to complete RCSQ	Questions were read to each participant and explanations were given by the researcher.	Of the 42 eligible; 5 patients were not included (no reasons provided); Finally 37 patients enrolled and completed the assessment Drop-out=0%	NR	patients in a Danish ICU setting assistance is needed to help patients to complete the questionnaire.

9 Hu et al.,2015 China	Internal consistency of the Chinese version: 0.84	NR	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/NR method of RCSQ administration	NR	Eligible patients: NR Of 50 enrolled; n= 5 patients were dropped out; 2 had postoperative complications, 2 refused earplugs and eye masks, 1 refused listen to music. All finally enrolled 45 patients. Drop-out=10%	NR	NR
10 Krotsetis et al.,2017 German	Internal consistency of the German version: 0.88	NR	Cut-off scores: (0-25) very poor; (26-50) poor; (51-75) good;(>75) very good	Self-report/ patients (between 0900 and 1100) Patients who were unable to complete the RCSQ themselves, the researcher assisted them in completing the tool	NR	Of 55 eligible, n=3 patients refused participation; n=1 patients had cognitive decline during the assessment. Finally, n=51 enrolled and completed RCSQ. Drop-out=0%	NR	Some patients were able to set a mark themselves on VAS. Some patients pointed to the VAS with assistant and investigator marked the RCSQ
11 Kamdar et al.,2013; USA 12 Kamdar et al.,2012 USA	Inter-rater reliability agreement: 33 patient-nurse survey pairings showed that nurses' ratings were generally higher than patients' ratings. ICC of patient-nurse pairs ranged from 0.13 to 0.49 across the survey questions and total sleep	NR	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/ patients Observation/ night-shift nurses completed RCSQ at 30 minutes before completion of their 12-hour shift ending at 7 am (one observation by each nurse)	Questions were read to each participants and explanations were given by the researcher. All nurses were provided with in depth instructions	Not clear eligibility 300 patients enrolled; 16 patients did not complete RCSQ during repeated assessment. Of 39 patients enrolled: 6 patients excluded during repeated assessment (did	Pre stage: 110 (90%) patients completed at least one RCSQ, and 160 (90%) in the post stage. 33 patients completed 121 RCSQs (a rate of 88% of available days and an average of 3.7	Reasons for 16 patients in which RCSQs were not completed: 8 days the patient was unable to communicate; 2 days patient was not present in the room; 2 days patient declined participate and 1 patient had change clinical status, and 3 reason was unspecified Reasons for missing 36 questionnaires from

	score (68 [19] vs 57 [28], P = .01). indicated that the nurses' mean scores were higher than patients' mean score.				regarding scoring RCSQ	not have a nurse to complete RCSQ assessment). Drop-out=15%	reports per patient) 101 RCSQs completed by nurses for patients who were unable to complete the RCSQ Time needed to complete RCSQ: NR	nurses: heavy workload during the shift. Patient-nurse interrater reliability on the RCSQ was slight to moderate with nurses overestimated patient' perceived sleep quality.
13Lewandowska et al. (2019) North Poland	NR	NR	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/NR method of RCSQ administration	NR	OF 93 eligible; 10 declined consent; 83 finally enrolled Drop-out=0%	NR	NR
14 Li et al.,2011 Taiwan	NR	NR	Cut-off scores: NR ; SEI > 85% indicates good sleep quality	Self-report/ (Nurses asked patients to complete RCSQ between 0700 and 1200)	Questions were read to each participants and explanations were given by the nurse	60 eligible and all enrolled. Of 60 enrolled ; n= 5 dropped-out, including 2 in the experimental group and 3 in the control group Reasons: a sedatives treatment during the study and transferred out of the ICU Finally enrolled and completed RCSQ n=55 Drop-out=8%	NR	NR

15 Menear et al.,2017 Australia	NR	NR	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/ patients. (Nurses asked patients to complete RCSQ between 0700 and 1200)	Questions were read to each participants and explanations were given by the **nurse**. Patients who were unable to complete the RCSQ themselves, the researcher assisted them in completing the tool	Of 71 eligible;17 excluded (3 declined) Of 54 enrolled; 4 dropped out 8% n=29 patients discontinued the assessment. N=21 patients discharged on the second day of the assessment, 5 were busy with medical reasons, and 3 discontinued (not reported the reasons) Drop-out=63%	Of 50 patients; n=4 completed RCSQ on 2 occasions. n=17 patients completed RCSQ on 3 or more occasions. mean number of occasions the RCSQ was completed was 4 (SD 3.5) per patient. Time needed to complete RCSQ: NR	Researcher feedback on using RCSQ by clinician: no difficulties in the use of the RCSQ
16 McKinley et al.,2013 Australia	NR	NR	Cut-off scores: 70 as a cut-off point between good and poor-quality sleep	Self-report/ patients by the researcher	Patients who were unable to complete the RCSQ themselves, the researcher assisted them in completing the tool	Of 344 eligible, n=79 refused; n=43 discharged before invited. Finally enrolled 222 patients completed the RCSQ. Drop-out=0%	NR	NR
17 Murata et al.,2019 Japan	Internal consistency of the Japanese version: 0.91	RCSQ was evaluated with reference to PSG. Falling asleep (item-2) was moderate correlated with PSG data (sleep latency) (r=0.408, p<0.05). Returning to sleep (item-4) was moderate correlated with PSG data (ratio of WASO) and (TST) (r=0423,	Cut-off scores: NR High scores indicate good-quality sleep.	Self-report/ patients by the researcher	Patients who were unable to complete the RCSQ themselves, the researcher assisted them in completing the tool	45 patients were eligible; 5 declined participation. Of 40 enrolled : 7 excluded because of limitation in the PSG monitors. Resulting in 33 patients enrolled in the final analysis	NR	J-RCSQ is easy can be used as alternative to PSG in assessing patents sleep

		p<0.05; r=471, p<0.05, retrospectively) The total score of the RCSQ was correlated with the SEI derived from PSG data 0.459 (p=0.007). The correlations of the RCSQ-items were evaluated. After excluding the four patients with subsyndromal delirium the correlation was 0.602 (p=0.001)				All finally enrolled 33 patients enrolled in the final analysis completed the RCSQ. Drop-out=17%		
18 Nicolas et al.,2008 Spain	Internal consistency of the Spanish version: 0.90. Inter-rater reliability/agreement Statistically significance difference between nurse-records of patients' sleep and patients-RCSQ (P<0.05) with variation coefficient of 35.88%. There was a total agreement in 44 cases (43.56%) and disagreement in 57 cases (56.44%) with nurses overestimated patients sleep	The translation process included forward-backward. No report on the specific followed guidelines for the translation process.	Cut-off scores: (0-33) poor sleep; (33-66) normal sleep; (>66) very good	Self-report/ Patients (between 0700 and 1200) (researchers marked the questioner according to the patient's oral or gesture expression). Observation/nurses notes/sleeping records	Questions were read to each participant and explanations were given by the **researcher**. Nurses were not advised on how to complete the sleeping records. Researcher feedback on using RCSQ: no difficulties in the use of the RCSQ	Eligible patients: NR Finally enrolled 104 patients in the final analysis completed the RCSQ. Drop-out=0%	NR	RCSQ is easy and can be used as alternative to PSG in assessing patents sleep

19 Naik et al.,2019 India	NR	NR	RCSQ score of ≥50 mm had a sensitivity of 88.2% and specificity of 86.7% in determining patients with good sleep as assessed by patient perception (ROC area 0.91, CI 95%)	Self-report/NR method of RCSQ administration	NR	Of 35 eligible, n=3 could not complete the study, because of early transfer out from ICU to the ward Finally, enrolled and complete RCSQ n=32 Drop-out=0%	NR	NR
20 Patel et al.,2014 UK	NR	NR	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/NR method of RCSQ administration	NR	Eligible patients: NR 167 patients included before interventions, and 171 after interventions. No reasons provided on non-completed 59 completed RCSQ. Drop-out=35%	NR	NR
21 Richards et al.,2000 USA	Internal consistency good (Cronbach's a = 0.90)	Content validity with four-panel experts. Face validity with 9-paitnets. Patients had no trouble completing the questionnaire when researcher assisted them., but they had difficulty when no assistance was provided. Criterion validity Items on the RCSQ were correlated with PSG	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/ Patients (between 0700 and 1200) (researchers marked the questioner according to the patient's oral or gesture expression)	Questions were read to each participant and explanations were given by the researcher. Researcher feedback on using RCSQ: no	Of 94 eligible, n=23 declined and one patient became unstable and did not complete the study.Finally enrolled and completed RCSQ n= 70	NR	RCSQ is a brief, cost-effective measure of perception of sleep that would be feasible to measure the outcomes of interventions to promote sleep in critically ill patients.

		data. Deep sleep item correlated significantly with the PSG stage 4 NREM *(r* = .59) and percent SWS(r = .56). The item "A good night's sleep/A bad night's sleep" correlated 0.64 for percent stage 2 and 0.55 for percent stage REM. The item "Fell asleep" was strongly associated with latency to sleep onset, (r = *-.51, p* = .07). Construct a principal component of factor analysis resulted in a single factor that explained cumulative variance was 72.2%			difficulties in the use of the RCSQ			
22 Ritmali et al.,2017 Finland	Internal consistency of the Finish version of RCSQ: 0.92. The nurses' documentation corresponded (partially) with the patients' own perceptions in 57% of the cases. The nurses' documentation and patient's perceptions corresponded in 51% (n=61) of the cases	Forward and backward translation was conducted by certified translators (No report on the specific followed guidelines for the translation process).	(0–33) poor sleep, (34–66) fair sleep and (67–100) good night's sleep	Self-report/ Patients (between 0700 and 1200) (researchers marked the questioner according to the patient's oral or gesture expression)	Questions were read to each participant and explanations were given by the researcher. Nurses were not advised on how to complete the sleeping records	Of 134 eligible, n=18 refused Of 116 ; 2 dropped out as their inability to answer the questions. Finally enrolled 114 patients in the final analysis and completed the RCSQ Drop-out=2%	NR	RCSQ was able to capture the majority of nurses' assessments of patients' sleep. RCSQ to measure ICU patients' sleep would provide a means to improve the whole nursing process related to sleep

23 Simons et al.,2018 Netherlands	NR	Translation was conducted (No report on the specific followed guidelines for the translation process).	Cut-off scores: NR High scores indicate good-quality sleep	Self-report/ Patients by the patient (around 0700).	No assistance was provided; patient who was not able to fill in the RCSQ, no score was recorded.	Of 71 eligible and enrolled. Of 71, 7 patients were removed from the final analysis due to missing audio data. Drop-out=9%	NR	NR

3.5 Characteristics of the studies included

The 23 studies examined included 16 observational studies; the majority (n=13) of these were cross-sectional in design and covered only short periods of sleep assessment, between one to two nights (Chen et al., 2018, Elliott et al., 2013, Elliott et al., 2014, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Lewandowska et al., 2019, McKinley et al., 2013, Murata et al., 2019, Naik et al., 2018, Nicolas et al., 2008, Richards et al., 2000, Ritmala-Castren et al., 2017, Simons et al., 2018), with only three studies of prospective repeated assessment design (repeated assessment of sleep using RCSQ with the same patients multiple times) (Aitken et al., 2017, Kamdar et al., 2012, Menear et al., 2017). The periods of assessment differed across these studies, with one 18-night assessment (Aitken et al., 2017); one 137-night assessment (Kamdar et al., 2012); and a multiple night assessment of non-specified duration (Menear et al., 2017). The other seven papers examined referenced clinical trials; three were RCTs (Bourne et al., 2007, Hansen et al., 2018, Hu et al., 2015), and four were non-controlled clinical trials of pre-post design (Faraklas et al., 2013, Kamdar et al., 2013, Li et al., 2011, Patel et al., 2014).

The studies' locations were mainly (n=8) in Europe: Denmark, Germany, Finland, the Netherlands, North Poland, Spain, Sweden, and the UK; another major group (n=6) were done in Australia, while five were done in the USA and four were done in East Asia, including China, Taiwan and Japan; one further study was done in South Asia, in India. The ICU settings also differed between studies; various studies recruited patients from medical ICUs (Kamdar et al., 2012), surgical ICUs (Nicolas et al., 2008), and mixed medical and surgical ICUs (Aitken et al., 2017), as well as burn ICUs (Faraklas et al., 2013) ; general ICUs (Frisk et

al., 2003), or more mixed ICU settings (i.e. cardiac , general, and medical ICUs) (Krotsetis et al., 2017).

Differences in the aims of using RCSQ were also identified between studies: some studies aimed to assess patients' perceptions of sleep quality (Naik et al., 2018, Nicolas et al., 2008, Simons et al., 2018) , while others sought to evaluate patient-nurse agreement with the use of RCSQ (Frisk and Nordstrom, 2003, Kamdar et al., 2012) or the effectiveness of various interventions with respect to patients' sleep quality (Hu et al., 2015, Patel et al., 2014). Others aimed to assess translations of the RCSQ into a particular language (Chen et al., 2018, Krotsetis et al., 2017) , while a few studies aimed to assess the feasibility of using RCSQ repeatedly in the ICU (Aitken et al., 2017, Menear et al., 2017) . Limited information on feasibility was provided in all cases, and none of the studies assessed patients' acceptance and willingness to complete RCSQ on a daily basis, despite this being necessary to the understanding of patients' experiences and perceptions required for any development. Feasibility and acceptability are important outcome measures that should be considered prior to implementing any assessment tool in clinical practice (Sekhon et al., 2017).

The sample sizes varied greatly between studies, with most studies having very small sample sizes. For example, Bourne et al. (2008) had only 24 participants, and Frisk et al. (2003) had 31 participants. A few studies had relatively large sample sizes, such as Kamdar et al. (2013), with 300 participants, and McKinley et al. (2013) with 222 participants. There were also differences in sample demographic data. Some studies included younger participants, such as Naik et al. (2018), where the participants’ mean age was 36.8±12.7 years, while other

studies, such as Lewandowska et al. (2019), included only older participants, with mean ages up to 91±16.46 yrs. Differences in percentage of males and females were further notable between studies; for example, the majority of the participants in a study by Krotsetis et al. (2017) were male (67% male, 33% female), and Chen et al (2018) also had a 64% male and 36% female distribution of participants.

There were further differences in sample clinical characteristics; for example, in Simons et al. (2018), all of the surveyed patients were on mechanical ventilation, while both mechanically ventilated and non-mechanically ventilated patients were included in Menear et al. (2017), and Nicolas et al. (2008) included only those patients not receiving mechanical ventilation. Several studies did not specify the participants' mechanical ventilation status (Aitken et al., 2017, Frisk and Nordstrom, 2003, Hu et al., 2015, Krotsetis et al., 2017, Lewandowska et al., 2019, McKinley et al., 2013, Naik et al., 2018). Values of severity of illness were also reported differently across studies; for example, in Naik et al. (2018), participants had a relatively low severity of illness, with a mean APACHE-II score of 11.5±5.8, while in Chen et al. (2018), participants had medium severity illnesses, with a mean APACHE-II score of 26±22; none of the studies included severely ill patients, however.

3.6 Psychometric properties of RCSQ

From the summaries of the 23 studies in Table 3.2 and Table 3.3, nine studies reported on the psychometric properties of the RCSQ in terms of its validity and reliability (Table 3.3). The results of this are thus discussed in more detail in the following sections.

3.6.1 RCSQ Validity

In addition to the evidence of RCSQ validity and reliability demonstrated by the original validation by its developer Richards et al. (2000) discussed in chapter 2, section 2.7.2, two further published studies that used RCSQ have demonstrated specific evidence of its validity (Chen et al., 2018, Murata et al., 2019).

Chen et al. (2018) carried out an observational cross-sectional study in China that featured 150 patients in medical, surgical, and emergency ICUs. The mean age of patients was 64.74±16.16 years, with the majority being female (86%). The severity of illness as measured by mean APACHE-II score was relatively high at 26.04±22, though 143 of the patients were not mechanically ventilated, with only seven patients on mechanical ventilation during the assessment. Chen et al. (2018) translated the original RCSQ into Chinese (RCSQ-C) using a forward and backward translation process; two bilingual specialist ICU nurses, a medical ICU doctor, a linguist, and a sleep professor were involved in this translation process, and throughout the process of translation, no RCSQ item required extensive modification for the Chinese cultural context.

Content validity was addressed by an expert panel of five members, who included nursing experts, a sleep specialist, a neuropsychologist, and an intensive care expert, all of whom reviewed the content of the translated version (Chen et al., 2018). The panel rated the relevance and adequacy of each item in the RCSQ-C in terms of measuring perceived sleep on a four-point scale. The RCSQ-C showed good content validity, and its items offered an adequate reflection of the construct (sleep). However, the intended population for the instrument (ICU patients) were not involved in this content validity assessment;

thus, while this was a very important initial step in the validation of the translated tool in a new culture, further testing with the intended audience would be required to ensure there was no confusion inherent in any items, as well as to determine whether respondents had any suggestions for possible improvements to questionnaire items. Evidence of the construct validity of the RCSQ-C was demonstrated using a CFA that resulted in a single factor explaining 76.59% of the total variance, implying that the concept of sleep has strong explanatory power and the five items of the RCSQ-C did indeed assess this unitary “sleep” construct (Chen et al., 2018).This offered additional support to the original RCSQ validation (Richards et al., 2000).

Another cross-sectional study providing evidence of RCSQ validity was carried out in a General ICU in Japan by Murata et al. (2019). This study included 45 non-mechanically ventilated patients with a mean age of 69±8.8 years, of whom 69% were male and 31% were female; the sample had a relatively low mean of severity of illness by APACHE-II score at 12.4±4.3. Murata et al. (2019) translated the original RCSQ into Japanese (J-RCSQ) and assessed the resulting content and construct validity. The authors used a forward and backward translation process, with three nursing science researchers and three linguists involved in the translation process; however, none of the translators were directly involved in the field of sleep medicine, and it would normally be recommended to involve at least one translator in the field of the concept that a questionnaire under translation is intended to measure in order to provide a translation that more closely resembles the original instrument. Nevertheless, evidence of content validity was demonstrated based on a cognitive debriefing interview with a

sample of five Japanese patients, and the authors also re-worded certain phrases in the J-RCSQ to improve comprehension based on this interview data.

Further evidence of J-RCSQ construct validity was offered by determining the association between sleep efficacy, measured using PSG in a one-night assessment, and the total score on the J-RCSQ (Murata et al., 2019). The results showed that there was a correlation between total J-RCSQ score and sleep efficiency as measured by PSG ($r=0.602$, $p <0.05$), similar to the correlation between the original RCSQ and sleep efficiency as measured by PSG ($r = 0.58$, $p < 0.001$) (Richards, et al.2000). Consequently, the authors concluded that the J-RCSQ could be used as an alternative to PSG for sleep assessment in ICU patients (Murata et al., 2019). Overall, the findings on RCSQ validity in its Chinese and Japanese versions support the existing evidence for original RCSQ validity.

3.6.2 RCSQ Reliability

3.6.2.1 Internal consistency

The RCSQ demonstrated good to excellent internal consistency generally across the literature examined, with Cronbach's alphas ranging from 0.88 to 0.92 across six different languages; these were Chinese, Finnish, German, Japanese, Spanish, and Swedish (Chen et al., 2018, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Murata et al., 2019, Nicolas et al., 2008, Ritmala-Castren et al., 2017). Despite explicit variations in sample characteristics, ICU-settings, and countries/cultures between the studies examining translated RCSQs and assessing internal consistency, all of the translated versions of RCSQ showed similar internal consistency to the original English version of RCSQ (Chen et al., 2018, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Murata et al., 2019,

Nicolas et al., 2008, Ritmala-Castren et al., 2017), which itself had a high Cronbach's alpha of 0.90 (Richards et al.,2000).

The Spanish version of RCSQ had a Cronbach's alpha of 0.89 in a sample of 104 non-mechanically ventilated patients in a surgical ICU in Spain with a mean age of 57.72±14.81 where the majority, 75%, were male (Nicolas et al., 2008). Similarly, the Swedish version, assessed by Frisk and Nordstrom (2003) in 31 patients with a mean age of 59 years in a surgical ICU in Sweden, where 61% were male and 39% were female, had a Cronbach's alpha of 0.92. The German version of the RCSQ had a Cronbach's alpha of 0.88 in a sample of 51 patients in three ICUs at a university hospital in Germany (Krotsetis et al., 2017), where six patients were mechanically ventilated; the patients' mean age was 63±14.7.

The Finnish version, investigated by Ritmala-Castren et al. (2017) in Finland, had a Cronbach's alpha of 91.0 in 114 non-mechanically ventilated patients, with a mean age of 59±14. Similarly, Cronbach's alphas of 92.0 and 91.0 were found for the Chinese version (Chen et al., 2018) and the Japanese version (Murata et al., 2019), respectively. Detailed information about the RCSQ translation process was offered only in Chen et al. (2018) and Murata et al. (2019), as discussed in section 3.6.1; other studies did not offer any details of the translation process (Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Nicolas et al., 2008, Ritmala-Castren et al., 2017) . The RCSQ was also used in North Poland (Lewandowska et al., 2019), the Netherlands (Simons et al., 2018), Denmark (Hansen et al., 2018), India (Naik et al., 2018), and Taiwan (Li et al., 2011); however, no data about the translation process or internal consistency measures in these cases were provided.

3.6.2.2 Equivalence (patient-nurse inter-rater agreement in RCSQ)

Patient-nurse reliability and agreement with regard to sleep quality ratings using the RCSQ were assessed in three studies, with RCSQ results obtained from both patients and nurses (Chen et al., 2018, Frisk and Nordstrom, 2003, Kamdar et al., 2012). Overall, RCSQ did not show evidence of reliability when used by nurses to observe patients' sleep, in contrast to the abundant evidence of its reliability and validity when used by patients to self-report on sleep quality, as discussed in sections 3.6.1 and 3.6.2. RCSQ was originally developed and validated for patients' self-reported assessment and it clearly remains most appropriate for this purpose (Richards et al., 2000). In particular, the evidence suggests that nurses overestimate the quality of patients' sleep and are unable to assess it accurately based on observation.

Kamdar et al. (2012) evaluated patient-nurse interrater reliability based on the agreement of perceived sleep quality ratings using the RCSQ in a medical ICU in the USA. The study period was around 24 days, during which repeated assessments were undertaken for 33 conscious and oriented patients with GCS scores of 14 or above. All of the nurses involved received educational sessions regarding completion of the RCSQ, and nightshift nurses then completed the RCSQ with regard to their patients' overnight sleep quality at a point 30 minutes prior to completion of the nightshift. Upon awakening in the morning, the target patients completed self-reports on their previous night’s sleep, also using RCSQ. Neither the nurses nor patients were aware of the other group’s ratings (Kamdar et al., 2012).

A total of 92 paired patient-nurse assessments were thus completed, and the results showed that, for all RCSQ items, the nurses' scores were higher (indicating "better" sleep) than the patients' scores, with significantly higher ratings for sleep depth (67±21 vs 48±35, p = 0.001), awakenings (68±21 vs 60±33, p = 0.03), and total RCSQ score (68±19 vs 57±28, p = 0.01). This wide variation in the results between nurses and patients suggests poor agreement. The correlation coefficients of patient-nurse pairs also ranged from 0.13 to 0.49, indicating low reliability. The reasons for disagreement between the patient-based RCSQs and nurse-based RCSQs, as suggested by the authors, included the fact that nurses are busy and have heavy workloads, with new admissions or clinical instability among other patients, that prevent focus, a theory supported by the fact that 36 nurse questionnaires were omitted (Kamdar et al., 2012).

Kamdar et al' s (2012) results were similar to those reported in a recent Chinese study by Chen et al. (2018), where 44 paired patient–nurse assessments were evaluated. Instructions were given to the nurses with regard to completion of the RCSQ, yet Chen et al. (2018) also found that the inter-rater agreement in the 44 patient-nurse measurement pairs indicated that nurses' mean scores were higher (indicating "better sleep") than patients' for all RCSQ items, and that these differences were statistically significant ($p<0.05$). The results also suggested that the reliability was only slight to moderate, with the correlation coefficients of patient-nurse pairs ranging from 0.31 to 0.61.

In contrast, an earlier Swedish study by Frisk and Nordstrom (2003) suggested reasonable agreement between nurses' and patients' scores when a comparison was made between the 13 patients' perception of their own sleep and nurses'

perception of those patients' sleep. The means of the total RCSQ scores of patients' perception and nurses' perception of the patients' sleep were not statistically significantly different (53.9 vs 59.8, p=0.125), indicating some agreement between nurses' sleep assessments and patients' self-reported sleep assessments. In addition, a correlation analysis of the nurses' and patients' assessments of the patients' sleep showed a high degree of correlation (r = 0.869; p= 0.000).

However, Frisk et al. (2003) did not mention whether any training or instructions were provided to the nurses regarding completing the RCSQ, which may have affected the reliability results, as inter-rater reliability testing requires raters to be adequately trained in completing a measure in order to avoid measurement errors. Furthermore, the number of paired patient–nurse assessments in Frisk and Nordstrom (2003) was small, only 13 in comparison to the 92 paired patient–nurse assessments in Kamdar et al. (2012) and the 44 in Chen et al. (2018), which may further have affected the results.

Evidence of poor agreement between nurses' observation of patients' sleep and patients' perception of their sleep was demonstrated in the other four studies that assessed the correlation results between patients' own perceptions of their sleep using RCSQ and nurses' documentation of patients' sleep through direct observation (Aitken et al., 2017, Bourne et al., 2008, Nicolas et al., 2008, Ritmala-Castren et al., 2017). Bourne et al. (2008) evaluated agreement between 24 mechanically ventilated patients' perceptions of their sleep using RCSQ and nurses' documentation of patients' sleep in a general ICU. The nurses recorded the patients' sleep through frequent observation every 60 minutes

during the nightshift, and the results demonstrated that the nurses' observations of patients' sleep efficiency differed from patients' perceptions of their own sleep. The authors suggested that the busy setting of the ICU and the demands on nurses' time made the nurses unable to accurately observe patients' sleep throughout the night, a factor emphasised by the missing sleep data observed in nurses' records.

The results on patient-nurse reliability and agreement of the RCSQ from these studies cannot be adopted in the same way as in the studies mentioned earlier, however, as they used different measures when assessing the correlation between patients' and nurses' estimations, with nurses using direct observation, and patients using the RCSQ. Nevertheless, the evidence from these studies does support the idea that nurses' observations of patient sleep are unreliable, even when direct observation is used rather than the RCSQ.

3.6.3 RCSQ feasibility and acceptability

Table 3.3 shows the relevant information regarding the feasibility and acceptability of RCSQ extracted from each study in order to help determine whether RCSQ is an easy instrument for nurses or researchers to administer with regard to collecting sleep data based on patients' perceptions of their sleep, as well as whether the RCSQ is an acceptable tool for ICU patients to complete on a daily basis during ICU stays. This type of assessment is necessary in order to understand whether RCSQ can be implemented as a standard tool for sleep assessment in ICU clinical practice.

Only two studies in Australia aimed to assess the feasibility of using RCSQ on multiple days to assess ICU patients' sleep quality throughout their ICU stays (Aitken et al., 2017, Menear et al., 2017), but some relevant information was also found in other studies. Overall, however, there is scant information and insufficient evidence on RCSQ's feasibility and acceptability as a standard tool for daily sleep assessment in ICU clinical practice.

3.6.3.1 RCSQ feasibility

The studies reported in varying detail on the method of RCSQ administration to patients used. Of the 23 studies, 15 reported that the RCSQ was administered to the patients by the researcher, and it was specifically administered by nurses in one study (Li et al., 2011), while seven studies did not mention the method of administration (Elliott et al., 2013, Elliott et al., 2014, Faraklas et al., 2013, Hu et al., 2015, Lewandowska et al., 2019, Naik et al., 2018, Patel et al., 2014). The processes involved in gathering patients' answers to the RCSQ were described in only eight studies (Chen et al., 2018, Hansen et al., 2018, Kamdar et al., 2012, Krotsetis et al., 2017, McKinley et al., 2013, Murata et al., 2019, Nicolas et al., 2008, Ritmala-Castren et al., 2017).

These studies reported that the researcher stood beside the patient during the assessment and assisted patients in marking the RCSQ based on patients' oral or gestured choices, indicating that administration of RCSQ required external assistance; of these studies, however, several briefly mentioned that RCSQ was an easy-to-apply tool for sleep assessment (Chen et al., 2018, Krotsetis et al., 2017, Murata et al., 2019, Nicolas et al., 2008).

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An observational prospective repeated assessment study was carried out by Menear et al. (2017) in a general ICU in Australia. This study assessed the feasibility of ongoing repeated use of the RCSQ to assess ICU patients' sleep quality over a three-month period. Data regarding RCSQ feasibility were collected using quantitative observational methods, and the study involved 50 patients, of whom seven were mechanically ventilated; all patients were calm and oriented, with RASS sedation level scores between -1 and 1. The RCSQ was administered by the researcher daily, once each morning throughout the patient's entire ICU stay. Assistance was provided to those patients who were unable to place a mark on the questionnaire themselves in the form of the researcher holding a pen and instructing the participants to provide a cue as to where they wished to place the mark on each scale.

The authors reported that the RCSQ was a feasible tool for routine administration and that no difficulties were experienced in using it to assess patients' sleep on multiple occasions in the ICU (Menear et al., 2017). However, no information was provided regarding the time required from the researcher in terms of administering the RCSQ to the patients or the effort required to calculate the scores and interpret them.

Another prospective observational repeated assessment study, carried out over a four-month period, was conducted in Australia to assess the feasibility of medical and surgical ICU patients self-reporting for sleep assessment using RCSQ on multiple days during their ICU stays (Aitken et al., 2017). The study involved 151 conscious and alert patients, but the resulting paper did not report on their ventilation statuses or sedation scores. The RCSQ was printed on A4 sheets of

paper, and the researchers collected the participants' RCSQs between 0700 and 1200 each day, generally soon after the patients awoke in the morning.

The researchers asked the patients to place marks on the RCSQ scales to indicate their perceptions of their previous night's sleep. The researchers reported that it was feasible for researchers to ask patients to self-assess their sleep regularly using RCSQ, a finding that corroborated previous work on RCSQ; they also described it as a simple brief assessment tool that was easy to use in terms of collecting patients' self-reported sleep quality data (Richards et al., 2000). However, no information about the time required for the evaluators to assess patients' sleep quality using the RCSQ was given, and no information was given about the effort required to calculate the RCSQ scores, despite such information being an essential indicator of the assessment tool's feasibility for both researchers and staff nurses in the ICU. Fitzpatrick et al. (1998) argue that more complex scoring systems in assessment tools reduce feasibility compared to simple systems, and successful implementation of a new measure in clinical practice thus not depends only on the acceptability of that measure to patients but also on the feasibility of that measure for researcher and healthcare professional use (Sekhon et al., 2017).

Other relevant indicators of feasibility were also extracted from the studies as possible sources of information about RCSQ feasibility for daily self-reporting of sleep assessments. These indicators included patient drop-out rates, defined as the number of patients who began the assessment but left before the assessment was completed based on choosing to withdraw or because they no

longer met the study inclusion criteria; and number of RCSQs completed by patients.

Drop-out rates were relatively low in most of the studies, ranging from 0 to 13%, offering initial evidence that patients do not perceive completing the RCSQ to be overly burdensome. Two studies had anomalously high drop-out rates, with 70% in Bourne et al. (2008) and 35% in Patel et al. (2014). Bourne et al. (2008) was a small RCT in UK that aimed to use the BIS instrument to examine the effects of exogenous melatonin medication on nocturnal sleep in 24 mechanically ventilated patients in a General ICU, which also used RCSQ for a four-night sleep assessment. All included patients were conscious and oriented, and none of them were on sedation during the assessment. Of the 24 enrolled patients, however, 17 (70%) dropped out; one patient was also unable to complete the assessment without a reason for this inability being provided. However, the reasons for the majority of the patients (n=16, 60.7%) dropping out were not related to the RCSQ itself: the patients developed delirium and therefore were unable to complete the RCSQ. The statistical power of the study was severely reduced by its decreased sample size, however, and no information was offered about how many RCSQs were completed by the remaining patients.

Patel et al. (2014) conducted an experimental non-controlled pre-post study design to assess the effects of multicomponent interventions on sleep quality in medical and surgical ICU patients. Patel et al. (2014) enrolled 338 patients into control (n=167) and experimental (n=171) groups. However, only 59 (17%) patients completed the study and no information was provided regarding the reasons why the 279 patients who dropped out did so. In addition, the authors

assessed patients' sleep quality using RCSQ on multiple nights, yet did not mention the period of assessment, randomly selecting only one RCSQ for each patient for inclusion in data analysis. There was also no information regarding over how many days the patients were asked to complete the RCSQ or how many RCSQs were completed overall (Patel et al., 2014). No information patient acceptability of RCSQ can thus be derived from this study.

Only three studies provided data about participants' RCSQ completion rates and reasons for not completing the RCSQ. An observational repeated assessment study in North America by Kamdar et al. (2012) assessed 33 medical ICU patients' sleep quality using RCSQ over 137 days. This study included mechanically and non-mechanically-ventilated patients, but it did not mention how many patients received mechanical ventilation during the assessment. Patients were conscious and oriented, with a mean age of 54 (43 to 63) years and low severity of illness, with a mean APACHE-II score of 13. Overall, 33 patients completed 121 self-report RCSQs, a rate of 88% based on available days, with an average of three to four reports per patient.

The reasons given for the 16 days on which RCSQs were not completed included two days when a patient was not present in the room during the assessment, two where the patient discontinued participation, nine where the patient had a change in clinical status (developed delirium), and three where the reason was unspecified. The study's findings suggest that ICU patients are able and willing to respond to RCSQs on multiple occasions. However, the study had only a small sample size, 33 patients, and it did not provide information on the time taken by patients to complete the RCSQ.

Aitken et al. (2017) performed repeated assessment of 150 medical and surgical ICU patients with a mean age of 60 (46 to 71) years over ICU stays of between 2 and 18 days. All patients had low severity of illness, with APACHE-II scores of between 10 and 20, and all were conscious and oriented; however, their mechanical ventilation statuses were not reported. In total, 151 participants reported on their sleep, using the RCSQ a total of 356 times. Patients reported on their sleep from one to 18 days, with half of the patients reporting for at least two days. This suggests that ICU patients can self-report on their sleep quality on multiple days using RCSQ. However, no information was provided about the reasons given by patients who provided RCSQs only once during the repeated assessment and this information would be required to fully understand whether this was due to the burden of completing RCSQ or for other reasons not related to the RCSQ such as patient discharge. In addition, no information was provided about the time required for completing the RCSQ by the patients.

Information about the completion rate of RCSQ by patients and the reasons offered for not completing the RCSQ by some participants was provided in an observational repeated assessment study carried out by Menear et al. (2017). The study involved 50 patients in a general ICU, with a mean age of 62.6±16.9 years and a low severity of illness, with APACHE-II scores of 12.5±6.3; the length of ICU stay was an average of 3 (1 to 8) days, and all patients were alert and oriented, as only lightly sedated patients with RASS score between -1 and 1 were included. However, 24 (48%) of patients received a low dose of Fentanyl opioid analgesic as needed, and seven (14%) patients were on mechanical ventilation.

RCSQ was administered to the patients daily each morning on an A4-sized sheet. Among the study participants, 42% completed more than one RCSQ. The reasons that repeated data were not collected from the remaining 29 participants were that 17 completed the RCSQ on the day of ICU discharge, four were recruited on a Friday and discharged over the weekend (data collection was not performed at the weekend), five were otherwise engaged (e.g. undergoing radiological investigation), and three discontinued data collection (Menear et al., 2017).

The mean number of occasions on which the RCSQ was completed was 4·2±3·5. The RCSQ repeated completion percentage was thus 72%, adjusted to exclude those who did not complete because they were discharged. The authors thus suggested that the RCSQ appears to be a non-burdensome tool and that patients were able to complete it on multiple days. This supports the results of Aitken et al. (2017) and Kamdar et al. (2012) with regard to RCSQ feasibility for daily self-reporting of sleep assessment in ICU patients.

3.6.3.2 RCSQ acceptability

Relevant indicators of acceptability were also extracted from the studies; these indicators included patient willingness to engage in assessment, defined as the number of eligible participants invited to participate in the study minus those who decided to decline; and patients' perceptions of completing the RCSQ on sleep quality on multiple days during their stays in the ICU. There is limited information about patients' acceptance of completing RCSQ on a daily basis during ICU stays, however, as none of the studies provided data about patients' perceptions of completing daily self-report RCSQ.

Of the 23 studies, five studies did not record the number of patients initially screened and approached, or even those who met the inclusion criteria yet refused to participate (Bourne et al., 2008, Chen et al., 2018, Hu et al., 2015, Nicolas et al., 2008, Patel et al., 2014). Of the remaining eighteen studies, the number of patients who were eligible but decided not to participate varied across the studies. Some studies had no refusal rate, such as Simons et al. (2018), whose 71 patients were all eligible and all enrolled in the study, while some studies had only a very small number of patients who declined participation, such as Frisk and Nordstrom (2003), in which 33 patients were eligible and only two patients refused participation.

Elliott et al. (2013) had the largest refusal number across the studies, with 266 eligible and 74 refusing participation. Reasons for refusal to participate were not given; however, Elliot et al. (2013) aimed to assess patients' sleep using PSG monitors alongside assessing patients' sleep using RCSQ, a decision likely to have affected patients' willingness to participate negatively, as PSG monitor use is known to be disagreeable and burdensome to ICU patients (Beecroft et al., 2008, Elliott et al., 2013, Trompeo et al., 2011). Elliot et al. (2013) did report that, while assessing patients' sleep using PSG, three patients asked for removal of the PSG electrodes, as they found these to limit mobility and even to impede sleep. Overall, the refusal rate in those studies using only RCSQ was relatively small, ranging from no refusal to a maximum of 18 (Ritmala-Castren et al., 2017), suggesting a general acceptance or willingness among patients with regard to participation in self-reporting sleep quality using RCSQ.

Overall, the three repeated measures studies, in addition to the data extracted from the other studies, provided initial evidence of RCSQ feasibility and acceptability for routine assessment of patient sleep in the ICU. However, there is limited information about patients' acceptance of completing RCSQ on a daily basis during ICU stays. In addition, none of the studies reported on the time necessary for completion of the RCSQ by patients, and none assessed patients' perceptions or experiences of completing daily assessments of their sleep quality using RCSQ or asked how patients found completing the RCSQ on multiple days during their ICU stays.

3.6.4 RCSQ interpretation and cut-off scores

The RCSQ total score can be considered as a measure of sleep quality, with higher scores indicating better sleep quality (Richards et al., 2000). Each scale in the RCSQ ranges from 0 (indicating the worst quality sleep) to 100 (indicating optimal sleep) (Richards et al., 2000), however, and the previous studies varied in terms of categorising cut-off scores for the RCSQ (Table 3.3). For example McKinley et al. (2013) proposed 70 as the cut-off point between good and poor-quality sleep, while a cut-off score of ≥50 was used to define good sleep quality in several other works (Aitken et al., 2017, Chen et al., 2018, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Naik et al., 2018).

Naik et al. (2018) performed a sensitivity-specificity analysis test using Receiver Operating Characteristic (ROC) curves to determine the utility of RCSQ scores for differentiating between patients with poor sleep quality and patients with good sleep quality, to aid in determining a cut-off point. An ROC curve is constructed by plotting the true-positive ratio (sensitivity), against the false-positive ratio (1

–specificity). The researchers reported that a total RCSQ score of ≥50 offered a sensitivity of 88.2% and specificity of 86.7% in terms of determining patients with good sleep as assessed by patient's perceptions (ROC area 0.91, confidence interval CI 95%). Thus, patients with total RCSQ scores <50 were considered to have poor sleep.

Frisk and Nordstrom (2003), Krotsetis et al. (2017), and Chen et al. (2018) agreed with Aitken et al. (2017) and Naik et al. (2019), using 50 as the cut-off point between good and poor-quality sleep; 25 was then set as the cut-off for very poor quality sleep, with a score of 26 to 50 indicating poor sleep quality; a score of 51 to 75 thus indicates good sleep quality, and a score of >75 indicates very good sleep quality. Nicolás et al. (2008) and Ritmala-Castren et al. (2017) used different categories to rate sleep, defining 0 to 33 as poor, 34 to 66 as fair, and 67 to 100 as good, a scale that approximates to the definition used by McKinley et al. (2013). These cut-off scores by McKinley et al. (2013) were, however, based on clinical experience and self-judgment, and these have not been evaluated using statistical methods, and may thus under-or over-estimate patients' sleep. Thus, the cut-off points of RCSQ suggested by Nike et al. (2019), based on a sensitivity-specificity analysis test, are probably the most appropriate in guiding the categorisation of RCSQ's scores; these were also the most commonly used in these studies.

Despite the importance of using a predetermined cut-off score to make the results of assessment easier to interpret and more meaningful and actionable (Machado, 2016), many studies did not specify how they scored the RCSQs, mentioning only that a high score indicated good-quality sleep (Chen et al.,

2018, Hu et al., 2015, Li et al., 2011, Murata et al., 2019, Patel et al., 2014, Ritmala-Castren et al., 2017). For such studies, analytical evaluation such as sensitivity-specificity analysis testing suggests that the validity of the results regarding self-reported sleep quality may be reduced (Habibzadeh et al., 2016).

3.7 Patients' perception of sleep quality in ICU

Based on the evidence of the psychometric properties, and feasibility and acceptability of the RCSQ for sleep assessment in ICU patients, this section examines the evidence on self-reported sleep quality in ICU settings offered by the studies that employed the RCSQ. Some studies that used RCSQ for sleep assessment also attempted to identify sleep disruptive factors during the assessment of patients' sleep, to help explain the reasons for poor sleep quality and to relate overall sleep quality to certain sleep disruptive factors from a patient perspective. Findings about reported sleep disruptive factors are thus presented alongside the patients' self-reported sleep quality to enable understanding of sleep quality from the patients' perspective and to determine whether any differences in the results for sleep quality are related to certain factors. A summary of sleep quality and sleep disruptive factors reported by ICU patients is offered in Table 3-2.

The results of the self-reported sleep quality for ICU patients from the studies in the current review confirms the results of those studies that evaluated patients' sleep using PSG, as discussed in chapter 2. Patients rated the overall quality of their sleep as poor; more specifically, they reported light and disrupted sleep

with frequent awakenings, and considerable difficulty in falling and returning to sleep (Table 3-2).

There are wide variations in the evaluation of ICU patients' self-reported sleep quality across the studies, however, which may be accounted for by the considerable variability in medical conditions of patients in these studies and by various methodological differences such as different ICU settings and methods of sleep assessment. In addition, differences in terms of setting out cut-off scores for RCSQ between studies may also have created variations in sleep data across studies, as discussed in section 3.9. However, the studies demonstrated remarkable consistency in terms of ICU patients experiencing poor quality of sleep and decreased sleep efficiency overall; most specifically, light sleep was a feature seen across all studies, with frequent awakenings and considerable difficulty falling and returning to sleep (Table 3-2).

The overall quality of sleep from the patients' perspective varied from very good to very poor across studies; some patients were able to sleep quite well, while many others slept poorly. The German study by Krotsetis et al. (2017) included 51 patients from cardiac, surgical, and trauma ICUs; more than half of the sample was male (67%), and the patients' mean age was 63±14.7 years. Six patients were mechanically ventilated, though severity of illness was not reported. Patients were alert, with RASS scores between 1 and -1, and none of the surveyed patients were sedated during the night, though the majority , 40 (78%), received intermittent low dose bolus opioid analgesics (Piritramide 1·87 to 3·75 mg) as needed.

Patients were asked between 9 and 11 a.m. to rate their previous night sleep quality using the RCSQ scales; after completing this sleep assessment, the patients were also asked an open-ended question to determine which factors they perceived as being disruptive to their sleep. The mean RCSQ total score was 47 ± 27·6 (ranging from 0 to 95) indicating generally poor sleep quality; 14 patients (27%) had total RCSQ scores of less than 26, indicating very poor sleep, with another 14 (27%) had scores between 26 and 50, indicating poor sleep; 13 patients (25%) scored between 51 and 75, indicating good sleep, while 10 (20%) scored more than 75, indicating very good sleep (Krotsetis et al., 2017).

Mean sleep depth as reported by patients was very low, however, at 38.04± 35.73, being the lowest of the RCSQ items, indicating that patients experienced light sleep; the scores for the other sleep items were reported as being slightly better, with ability to fall asleep (item 2), the state of wakefulness (item 3), and ability to return to sleep after awakening (item 3) achieving means of between 50 and 52, indicating that patients mainly have trouble achieving restorative deep sleep, resulting in overall poor sleep quality. Patients also reported multiple factors that they perceived as being disruptive to their sleep; a predominance of worries and fear was a frequently reported reason for disrupted sleep (n=15); followed by arousal by staff (n=6) for care interventions and the noisy environment (n=5) (Krotsetis et al., 2017).

The findings of Krotsetis et al. (2017), that ICU patients' perceptions of their overall quality of sleep vary from very poor to very good and that depth of sleep was rated lowest by patients, are confirmed by data obtained in other studies and countries. For example, Aitken et al. (2017) performed an observational

repeated assessment study with 151 medical and surgical ICU patients with a mean age of 60 (46 to 71) and low mean severity of illness scores of 15 (range 10 to 20). These patients were asked to report on their sleep quality on a daily basis in the morning, using the RCSQ; after completing the RCSQ, the patients were also asked what activities had disrupted their sleep during the previous night. These patients identified multiple factors that they perceived as disruptive to sleep, including patient care activities, pain, discomfort, noise from staff and equipment, fear, worry, vivid dreams, and light levels.

The mean overall score of the RCSQ was 46 (26 to 65), indicating that patients had overall poor sleep quality, though patients' perceptions of their sleep quality ranged from very poor to very good. Depth of sleep was rated the worst, with a mean of 44 (16 to 64), indicating that most patients had only light sleep; other items had mean scores slightly higher than that seen for depth of sleep, although the mean scores were all below 50, indicating that patients suffered frequent interruptions to sleep and experienced difficulty in resuming sleep once awoken.

Aitken et al. (2017) also reported on the quantity of patients' sleep by converting the RCSQ score into an estimation of sleep efficiency (the percentage of actual hours of sleep divided by hours spent in bed), using the formula suggested by the questionnaire developer (Richards et al., 2000): SEI = 46.88 + (039*RCSQ). The SEI for Aitken et al. (2017) was 65%, indicating that patients had reduced sleep time as compared to the normal range seen in healthy adults (70 to 85%).

The value of SEI calculated by Aitken et al. (2017) was also slightly lower (65% vs 69%) than that reported in the control group in a sample of non-mechanically ventilated surgical patients in an experimental pre-post study design used by Li et al. (2011) to examine the effect of sleep care guidelines on controlling night-time noise with regard to patients' sleep quality. The guidelines included reducing the volume of monitor alarms, teaching staff to lower their voices after 11:00 p.m., clustering nursing care activities before 11 p.m. to maintain an almost undisturbed period between midnight and 5:00 a.m., and identifying and modifying other sources of noise. The latter study included 55 patients split between control (n=27) and experimental (n=28) groups, with patients' mean age being 50±2.5 years; all patients in that study had a low severity of illness, with mean APACHE-II scores of 12.3±1.9 (Li et al., 2011).

Patients were asked to rate their sleep quality using RCSQ in a one-night assessment, as well as being asked to rate levels of potential sleep disruptive factors using the SICQ on a scale of 1 (no disruption) to 10 (significant disruption), and their daytime sleepiness on a scale of 1 (unable to stay awake) to 10 (fully alert and awake). Patients in the experimental group reported significantly less daytime sleepiness (5.33±1.69 vs 6.75±2.19; p=0.01) and fewer sleep disruptions from staff talking than the control group (4.82±1.04 vs 3.21±1.19; p>0.0001). The SEI of the experimental group was significantly higher than that of the control group (69.3± 10 vs 72.2 ±7.5; p=0.047). However, the SEI of the experimental group was still less than 85%, indicating compromised sleep efficiency in ICU patients even where the guidelines were implemented. Patients' sleep was assessed only once, on their second night in the ICU, however, and thus the researchers were not able to determine whether patients'

sleep changed over the course of their ICU stay or after implementation of the guidelines (Li et al., 2011).

Despite the development of multicomponent interventions or sleep promoting guidelines in intervention studies aiming to improve sleep in the ICU (Kamdar et al., 2013, Li et al., 2011, Menear et al., 2017, Patel et al., 2014) , there is no general evidence of such interventions leading to an improvement in patients' self-reported sleep quality. This may due to problems with the methodology in intervention studies, such as small sample size or limiting sleep assessment and sleep disruptive factors assessment to short periods, or it may be due to lack of consistency or routine monitoring of patients' perception of sleep in ICU clinical practice due to the lack of a standardised tool for sleep assessment in the ICU.

One observational repeated assessment study was carried out by Meaner et al. (2017) in the General ICU where locally developed sleep promoting guidelines had been in use for four years by the time the study was conducted. The guidelines included optimisation of the ICU environment by adherence to night-time light reduction, reducing noise levels, clustering nurses' activities, and manging pain; however, routine assessment of patients' sleep using a standardised sleep assessment tool was not included in these guidelines (Menear et al., 2017). The study thus compared self-reported sleep quality assessment during use of these guidelines with previously reported figures to assess any improvement in self-reported sleep quality since implementation (Elliot et al., 2011).

A small sample of fifty patients was included, with a mean age of 62.6 ±16.9 and low severity of illness, with a mean APACHE-II score of 12.5±6.3. The results showed that the overall patient sleep quality in all participants (n=50) did not show any statistically significant improvement on the use of sleep promotion guidelines in the ICU, as patients mean overall sleep quality was 51·3±24·4 as compared with the overall sleep quality of 47.9±24·4 from all participants in the investigation in the same ICU prior to the implementation of the guidelines (Elliot et al., 2011).

Patients' sleep quality was poor, light, and fragmented, with sleep depth having the lowest score of 39.9±25.8 and returning to sleep after awakening having the highest score at 55.9±31.3. These were comparable to the results of the observational cross-sectional study by Chen et al. (2017), where 150 patients were included with a mean age of 64.74±16.16 and a medium APACHE-II score for severity of illness of 26.04±22. Depth of sleep had the lowest score with a mean of 40.44± 23.93, similar to that found in Meaner et al. (2017), and the mean RCSQ total score, representing poor sleep quality, was 44.76±19.96.

Similar results were found in Frisk and Nordstrom (2003) in 31 patients with a mean age of 59 (range 19 to 85); severity of illness and mechanical ventilation status were not reported in that study, and though 12 patients (39%) were given some form of sedative during the night, the type of sedative was not mentioned. Mean depth of sleep was rated low, at 40.2 (range 0 to 98), similar to the 40.44 rating given in Chen et al (2017); however, quality of sleep (item 5) was rated the lowest in the RCSQ, with a mean of 39 (range 0 to 96), while the state of wakefulness was rated slightly better, with a mean of 52.8 (range 0 to 95), indicating fewer awakenings in this sample. Nevertheless, the overall total sleep

score was 45.5 (range 0 to 97), indicating poor sleep quality (Frisk and Nordstrom, 2003). Those patients who did not receive hypnotics during the night reported significantly better sleep (mean 54.3) compared to those who did (mean 31.6, p=0.037), indicating that sedatives do not produce a normal pattern of sleep and have an overall negative effect on the quality of sleep. A few patients in Frisk and Nordstrom (2003) commented that noise disturbed their sleep (40%), while the majority of patients (60%) indicated that the cause of their disturbed sleep was discomfort, expressed in the form of pain and worry. A cross-sectional study carried out by Nicolas et al. (2008) included 104 non-mechanically ventilated surgical ICU patients with a mean age of 57.72±14.81 years; severity of illness was not reported, though 69 patients received non-opioid analgesics during the night and 35 patients received opioid analgesics. These patients' perceptions of their sleep varied from very poor to very good, similar to other studies (Aitken et al., 2017, Frisk and Nordstrom, 2003, Krotsetis et al., 2017), with 29 of 104 patients (27.89%) reporting very good sleep; 48 patients (46.15%) reporting good sleep, and 27 patients (25.96%) reporting poor sleep quality.

The mean total RCSQ score was intermediate at 51.42 ±12.7, better than seen in the other studies. The state of wakefulness (item 3) was also the lowest reported, being the only item reported below 50 with a mean of 42±29.27, which nevertheless indicates some fragmented sleep in the study sample; this contrasted with (Frisk and Nordstrom, 2003), however, who found the state of wakefulness item rated the highest, with a mean of 52.8.

Nicolas et al. (2008) reported that patients who received non-opioid analgesics had lower quality sleep than patients who received opioid analgesics. The difference between the two groups was statistically significant (47±23.17 vs 60±15.97; p=0.003), though the limited sample sizes may have affected the validity of the comparison results, as only 35 patients received opioid analgesics compared to 69 patients who received non-opioid analgesics.

The cross-sectional Japanese study by Murata et al. (2019) in a general ICU including 45 non-mechanically ventilated patients with a mean age of 69.1±8.8 with low severity of illness APACHE-II scores of 12.4±4.3 showed the state of wakefulness item as having the lowest mean score at 30.28±20.46, indicating highly fragmented sleep in the study sample, comparable with the results of Nicolas et al. (2008). In the former case, overall patient sleep quality was also poor, with a mean total RCSQ score of 42.39±19.51, lower than the 51.42 ±12.7 reported in Nicolas et al. (2008). However, in both studies (Nicolas et al., 2008; Murata et al., 2019), the samples were small, and the patients' self-reported sleep quality assessments were limited to one off assessments, making it unclear whether patients' sleep quality changed with changes in their health conditions or with changes in the ICU environmental conditions throughout the periods of their ICU stays.

Another cross sectional study was carried out in three different ICUs in the Netherlands by Simons et al. (2019) to determine the effect of noise on patients' self-reported sleep quality using RCSQ; a regression analysis was then used to determine associations between objective noise parameters and ICU patents' self-reported sleep quality. Sixty-four patients were included, with a mean age of 63.9± 11.7 and medium severity of illness scores of 21±7.1; 68% were male

and 32% were female, 11 (17.2%) patients were receiving intermittent opioid analgesics as needed, and all patients were alert, with RASS scores between -1 and 1. Twenty (31%) patients were on mechanical ventilation. The mean of the 24-hour average sound pressure levels was 54.0±2.4 dBA, indicating high noise levels in the ICUs.

Patients were asked to rate their previous night's sleep quality using RCSQ at 7.00 a.m. each day; after RCSQ completion, patients were also asked to indicate which noise they found the most disrupting during the night. The majority of patients (n=49) cited monitor alarms as the most disturbing, followed by staff speech (n = 9), and staff activities (n = 6). Average sleep quality was 56±24, indicating that patients' perceived sleep quality was generally poor. A regression analysis revealed that noise factors were negatively associated with sleep ($\beta = -0.51$, $p < 0.05$), indicating a negative impact of noise on patients' sleep, while an examination of sex effects showed that being female was positively correlated with sleep quality ($\beta = 1.25$, $p < 0.01$), indicating that female patients had better sleep quality than male patients. However, the study was limited by small sample size and a short period of sleep assessment, making it unable to ascertain whether patient' sleep quantity or sleep disrupting factors varied during the period spent in the ICU.

3.8 Summary

There is evidence that the RCSQ is now frequently used in ICU-based sleep studies. This chapter thus discussed the emergent evidence of RCSQ validity, reliability, feasibility, and acceptability in ICU clinical practice provided by a review of those studies that have previously used RCSQ in ICUs. This chapter also

discussed the quality of sleep from patients' perspectives based on the use of RCSQ, as well as reviewing sleep disrupting factors as assessed in existing studies performing sleep assessments using RCSQ. The methodological strengths and limitations of these studies were also discussed.

The studies varied widely in methodology and quality, as summarised in tables 3.2 and 3.3. Overall, widespread use of RCSQ internationally can be assumed, as it has been translated into many different languages, including Chinese, Finnish, German, Japanese, Spanish, and Swedish. Overall, the evidence supports the validity of the RCSQ for sleep assessment in ICU patients, as demonstrated in the original validation of the RCSQ (Richards, et al., 2000). The RCSQ also showed evidence of reliability when used for ICU patients self-reporting on sleep quality, though there is no evidence of inter-rater reliability when it is used by ICU nurses to observe patients' sleep quality, based on poor agreement between nurses' observations of patients sleep and patients' own assessments of their sleep; overall nurses tend to overrate the quality of patient sleep.

There is some initial evidence that RCSQ is a brief and simple tool that can thus be usefully applied in the ICU for self-reporting of sleep assessments; however, its feasibility and acceptability for daily use in ICU clinical practice has not yet been sufficiently demonstrated, as the majority of the studies have limited the use of RCSQ to one night of patients' ICU stays, and small sample sizes were predominant across all studies. In addition, some studies were not clear in terms of reporting information about patients' refusal rates during the recruitment process or their drop-out rates and reasons for dropping out, making the extracted information on RCSQ feasibility and acceptability insufficient. Only

three studies used RCSQ in repeated assessment throughout patient stays in the ICU, and none of these studies reported data about patients' acceptance or experience of completing RCSQ on a daily basis during their ICU stays. It is important to consider patients' views of the nature of the assessment to understand whether daily self-reporting of sleep assessment using RCSQ is acceptable to patients; this could be done by asking the patients about their experience of completing RCSQ on a daily basis in the ICU (Fitzpatrick et al., 1998). Only by ascertaining patients' experience of or satisfaction with providing a daily self-reported RCSQ on sleep quality in the ICU can the usefulness and effectiveness of the RCSQ in ICU clinical practice be explored.

There has already been a widespread use of the self-report assessment methods using RCSQ for sleep studies in ICU settings, however. Those studies which have used RCSQ identified that ICU patients suffer from sleep disturbances and that the quality of their sleep is poor; issues include frequent awakenings, decreased sleep efficiency, difficulty in returning to sleep after awakening, and insufficient deep sleep. The aspect of sleep depth in RCSQ is predominantly reported as being the worst among all sleep aspects, although the variation in reported values of all sleep aspects from the patients' perspective between studies is wide. There is also considerable variation in the reporting of sleep disrupting factors across the studies, including environmental, demographic, and clinical factors. This variation in reporting sleep disruptive factors between studies provides evidence of the importance of assessing sleep disruptive factors alongside sleep quality, especially in ICU settings not previously studied, as disruptions to sleep and reported sleep disruptive factors vary between both individual patients and individual ICU settings.

It is also worth noting that the majority of the studies covered short periods of self-reported sleep quality and self-reported sleep disruptive factors assessment of between one to two nights. Assessing both patients' sleep quality and sleep disruptive factors on multiple days is important to obtain a more comprehensive picture of patients' sleep quality and to identify common sleep disruptive factors in the ICU. Only three studies assessed self-reported sleep quality with the same participants on multiple days, and of these studies, only one study assessed self-reported sleep disruptive factors on multiple days. Further, none of the studies in the current review offered data about self-reported sleep quality and self-reported sleep disruptive factors during intubation and after extubation in groups of intubated patients, despite their inclusion of intubated patients. Such assessment is crucial to understanding whether differences in self-reported sleep quality and sleep disruptive factors can be explained in terms of intubation status. Intubation is also a very important period for ICU patients generally, as more than half of all ICU patients are intubated on ICU admission (Wunsch et al., 2010).

Overall, there is evidence that ICU patients experience disrupted sleep, and the growing awareness of the role of sleep in ICU patients' recovery and the growing use of RCSQ to assess sleep quality in this setting is clear in the literature. Nevertheless, there is currently no Arabic version of RCSQ generally available, and thus, there is no data about RCSQ use in Middle Eastern countries. Furthermore, there is a general lack of knowledge about patients' self-reported sleep quality and sleep disruptive factors in Middle Eastern countries, in particular in Saudi Arabian ICUs.

Based on the limitations of existing studies and the gaps in the evidence in this area, there is a clear need for further research to develop an Arabic version of the RCSQ (RCSQ-A) based on translating the instrument into Arabic and testing its content validity, and internal consistency reliability among Arabic speaking ICU patients in Saudi Arabia. Both content validity and internal consistency are essential properties that should be considered as first step in the process of translation and adaptation of the original measurement scale, in order to ensure that the concepts of the items in the translated RCSQ-A provide an adequate reflection of the performance of the items in the original version of the RCSQ. In addition, it is necessary to test the feasibility and acceptability of the translated RCSQ (RCSQ-A) for daily self-reported assessment of sleep quality in an ICU setting in Saudi Arabia and to report on sleep quality and sleep disruptive factors among ICU patients in Saudi Arabia.

Chapter 4 Concepts and background pertaining to methods

The literature review presented in Chapter Three offered evidence of the disrupted sleep in ICU patients that are common subjective complaints, which they are mainly manifested as a light sleep and frequent interruptions. The RCSQ has become one of the most widely used self-report assessment methods for sleep studies in ICU settings, yet no Arabic version of the RCSQ was generally available prior to the current study, and thus there has been limited data about RCSQ use in Middle-Eastern countries. Furthermore, there is little knowledge about ICU patients' self-reported sleep quality and sleep disruptive factors in ICUs in Middle Eastern countries overall, and in Saudi Arabia in particular. The literature review also revealed that there was insufficient evidence for RCSQ's feasibility and acceptability in terms of routine assessment of patients' self-reported sleep quality in ICU clinical practice.

key concepts emerged from the gaps in the literature review that informed the research questions, design, and methods of the current study, and this chapter thus consists of two main sections. Section 4.1 reviews the basic concepts underlying this study, presenting and summarising the conceptual definitions adopted. It also presents the framework that emerged from these concepts to underlie this study, which helped in understanding the nature of the data that needed to be collected to answer the research questions. Section 4.2 examines the research approach adopted in this thesis, clarifying and discussing the factors that influenced the researcher in terms of the organisation and structure underlying this approach. This section then outlines the philosophy (paradigm) underpinning the research approach taken, highlighting the researcher’s positivist stance and the subsequent choice of a descriptive quantitative

approach. This section also explains in detail the overall rationale for adopting the observational correlational research design, and, further, lays out the reasons for the adoption of the final research method, prospective repeated assessment, used in this study. The data collection process, including all materials and instruments used in this study, along with an explanation of the collected variables, the methods used to analyse and interpret data, and ethical considerations, is presented in Chapter 5.

As described in Chapter One, the overall aim thus emerged to be achieved in this study:

To develop and test the psychometric properties, feasibility, and acceptability of daily self-reported assessment of sleep quality in an ICU setting in Saudi Arabia using an Arabic version of the RCSQ (RCSQ-A) and to report on sleep quality and sleep disruptive factors among ICU patients in Saudi Arabia.

Consequently, the following research questions were developed:

1. Can an Arabic version of the RCSQ (RCSQ-A) be developed for daily self-reported assessment of sleep quality in ICU setting in Saudi Arabia?
2. What is the content validity and internal consistency of the resulting RCSQ-A in terms of daily self-reported assessment of sleep quality in ICU patients in Saudi Arabia ?
3. What is the feasibility and acceptability of the RCSQ-A in terms of daily self-reported assessment of sleep quality in ICU patients in Saudi Arabia?
4. What is the self-reported quality of patients' sleep in an ICU setting in Saudi Arabia?
5. What factors related to patients' self-reported sleep quality arise in an ICU setting in Saudi Arabia?

4.1 Concepts underpinning this study

This study relied mainly on relatively standard conceptual definitions of content validity, internal consistency , feasibility and acceptability, sleep quality, and sleep disrupting factors, which guided the researcher throughout the research process. Polit and Beck (2014) emphasise that researchers should provide clear definitions of the concepts adopted in a particular study, based on the context of the study, however, as there may be several interpretations in the literature of a given concept, and these may also be understood differently by various individuals. Providing definitions is thus a fundamental step prior to discussion of the actual methods used for research (Polit and Beck, 2014).

The basic concepts underlying the current study were defined as based on information obtained from the literature review laid out in Chapters 2 and 3. This section therefore offers a summary of the definitions of these concepts as adopted in this study, which formed the basis of the study aims, as shown in Figure 4-1. Further clarification on how these concepts were involved in guiding each process of this research, including the selection of the research approach paradigm and the final design, and methods is offered in section 4.2.

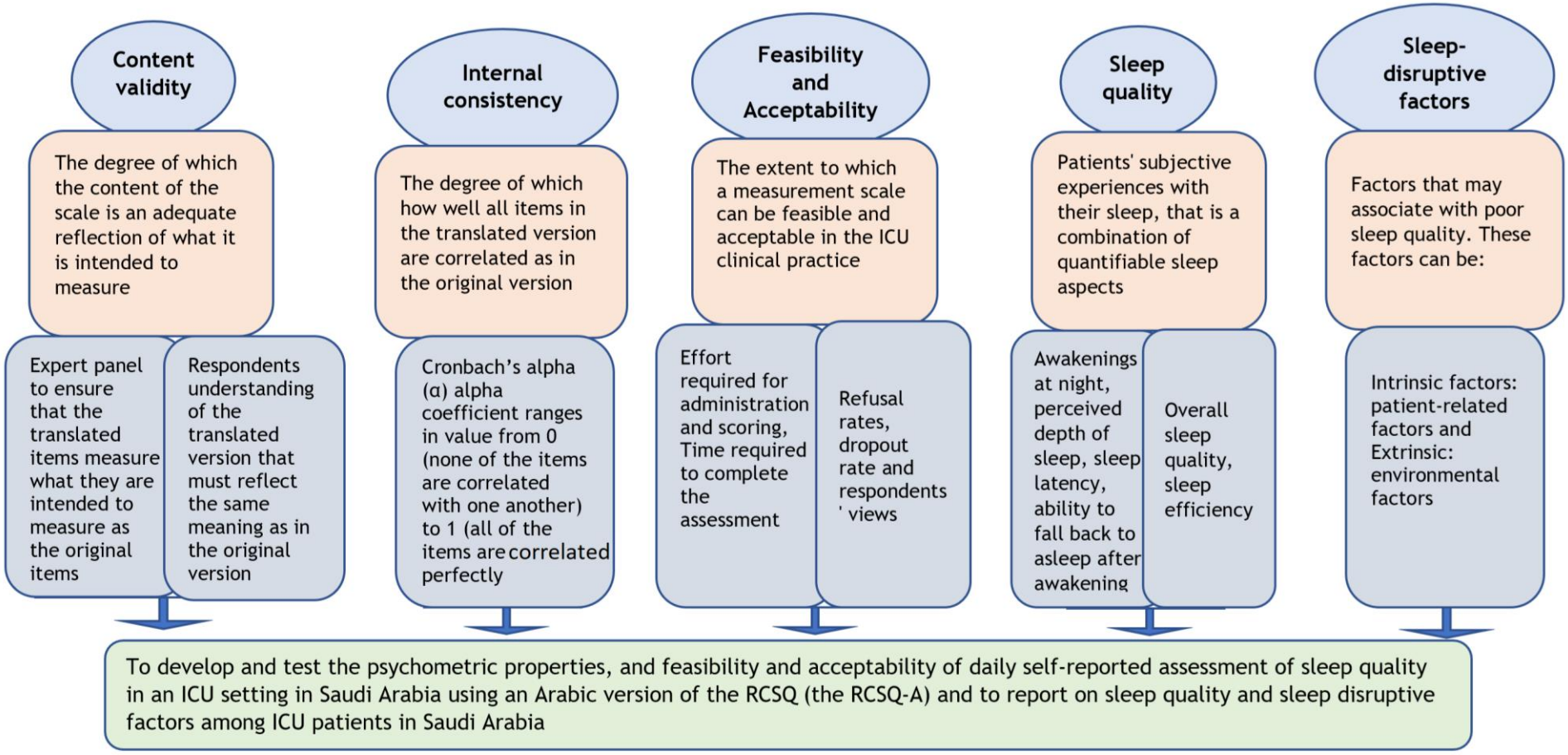

Figure 4-1 Key concepts underpinning the study

Additionally, Polit and Beck (2014) assert that identifying and locating the components and indicators that reflect the concepts under study facilitates and supports the researcher's selection of valid and reliable measures to best capture the relevant variables. Parahoo (2014) argues that research does not necessarily have to test a theory, as its purpose is often to find answers to specific research problems. This applies to this case, where the researcher was interested in finding answers to specific research questions, which in turn relies on identifying the key concepts underlying the research problem, defining the components that best reflect these concepts, and consolidating existing knowledge about these concepts based on relevant literature to develop a conceptual framework to underpin further study (Parahoo, 2014).

The concept of *content validity* adapted in the current study includes the evaluation of the concepts of the items identified in the RCSQ-A during the translation process by an expert panel in the field of sleep and ICU medicine, to ensure that the RCSQ-A's items provide an adequate reflection of the performance of the items in the original RCSQ. This adapted definition was also applied in the study that translated RCSQ into Japanese (Murata et al., 2019). The adapted definition of content validity in the current study thus also includes the evaluation of the items in the RCSQ-A by ICU patients in order to ensure that the translated items retain the same meaning as in the original RCSQ and that the items thus measure what they are intended to measure (Sousa and Rojjanasrirat, 2011, World Health Organisation, 2017). This adapted definition was similarly used in a study by Chen et al. (2018) that translated the RCSQ into Chinese.

The concept of *internal consistency* adapted in the current study involves assessment of how well all items of the RCSQ-A are correlated and thus measure the same underlying construct, "sleep", as the original RCSQ (Roach, 2006). This was done using the most popular test of internal consistency, which is used in all ICU sleep studies that have translated the RCSQ, the Cronbach's alpha, which estimates the average level of agreement between the items in a scale(Chen et al., 2018, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Murata et al., 2019, Nicolas et al., 2008, Ritmala-Castren et al., 2017).

Feasibility and acceptability concepts in this study were defined by integrating and understanding the definitions proposed by Fitzpatrick et al. (1998) and Sekhon et al. (2017), in addition to considering the definitions and indicators emerging from the ICU-based sleep studies that have previously assessed the feasibility of RCSQ (Aitken, et al.,2017; Meaner et al., 2017), as discussed in chapter 3. The indicators of feasibility and acceptability used in this study were thus defined as time required to complete the RCSQ-A by participants; number of completed RCSQ-A, respondents' burden as measured by refusal rates, withdrawal rate, dropout rate, participants' ability to make self-reports by themselves and participants' views (open ended question); and the effort required from the researcher for scoring and interpretation of RCSQ-A.

The concept of *sleep quality* adopted in this study, as previously discussed in Chapter 2, is a complicated construct that is difficult to measure objectively, as it includes individuals' subjective experiences and satisfaction with their sleep (Ohayon et al., 2017). It does have some specific quantifiable components, however, which include awakenings at night, time taken to fall asleep (sleep

latency), ability to fall back to asleep after waking up, perceived depth of sleep, sleep efficiency, and general sleep satisfaction (overall sleep quality)(Ohayon et al., 2017, Richards et al., 2000). In this study, the operationalised definition of patients' sleep quality was thus set as the patient's self-rating for each component of sleep on the pre-specified scales, thus acquiring quantifiable values for patient perceptions of each component (Aitken et al., 2017, Ohayon et al., 2017, Richards et al., 2000).

The concept of *sleep-disruptive factors* adopted in the current study includes factors that may be associated with poor sleep quality in ICU patients, those which increase the state of wakefulness, and those which limit the depth of sleep (Pisani et al., 2015, Simons et al., 2018). These factors should thus cover anything that may keep a patient awake or interrupt sleep patterns (Pisani et al., 2015, Simons et al., 2018). These factors are categorised in this study as extrinsic and intrinsic factors, based on the literature discussed in Chapter 2, particularly section 2.6. Hence, the available evidence on sleep disruptive factors was used to guide the factors included and assessed in this study (Bihari et al., 2012, Freedman et al., 1999, Aitken et al., 2017, Frisk and Nordstrom, 2003, Krotsetis et al., 2017)

Intrinsic-factors are thus defined as all patient-related factors, including patients' demographic and clinical characteristics such as age and sex, sleep patterns prior to ICU admission, pre-existing sleep pathologies such as sleep apnoea, regular use of sleep aid medication at home, type and severity of underlying illness, ongoing or prior treatments, length of ICU stay, and

psychological propensities to stress and fear, as all of these have been hypothesised as being associated with poor sleep quality in ICU patients. (Elliott et al., 2014, Li et al., 2011, Beltrami et al., 2015, Pisani et al., 2015).

From the review of the literature in Chapter 3, in previous ICU based sleep studies, researchers have tended to exclude patients with pre-existing sleep pathologies such as sleep apnoea and patients who regularly take sleep aid medication at home, in order to isolate the influence of ICU factors on the quality of patients' sleep. Thus, to help understand the association between the factors that emerge from the ICU environment, factors that are related to the nature of the critical illness of patients, and poor sleep quality in ICU patients during their stay in the ICU, in this study, the researcher followed previous ICU-based sleep studies in terms of defining sleep disruptive factors to allow discussion of this study's results in conjunction and comparison with other relevant research studies. Extrinsic factors were thus defined as factors related directly to the ICU environment. These factors, including sources of noise, light, and patient care activities, were identified based on the review of the literature (Chapter 3).

Based on these definitions of the concepts that underpin this study, and the components and indicators that reflect these concepts, the next section of this chapter discusses and presents the justifications for the chosen approach, which was selected specifically to address these concepts, to measure them, and to thus obtain answers to the research questions.

4.2 Choosing the research approach

A research approach can be defined as the plan or the proposal used to carry out a study (Polit and Beck, 2014). In order to support the credibility of any research findings, an appropriate research approach should be chosen based on three basic components that address the research questions: the philosophical worldview (paradigm) adopted, which informs and guides the second and third components; the research design; and the methods (Cresswell, 2014, Mertens, 2009).

Cresswell (2014) notes that there are multiple factors that influence researcher decisions with regard to research approach and how to answer research questions. These factors include the nature of the research problem or the concepts being addressed; the philosophical assumptions the researcher brings to the study; the required research design; and the nature of the target population (Cresswell, 2014). These factors interact to guide researcher decisions on structuring and organising the research approach and methods to answer the research questions (Cresswell, 2014).

Following Cresswell (2014), in this study, the researcher opted to adopt a quantitative research approach based on multiple influential factors, including the definitions adopted for the concepts underpinning the study, which are central to guiding the research process and which therefore form the framework for this study (section 4.1). The literature review then informed the design of the current study; in particular, the gaps and methodological limitations identified in the structured review of the literature (Chapter 3) highlighted the need for a repeated assessment study design. Consideration was also made of the ability of the target population (ICU patients) to provide answers.

Figure 4-2 presents the framework for this study, presenting the influential factors and their interactions in terms of organising the research approach and informing the assessment methods, as applied to this study. Further details of how these factors guided this research are presented within the descriptions of each of the research approach components (paradigm, design, and methods) in the appropriate sections of this chapter.

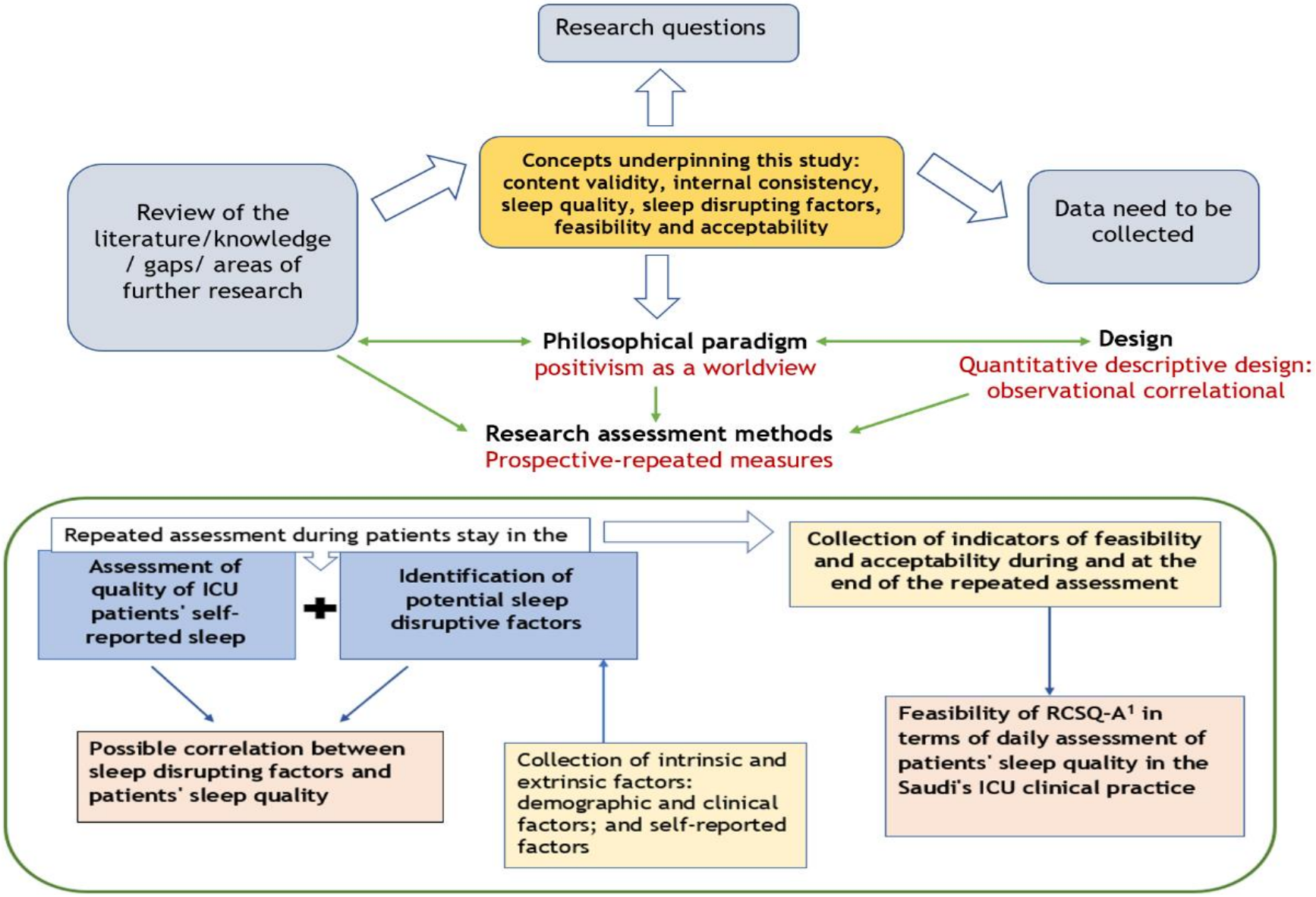

Figure 4-2 Organised research framework with underlying influential factors as applied in this study

[1]The Arabic version of RCSQ as developed and used in this study; details of the translation process are provided in Chapter 5.

4.2.1 Research philosophy: the paradigm underpinning the research approach

A paradigm is a worldview or a set of philosophical assumptions that a researcher espouses to shape and structure their research approach (Parahoo, 2014, Polit and Beck, 2014). Kuhn (1962) suggests that the idea of the paradigm can be construed as the concept that every researcher has their own beliefs that guide their views of, and thinking about the surrounding world and the "truths" inherent in that; this thus guides the researcher in terms of solving the problem.

These beliefs relate to the ontological, defined by what the researcher believes about the nature of social reality (Bryman, 2012) ; the epistemological, that is, what the researcher believes can be known about reality and what sources of such knowledge exist that the researcher may access to come to know more about the world; and the axiological, or what the researcher believes to be true (Howell, 2016). A paradigm thus guides the researcher to think in certain ways determined by the beliefs that form their view of the problem which then helps them decide on the appropriate approach (Howell, 2016).

A suggestion that is frequently made concerning philosophical research paradigms is that positivism is aligned with quantitative approaches and interpretivism is aligned with qualitative approaches (Bryman, 2012, Parahoo, 2014, Phillips and Burbules, 2000). Both approaches seek access to scientific knowledge, yet each approach is based on a separate paradigm with its own assumptions and is thus associated with specific research methods.

In this study, a positivist paradigm was adopted to form the framework within which the research took place and the answers to the research questions were sought. The philosophical stance of the researcher in terms of the choice of this positivist paradigm is thus provided and discussed in the following section.

4.2.1.1 Positivism as a worldview underpinning a research approach

Positivism is a scientific approach that posits that reality exists separately of the researcher, and that the ambition of the researcher must thus be to discover facts conceived in terms of specified correlations and associations among variables (Bryman, 2012; Howell, 2016). A central tenet of positivism is that true knowledge about existing phenomena can be derived from experiments, observation, and measurement (Kim et al., 2006; Parahoo, 2014).

From this perspective, any phenomena being studied must be either directly measurable or capable of being defined by variables or indicators in order to contribute to knowledge. Further, the positivist philosophy usually includes deductive reasoning, with an emphasis on predefined concepts or the testing of an existing theory, and these guide the choice of measurements (Parahoo, 2014; Polit and Beck, 2014). This definition of the positivist stance makes it the most suitable approach for achieving the aim of the current study and answering the research questions .

The current study aimed to develop and test the psychometric properties, and feasibility and acceptability of daily self-reported assessment of sleep quality in an ICU setting in Saudi Arabia using an Arabic version of the RCSQ (the RCSQ-A), and thus to report on sleep quality and sleep disruptive factors among ICU patients in Saudi Arabia. Based on this overall aim and the adopted definitions of concepts underlying this study, a positivist stance was thus the most suitable

(Figure 4-2). However, positivism has certain inherent weaknesses: the measurement process are at high risk to be false rather than real, where the measurement relied mainly on tests, structured interviews, assessment tools(Bryman, 2016). Therefore, the choice of the method of assessment and valid and reliable tools for measurement is essential to ensure validity of the results. Furthermore, positivists believe that objective inferences can be reached as long as the researcher doing the observation and measurement is objective and neglects the emotions (Bryman, 2016, Cohen, 2007). Additionally, some researchers believe that since positivists believe the phenomena being studied can be measured and computed, they tend to be inflexible (Tajvidi and Karami, 2015). Positivists see things as they are and tend to disregard unexplained phenomena (Tajvidi and Karami, 2015). This belief can reduce lateral thinking, which is the process of finding answers by creatively and indirectly finding out ways to solve a problem. Although positivism inspires researchers to disregard individual emotions and relied mainly on objective stance, its feature of generalisation, prediction, validity and reliability help researchers carry out the research which is transparent from personal biases, so as to be applicable universally (Bryman, 2016).

In contrast, interpretivism relies on qualitative approaches, seeking to use inductive processes based on collecting narrative information to generate theories or concepts using relatively unstructured approaches (Cresswell, 2014; Polit and Beck, 2014). Thus, the interpretivist stance was unsuitable for this study, where the concepts measured were defined and determined using specific quantifiable components and indicators.

A key feature of interpretivism approach is their ability to explore individual experiences, emotions, and perceptions (Denzin and Lincoln, 2005). There are,

however, several principles of qualitative research that make it less suitable for the current study in terms of answering the research questions, with a quantitative approach appearing more suitable. Nevertheless, the point of method selection is perhaps best expressed by the idea that there is no right or wrong approach, and certainly none that is always “best” (Cresswell, 2014). The goal is thus simply to ensure that the approach chosen suits the purpose of the study, the research questions and aims, and makes use of the defined concepts underlying the research problem (Ryan, 2018).

The quantitative approach was thus deemed more suitable and consistent with the current study than the qualitative approach for many reasons. In particular, the current study sought generalisation and measurement of the concepts across a large number of ICU patients, which could not be easily achieved with qualitative approaches. Qualitative research explores the uniqueness of perception or experience of particular individuals or groups in particular contexts (Polit and Beck, 2013), and thus, it generally does not seek to obtain data from large numbers of individuals, in contrast with the aim of the current study (Polit and Beck, 2013). It is quantitative approaches which usually seek to create generalisations to larger groups, in defiance of uniqueness of experience, and this therefore favours the use of a large number of participants rather than examining particular smaller groups (Polit and Beck, 2013).

The current study also sought to determine the quality of patients’ sleep in ICU settings using a self-report technique, as well as to identify what factors are correlated to patients' self-reported sleep quality. A quantitative approach is the best for generating numerical data from such self-reporting and for identifying correlations (Sousa et al., 2007).

Due to the inherent poor health status of ICU patients and their clinical needs, which require constant medical and nursing care, a quantitative approach using self-reports was also easier and quicker than a qualitative approach, as the ICU patients' responses could be gathered in a simple and rapid manner (Parahoo, 2014, Polit and Beck, 2014). In a qualitative approach, the interview methods tend to require more time and effort to gather participants' responses (Polit and Beck, 2013, Grove and Gray, 2014).

Taking these characteristics and features of positivism into consideration, a positivist position was thus adopted in this study; it is thus assumed that there is an objective reality of multiple dimensions, indicators, and facts that can be measured. This adoption of positivism also prompted the researcher to choose a quantitative approach as being the one that could best provide insights into that reality and thus answer the research questions in this study. In undertaking the quantitative study implied, the researcher also embedded the principles of description and observational correlational design. Justifications for choosing this design to address the research questions are provided in further detail in the next section.

4.2.1.2 Justifications for a quantitative descriptive design: observational correlational study

The fundamental purpose of a study design is to guide the work towards the most productive method of answering the research questions (Parahoo, 2014). In this study, the researcher opted to employ a descriptive correlational observational repeated assessment study design, based on the nature of the study aim and the research questions. Observational correlational design is a form of descriptive research that aims to represent the characteristics of individuals based on observing events, measuring any variables of interest as

accurately as possible and examining the relationships between these variables without attempting to manipulate either individuals or events (Polit and Beck, 2014).

Observational research is of value in most clinical nursing areas, as it allows nurses to get to know their patients better, whether through observations of indicators such as self-reports from patients or by observing symptoms to determine whether the patient is getting better based on the care they are receiving (Parahoo, 2014, Polit and Beck, 2014). Observational assessment is primary concerned with "what is", and descriptive methods using valid well-designed questionnaires with quantitative scales are thus usually used to measure and collect descriptive data about concepts of interests in such nursing and clinical research (Grove and Gray, 2014).

The decision to use descriptive methods in the current study was informed by the literature on previous ICU sleep studies (chapter3) (Aitken et al., 2017; Krotsetis et al., 2017; Nicolas et al., 2008). For example, a descriptive method was utilised in the German study by Krotsetis et al. (2017) which aimed to develop a German version of the RCSQ, to determine its reliability, and to assess perceived sleep quality in 51 ICU patients, as discussed in chapter 3, section 3.7. In the current study, descriptive methods were thus applied, with quantitative numerical data gathered to answer the first and second research questions, which were mainly concerned with developing an Arabic version of the RCSQ (RCSQ-A) and assessing its validity and reliability in terms of assessing self-reported sleep quality in ICU patients in Saudi Arabia. In addition, these methods helped to answer the fourth and the fifth research questions, which were mainly concerned with discovering patients' perceptions of their own sleep quality using

self-reporting during ICU stays and identifying factors potentially correlated to this self-reported sleep quality. Further details of the assessment tools used in this study and the quantitative variables collected are provided in Chapter 5.

In order determine the answer to the fifth research question, a correlational design was selected to assess the relationships between potential sleep disruptive factors and self-reported sleep quality; the factors of interest included factors self-reported by the patients, demographic, and clinical factors. Prematunga (2012) suggests that developing an understanding of the relationships among various variables is the abiding impetus for scientific enquiry and is thus a significant part of healthcare research, and a correlation occurs where one variable increase when another variable increases or decreases, regardless of the causality of such changes (Sousa et al., 2007, Prematunga, 2012). However, it is important to remain aware that a direct cause-and-effect relationship cannot be inferred from correlations between variables (Miles et al., 2015). At most, these allow a researcher to make predictions about the nature of the relationship, identify how strong the relationship is, and to determine whether changes in one or more predictors (in this case, sleep disrupting factors) are associated with changes in the dependent variable (here, self-reported sleep quality) (Miles et al., 2015, Vogt and Johnson, 2012).

In the Australian ICU sleep study by Elliot et al (2014), a descriptive correlational design was used, with all potential relationships between intrinsic and extrinsic sleep disruptive factors and patient sleep quality assessed. Variable data on potential sleep disrupting factors were thus collected, assessed, and analysed descriptively, and the predictive associations with pathway use were assessed

using a multiple regression model. Elliot et al (2014) note that this correlational assessment contributed to them developing an understanding of the factors that most likely related to patient sleep quality; however, as sleep quality was assessed only once, and the factors were multiple and varied, a further correlational assessment with serial measurements of patient sleep quality and sleep disruptive factors was thus recommended. Thus, taking into consideration the features and characteristics of correlational design and the guidance from the literature review, a correlational design was applied in the current study.

With regard to answering the third research question (What is the feasibility and acceptability of the RCSQ-A in terms of daily self-reported sleep quality in ICU patients in Saudi Arabia?, the researcher adopted the quantitative observational design in order to answer the question by means of observation and description of various pre-identified indicators.

Parahoo (2014) states that, in quantitative observational research, the researcher should observe and document particular aspects of a phenomenon to be quantified through various measures without intervening in any way. The researcher can thus describe what actually occurs as well as determining the frequency with which it occurs and descriptively analysing and categorising the information (Parahoo, 2014). In this study, by applying a quantitative observational design, the observational data necessary to assess the feasibility of RCSQ use were gathered to be quantified and analysed, based on predetermined indicators of feasibility such as the number of completed RCSQs and the time taken to complete each instrument. The selection of the indicators of feasibility was based on the conceptual definitions explained in Chapter 3, section 3.1, and

further details about the collected indicators of feasibility are offered in Chapter 5.

In light of the factors discussed in the previous paragraphs in this section, observational and correlational design principles were embedded into the descriptive quantitative study in order to answer all five research questions. The following paragraphs offer further explanations of why the prospective-repeated assessment method was used in this study.

4.2.1.3 Justifications for method of assessment: prospective repeated measures

Quantitative observational research can be undertaken either by using a cross-sectional method or by utilising repeated measures. Cross-sectional research aims to measure the status of a phenomenon or a relationship among the different variables under study at single point in time (Parahoo, 2014). The main advantage of cross-sectional research is that it is economical and easy to manage (Parahoo, 2014), and this method of assessment has been predominant in previous ICU sleep studies that have assessed ICU patients' sleep quality, and factors associated with patients' sleep in the ICU, as discussed in Chapters 2 and 3 (Cabello et al., 2008, Elliott et al., 2014, Freedman et al., 2001, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Li et al., 2011, Nicolas et al., 2008). There are, however, problems in inferring any changes and trends over time when using cross-sectional designs, which made this an unsuitable method for the current study (Aitken et al., 2017, Parahoo, 2014).

In cross-sectional studies carried out by Cooper et al. (2000), Freedman et al. (2001), and Elliot et al. (2014), where sleep quality and sleep disruptive factors were assessed in ICU patients, it was reported that, due to assessing patients'

sleep only at one point during their stays in the ICUs, the researchers were unable to ascertain whether patient' sleep quality or sleep disrupting factors changed during the patients' stays in the ICU. As ICU patients' perceptions of sleep quality may be affected by ongoing changes in factors that may disturb their sleep during their ICU stays or by acclimatisation to such factors (Cabello et al., 2008, Elliott et al., 2014, Freedman et al., 2001), these researchers thus recommended that sleep studies employing daily basis assessments of patients' sleep, alongside daily evaluation of sleep-disrupting factors in the ICU, were needed to provide a more complete picture of patients' sleep and sleep disruptive factors.

The evidence in this field, as discussed in Chapter 3, is that the majority of ICU sleep studies have been cross-sectional in design and covered short periods of sleep assessment of between one to two nights; only three of the ICU sleep studies that utilised RCSQ for sleep assessment were of prospective repeated assessment design (Aitken et al., 2017; Kamdar et al., 2012; Menear et al., 2017). The prospective repeated-assessment method, also known as the panel study, aims to assess a concept under study by involving same participants multiple times over a specified duration (Polit and Beck, 2014). The term "panel" thus refers to the same sample of individuals, which is reinvestigated at each data collection point in the study (Polit and Beck, 2014).

A study by Aitken et al. (2017) aimed to describe ICU patients' self-reported assessments of sleep throughout their ICU stays to determine the feasibility of sleep assessment using RCSQ. That study showed the effectiveness of the repeated assessment method in terms of gaining data about the feasibility of ICU patients self-reporting to develop sleep assessments throughout their ICU stays.

Several data types gathered from repeated assessment on feasibility were reported, such as the number of completed RCSQ instruments and how easily the instrument could be applied to ICU patients' sleep assessment. Additionally, patients' perceptions of their sleep quality were assessed prospectively each morning, soon after the patients awoke, to limit any risk of recall bias and to assure optimal reminiscence of the most recent night's sleep (Aitken et al., 2017).

Aitken et al. (2017) recommended further prospective repeated assessment ICU sleep studies to examine the feasibility of self-reported RCSQs for sleep assessment in ICU patients, as these could yield more information and thus develop a more comprehensive picture of ICU patients' perceptions of their sleep quality and sleep disruptive factors. This study was discussed in more detail in chapter 3.

After considering the features of the prospective repeated assessment method, and taking guidance from the literature review, prospective repeated assessments were thus applied in this study to answer the research questions most effectively. This was particularly applicable to the third research question, which was concerned with the feasibility and acceptability of using a self-reported sleep assessment method (the RCSQ) over a number of consecutive days rather than as a one-off assessment (Aitken et al., 2017; Kamdar et al., 2012; Menear et al., 2017).

Furthermore, the current study sought to determine whether any changes in patients' self-reporting of sleep disruptive factors arose at various time points during the full periods of their stays in the ICU, to provide a more comprehensive view of factors relating to patients' self-reported sleep quality.

The selected assessment method was prospective in nature rather than relying on retrospective assessment when patients were discharged from the ICU to facilitate a reduction in recall bias (Aitken et al., 2017, Polit and Beck, 2014). Further details on the data collection process are provided in Chapter 5.

The most common problem that researchers face using repeated assessment methods is the loss of participants at various points during the repetition of the assessment (Polit and Beck, 2014). This is likely to result in an ever-decreasing sample size throughout the course of a study. The current researcher was mindful of this point during this study, and thus ensured that the self-administered questionnaires used in the current study was kept as short and simple as possible, to lessen the burden of the questionnaire on participants and to avoid drop-outs insofar as possible. Further details on the assessment tools used in the current study are also provided in Chapter 5.

4.3 Summary

This chapter reviewed and defined the concepts that formed the basis of this thesis, which were sleep quality, sleep disruptive factors, and feasibility and acceptability concepts. The chapter also discussed the roles of these concepts in guiding the development of the research questions and in formulating the framework applied in this study, as seen in Figure 4-2. The chapter also examined the research approach used in this thesis and presented justifications for the selected approach, along with the influential factors that influenced the development and organisation of the research design in this study.

A positivist paradigm was adopted as the guiding philosophical stance to answer the research questions. The quantitative approach thus was adopted as a

pragmatic approach to answering the research questions in alignment with this philosophical stance. An observational and correlational prospective repeated assessment design was applied in the current study to answer the research questions most effectively, with the decision to adopt this design informed by consideration of the features of this design and by guidance from previous ICU sleep studies, as described and discussed in this chapter. Having justified the research approach and established the organisational structure of the research design in this chapter, the next chapter presents the methods employed by the researcher to conduct the study, including the instruments used and the procedures and processes applied during the course of the study, in more detail.

Chapter 5 Materials and methods

A quantitative, prospective observational design utilising repeated measures assessment was used to address the research questions, as presented and justified further in Chapter 4.

As illustrated in Figure 5-1, this study was carried out in Saudi Arabia using a two-phase design. Phase 1 was carried out during March and April 2018, to address the first and second research questions in this study, which were to develop an Arabic version of the RCSQ (the RCSQ-A) and determine its validity and reliability. Phase 1 (covered in more detail in section 5.5) initially involved translating the existing RCSQ into Arabic using the World Health Organisation's (WHO) recommended translation and adaptation processes World Health Organisation (2017) as no Arabic version of the tool was previously available. This was then pilot tested for internal consistency and reliability with 57 patients. Content validity was also examined in a subsample of 30 ICU patients during the pilot test, using a cognitive interviewing method used to assess understanding of the meaning of each item in the RCSQ-A (Reeve et al., 2011).

Phase 2 (Section 5.6) of the study was a prospective repeated measures study, carried out over a three month period from May to August 2018, to address the third, fourth and fifth research questions in the study, and thus assessing the feasibility and acceptability of the RCSQ-A in an ICU setting in Saudi Arabia for collecting data on sleep quality and sleep disruption factors in ICU patients in Saudi Arabia. In Phase 2, the RCSQ-A was completed on a repeated daily basis (until date of discharge) by 120 ICU patients, and correlations between sleep disruptive factors, demographic, and clinical variables, and self-reported sleep

quality were thus explored. An evaluation of the feasibility and acceptability of the RCSQ-A was also performed.

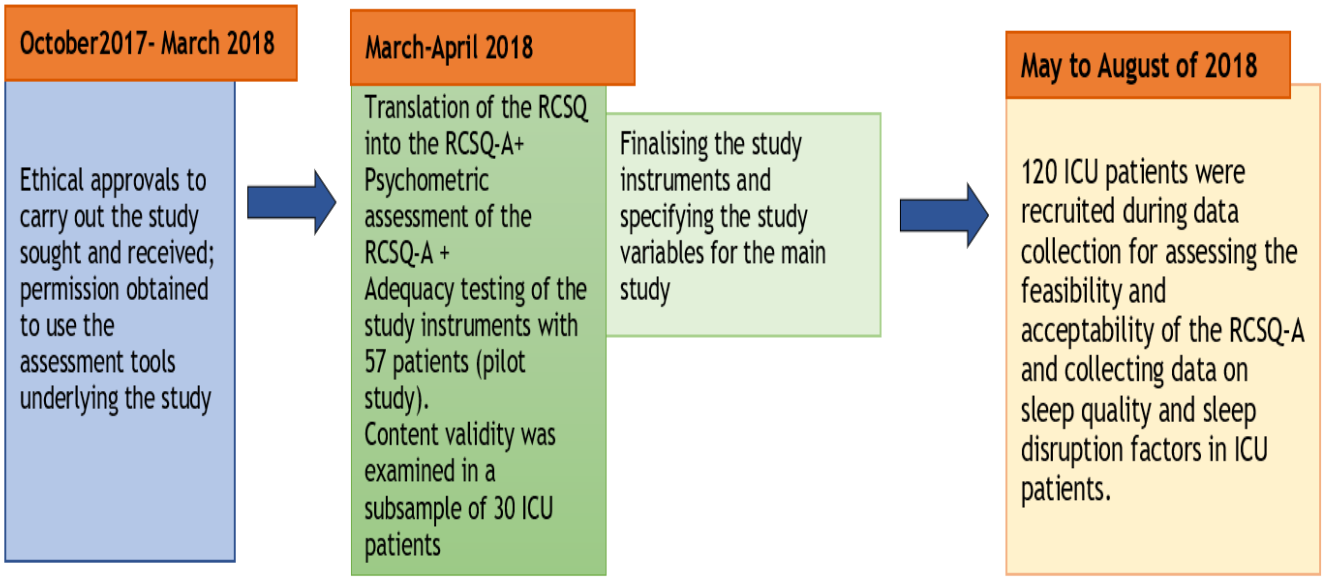

Figure 5-1 Overall method plan

5.1 Ethical approval

Ethical approval for this study was granted by the King Abdu Aziz University Hospital (KAUH) Unit of Biomedical Ethics Research Committee (reference number 11-18) on 18th January 2018 (Appendix 1). Further permission was obtained from the medical director acting as head of the adult critical care unit on 19th January 2018 (Appendix 2). Ethical approval to conduct the study was also obtained from the University of Glasgow College of Medicine, Veterinary, and Life Sciences (reference number 200170066) on 2nd March 2018 (Appendix 3). In addition, the Furth of Glasgow also granted approval permission to carry out the study in Saudi Arabia, (Appendix 4).

The study was undertaken in accordance with the ethical principles for medical research involving human subjects, as set out by the World Medical Association

(2013) in the Declaration of Helsinki. It was thus subject to ethical regulations as required by the Saudi National Committee for Medical and Bio-ethics (NCMB) (https://www.kacst.edu.sa). Ethical considerations involved in the current study are addressed further in Section 5.6.

5.2 Study setting

The study was undertaken in the Medical and Surgical adult ICU at tertiary King Abdullah University Hospital (KAUH) in the western region of Jeddah city, Saudi Arabia. The Saudi Ministry of Health (MOH) provides health services at different types of hospitals: primary, secondary and tertiary hospitals, which provide different levels of critical care, as shown in Table 5-1 (Al-Omari et al., 2015).

Table 5-1 levels of ICUs in different hospital types in Saudi Arabia

Levels	Description
Primary hospitals (n=2037*)	Small ICUs with limited equipment Staff with no or little ICU training Found in remote areas and villages
Secondary hospitals (n=244*)	Larger and better-equipped ICUs Open ICUs with intensivist coverage Found in small cities
Tertiary Hospitals (n=56*)	Well-equipped specialised ICUs Nurse-patient ratios of 1:1 Most are closed ICUs covered by on-site certified intensivists 24 hours a day, 7 days a week
*numbers indicate the number of hospitals with ICUs.	

(Al-Omari et al., 2015)

The KAUH hospital was selected for the current study for many reasons. It is a governmental tertiary referral facility for speciality services such as cardiac, renal, neuroscience, and burns cases. In addition, the hospital has a total capacity of 845 beds, of which 26 are in the ICU facility providing care for both

medical and surgical critically ill patients. The hospital's ICU unit admits approximately 1,500 patients each year, with a mix of medical and surgical admissions including neurosurgical, trauma, and cardiothoracic cases. More than 70 patients are admitted to the ICU unit per month. The average length of stay of ICU surgical patients is 3 to 7 days and 7 to 20 days in ICU medical patients. This capacity led the researcher to expect sufficient throughput of ICU patients to obtain a sample for the study in an appropriate period of time.

Additionally, this hospital is active in research, as well as having a medical training and research centre administration staff that organise and oversee research processes officially. The hospital has a sleep research centre, which attracted the researcher to carry out the study in this hospital, as this allowed further consultation and advice regarding the sleep assessment from specialists in sleep medicine. Three months before the study began, the researcher thus visited the director of the Sleep Medicine and Research Centre, who is a consultant doctor in sleep medicine and the head of the ICU. The purpose of this visit was to make contact with the clinical team, and to introduce the researcher and her study to facilitate building working relationships. A further reason for selecting this hospital was that the hospital is located in an area within an appropriate distance of where the researcher was based, facilitating easy access and controlling study costs.

The unit is located on the third floor of the hospital and offers a single room for each patient, with accredited ICU staff who are ultimately responsible for the admission and management of all patients. The Registered Nurse to ICU patient ratio is held at roughly one to one. The unit is circular in design, with an administrative head nurse's desk at the single main entrance. The centre of the

unit is comprised of a store room, a meeting room, and an open nursing station; the patients' rooms are then arranged in a U shape around the nursing station.

The unit has a closed-plan design for its rooms, with very small windows fitted with blinds in each patient's rooms. Each patient's bed is enclosed by fixed walls on three sides, and a sliding glass door on the fourth side opens up to the nurses' station. The sliding glass doors are usually kept open for ease-of-access by ICU personnel. Patients are generally connected by leads to various cardiac and hemodynamic monitors that emit audible warning signals in response to changes in patient condition.

ICU nurses staff work in 12-hour (7:00 AM to 7:00 PM) shifts. Wound care, bathing and routine care most typically occur overnight, generally within the 10:00 PM to 6:00 AM period. There are no policies in place to schedule nursing care activities during the night, or for opening and closing the blinds to aid maintenance of circadian rhythm by altering natural light levels to match the time of day. Patients’ room lights are switched off during the night, though the bed lights and corridor lights remain on. There are no set policies or guidelines regarding the patients’ sleep quality within the ICU unit.

Griffiths and Bridges (2009) suggests that multi study sites may be useful to obtain large samples, however, in this study, the researcher's pragmatic stance was to limit the study to a single hospital site, as it was not possible with the available time and resources to include more than one hospital. This decision was balanced against the practical restrictions of having one data collector " the researcher"; especially given that the nature of the assessment method was

repeated assessment where the researcher was required to be available in the hospital every day during the whole 3 months of the data collection period.

5.3 Inclusion and exclusion criteria

Inclusion and exclusion criteria were established to guide the identification and recruitment of the study population in both phases. These criteria were developed, guided by the literature review of previous ICU based sleep studies (Chapter 2 and Chapter 3), to select those patients most able to provide appropriate responses. Participants were eligible to take part in the study if they were adult patients (≥18 years old) who were able to speak Arabic and who were being treated in the ICU for ≥24 hours, to allow time for a night's sleep in the ICU. This approach to recruiting patients being treated in the ICU for ≥24 was supported by previous ICU sleep studies (Aitken et al., 2017, Elliott et al., 2013, Freedman et al., 1999)

It was important that eligible patients were alert and oriented, due to the nature of the self-report instrument used in the study; patients needed to be alert and conscious to provide accurate data when self-reporting on their sleep quality and sleep disruptive factors (Bourne et al., 2007). The process of assessing patient orientation and consciousness levels in the current study was guided and supported by previous ICU self-reported sleep studies (Elliott et al., 2014, Frisk and Nordstrom, 2003, Kamdar et al., 2013, Li et al., 2011, Menear et al., 2017). Patients' orientation was determined through discussion with each patient's bedside nurse, as well as an assessment using the Glasgow Coma Scale (GCS)(Elliott et al., 2014, Fischer et al., 2010, Menear et al., 2017) (Fischer et al., 2010), as described in section 5.4.2.4. The threshold was set to be 15, suggesting that patients should be fully conscious, able to open their eyes in

response to voices, be oriented, and be able to move all extremities on command (Fischer et al., 2010).

Based on guidance from previous ICU self-report sleep studies, participants were excluded from the study if they were sedated or agitated, based on RASS scores of <-1 or >+1 (Sessler et al., 2002), as described in section 5.4.2.4. This was done due to the fact that sedation and agitation could affect the patients' ability to answer the questionnaires (Bourne et al., 2007, Aitken et al., 2017, Hu et al., 2015, Kamdar et al., 2013, Nicolas et al., 2008). Patients with pre-existing cognitive dysfunction (defined as any current presence or history of dementia, traumatic brain injury, suspected encephalopathy, or stroke) or active delirium (positive CAM-ICU), were also excluded, as they could not be relied upon to provide accurate data using the sleep questionnaires (Aitken et al., 2017, Elliott et al., 2014, McKinley et al., 2013, Patel et al., 2014).

Patients with pre-existing sleep pathologies such as sleep apnoea were further excluded in order to isolate the influence of ICU factors on the quality of patients' sleep to help develop an understanding of any associations between the factors that emerged from the ICU environment and factors related to the nature of the critical illness of the patients and poor sleep quality (Elliott et al., 2014). Previous ICU sleep studies have also excluded patients with pre-existing sleep pathologies, as their sleep does not reflect that of the general ICU population (Bihari et al., 2012, Elliott et al., 2014, Freedman et al., 1999, Kamdar et al., 2013, Patel et al., 2014).

5.4 Phase 1: RCSQ translation into Arabic and pilot-testing for validity and reliability

This section describes Phase 1 of the current study, the development of the Arabic version of the RCSQ, in more detail. Specifically, this section begins by describing the first step, the translation process, in detail . It then presents the second step, the pilot test in 57 ICU patients, which was used to test the RCSQ-A for internal consistency, while content validity was tested in a subsample of 30 ICU patients, using the cognitive interviewing method. The sampling, recruitment process, and data collection methods for this phase are also described in further detail. The findings regarding RCSQ-A validity and reliability derived from phase one provided a reasonable basis for carrying out data collection for phase 2 (Parahoo, 2014); this is reported in more detail in chapter 6.

5.4.1 Step 1: Translation of the RCSQ to Arabic RCSQ-A

A letter seeking permission to use the RCSQ for this study, was sent via e-mail to the original developers of the instrument (Richards et al., 2000). Permission to both use the RCSQ and translate it into Arabic was obtained from Professor Kathy Richards via e-mail on the 7th of October 2017 (Appendix 5). The RCSQ (Appendix 6) includes a five-item VAS of sleep aspects: sleep depth, falling asleep, wakefulness, sleep latency and the overall quality of sleep. Each VAS ranges from 0 (the poor quality) to 100 (excellent quality). Sleep scores are identified by measuring in millimetres from the low end of the scale to where the patient made their mark. The total RCSQ score is the mean of the five VAS

score. Further details of the RCSQ are previously described in Chapter 2, section 2.7.2.4).

To develop the RCSQ-A, a well-established process for tool translation and adaptation as published by the World Health Organization (WHO) (World Health Organisation, 2017) was applied. This rigorous translation process was required to produce an Arabic version of RCSQ with acceptable semantic equivalence to the original RCSQ. Semantic equivalence indicates that each item of the translated instrument reflects the exact meaning of the original instrument within the target culture (Beck and Gable, 2001). Implementation of the translation process thus included the following steps: forward translation, use of an expert panel, back-translation, and cognitive interviews with a sample of Arabic-speaking ICU patients to ascertain participant understanding of each translated item; this was followed by pre-testing (World Health Organisation, 2017).

There are several important aspects of translating instruments from one language to another that had to be considered for this translation of the RCSQ. These aspects included the fact that the translation must reflect the conceptual meaning underlying the words of the original instrument (Boynton and Greenhalgh, 2004). In addition, expert panel reviews of instrument translations must ideally include multidisciplinary teams of individuals who are bilingual experts in the field of the translated instrument (Ohrbach et al., 2009, World Health Organisation, 2017). Thus, for this RCSQ translation, the panel's specialties included sleep medicine, ICU medicine, and linguistics. This combination of expertise played a major role in determining the differences between, and alternatives for elements of, the translated version of RCSQ-A and

the original(World Health Organisation, 2017) . The process of RCSQ translation is summarised in Figure 5-2.

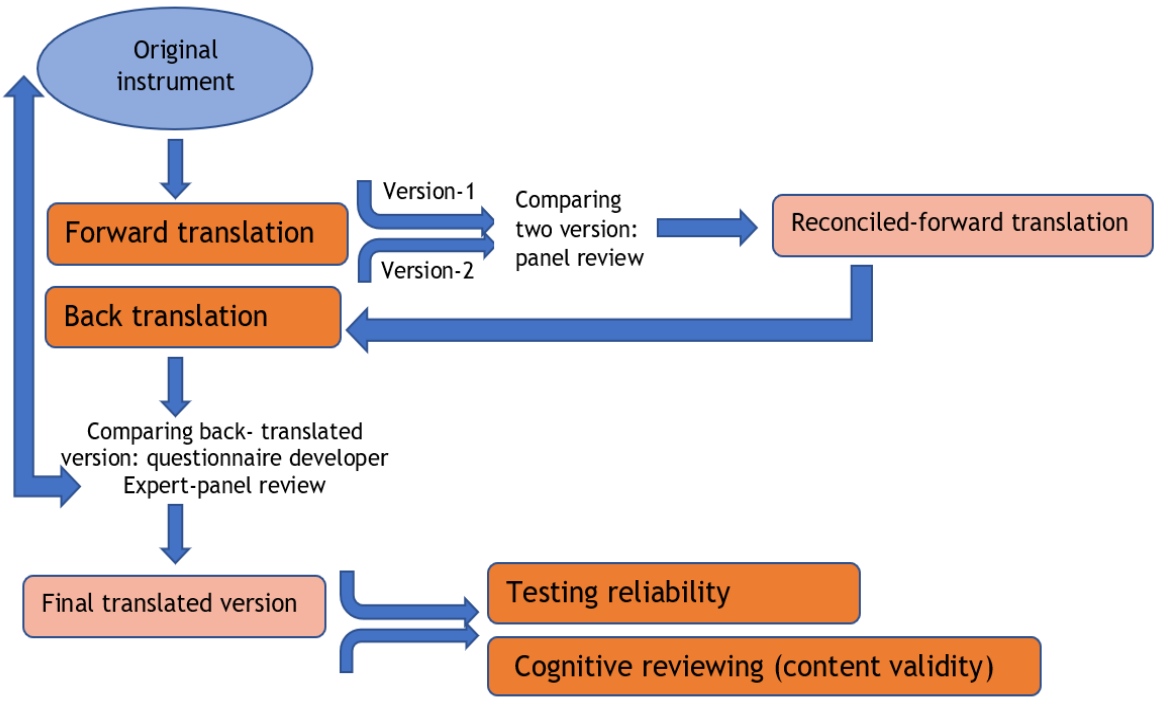

Figure 5-2 The process used to develop the Arabic version (RCSQ-A)

5.4.1.1 Forward and backward translation

A forward translation was the first step in the translation process. The RCSQ was translated into Arabic independently by two native Arabic speakers with excellent knowledge of the English language. One translator was a professor working in the field of sleep medicine in the hospital, and the other was a certified translator who had previously worked as a professional translator in Australia (Appendix 7).

After this, a three-person panel of medical staff experienced in the field of sleep medicine and in the ICU compared and reconciled the two forward

translated versions of the RCSQ, paying particular attention to differences in word choice or grammar. Any contentious concepts and inconsistencies were deliberated upon and resolved, generating a final fully-reconciled forward translation. The Arabic version of the RCSQ was then back translated into English by an Arabic-speaking translator in the United Kingdom. The researcher then compared the back translated RCSQ-A with the original RCSQ (Appendix 8). This back translated RCSQ-A was also sent via email to the RCSQ developer, Professor Richards, she reviewed and approved the back translation with no further comments (Appendix 9).

5.4.1.2 Expert panel review

Finally, a panel of four Arabic-speaking medical staff in the field of sleep medicine and the ICU performed a review of the consistency between the translated (RCSQ-A) and the original RCSQ. Three of these experts had been involved at an earlier step in the translation process (i.e. the reconciliation of the forward translation). They were the consultant doctor in sleep medicine, the registered critical care nurse and the consultant in critical care medicine. The additional panel member was a sleep medicine professor with over fifteen years' clinical experience at a sleep medicine research centre. Each member of the panel was requested independently to complete a translation validity form regarding the extent of similarities and differences between the RCSQ-A and the original RCSQ (Appendix10). The panel informed that "similar" and "somewhat similar" options were considered acceptable, and " different" and " somewhat different" responses were considered non-equivalent. None of the RCSQ-A five-items needed revision, as all the panel approved the final version of the RCSQ-A (Appendix 11). Thus, the original RCSQ demonstrated evidence of simplicity in

translation, with no requirement for replication of any step of the translation process, this highlights the ease and clarity of the construction of the RCSQ.

5.4.2 Step 2: Assessment of the content validity and reliability of the RCSQ-A: initial pilot test

This section details the pilot test of the RCSQ-A in a sample of 57 medical and surgical ICU patients that was conducted in March and April 2018. The first step of this pilot testing was the assessment of RCSQ-A reliability in 57 patients, with evidence of its internal consistency provided by a Cronbach's alpha test (Ohrbach et al., 2009). The aim of this was to test the ability of the tool to function adequately and to estimate the average inter-item correlation among RCSQ-A items to ensure that the items measured different domains. The RCSQ-A was further tested for content validity using cognitive interviewing in a subsample of 30 ICU patients. This method focuses on testing the participants' understanding of the meaning of each item of the instrument (Reeve et al., 2011).

Additionally, the self-report assessment tool (SICQ) used to identify sleep disrupting factors as perceived by patients' during the previous night was tested for content validity prior to its use with participants in phase 2. This was done to determine the appropriateness and usefulness of the tool in the Saudi ICU context. The SICQ was thus modified and tested in phase one to take into account patients' cultural backgrounds and the environment of the ICU. Details of this content validity assessment, the implemented cognitive interviewing method, the reliability assessment of the RCSQ-A, the sampling method and sample size, and the recruitment and data collection processes are thus offered below.

5.4.2.1 Sampling and sample size

Convenience sampling was used to select participants. This is type of non-probability (non-random) sampling relies on recruitment of members of a conveniently available population (Polit and Beck, 2013) . The most obvious criticism about convenience sampling is thus the increased risk of sampling bias and lack of representativeness, as it is the most convenient and available subjects who meet the specified eligibility criteria who are selected to participate (Parahoo, 2014).

However, the simplicity of the convenience sampling makes it the most commonly used method in small studies or where data collection is required over a short time period, such as for a pilot test, as it allows the required sample size to be achieved in a relatively rapid and inexpensive way (Griffiths and Bridges, 2009). Convenience sampling was thus used in this phase, as the main purpose was to test participants' understanding of the RCSQ-A (content validity) and its internal consistency. A similar example was found in a cross sectional descriptive German study by Krotsetis et al. (2017), which translated the RCSQ into German and assessed its reliability in a convenience sample of 51 patients from mixed ICUs. The sample size in the current pilot was further based on recommendations by Streiner and Kottner (2014) and Johanson and Brooks (2009), who estimated that a minimum of 50 participants are needed for an effective pilot test to assess the internal consistency reliability of an assessment tool: a total of 57 patients was thus recruited. Care was also taken that patients included in the pilot test were not included in the sample for the second phase of this study (Parahoo, 2014). A subsample of 30 patients was recruited for the

cognitive interviewing in the current study, based on the work of Lavrakas (2008), who suggested a small sample size for cognitive interviews, typically of between 8 and 12 participants. Meanwhile, Blair et al. (2006) advocate employing a larger sample size in cognitive interviews as this facilitates a wider variety of individuals, which enables the researcher to identify problems or mistakes that can inform subsequent decisions. Cognitive interviewing is frequently dependent on volunteers who are recruited explicitly to represent as wide a possible range of the population of interest (Blair et al., 2006). Therefore, the current study‘s researcher wanted to invite and recruit a larger and broader sample size for the cognitive interviewing based on volunteer patients from the recruited sample of 57 who could participate in the interview process.

5.4.2.2 Recruitment process

Four main steps of patient recruitment were carried out and applied for both study phases (phase 1 and phase 2). These steps were identifying eligible participants, inviting these individuals to participate, explaining the study to the potential eligible participants, and obtaining informed consent (Polit and Beck, 2012). Patient recruitment was undertaken based on arrangements made with the Unit of Ethics Research Committee at the hospital once ethical approval, as described in 5.1, was acquired. The recruitment process for the pilot test was facilitated by the head nurse of the ICU.

Potential participants were identified and screened for eligibility by the head nurse of the ICU, who was briefed of the eligibility criteria by the researcher, each morning during March and April 2018 (5.3). To facilitate identification of

eligible patients, a screening survey was used (Polit and Beck, 2012) (Appendix 12). The study screening survey, which was adapted from Stewart et al. (2017) and Elliott et al. (2013), included two sections: inclusion and exclusion criteria and patient cognition assessment. As patients were required to be alert and oriented to participate in this study, their cognition and consciousness and sedation and agitation levels were initially assessed by the head nurse using the GCS and the RASS (section 5.4.2.4). Patients were eligible for the study where they had had RASS scores between -1 and +1, a GCS of 15 or more, were able to open their eyes spontaneously in response to voices, were able to move all extremities on command, and were conscious and oriented (section 5.3). Potential participants were initially invited by the head nurse to participate in phase one, at which point they were also informed about the general aim of the research and reassured that participation in the study was voluntary and that they had the right to refuse to meet the researcher without any consequences.

The head nurse also asked interested people who met the inclusion criteria whether they would be willing to meet the researcher to receive further details and information about the research and participation. This step was undertaken to provide potential participants with the opportunity to decide whether they wanted to participate in a research study in general prior to meeting the researcher. This helped to protect their rights, preventing unnecessary identification for those not interested in participating in research studies.

Potential participants who indicated a willingness to meet the researcher, either by giving their verbal consent to the head nurse or by pointing to a word board with yes or no options for those who were intubated and thus unable to communicate verbally, were then approached by the researcher. At this point,

the researcher introduced herself to the potential participants and reminded them that participation was voluntary and that they had the right to refuse participation without any consequences. The prepared information sheet for phase 1 was then provided to potential participants (Appendix 13), to meet the ethical considerations explained in section 5.6. The information sheet (Appendix 13) was in Arabic.

The researcher also read the information sheet aloud to these patients, and the patients were asked to stop the researcher at any parts they did not understand, in order to facilitate further explanation. The researcher carefully explained the assessments that were to be carried out in phase one, and informed the potential participants that their anonymity in terms of demographic and clinical data would be assured, with such items collected from their medical records for the research purpose only. Further ethical considerations were also noted, as described in 5.6 .

The researcher then introduced the translated RCSQ-A to the patients and explained that they were required to complete it during the pilot test. The SICQ was also introduced to the patients, and they were informed that they should give their feedback on the content and clarity of the questionnaire. This was done to ensure that the patients understood the nature of the research assessment, to allow them to decide whether to participate or not under conditions of adequate information. Patients who were willing to participate in this phase one provided their agreement verbally or by pointing to a word board with yes or no options, for those who were intubated and were unable to communicate verbally. A written informed consent (Appendix 14) was obtained from those patients who willing to participate in this phase one of this study.

Details of the methods used by the researcher to obtain consent forms are described in the next section.

5.4.2.3 Obtaining informed consent

Prior to obtaining informed consent from potential participants who indicated their willingness to participate in phase1, their ability to provide informed consent was assessed by the researcher using a predetermined method adapted from Elliott et al. (2013):

1. The cognition levels of the patients, including orientation with regard to time and place, and ability to follow simple instructions, were carefully considered and discussed with their bedside nurses.

2. Patients were asked by the researcher to state their names, using lip movements only if intubated. If a patient was able to perform this instruction, a further check was made.

3. The patient's understanding of and ability to follow instructions was checked by asking them to nod when the correct colour of card was held up from among a selection of three.

Patients who were willing to participate in phase one and who showed sufficient cognitive abilities to understand the informed consent principle were asked to sign the consent form. Patients who were unable to sign the consent form due to physical limitations authorised their next-of-kin to sign the forms based on their confirming that the patient had given informed consent, whether verbally, by means of head movements, or by pointing to a word board (Yes or No options). All participants received a copy of the study information sheet and a copy of the signed consent form to keep for future reference; this included contact details for the researcher if they were interested in the results of the study.

5.4.2.4 Data collection procedure

Data regarding RCSQ-A content validity and internal consistency were collected by the researcher in March and April 2018 in a mixed medical and surgical ICU, with full patient consent. All participants included in phase 1 (n=57), were asked to complete the RCSQ-A to provide evidence to allow evaluation of RCSQ-A internal consistency and reliability. A subsample of these participants (n=30) who were not mechanically ventilated, and who thus were able to communicate verbally, also took part in cognitive interviews about their experience with the RCSQ-A. These patients (n=30) were asked specific questions on their understanding of the five items within RCSQ-A in order to evaluate its content validity. Details of the assessment methods (cognitive interviews and internal consistency assessment), the instruments used, and the data collection methods are offered below.

5.5.2.4.1 Patient demographic and clinical data

All 57 recruited patients' demographic and clinical data were collected from the unit's medical records. Collected data included age, gender, diagnostic group, mechanical ventilation status (intubated or non-intubated), ICU length of stay, and severity of critical illness based on APACHE-II scores. The APACHE-II is a prognostic system with scores ranging from 0 to 71; higher scores correspond to more severe diseases and associated elevated risk of death. It was developed to predict severity of disease and mortality risk in adult ICU patients (Knaus et al., 1985). It has thus been validated in ICU patients and found to be reliable in terms of predicting diagnosis (Vincent and Moreno, 2010).

The total APACHE-II score for patients in the study site is usually calculated by the ICU doctor on a single occasion during first 24 hours of the patient's admission to the ICU. This is saved to the patient's electronic medical records. The patient APACHE-II scores for this study were thus extracted from the ICU database, while patients' consciousness levels, cognition and sedation statuses were rechecked by the researcher using the GCS (appendix 15) , RASS (appendix 15) , and CAM-ICU (appendix 16) from each patient's 24-hour observation charts, along with advice from the bedside nurse of each patient. This was done to make sure that their consciousness status had not changed in between the time they were identified and when data was due to be collected.

5.5.2.4.2 Cognitive interviews regarding RCSQ-A: a content validity check

During the assessment, a subsample of the 57 participants (n=30), who were not on mechanical ventilation and were thus able to communicate verbally, was invited by the researcher to participate in the cognitive interviews about the RCSQ-A. Cognitive interviewing is one approach to applying Cognitive Aspects of Survey Methodology (CASM), a systematic, in-depth approach for assessing the validity of a tool's content. This method involves introducing specified questions to a group of the target population related to tool clarity and participant understanding. Cognitive interviewing then uses a "think-aloud" method to evaluate each stage of question answering (Peterson et al., 2017).

Peterson et al. (2017) explained that the cognitive interviewing method offers a key way to ensure the quality and accuracy of translated survey instrument, and that it culturally appropriately captures the concepts intended for measurement with the original instrument. In this case, it was crucial to ensure that the

translated RCSQ-A measured what it was intended to measure (good content validity) in the same manner as the original RCSQ, and participant understanding of the RCSQ-A items was therefore crucial to the content validity of the RCSQ-A (Willis and Miller, 2011).

The subsample of 30 non-mechanically ventilated ICU patients was asked the following questions about each item on the RCSQ-A in the manner recommended by the WHO for application of the cognitive interviewing method of translated questionnaires:

a) What is the question asking?
b) Can you repeat the question in your own words?
c) Are there any words you did not understand or any words you found ambiguous?
d) What came to your mind when you heard this term?

Participant responses to the questions were recorded manually on a data collection form for cognitive interviews (Appendix 17). This form had four columns: RCSQ-A item, number of correct explanations, number of wrong explanations, and any recommended amendments and comments.

5.5.2.4.3 Reliability assessment of the RCSQ-A: internal consistency

All patients in Stage 1 (n=57) were requested by the researcher to complete the self-report RCSQ-A with reference to the previous night's sleep quality between 9 a.m. and 12 p.m., preferably soon after they awoke in the morning. This approach was chosen to limit the potential of recall bias and to ensure optimal recall of the previous night's sleep (Aitken et al., 2017, Krotsetis et al., 2017). The RCSQ-A's five items were read aloud to patients one by one, and after each

item, patients set a mark on a paper-based VAS which consisted of a non-divided line of 100 mm length, where 0 = poorest and 100 = optimum rating. In those cases where patients could not set the mark themselves, they pointed with the tip of their finger at the chosen spot and the investigator marked the scale accordingly. The internal consistency reliability of the RCSQ-A was computed, and the result of this is presented, along with the other results from the study, in chapter 6.

5.5.2.4.4 Content validity of the Sleep in Intensive Care Questionnaire (SICQ)

Permission to use and to adapt the SICQ to identify sleep disruptive factors as perceived by patients was obtained from Dr Richard Schwab and from the publisher of the instrument, the American Journal of Respiratory and Critical Care Medicine (Appendix 18).

As discussed in Chapter 2, section 2.7.2, the SICQ is a descriptive self-report tool useful for gaining patient perspectives on specific factors that may potentially be disruptive to sleep (Freedman et al., 1999). The main section of the SICQ includes 20 items that evaluate patient perceptions of a variety of factors known to affect sleep quality in the ICU, scored on a Likert scale of 1= no disruption to 10 = significant disruption. Potential sources of sleep disruption include health care personnel activities, specific environmental noises, and overall sleep quality at home. In addition, the test assesses the patient's degree of daytime sleepiness using a further Likert scale (1= unable to stay awake to 10 = fully alert and awake).

Daytime sleepiness or difficulty in maintaining a desired level of wakefulness during the day is one of the most common and obvious consequences of insufficient sleep at night or poor sleep quality (Ohayon et al., 2017). However, daytime sleepiness can also be caused by other circumstances, and may then decrease the chance of good sleep the next night. Sleepiness is often circumstance-dependent, being exacerbated by many aspects of the environment (Slater and Steier, 2012). In the ICU environment, such factors may include absence of scheduled sleep times or darkness; a lack of patient exposure to natural daylight through routine opening of the blinds in patients' rooms; or overall low daytime light exposure, none of which are conducive to the encouragement of normal circadian rhythm (Elliott et al., 2013, Freedman et al., 2001, Patel et al., 2014, Pisani et al., 2015). The ICU environment thus disrupts the circadian rhythm, which contributes both to increased daytime sleepiness and to a decreased tendency to sleep at night.

For this study, the researcher was thus mindful that while daytime sleepiness could be a consequence of poor sleep quality at night, it could also be a factor contributing to poor sleep at night. This is in agreement with previous ICU-based sleep studies that considered daytime sleepiness to be one of the factors potentially associated with poor sleep quality at night (Bihari et al., 2012, Elliott et al., 2014, Freedman et al., 2001).

The main section of the SICQ concerning sleep disrupting factors was thus used in phase 2 to assess patients' perception of sleep disruptive factors in the ICU, based on guidance from the literature review (Chapter 3). The SICQ was used in multiple ICU based sleep studies and was found to be effective in identifying a variety of sleep disruptive factors from the patient's perspective. In addition,

SICQ is a flexible tool that can be modified by removing any items that do not apply in a given ICU environment, or by adding any items that the researcher deems necessary (Bihari et al., 2012, Elliott et al., 2014, Li et al., 2011). The SICQ was thus modified in this study to fit patients' cultural backgrounds and the environment of the ICU. A panel of three experts who participated in RCSQ-A translation, and who are recognised for their expertise in the areas of study, the ICU and sleep medicine unit, was consulted. Thereafter, the questionnaire was tested with the 57 ICU patients during the pilot test; after RCSQ-A completion by the participants, they were invited to review the SICQ to help increase the appropriateness and usefulness of the tool in the Saudi ICU context.

Modifications made to the SICQ during phase one were based on panel recommendations and researcher knowledge; these were implemented to ensure the questionnaire's appropriateness in terms of meeting the study purpose. The changes included modifying the wording of the questions to better suit the study's aims. For example, the question “Rate how disruptive the following activities were to your sleep during your ICU stay” was modified to "Rate how disruptive the following activities were to your sleep last night”, as this study involved repeated assessment, with potential sleep disrupting factor identification required on a daily basis. This modification thus enabled enquiry only about disruptive factors which occurred the previous night, to ensure optimal recall of the various sleep disrupting factors and to limit potential recall bias.

Additionally, the items for sleep interruptions from television noise and doctor pagers were removed, as these were not used in the study setting. Items regarding several similar sources of noise (heart monitor alarms, ventilator

alarms, I.V. pump alarms) were then collated into one category item (machine alarms), and items of diagnostic significance, such as tests for vital signs, blood samples, and administration of medication, were similarly collated into a category item, clinical interventions. The decision to categorise these items was made to ensure that the self-administered SICQ remained as short and simple as possible; this was deemed particularly important for critically ill patients, to lessen the burden of the questionnaire. It was also considered that patients might not accurately remember or detect the source of an alarm that caused sleep disturbance, as the ICU environment has many complicated machines (Elliot et al., 2014). An "other" option was also added to the questionnaire in order to offer patients the opportunity to add items (Polit and Beck, 2013). This also helped develop a better understanding of ICU patients' perception of sleep disrupting factors in ICU settings in Saudi Arabia.

Beck and Gable (2001) highlighted the importance of members of the target population of an instrument being involved in content validation of any assessment tool. The researcher in the current study was thus keen to involve the target population of ICU patients in reviewing the amended SICQ during the pilot study, particularly as the concept of sleep-disrupting factors developed by the questionnaire is related to patients' perception and experiences. Subsequently, factors of fear, pain, and being attached to machines were added, based on patients' responses from the pilot-test. The final modified SICQ contained 10 items referring to different potential sleep disrupting factors (Appendix 19) and demonstrated good content validity. It was easily understandable by patients, and no comments were made with regard to difficulty or ambiguous items.

5.5 Phase 2: prospective repeated measures

This section explains Phase 2 of the current study, which was carried out in Saudi Arabia, in the same setting as Phase 1, during the period from May to August 2018. This phase aimed to assess the feasibility and acceptability of the RCSQ-A in a sample of 120 ICU patients and to examine their reported sleep quality and sleep disruptive factors, as measured on a daily basis using the SICQ. The data thus allowed associations between the self-reported sleep disruptive factors, patients' demographic and clinical variables, and patients' self-reported sleep quality to be explored. Details of the sampling methods, sample size, recruitment protocol, and data collection procedures are described in the following sections.

5.5.1 Sampling

In phase two, consecutive sampling was used to select participants. Consecutive sampling is a non-probability sampling method which seeks to recruit all subjects who meet specified eligibility criteria from an accessible population over a set of time-period, potentially ceasing when an appropriate sample size is achieved (Polit and Beck, 2013).

Consecutive sampling involves the use of non-random methods, in contrast to probability sampling methods where the selection of the participants is made randomly, and each element in a population has an equal chance of being selected (Gerrish and Lacey, 2013). Probability sampling has the greatest freedom from risk of bias and yields more representative samples (Polit and Beck, 2013). Nonetheless, probability sampling represents the costliest sampling method in terms of time, as it requires access to a full list of the population.

Efforts to identify a full study population in this way can be difficult for researchers, who more frequently aim to evaluate finite populations (Gerrish and Lacey, 2013).

In the case of the current study, the target population is ICU patients, who are known to presenting unique challenges to researchers (Urden et al., 2018). Such challenges arise from the complexity of the patients' clinical disorders, and the possibility of cognitive problems (Urden et al., 2018). These challenges can limit sampling process as severely ill patients, or patients with cognitive disabilities are not able to participate in research studies. For example, in a repeated measures study by Aitken et al. (2017) who used a non-probability sampling to assess ICU patients self-reported sleep quality, they reported some challenges with regard to the characteristics of the ICU population, in particular there were many heavily sedated patients who were unable to provide self-reports on their sleep quality. However, Aitken et al (2017) mentioned that they enhanced the process of sampling by consecutively recruiting patients using a repeated measures method over four months period, resulting in them obtaining relatively appropriate sample size of 150 participants.

Therefore, in this current study, the researcher took this into consideration, and non-probability sampling was considered to be more appropriate and feasible in terms of achieving an appropriate sample size (section 5.6.2). Parahoo (2014) indicates that most nursing studies also rely on non-probability sampling, as it is practical and economical, and individuals are more likely to be readily approachable when asked to be included in the sample.

Polit and Beck (2013) imply that non-probability sampling is rarely representative of populations; nevertheless, this type of sampling is reasonable

when used with caution in terms of drawing conclusions and making recommendations with regard to generalisability. Consecutive sampling is considered the best type of non-probability sampling, being more robust than convenience or purposive sampling in terms of controlling for bias, as it includes all accessible and eligible subjects as part of the sample (Polit and Beck, 2012).

In addition, researchers can further reduce the risk of bias by using a sufficiently long sampling period so that all individuals within an available population are invited for participation over a fixed time of period, which reduces bias from time related fluctuations (Polit and Beak,2012). In this phase, to reduce bias and address the issue of representativeness within the sample, recruitment and data collection (where new patients were continuously enrolled) spanned a three-month period. It was deemed reasonable to apply consecutive sampling to those ICU patients who met the predetermined study inclusion criteria (section5.3) and who could provide their perceptions helping to address the research questions (Aitken et al.,2017).

5.5.2 Sample size

The size of the study sample is an important aspect of any research study as it influences the precision of any estimates as well as impacting on the power of the study in terms of offering the ability to draw inferences (Griffiths and Bridges, 2009). Polit and Beck (2013) state that there is no 'fool-proof' method for ensuring a sample is representative, but that a quantitative researcher is advised to use a largest sample as possible to increase the statistical power and to reduce estimation errors. However, Polit and Beck (2012) caution that even a large sample size is not an assurance of accuracy in non-probability sampling, as not all members of the population has a chance of participating in the study.

Gerrish and Lacey (2013) advise that when planning or estimating the sample size required to carry out a research study, a focus on selecting a less biased sample should be made. Estimation of the sample size in the planning stage of any study depends on many aspects, including the type of statistical analysis that the researcher plans to perform, and the power and level of significance that they wish to achieve (Gerrish and Lacey, 2013). In addition, the practical realities of conducting research, such as time scale; availability and cooperation of participants in clinical field work; and financial costs may all limit the size of samples (Polit and Beck, 2014).

The proposed statistical analysis for the current research was a multiple regression analysis, used to predict the association between multiple potential sleep disrupting factors and patients' self-reported sleep quality. The researcher thus sought statistical advice and discussed this with a medical statistician to determine the required sample size for this procedure. Several authors (Feinstein, 2002, Harris and Taylor, 2014, Lu et al., 2015) have argued that the researcher must first estimate the number of predictor variables in the model, the effect size and the power to be achieved in order to estimate the sample size.

It was difficult for the researcher to determine the exact number of the variables that needed to be included in the regression analysis model before conducting the current study, as these were dependent on the results of patients' self-evaluation of potential sleep disruptive factors. The statistician thus advised that only the variables that rated most highly by the patients as being sleep disruptive factors should be included in the model, in order to avoid over-fitting, the model (Cohen, 1992).

However, the researcher estimated the number of variables to be included in the model at between 14 and 17 independent variables in any case. Power calculations were undertaken using G. Power software version 3.1.9.2 (Faul et al., 2007) to determine the sample size for multiple regression, with a fixed model R2 increase also included based on an alpha level of 0.05. As suggested by (Cohen, 1992)), using a medium effect size (between 0.18 and 0.22), and a power (between 0.80-0.88), the minimum required sample size was 110.

The effect size reflects the alpha. which is a value for the probability of a type-I error (Harris and Taylor, 2014, Miles et al., 2015). Cohen's (1992) regression analysis roles indicate that the effect size can be 0.02=small, 0.15=medium, 0.35=large. The power reflects the beta, which is the probability of a type-II error and 80.0 is the minimum required power (Cohen, 1992, Harris and Taylor, 2014, Miles et al., 2015). Type-I and type-II errors may be minimised using a smaller effect size and as great as possible power. However, (Harris and Taylor, 2014, Miles et al., 2015) advise that where a large sample size is required, a very small effect size is cost-effective. In the present study, the researcher calculated the minimum required sample size by estimating that the required effect size was medium between 0.18 and 0.22 with a power between 0.80-0.88.

However, the statistician's advice in this case was to perform an additional power analysis test, a "post hoc power analysis", after completing the study, to determine the maximum number of independent variables to be included in future regression analysis, and to ensure the results met the recommended power of at least 0.80, for a medium effect size (Cohen1992). Details of the post

hoc power analysis, the variables included in the model, and justifications are presented in detail in section 5.10.

5.5.3 Recruitment process

In Phase 2, consecutive sampling was conducted in the medical and surgical ICU setting employed in Phase 1 (section 5.2). The sample in Phase 2 was an entirely new sample of participants, however, with no one from Phase 1 participating in Phase 2. The same eligibility criteria and recruitment process as implemented in Phase 1 were implemented in Phase 2, again facilitated by the head nurse in the ICU (Section 5.5.3). The nurse was thus briefed on the purpose of Phase 2 and reminded of the eligibility criteria, and potential participants were identified and screened for eligibility each morning over the three-month period between May and August 2018 using the screening survey (Appendix 12).

On those occasions where the head nurse was not available, the charge nurse, who had been informed about the recruitment process by the head nurse and the researcher, was involved in the screening process. As per Phase 1, screening for cognition, consciousness, agitation and confusion was done using the patients' GCS and RASS scores and the CAM-ICU to ensure that the same criteria applied to participants in Phase 2 (Section 5.4). All patients meeting the criteria were approached by the nurse and asked to consider participating in the study, while being informed of their right to refuse as described previously.

Patients were also informed that, if they chose to participate, they would be required to complete the two assessment tools daily each morning between 7.00 am and 12.00 pm. This was to ensure that the patients understood the nature of

the research assessment, to allow them to decide whether to participate or not. Patients were also informed that if they became bored or tired of completing the questionnaires on daily basis, they were free to withdraw from the study for any reason at any time without any consequences. A written informed consent (Appendix 14), was thus obtained from all patients who were willing to participate in phase 2 of this current study, or their designated representatives as required. Patients also provided agreement to participate verbally or by pointing to a word board with yes and no options according to the method (adapted from Elliott et al. (2013) described in section5.4.2.3 for phase 1.
All participants received a copy of the study information sheet and a copy of the signed consent form to keep for future reference; this included contact details for if they were interested in receiving a copy of the study results. On enrolment to the study, all participants were assigned a unique project identification number so that none of the participants were identifiable. Personally identifiable information was not collected, and consent forms were stored in a locked filing cabinet away from the raw data so that these could not be linked in any way to the patients' details (further details are provided in Section5.7).

Recruitment rate was also considered an indicator of the assessment of patients' willingness and acceptability, which was based on their readiness to engage in the repeated assessment to provide RCSQ-A on a daily basis. This was reflected in the number of eligible participants who were invited to participate in the study and decided to decline (Sekhon et al., 2017)

5.5.4 Materials and instruments

This section summarises the data collection tools and instruments deemed appropriate during pilot-testing that were then used for data collection in phase 2. It presents a description of their contents and the variables that were included, and offers justifications for each selection, presented in conjunction with the core concepts of the study (sleep quality, sleep-disruptive factors, and feasibility and acceptability) in order to offer a proper understanding of the instruments used for data collection.

All instruments and data collection sheets used for Phase 2 are noted in Table 5-2. Details of data collection procedure, including the times at which the instruments were administered to the patients, are presented in section 5.5.4.5.

Table 5-2 Instruments used in this phase two of this current study

Key assessed concepts	Content/Variables included	Instrument/tool	Time administered
A. Self-reported sleep quality	Five variables: Sleep depth, sleep latency, a state of wakefulness , ability to fall back to asleep after waking up, overall sleep quality	RCSQ-A (five-items)	Daily at each morning, during patients stay in the ICU
B. Potential sleep disruptive factors associated with patients' sleep quality	Patients' perception of sleep disturbances in the ICU: 1 Noise; clinical interventions (i.e. blood samples, vital signs, etc.); light; talking; machines' alarm (i.e. heart monitor, ventilator, etc.); telephone; fear; discomfort of being attached to the devices; pain; daytime sleepiness	Modified SICQ (ten-items)	Daily at each morning, during patients stay in the ICU .
	2 Patients' self-reported quality of sleep prior to hospitalisation	First question of the SICQ	On enrolment
	3 Demographic and clinicalvariables	Demographic data collection sheet: patient's medical record: age, gender,	One-time, on enrolment

		sseverity of illness/ APACHE-II score /ICU admission diagnosis Mechanical-ventilation statues, medication administered during the study/previously taken sedation. Length of ICU stay	 On enrolment and updated daily during patients stay in the ICU At patient discharge from the ICU
C. Feasibility and acceptability of RCSQ-A	1 Participants' burden/acceptability 2 Effort required for RCSQ-A scoring and interpretation by the researcher	Researcher's data collection sheet developed for Phase 2: refusal rates, missing responses, dropout rate, and respondents ' views . Researcher's data collection sheet developed for Phase 2	On enrolment /during assessments/at the end of the repeated assessment. During and after the repeated assessments

5.5.4.1 Demographic and clinical variables data collection sheet

A data collection sheet was designed by the researcher for the collection of relevant demographic and clinical data (Appendix 20). The variables within this data collection sheet are described in detail in the following paragraphs. These variables were collected based on guidance derived from the literature review (chapter 2 and chapter 3), which showed certain variables as being clearly associated with sleep quality in the ICU patients. It was thus reasonable to collect data on these variables and to evaluate them in relation to patients' self-reported sleep quality.

The demographic and clinical variables data collection sheet collected the following data: age; gender; ICU-admission diagnosis; severity of illness; length of stay in the ICU; mechanical ventilation status (mechanically ventilated or

non—mechanically ventilated); type of ventilation (invasive ventilation via mouth using an endotracheal tube or via a stoma in the windpipe using a tracheostomy tube or non-invasive ventilation using a face mask or nasal mask); medications administered during the study; and previously administered sedation medications. All of these variables were considered to be intrinsic factors, related to the patient, that might be associated with sleep quality (Elliott et al., 2013, Elliott et al., 2014, Frisk and Nordstrom, 2003, Kamdar et al., 2013, Nicolas et al., 2008). Patients' perceptions of their quality of sleep prior to hospitalisation were also included in this data collection sheet, using a simple rating scale (1 to 10 with 1 = poor and 10 = excellent) derived from the SICQ (Freedman et al., 1999).

5.5.4.2 The Arabic version of RCSQ (RCSQ-A) for self-reported sleep quality assessment

The RCSQ-A used in Phase 2 was informed by examination of its psychometric properties from Phase 1 (as discussed in Chapter 6). The RCSQ-A included a five-item VAS of sleep aspects, mirroring the original RCSQ: sleep depth, falling asleep, a state of wakefulness, sleep latency, and overall quality of sleep. Each VAS ranged from 0 (poor quality) to 100 (excellent quality), with higher scores indicating better sleep quality. The total RCSQ-A score was defined as the mean of the five VAS scores, offering a singular measure of sleep quality (Richards et al., 2000).

The total RCSQ-A score was categorised with a cut off-point of <26 indicating very poor sleep quality, a score of 26 to 50 inclusive indicating poor sleep quality, a score of 51 to 75 inclusive indicating good sleep quality, and a score of >75 indicating very good sleep quality (Frisk and Nordstrom, 2003, Krotsetis et

al., 2017, Aitken et al., 2017, Naik et al., 2018). Details of RCSQ-A content validity and reliability are presented in detail in chapter 6.

5.5.4.3 Modified SICQ for identifying sleep disruptive factors

The final modified SICQ used in Phase 2 contained 10 items referring to potential sleep disrupting factors (appendix 19); this was used to identify sleep disruptive factors as perceived by patients during the previous night and throughout their stays in the ICU. This data was then used to address the fifth research question: "What factors are related to patients' self-reported sleep quality in ICU settings in Saudi Arabia?". The SICQ was modified in this study during Phase one (section5.5.2.4.4) to fit patients' cultural backgrounds and the ICU setting in Saudi Arabia. However, it was identified as being easily understandable by a sample of Arabic speaking ICU patients in phase one and demonstrated good content and face validity more generally.

5.5.4.4 Data collection sheet for RCSQ-A feasibility and acceptability

A data collection sheet was designed by the researcher to collect information on the feasibility and acceptability of using the RCSQ-A for repeated daily sleep assessment (Appendix 21). This data collection sheet included a specific section for researcher use that recorded multiple indicators of RCSQ-A feasibility and acceptability. These indicators of feasibility and acceptability were based on the concepts of feasibility and acceptability adopted in the current study that were based on the definitions proposed by Fitzpatrick et al. (1998) and Sekhon et al. (2017) (Chapter 4; section 4.1), in addition to the definitions and indicators emerging from ICU-based sleep studies that have previously assessed the feasibility of RCSQ (Aitken et al., 2017, Menear et al., 2017) as discussed in

chapter 3. Details of the collected indicators of acceptability and feasibility of the RCSQ-A for daily self-reported assessment of sleep quality in ICU patients are thus described in more detail below.

Indicators of acceptability, referring to “the extent to which the RCSQ-A for daily self-reported assessment of sleep quality in ICU patients was acceptable to the patients”, included patient willingness to engage with and to participate in the study, as reflected by the number of eligible participants invited to participate in the study who decided to decline; any reasons provided by declining patients were thus recorded (Sekhon et al., 2017); patients' perceived burden, or the perceived amount of effort necessary for patients to continue participation in the study; and their ability to provide self-reports on a daily-basis (Fitzpatrick et al., 1998; Sekhon et al., 2017). Indicators of burden were collected by recording drop-out rates (the number of patients who dropped out, choosing to stop taking part) and withdrawal rates (the number of patients withdrawn from the study by the researcher because they no longer met study inclusion criteria). The total number of patients who discontinued participation at some point during the assessment and the total number of completed RCSQ-As were compared. In addition, all reasons for cessation of participation were recorded to ascertain whether patient discontinuation was due to difficulties related to the RCSQ-A or to other issues. In addition, patients' views of completing the RCSQ-A on multiple days were collected.

Indicators of feasibility, reflecting “how easily the RCSQ can be answered by the ICU patients and how easily it can be administered and interpreted by the researcher” included the time taken by each patient to complete the RCSQ-A, the number of patients who were able to set marks on the RCSQ-A scales

unassisted, and the researcher's observations of the effort needed to score and interpret the RCSQ-A.

5.5.4.5 Data collection procedure and process

Data collection was carried out on a daily basis during each patient's stay in the ICU. This meant that data was collected from each patient on enrolment, on each day during their stay (ranging from 2 to 14 days), and on the day of their discharge. Data collection was undertaken in the morning between 7am and 12pm. Figure 5 3 shows the procedure for data collection, and the following paragraphs provide more details of this data collection procedure, particularly with regard to the times of collecting each variable.

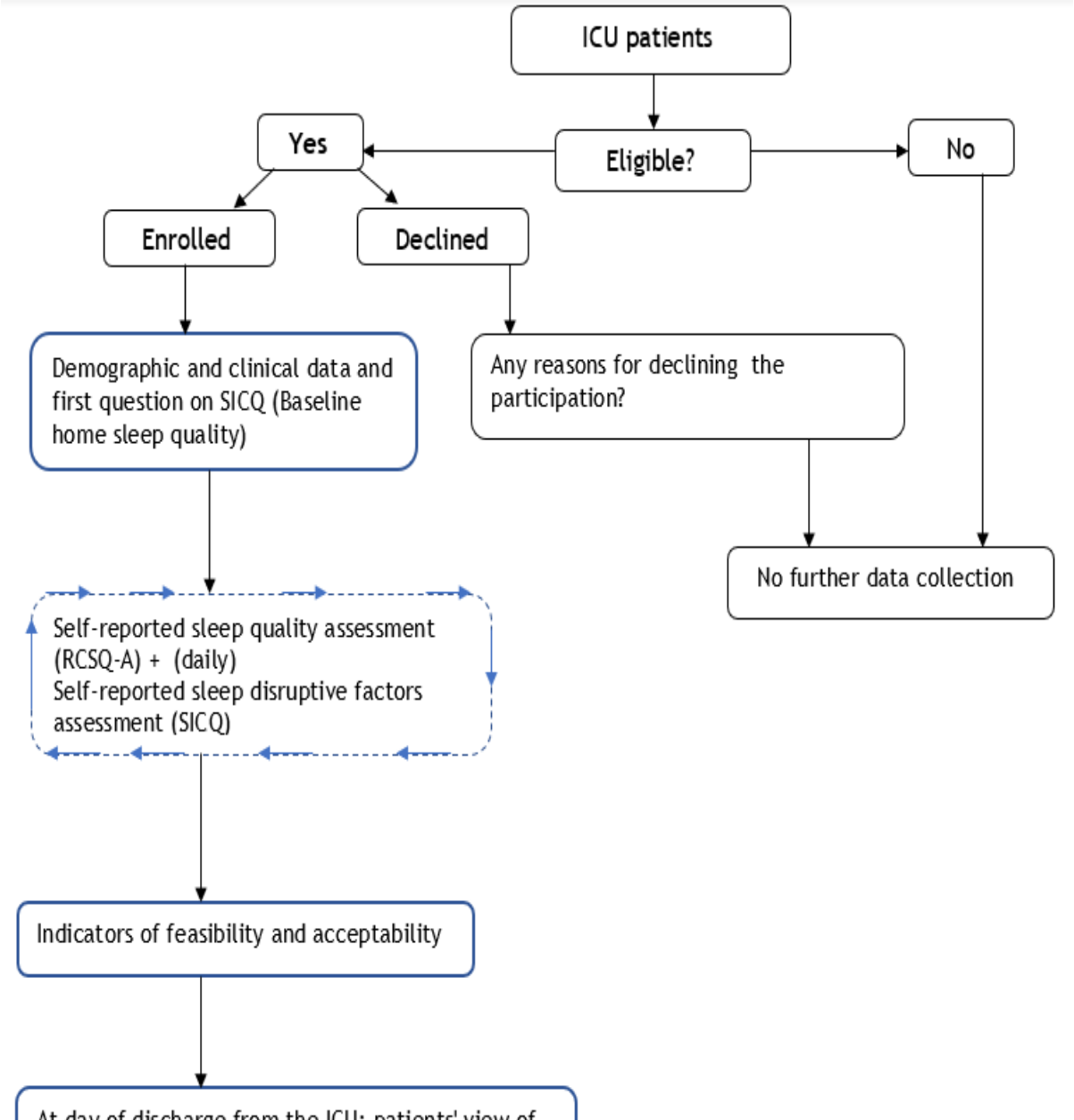

Figure 5-3 Data collection process

On enrolment, demographic and clinical data for each patient was collected from their medical records (Section 5.5.4.1). This included age, gender, ICU-admission diagnosis, and APACHE-II score. Their mechanical ventilation status (mechanically ventilated or non—mechanically ventilated), the type of any ventilation (invasive ventilation or non-invasive), and details of any medications administered were also collected from patients' medical records on enrolment, though these were updated daily. Patients were also asked on enrolment to rate the overall quality of their sleep at home on a rating scale from 1 to 10, with 1 = poor and 10 = excellent (Freedman et al.,1999). The patient's length of stay in the ICU was recorded at patient discharge from the unit.

It was crucial to ensure that each patient was alert and calm for every assessment. Thus, patients' cognitive status, and any presence of delirium, were assessed both on enrolment and each morning prior to data collection. This involved the researcher checking their GCS, RASS and CAM-ICU scores as recorded on the 24-hour observation sheet and also observing the patient prior to data collection. The self-reported RCSQ-A was administered by the researcher to the participants each morning soon after they awoke, to limit any risk of recall-bias and to assure optimal reminiscence of the most recent night’s sleep (Aitken et al., 2017, Krotsetis et al., 2017).

The RCSQ-A's five-items were read out aloud to each patient one by one, and after each item, the patient placed a mark on the answer line (VAS), which was 100 mm long (0 mm = poorest, 100 mm = optimum). In cases where the patients were not able to place such marks themselves, the researcher tracked a pen along each VAS on the RCSQ and asked the participant to point out where they wanted to place the "X"; the researcher then marked the chosen place, and correct placement was confirmed with the participant (Aitken et al., 2017, Richards et al., 2000).

During the administration of each RCSQ-A, the researcher stood beside the patient to provide assistance or to respond to any queries about the questionnaire. The researcher used this opportunity to observe the process and to record the time taken for the participant to complete the RCSQ-A, as well as recording whether the participants completed RCSQ-A by themselves or required assistance in completing it. These were important indicators in assessing the feasibility of the RCSQ-A completion.

During the repeated assessment of RCSQ-A on subsequent days, patients who declined to complete the RCSQ-A at any point were asked to clarify whether they were simply not completing the questionnaire on that individual occasion, or if whether they wished to withdraw from the study entirely. Patients who decided to withdraw from the study were not approached again; however, their consent for data they had already given to be used for analysis was retained.

After each RCSQ-A completion, the participants were also asked to rate their perception of factors that had disrupted their sleep during the previous night on the modified SICQ scale consisting of 10 items referring to different

potential sleep disrupting factors (1= no disruption to 10= significant disruption). An open-ended question was also read aloud by the researcher: “What other activities were disruptive to your sleep last night?” Answers were communicated verbally by most participants, and in writing and through actions by others. The researcher noted the responses for each factor.

On the day of patient discharge, the total number of RCSQs completed by that patient was computed and recorded. At that point, participants were asked: “How did you find completing the questionnaire on sleep quality on multiple days while you were an inpatient in the ICU?” Patients' answers were communicated verbally, and all verbal explanations received were recorded manually by the researcher and transcribed for inclusion in the study.

5.6 Ethical considerations

Participants retained the right to anonymity, and all data was handled to promote confidentiality and protection of their human rights, self-determination, and full privacy. On enrolment to the study, all participants were assigned a unique project identification number, so no identifiable personal details were recorded throughout the study. Consent forms were stored in a locked filing cabinet away from raw data so that these could not be linked in anyway. The cognition levels of the patients, including orientation to time and place and ability to understand study information, were carefully considered during recruitment process for both phases 1 and 2 (section 5.5.3) and (section 5.5.3) and discussed with the bedside nurses prior to approaches being made to each patient to ensure informed consent.

An Arabic version of the information sheet (Appendix 13) was given to the potential participants, who were assessed as oriented and conscious along with a form to obtain written consent if the patient was willing to participate in the study. Patients were informed that participation in the study was voluntary and that they had the right to refuse to participate without any consequences. Patients in phase 1 were informed that there are no direct benefits to their own health but that this would have wider benefits in terms of research and development in the health care service by assisting with improving sleep assessment tool in ICU clinical practice (i.e. Phase 1).

Participants in phase 2 were also informed that there were likely to be no direct benefits to their own health but that sharing their perceptions and experiences of sleep quality in the ICU and the utility of the RCSQ-A would help to improve assessment of sleep quality in the ICU setting and inform ways in which patients' quality of sleep could be improved during their stay in an ICU.

Patients in both phases were also informed that participation was not anticipated to cause any harm beyond that encountered in the setting, but that they might become bored or tired when completing the questionnaires. They were free to withdraw from the study for any reason at any time without any consequences. Written consent (Appendix 15), which included agreement to participate in the study, was obtained from all patients who were willing to participate in the study as recorded in section 5.4.2.3.

5.7 Data organisation and storage

All paper data collection materials for this current study were coded with participants' unique identification numbers so that these were not linked in any

way to identifiable information. All data collection materials were stored in a locked cabinet in the researcher's office or stored on a password protected computer in accordance with General Data Protection Regulations (GDPR) (Tikkinen-Piri et al., 2018). In accordance with the University of Glasgow regulations, the data collected will be stored for a period of ten years and will then be destroyed.

5.8 Data entry

To manage data entry, data were entered first into a password-protected Microsoft Excel database in the researcher's personal computer. The recommended three stage screening, diagnosis, and editing process for data cleaning advanced by Van den Broeck et al. (2005) was adopted, and values outside of a predetermined range and any inconsistences were cleansed.

Data were prepared for statistical analysis by being coded and transferred into IBM SPSS as numeric variables. Variables were defined by giving each an exact name, with ranges and classifications for values that were assigned a code. A numeric code was assigned to nominal data, such as ventilator status (1 = not ventilated, 2 = ventilated). Age was entered directly as a continuous variable. Metric data measured at a continuous level, for example, sleep quality scores the using RCSQ-A, were entered both as continuous ordinal variables and as dichotomised categoric variables; in this example, 0-25 = very poor , 26-50= poor, 51-57 = good, and 58-100 very good. These cut-off scores were set according to guidelines established previously (Naik et al., 2018).

Participants' responses from the open-end questions in the questionnaire were manually coded, and these codes were combined into categories that were then

entered into the Excel sheet so that their frequency could be measured. Each participant was given a unique identifier and entered as a single observation.

5.9 Missing data

Every attempt was made during data collection for both phases one and two to ensure that there were no missing or erroneous data based on screening each patient's data collection sheets daily. The data extracted from the patients' medical records were checked for accuracy and completeness. There were no missing data in phase one, as all included patients 57 were provided completed RCSQ-A during the pilot test. While , in phase two, there were missing RCSQ-A responses from seventeen patients who had not completed the RCSQ-A at some point during the repeated assessment. These RCSQ-A questionnaires with missing data were not considered or included in the analyses, as an RCSQ-A total score could not be computed if the data were incomplete (Richards et al., 2000). Details regarding reasons for not completing the questionnaires, together with drop-out rates and withdrawal rates, are provided in the results chapter.

5.10 Data analysis

All statistical analysis for both phases one and two was performed with the support and guidance of a medical statistician, a lecturer and statistician at the Umm Al-Qura University, Saudi Arabia.

The researcher assessed normality distributions of continuous variables by checking Q–Q plots and histograms and using the Shapiro-Wilk test. The Shapiro-Wilk test revealed a p-value of >0.05, indicating that the data were normally distributed (Shapiro & Wilk, 1965). Data analysis, including the use of descriptive statistics, was applied to both the data for phase one and phase two of the

current study. Demographic and clinical data were analysed using descriptive statistics in order to describe the data. For categorical data, such as gender and admission diagnosis, frequencies and percentages were used. Mean, range, and standard deviation were used to describe the continuous data, such as self-reported sleep quality and self-reported sleep disruptive factors (Pallant, 2013, Razali et al., 2011).

In phase 1, a Cronbach's Alpha test was used as an internal consistency estimate of the reliability of the average inter-item overall correlation of RCSQ-A items (Streiner, 2003, Tavakol and Dennick, 2011). Cronbach's alpha is most popular test of internal consistency, which essentially estimates the average level of agreement between the items in a scale (Tavakol and Dennick, 2011). Cronbach's alpha coefficients with $\alpha \geq 0.70$ are considered evidence of adequate internal consistency, though the higher the Cronbach's alpha, the more reliable the scale can be said to be (Thorndike, 1995). A low Cronbach's alpha value, anything less than 0.70, indicates poor inter-relatedness between items in a measurement scale, suggesting that some be discarded or at least revised (Tavakol and Dennick, 2011). For content validity, analysis of the cognitive interviews in a subsample of 30 ICU patients was based on examining the emergent descriptive statistics, including the ratio of correct/wrong responses on the cognitive interviewing form.

In phase 2, descriptive analysis, specifically frequency counts and percentages, was used to describe indicators of acceptability. These included the number of eligible participants who were invited to participate in the study and decided to decline, withdrawal rates, dropout rates, the total number of patients who decided to discontinue at some point during the assessment, the total number

of reports (RCSQ-A) completed by patients, the total number of patients' able to place marks by themselves when using the paper-based VAS of the RCSQ-A, and the time necessary for the completion of the RCSQ-A.

Inductive content analysis was used to interpret and synthesise the data collected in the open-ended question “How did you find completing the questionnaire on sleep quality on multiple days while you were an inpatient in the ICU?”. It was thus possible to establish a range of keywords frequently used by patients to describe their experiences. These keywords were subsequently coded, and grouped into categories for reporting results (Polit, 2016).

The total scores for sleep quality from the RCSQ-A were calculated by dividing the sum of the scores of the items by five for each assessment (Richards et al., 2000; Aitken et al., 2017). Further, the total RCSQ-A score was converted into an estimation for the sleep efficiency index using the following formula: SEI=46.88+ (0.39*RCSQ) (Aitken et al., 2017, Li et al., 2011, Richards et al., 2000) . A paired sample t-test was conducted to determine whether there was a significant difference in mean sleep quality scores for the same participants on intubation and after they were extubated, and whether there were significant differences in self-reported sleep disruptive-factors during ventilation and after extubation (Harris and Taylor, 2014). The purpose of this comparison was to understand whether differences in self-reported sleep quality and sleep disruptive factors can be explained in terms of intubation status. The two-sided statistical significance level was set to 0.05 and 95% CIs were used. The effect size statistic was calculated in an attempt to provide a measure of the practical significance of the magnitude of the difference between the two means of the results (Fritz et al., 2012). The effect size "d" was calculated using the following formula, (Cohen, 1989): d = (mean ÷ SD). So that d is the difference between the

two means, divided by the standard deviation. The results were then interpreted based on Cohen's (1989) criteria as being strong (0.8), moderate (0.5) or weak (0.2).

To assess how sleep disruptive factors are related to patients' self-reported sleep quality, and whether certain sleep disruptive factors were predictive of self-reported sleep quality, a forward stepwise multiple regression was run for the total sample (n = 120).

The potential sleep disruptive factors were considered as independent variables, with self-reported sleep quality considered as the dependent variable. Regression analysis facilitates future outcomes being predicted according to the predictor variables (Field, 2013), while (Parahoo, 2014) advises that the forward stepwise method of multiple regression calculates the contributions of each predictive variable by looking at the significance value of the f-test for each predictor. The forward stepwise regression method is designed to select one variable from a group of independent variables at each step; this one variable has the largest prediction of the dependent variable and therefore makes the largest contribution to R2. If the predictor meets the removal criterion, that is, if it is not making a statistically significant contribution to how well the model predicts the outcome variable, it is removed from the model (Field, 2013). In the forward stepwise multiple regression conducted for this study, the probability of F for entry to the model was set at $p < 0.05$, and probability of F for removal was set at $p > 0.10$.

A post-hoc power analysis (Faul et al., 2009) was conducted to determine the maximum number of independent variables to be included in the regression

analysis to ensure the results met the recommended power of at least 0.80 suggested by Cohen (1992). The power analysis revealed that a sample size of 120 was adequate given 16 to 17 variables to be included in the analysis at a significance level of $\alpha = 0.05$. This offered an effective power of 0. 82, given a moderate effect size ($f^2 = 0.19$) (Cohen, 1992).

Independent variables of interest included in the model thus encompassed both demographic and clinical characteristics: age, gender, daytime sleepiness, APACHE II score severity of illness, baseline home sleep quality, ICU length of stay, analgesic use, nightly mechanical ventilation status, and any sedatives received (Midazolam, Propofol, Dexmedetomidine). To avoid overfitting the model, only the predictors that were rated most highly by the patients as being sleep disruptive factors, such as noise, clinical interventions, talking, machine alarms, and fear, were included in the model. These are detailed further in the results chapter.

Data regarding medications commonly administered to patients during the study (beta-blockers, diuretics, calcium channel blockers, corticosteroids and adrenergic) were not included in the model, as these medications were typically given together and each patient was on more than one medication; hence, it would not have been possible to study the influence of these medications in isolation or their individual associations with self-reported sleep quality. However, descriptive statistics were used to describe the number of patients receiving medications. The majority of the patients (n = 105, 87.5%) received concomitant opioid-fentanyl analgesics along with non-opioid analgesics. To avoid multicollinearity, these two variables were combined into a single variable and entered to the model "analgesic" (Kamdar et al.,2015) .

Using this approach, possible predictors were fed into the model one step at a time, and the new resulting model was assessed to determine whether they added anything significant to the statistical model being built in terms of predicting the outcome variable. When no additional possible predictor variables added anything to the model, the analytical process ceased. As a result, not all predictor variables made it into the final predictive model. The assumptions relating to the accuracy of the predictions and the fit of the data to the multiple regression model were also considered, and the appropriate modelling of continuous variables was confirmed by evaluating their linearity in relation to the dependent variable "total sleep quality". Variables were also checked for independence of observation (residuals), homoscedasticity of residuals (equal error variances), absence of multicollinearity, and outliers (Diggle et al., 2013). Linearity was assessed by use of partial regression plots and a plot of the studentised residuals against the predicted values. There was independence of residuals as assessed by a Durbin-Watson statistic of 1.299. There was also homoscedasticity, as assessed by visual inspection of a plot of studentised residuals versus unstandardized predicted values. The intercorrelation between independent variables for the repeated assessment was assessed using variance inflation factor (VIF) values less than 10; there was no evidence of multicollinearity, as tolerance values were greater than 0.1. There were no studentised deleted residuals greater than ±3 standard deviations, no leverage values greater than 0.2, and no values for Cook's distance above 1.

5.11 Summary

This chapter presented a detailed description of the two phases in this prospective observational study. The description of Phase one included the method used for RCSQ translation into Arabic (RCSQ-A), and details of the initial pilot test on 57 ICU patients, which was used to examine the internal consistency reliability, and content validity of the translated RCSQ. The description of Phase 2 reported on the method used to obtain repeated measures to examine RCSQ-A feasibility and acceptability in a sample of 120 ICU patients, as well as the ways in which patients' perceptions of sleep quality and sleep disruptive factors during their ICU stays were assessed in the repeated measures phase. Details of the ethical approval sought and the study setting of in the Medical and surgical ICU at KAUH were provided, and the eligibility criteria for study participants and the sampling, and recruitment process were discussed in detail. The instruments utilised in the study and the data collection procedure were also explained in detail, ad data organisation and analysis were then outlined. In the next chapter, the study results are presented in full for both Phase one and Phase two.

Chapter 6 Results

This chapter presents the results of the study in two main sections: section 6.1 offers the results of Phase one, while section 6.2 offers the Phase two results. This chapter also describes the final sample and the results for each phase with respect to the research questions and aims.

6.1 Phase 1

This section presents the results from Phase one of the current study, which was undertaken to meet the aim of this study, developing a usable Arabic version of the RCSQ (RCSQ-A). The screening and enrolment of patients in this phase are thus presented first, followed by the descriptive statistics for these participants. Thereafter, the results of tests for RCSQ-A internal consistency and reliability in the resulting sample of 57 ICU patients, and the results of content validity testing (cognitive interviewing) in a subsample of 30 patients, are presented.

6.1.1 Patient screening and enrolment

In total, 178 patients were admitted to the ICU and screened for eligibility during the Phase one period of the study (2nd March to 20th April 2018). Of these 178 patients, 57 met the study inclusion criteria as detailed in chapter 5, section 5.3. Figure 6-1 presents details of the patients screened and enrolled in Phase 1.

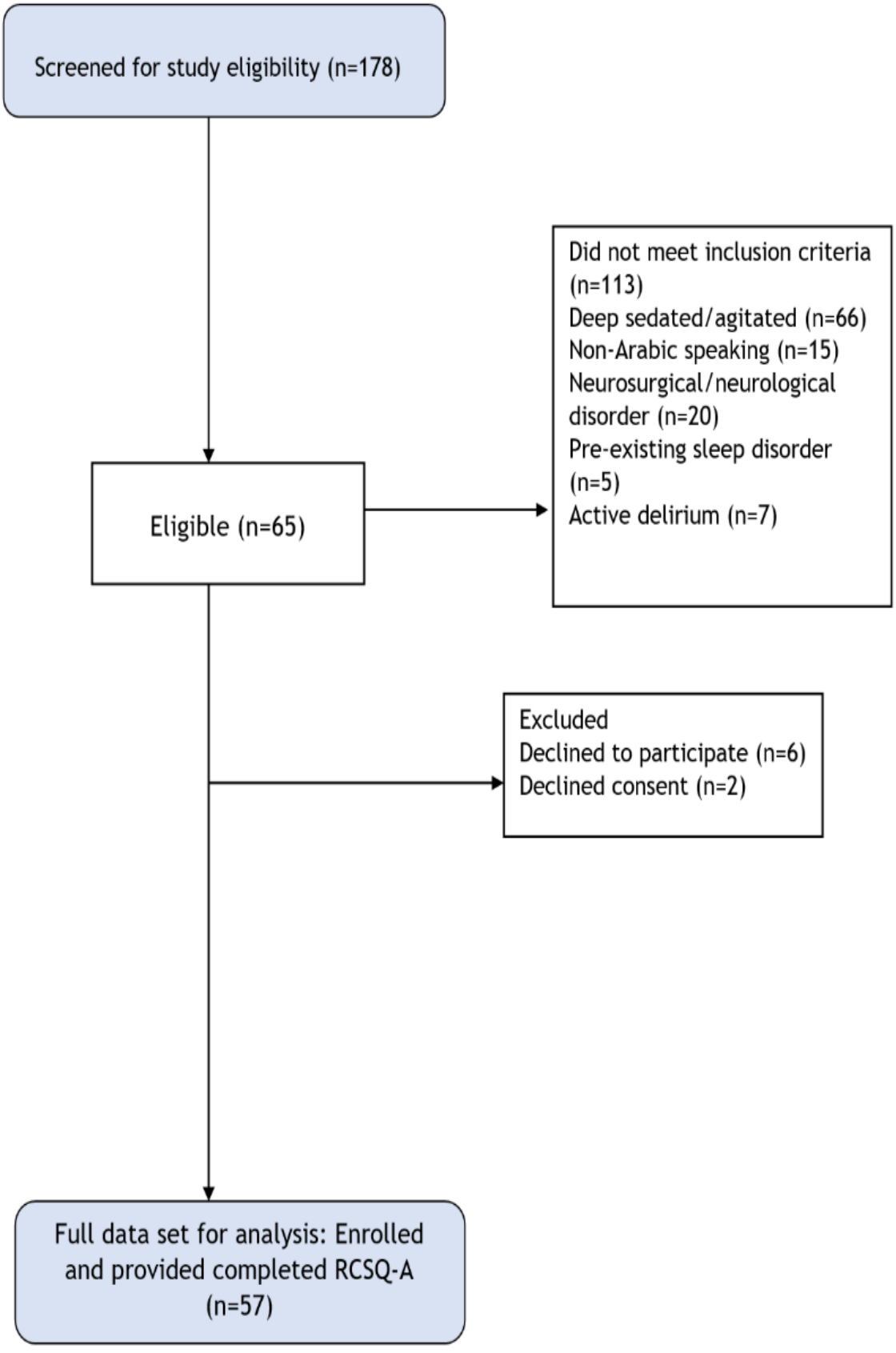
Screened for study eligibility (n=178)
Did not meet inclusion criteria (n=113)
Deep sedated/agitated (n=66)
Non-Arabic speaking (n=15)
Neurosurgical/neurological disorder (n=20)
Pre-existing sleep disorder (n=5)
Active delirium (n=7)
Eligible (n=65)
Excluded
Declined to participate (n=6)
Declined consent (n=2)
Full data set for analysis: Enrolled and provided completed RCSQ-A (n=57)

Figure 6-1 Flow diagram for participants in Phase one pilot testing

6.1.2 Demographic and clinical characteristics of the sample

Table 6-1 shows the demographic and clinical characteristics of the sample for Phase 1. The mean age of the participants was 54 and the majority (n=35, 61%) were male. Of those in the sample, 36 (63%) were postoperative and 21 (37%) were admitted with a medical diagnosis. The mean APACHE II score on ICU admission was 17.80 ±4.48, with scores ranging from 10.00 to 18.00, indicating that the severity of illness among this sample was relatively low (Knaus et al., 1985). A total of 38 of the patients (67%) received non-opioid analgesics and the remainder received intermittent low-dose boluses of opioid analgesics as needed to manage moderate to severe pain. None of the patients were sedated during the assessment, and all patients were alert, interactive, and calm during the assessment, with RASS scores of zero and GCS scores of 15. Patients' lengths of stay in the ICU ranged from 3 to 10 days, with a mean length of stay of 6.45 days±2.80.

Table 6-1 Demographic and clinical characteristics of the pilot test sample (n=57)

Characteristics	Category	n (%)	Range
Age (Mean ±SD)	54.7±8.58		37.00-66.00
Gender	Male Female	35 (61) 22 (39)	
Admission diagnosis	Medical cardiac* Medical respiratory¥ Medical Gastrointestinal§ Other¶ Surgical post-operative	10(18) 5 (9) 4 (7) 2 (3) 36 (63)	
APACHE II score [a] (Mean ±SD)	17.80 ±4.48		10.00-18.00
Non-Opioid-analgesic; Opioid analgesics		38 (67) 19 (33)	
Length of ICU stay-days (Mean ±SD)	6.45±2.80		3.00-10.00
RASS score on enrolment [c]	Alert and calm (zero-score)	57 (100)	
GCS [d]	Fully conscious (15-score)	57 (100)	
Intubation status	Intubated (invasive ventilation)[f]	27 (47)	

***** Heart failure, and coronary heart disease. **¥** Respiratory failure, chronic obstructive pulmonary disease, acute respiratory distress syndrome and pulmonary embolism. **§**Gastrointestinal bleeding, and acute pancreatitis.**¶** Renal failure **[a]** Acute Physiology and Chronic Health Evaluation. **[b]** Non-opioid-analgesic= paracetamol; Opioid analgesic=Intermittent bolus, as needed, of morphine. **[c]** Richmond Agitation Sedation Scale, **[d]** Glasgow Coma Scale; **[f]** ventilation applied via tracheotomy or endotracheally.

6.1.3 Internal consistency and reliability results for the RCSQ-A

The internal consistency and reliability of the RCSQ-A was assessed during Phase 1. The RCSQ-A proved to have very good overall internal consistency, as indicated by a Cronbach's alpha of 0.89 (Tavakol and Dennick, 2011). This suggests that the Arabic version of the RCSQ-A should function properly when used in an Arabic-speaking ICU population, as well as confirming that the five items on the scales are correlated, creating a consistent method of measuring the required underlying dimension (sleep quality).

6.1.4 Content validity of the RCSQ-A: cognitive interview results

The results of the cognitive interviews about RCSQ-A were satisfactory and comparable with those achieved for the original RCSQ. All of the RCSQ-A items were well understood and interpreted correctly and consistently. Additionally, there were no comments from the 30 patients participating in the cognitive interviews that would suggest the presence of difficult or ambiguous items. RCSQ-A thus offers an easy to understand scoring system for use with Arabic-speaking ICU patients.

The Arabic version of the RCSQ adequately measures the same five aspects of sleep quality as the original RCSQ: sleep depth, sleep latency, a state of wakefulness, ability to fall asleep when awoken, and quality of sleep. The findings from Phase 1 provided adequate evidence of the effectiveness of RCSQ-A, and its internal consistency reliability and content validity in an Arabic speaking setting to allow the researcher to proceed to Phase 2, using RCSQ-A to achieve answer the rest of the research questions.

6.2 Phase 2

This section offers the results of phase 2 of this study, in which the translated and tested RCSQ-A was used to gather self-reported data on sleep quality among ICU patients on a repeated daily basis. Participant screening and enrolment for Phase 2 are presented in section 0, with participants' demographic and clinical characteristics presented in sections 6.2.2. Section 6.2.3 addresses the third research question in the study by assessing the feasibility and acceptability of the RCSQ-A in daily self-reported assessment of sleep quality in ICU patients in Saudi Arabia. Sections 6.2.4 and 6.2.5 address the fourth and fifth research

questions in the study, examining the quality of patients' sleep and the sleep disruptive factors identified in an ICU setting in Saudi Arabia.

6.2.1 Patient screening and enrolment

Overall, 354 patients were admitted to the ICU during Phase 2 (5th May to 6th August 2018). Of these 354 patients, 130 patients met the study inclusion criteria (chapter 5, section 5.3), and of these, 10 patients declined to participate; the remaining 120 patients consented to take part and were enrolled in this phase, providing at least one assessment. During repeated assessment, of the initial 120 patients, three dropped out by choosing to stop taking part and 11 were withdrawn from the study by the researcher because they no longer met study inclusion criteria after providing some data on self-reported sleep quality using the RCSQ-A; this data was retained in the analysis. Reasons for dropouts/withdrawal, and the points at which patients dropped out/withdrew are provided in more detail in section 6.2.3.1. Section 6.2.2 presents further details of the patients enrolled in the study.

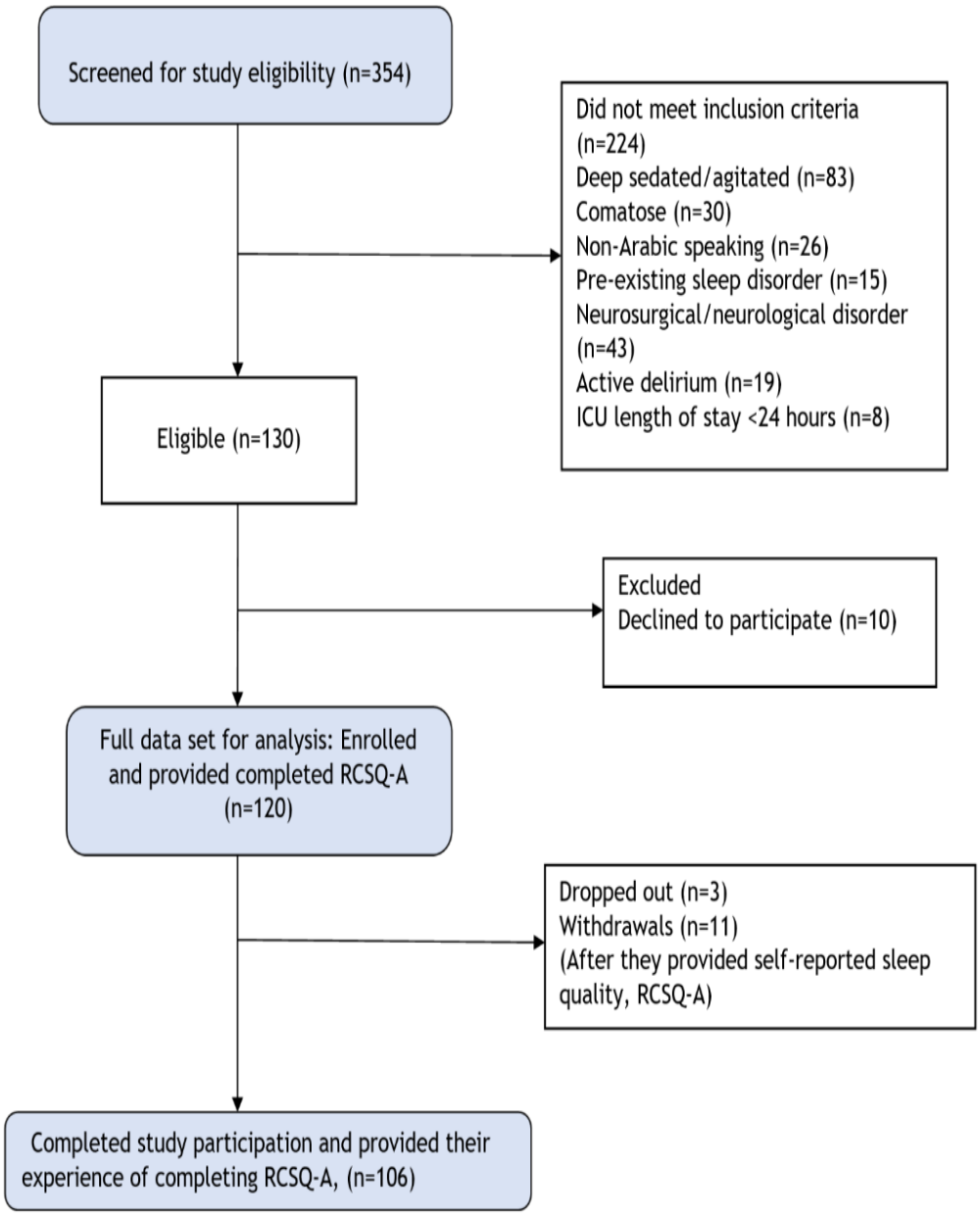

Figure 6-2 Diagram for flow participants in the repeated assessment (i.e. phase two)

6.2.2 Demographic and clinical characteristic of the sample

Table 6-2 shows the sample demographic and clinical characteristics. The sample of n=120 participants consisted of both males 72 (60%) and females (48, 40%), with ages ranging from 19 to 75 years; the mean age was 59.7 years. In this sample, 59 (49.2%) were admitted following a surgical operation and 61(50.8%) were admitted with a medical diagnosis. Of those patients admitted with a medical diagnosis, 21 (17.5%) were cardiac patients, 21 (17.5%) were respiratory patients, 11 (9.2%) were gastrointestinal patients, and eight (6.7%) had other diagnoses (e.g. traumatic fractures, renal failure). Participants' APACHE II scores on ICU admission ranged from 10 to 24, with a mean of 15.78±2.606. This indicates that the severity of illness in this sample was relatively low (Knaus et al., 1985). More than half of the participants 71 (59.2%) had a score between 10 and 15, while 49 participants (40.8%) had a score of 16 to 24, placing them in the medium category. All patients were alert, interactive, and calm on enrolment, with RASS scores of zero and GCS scores of 15. The lengths of stay in ICU ranged from 4 to 21 days, with a mean length of stay of 9.35 days±3.15.

In total, 75 (62.5%) patients were prescribed beta-blockers, 76 (63.3%) were prescribed diuretics, 99 (82.5%) were prescribed calcium channel blockers, 45 (37.5%) were prescribed corticosteroids, and 39 (32.5%) were prescribed adrenergic medications. The majority of the participants were prescribed some form of analgesic, with 105 (87.5%) receiving non-opioid analgesics in addition to intermittent low-dose boluses of fentanyl-opioid analgesic (10-50 mcg/hr) as needed to manage moderate to severe pain that did not respond to non-opioid analgesics. A further 15 (12.5%) were prescribed non-opioid analgesics, including paracetamol, and non-steroidal anti-inflammatory drug (NSAIDs) or Celebrex. None of the patients were sedated during the study assessment, though data on

previously administered sedation medications prior to enrolment were collected. Of all the patients included, 54 (45%) had been prescribed Propofol, 40 (33.3%) Benzodiazepines (Midazolam), and 26 (21.7%) Dexmedetomidine (Precedex).

Throughout the study, data regarding patients' sedation statuses, incidence of delirium, and agitation levels were collected and updated daily. The majority of the patients, 109 (90%), were alert and calm during the repeated assessment. A total of 11 patients (9.2%) became agitated during the study assessment, returning RASS scores of +2/+3 and positive CAM-ICU scores, indicating that they had developed delirium. As a result, data collection was discontinued with these patients, as they no longer met the study inclusion criteria (section 6.2.4). With regard to the ventilation status of participants, 43 (35.8%) were on mechanical ventilation, of whom 13 (30.2%) were on non-invasive ventilation, while 30 (69.8%) were recipients of invasive ventilation. The characteristics of the participants are shown in Table 6-2.

Table 6-2 Demographic and clinical characteristics of study sample (n=120)

Characteristics	Category	n (%)	Range
Age (Mean ±SD)	59.7±9.44		19.00- 75.00
Sex	Male Female	72 (60) 48 (40)	
Admission diagnosis	Medical cardiac* Medical respiratory¥ Gastrointestinal§ Other¶ Surgical post-operative Cardiothoracic Thoracic traumatic Abdominal	21(17.5) 21 (17.5) 11 (9.1) 8 (6.7) 59 (49.2) 37 (30.9) 12 (10) 10 (8.3)	
APACHE II score [a] (Mean ±SD)	15.78 ±2.606 Low Medium	 71 (59.2) 49 (40.8)	10.00-24.00 10.00-16.00 17.00-24.00
Length of ICU stay-days (Mean ±SD)	9.35±3.15		4.00-21.00
Medications [b]	Beta blockers Diuretics Calcium channel blockers Corticosteroids Adrenergic Non-Opioid and Opioid Non-Opioid-paracetamol	75 (62.5) 76 (63.5) 99 (82.5) 45 (37.5) 39 (32.5) 105 (87.5) 15 (12.5)	
Previous received sedation	Propofol Benzodiazepines(Midazolam) Dexmedetomidine(Precedx)	54 (45) 40 (33.3) 26 (21.7)	
RASS score on enrolment [c]	Alert and calm (zero-score)	120 (100)	
GCS [d]	Fully conscious (15-score)	120 (100)	
Developed delirium	Positive CAM-ICU [e]	11 (9.2)	
Intubation statues Method of ventilation	Intubated Invasive ventilation [f] Non-invasive	43 (35.8) 30 (69.8) 13 (30.2)	
Duration of MV (Mean ±SD)	6.26 ±3.381		2.00-17.00

***** Includes heart failure, coronary heart disease, arrhythmia, and aortic regurgitation. ¥ Includes respiratory failure, chronic obstructive pulmonary disease, acute respiratory distress syndrome and pulmonary embolism. §Include gastrointestinal bleeding, intestinal obstruction and acute pancreatitis.¶ Includes renal failure and fracture. [a] Acute Physiology and Chronic Health Evaluation. [b] Beta blocker=Metoprolol, Carvedilol; Diuretics= metolazone, furosemide, amiloride; Calcium channel blockers= amlodipine, verapamil; Corticosteroids = prednisolone, dexamethasone, hydrocortisone; Adrenergic= noradrenaline, adrenaline or dopamine; Non-opioid= paracetamol; Opioid analgesic: Intermittent-bolus as needed (morphine or fentanyl).[c] Richmond Agitation Sedation Scale, [d] Glasgow Coma Scale; [e] Confusion Assessment Method for the ICU; [f] ventilation applied via tracheotomy or endotracheal. [g] Ventilation applied via face or nasal mask

6.2.3 Feasibility and acceptability of RCSQ-A in terms of daily assessment of ICU patients' sleep quality

6.2.3.1 Feasibility of the RCSQ-A for daily self-reported assessment of sleep quality in ICU patients

The results reflecting patient burden (ability to provide RCSQ-A on a daily basis) are characterised by the perceived amount of effort necessary for patients to continue to provide self-report about their sleep quality using RCSQ-A on daily basis. The various indicators of patient burden, including dropout and withdrawal rates, number of completed RCSQ-A instruments, time taken to complete each RCSQ-A instrument, and patient ability to self-report without assistance (Fitzpatrick et al., 1998, Harris and Taylor, 2014, Sekhon et al., 2017), are discussed in the following paragraphs.

Dropout and withdrawal rates: The number of participants who dropped out was very small, n=3 (2.5%). These participants dropped out on the second day of assessment where reasons for cessation were not provided. The number of withdrawals was also very small at n=11 (9.2%), with four participants withdrawn on the second day of the assessment, five on the third day, and two on the fifth day of the assessment. The reason for withdrawal for all applicable patients was because they no longer met study inclusion criteria, having become agitated and developed delirium. The majority of participants, n=106 (88.4%), were thus able to complete study participation, indicating that provision of RCSQ-A on a daily basis was feasible for, and added little or no burden to, patients.

The number of completed RCSQ-As: In total, 381 reports were collected from 120 participants, indicating that patients were able to complete RCSQ-A self-reports on their sleep quality daily and repeatedly without excessive burden. Participants each provided RCSQ-As for between one and six days, with an

average of three days per participants. Among the participants, n=111 (92.5%) provided more than one RCSQ-A, while only nine participants (7.5%) provided RCSQ-A only once. Four of these participants became delirious and agitated on the second day of assessment, while three patients asked to stop taking part; two patients were discharged from the ICU on the second day of assessment.

The time taken to complete each RCSQ-A was between two and three minutes. Patient self-assessment of sleep using the RCSQ-A was aided by the researcher's assistance and supervision. More than half of the participants 68 (56.7%) were unable to set a mark on a paper-based VAS of the RCSQ-A themselves due to various barriers created by them being critically unwell, including tremors and muscle weakness. These patients were only able to point with the tip of their finger at their chosen spot; the researcher then marked the scale accordingly. The remaining patients, 52 (43.3%), did not experience any difficulties during their interactions with the RCSQ-A and were able to set a mark themselves. This indicates that RCSQ-A may tend to be less feasible for patients with physical issues in terms of self-completion. The current researcher also experienced some burden with regard to the scoring and interpretation of the RCSQ-A, as each VAS of the RCSQ-A had to be measured in terms of distance from the origin (zero) to the patient's mark (X) on the VAS. Time and effort were thus required to calculate the scores, reducing RCSQ-A feasibility with regard to scoring and interpretation.

6.2.3.2 Patient acceptability of providing daily self-reports on sleep quality using RCSQ-A

6.2.3.2.1 Patient willingness to participate in repeated assessment using RCSQ-A

Assessment of patients' willingness was based on their readiness to engage in the assessment, which was reflected in the number of eligible participants invited to participate in the study who decided to decline (Sekhon et al., 2017). There were 130 eligible patients invited to participate in the study, and the majority presented as willing to participate during the recruitment process 120 (92.3%). However, a small percentage of patients were eligible but declined to participate 10 (7.6%). Of these, three patients declined participation because of their unwillingness to participate in any research studies and seven patients did not provide any explanation why they declined participation.

6.2.3.2.2 Participant views of daily self-reported assessment of sleep quality using RCSQ-A

Free text answers to the open-ended question “How did you find completing the questionnaire on sleep quality on multiple days while you were an inpatient in the ICU?” identified that most of the participants n=89 (83.9%) were happy to complete the RCSQ-A daily during their stays in the ICU. The comments further revealed that patients found the RCSQ-A simple to complete and easy to understand:

“It was easy to answer the questionnaire, I was just pointing” ***(patient 5)***

“The questionnaire was simple and short” ***(patient 9)***

Some patients noted that answering made them feel safe and as if someone were paying attention to their needs with regard to sleep quality:

"I felt safe having someone asking about my sleep" ***(patient 11)***

"I felt happy to find someone asking about my sleep, especially at that time no one was caring about this problem I have" ***(patient 12)***

Some patients found the daily self-report assessment offered an opportunity for human interaction whilst they were in the ICU, enhancing communication and reducing feelings of loneliness:

"I was feeling happy at that time when I was on the ventilator machine, unable to talk and when you come to me and try to communicate with me"
(patient 18)

"I was feeling lonely most of the time, everybody was busy, so I was pleased that I had opportunity to interact with someone" ***(patient 23)***

Other patients found that daily assessment of their sleep quality improved their awareness of the importance of adequate sleep for health, causing them to pay more attention to their sleep:

"It is really opened my eyes on how is important to my health to get enough sleep" ***(patient 2)***

"The assessment was at each morning which gave me attention that my sleep is important to me" (***patient 28)***

Conversely, some of the participants, n=17 (16.1%), who had not completed the RCSQ-A at some point during the repeated assessment, noted some difficulties in completing the questionnaire for personal reasons such as feeling tired or bored: *"I felt tired at sometimes and I did not want to make any activity"* ***(patient 5)*** *"I was feeling bored and empty at sometimes, and I did not want to do anything"* ***(patient 16)***.

6.2.4 Quality of ICU patients' sleep

Patients' perceptions of their sleep quality during their ICU stays as assessed using the RCSQ-A (with the SICQ used for sleep disruptive factors) are provided in subsection 6.2.5.2. In addition, results for sleep quality for the subsample (n=43) who were placed on a ventilator at some point during the Phase two period are presented in subsection 6.2.5.3; these results include a description of self-reported sleep quality both when patients were on ventilation and after they were extubated.

6.2.4.1 Patients' self-reported assessments of sleep quality

The full sample (n = 120) reported sleep quality via repeated assessment using the RCSQ-A. Total RCSQ-A scores ranged between 23 and 48, with a mean average of 34.41±5.60, reflecting the fact that participants generally perceived they had poor quality of sleep. The total RCSQ-A score was categorised, with a cut off-point of <26 indicating very poor sleep quality, a score of 26 to 50 inclusive indicating poor sleep quality, a score of 51 to 75 inclusive indicating good sleep quality, and a score of >75 indicating very good sleep quality (Frisk and Nordstrom, 2003, Krotsetis et al., 2017).

A total of 113 participants (94.2%) had total RCSQ-A scores between 26 and 50 indicating poor quality of sleep. The remaining participants 7(5.8%) returned total scores below 26, indicating they had very poor quality sleep. The total RCSQ-A scores were also converted into estimations of the sleep efficiency (SEI) (Li et al., 2011, Richards et al., 2000), expressed as percentage. The calculated mean value within the cohort was 60.3%, where a SEI less than 85% indicates poor sleep quality (Richards et al., 2000) .

Of the five RCSQ-A items, sleep depth (the quantity of deep sleep) was rated the worst, with a mean of 31.82±7.03, indicating that patients' sleep was very light. The mean scores for the other RCSQ-A elements (falling asleep, a state of wakefulness, and returning to sleep) were also below 50, indicating that patients' sleep patterns were also fragmented: they had difficulty falling asleep, and once awake, had trouble resuming sleep. Table 6-3 provides the descriptive statistics for all RCSQ-A items.

Table 6-3 Patients' self-reporting of sleep quality, (n=120)

Richards-Campbell items	**Mean ±SD**	**Range**
(RCSQ-A.1) Sleep depth	31.82±7.03	19-56
(RCSQ-A.2) Falling asleep	33.07±6.73	21-54
(RCSQ-A.3) Awakenings	35.06±5.76	18-47
(RCSQ-A.4) Returning to sleep	36.29±5.36	25-50
(RCSQ-A.5) Overall sleep quality	35.36±5.34	22-51
Total RCSQ-A score [a]	34.41±5.60	23-48
SEI [b] (%)	60.30	-

[a] Total RCSQ-A = average of 5 items (Q1-Q5). [b] SEI= Sleep efficacy index= < 85% indicates poor sleep quality

In the 120 patients, the nature of change in the self-reported sleep quality from day-to-day was irregular (see Figure 6-3). In particular, patients self-reported sleep quality slightly differently each day during their ICU stay, which suggests that their perceptions of sleep quality varied daily, while it ranged from very poor (30) to poor (48).

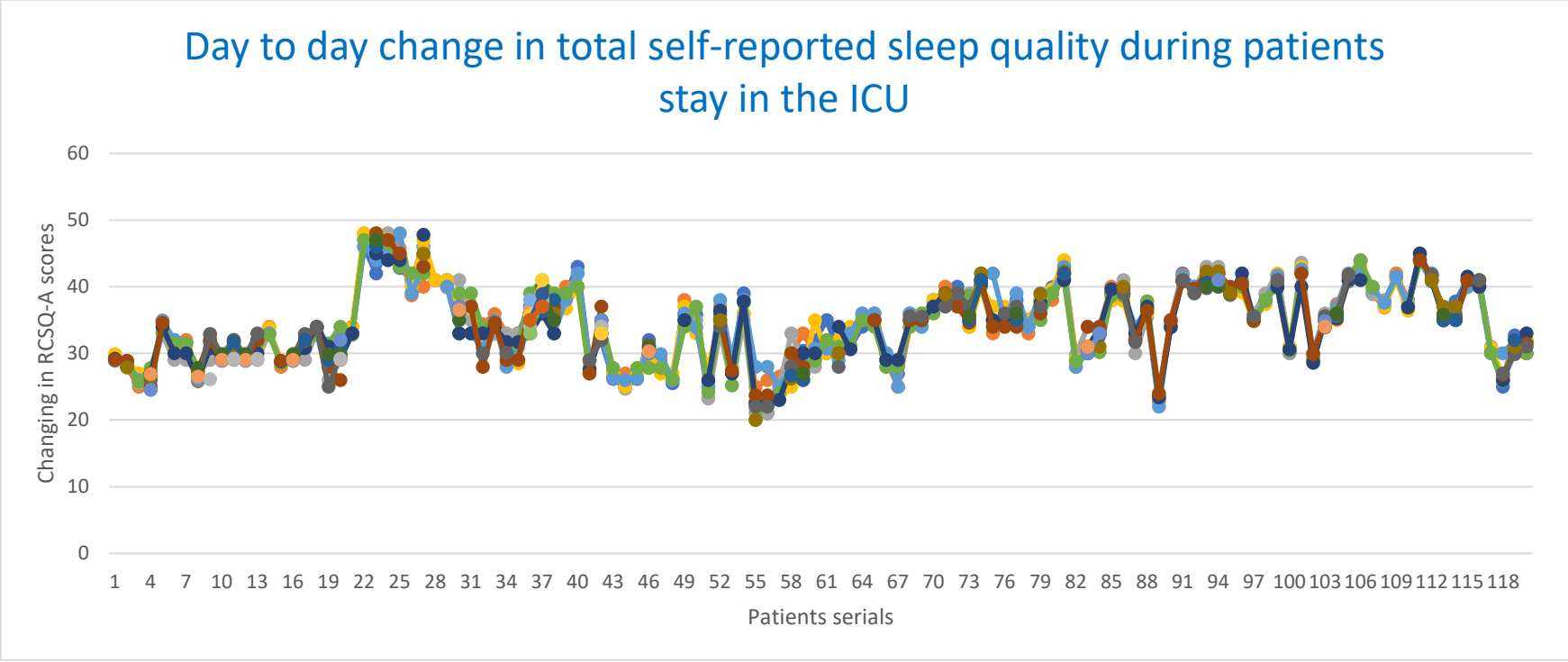

Figure 6-3 Day to day change in total self-reported sleep quality during patients stay in the ICU

6.2.4.2 Patients' self-report assessments of sleep quality during ventilation and after extubation

The sample of intubated patients (n = 43) reported their sleep quality on a daily basis during both the periods of their ventilation and after they were extubated using the RCSQ-A. Section 6.2.4.2 describes the self-reported sleep quality by the participants during intubation and after extubation. Patients reported different mean scores for the RCSQ-A overall during intubation and after extubation, though both mean scores were below 50, indicating poor sleep quality. A paired sample t-test was conducted to determine whether there was a significant difference in mean sleep quality scores for individual participants when they were on intubation and after they were extubated. The paired t-test confirmed that there was significant difference between mean total sleep quality during intubation (31.88± 6.16) and after extubation (35.04 ±6.47) (p <.0005), with a large effect size (d=1.9). This result indicates that the self-reported sleep quality improved following extubation compared to the sleep quality while on ventilation (Table 6-4).

Table 6-4 Self-reported sleep quality of patients when intubated and after extubation, (n=43)

RCSQ-A items	Patients on ventilation n= (43)		Patients after extubation n= (43)		
	Mean± SD	Range	Mean± SD	Range	P value [a]
(RCSQ-A 1) Depth of sleep	32.00 ±9.13	21-53	33.43±8.58	18-51	.001*
(RCSQ-A 2) Falling asleep	33.00 ±8.67	19-53	34.38±8.41	22-56	.001*
(RCSQ-A 3) Wakefulness	30.63±5.79	15-41	36.81±6.83	19-56	< .0005**
(RCSQ-A 4) Returning to sleep	31.85±5.50	21-40	36.20±5.99	28-49	< .0005**
(RCSQ-A 5) Overall sleep quality	32.14±5.51	21-41	34.40±5.54	25-47	< .0005**
Overall (RCSQ-A) Score [b]	31.88±6.16	20-45	35.04±6.47	24-49	< .0005

[a] Paired t test, *p< .05; **p< .0005 is highly significant.

6.2.5 Factors associated with patients' self-reported sleep quality

This section opens with a description of participants' baseline home sleep quality and daytime sleepiness in the ICU (Section 6.2.5.1). Then, the factors that patients perceived affected their sleep quality during their ICU stays are presented (Section 6.2.5.2). The results for perceived sleep disruptive factors both during intubation and after extubation in the subsample of participants placed on mechanical ventilation during the study (n = 43) are then presented (Section 6.2.5.3), and finally, the results of a multiple regression of the association between sleep disruptive factors and patient self-reported sleep quality are presented in Section 6.2.6.3.

6.2.5.1 Participants' baseline home sleep quality and daytime sleepiness in the ICU

Using the first question of the modified SICQ (Freedman et al., 1999), each patient's baseline home sleep quality was assessed on enrolment into Phase two as scored on a scale of 1 to 10 (1 = poor, 10 = excellent). Scores for sleep quality at home ranged from 3.0 to 9.0, with a mean of 7.16±1.754, indicating that participants perceived they had generally good sleep quality at home prior to admission to the ICU. Only two participants (10%) reported poor quality sleep at home, with scores of 3 and 4, while 24 (20%) had somewhat good quality sleep at home, with scores of 5 and 6; the majority, 84 (70%), reported good quality sleep at home, with values ≥7.

Participants' daytime sleepiness over the duration of their ICU stay was similarly rated on a scale 1 to 10 (1 = unable to stay awake, 10 = fully alert and awake) (Freedman et al.,1999). The scores ranged from 1 to 8.70 with a mean of 5.52±1.52, suggesting that most patients were somewhat sleepy during their

stays in the ICU. In all, 14% of patients rated their daytime sleepiness between 1 to less than 4, indicating that they felt unable to stay awake; 68.3% rated it between 4 and less than 7, indicating that they felt somewhat awake; and 17.5% rated it ≥ 7, indicating that they felt fully alert and awake.

6.2.5.2 Participants' perceptions of sleep disruptive factors

Table 6-5 provides a descriptive analysis of sleep disruptive factors, including both extrinsic factors (related to the environment) and intrinsic factors (related to the patients), reported by the entire sample (n = 120) using a modified SICQ scale (1=no disruption, 10= significant disruption). Noise was rated the most disruptive factor at 7.48 ±1.57, followed by clinical interventions at 5.95 ±1.57; the highest rated noise was talking at 6.80 ±1.25, indicating high levels of sleep disruption from this. The highest-rated disruptive intrinsic factor was fear at 3.64 ±2.01, indicating mild disruption.

Table 6-5 Self-reported sleep disruptive factors on a modified SICQ, scale (0-10) (n =120)

Sleep disruptive factors [a]	**Mean ±SD**	**Range**
Sleep disruptive activities in rank order		
Noise	7.48±1.57	3.00-9.00
Clinical interventions (i.e. bath, vital signs, blood sample)	5.95±1.86	2.30-9.00
Light	2.36±0.94	1.00-5.00
Noise disruptions in rank order		
Talking	6.80±1.25	1.00-9.00
Machines' alarm (i.e. heart monitor, ventilator, I.V. pump)	4.31±2.35	1.00-9.00
Telephone	1.12±0.36	1.00-7.30
Other intrinsic factors in rank order		
Fear	3.64 ±2.01	1.00-8.25
Pain	2.30±1.10	1.00-7.30
Discomfort of being attached to the devices	2.26±1.18	1.00-5.75

[a] Sources of perceived sleep disruption, factors are rated on a scale of 1 to 10. 1 is no disruption, 2-4 mild disruption, 5-6 moderate disruption, 7-9 high disruption and, 10 is significant disruption

Table 6.6. shows the results of inductive content analysis of the open-ended question added to the SICQ "What other factors or activities were disruptive to your sleep last night?". Several categories and sub-categories of sleep-disruptive factors were revealed, in accordance with the classifications created by Edell-Gustafsson et al. (1994) and Nicolas et al. (2008). One third (n = 40) of patients did not respond to this open-ended question, and thus did not add to the disruptive factors that they rated in the modified SICQ.

Two main categories emerged from the content analysis: an environmental factors category, with a subcategory for noise disruption factors; and a patient factors category with two sub-categories, psychological factors and clinical condition factors. The content analysis revealed that noise disruption from other patients' voices was the most commonly cited factor that disrupted patients' sleep, followed by psychological factors (worries and nightmares) and clinical condition factors (coughing, choking sensations, and nausea).

Table 6-6 Categories arising from the comments of patients in relation to the open-ended question in the modified SICQ

Category	Subcategories	(n=120) %
Environmental factors	**(Noise disruption)** **-Voices of other patients** *'I woke every time because of the sounds of suction of patient next to me'* *'I could not sleep last night because of the man who was moaning all night'* *'I woke up many times from my sleep because of snoring from the next patient'* **-Sounds of footsteps/moving equipment** *'I slept on and off, there was footsteps sounds along the night'* *'Sometimes I could hear moving of equipment, sounds of people steps, I did not sleep well because all of that"*	28 9
Factors related to the patient	**(Psychological factors)** **-Worries** '*I did not sleep until the morning, I was worried'* *'I was worried about whether I'd be better or not'* *'I was concerned and thinking all night about my family'* **-Nightmares** *'I woke every time last night of bad dreams'* *'I was so scared, and I could not sleep of a terror dream'* *'I woke up of a scary nightmare and I could not get back to sleep'*	20 15
	Clinical condition factors **-Coughing** *'I did not sleep because of the coughing all night'* *'I have a very bad cough which keeping me awake'* **- Choking sensation** *'I could not sleep of a chocking feeling I was breathing through my mouth'* *'I woke up of sudden chocking feeling and I could not get back again to sleep'* -**Nausea** *'I had bad sleep of unpleasant nausea'* *'I had feeling of throwing up all night, I could not sleep'*	18 10 7

6.2.5.3 Participants' perceptions of sleep disruptive factors during and after intubation

Table 6.7 shows the mean and standard deviations of multiple extrinsic and intrinsic sleep disruptive factors, rated daily using the modified SICQ, among the subsample of patients who were on mechanical ventilation during the study. It also shows a comparison between self-reported sleep disruptive factors during intubation and after extubation, as determined by using paired-sample t-tests.

Table 6-7 Self-reported sleep disruptive factors, using the modified SICQ, as reported by patients during and after ventilation

Sleep disruptive factors [a]	Patients on MV [b] (n=43)		Patients after extubation [c] (n=43)			
	Mean ±SD	Range	Mean ±SD	Range	P value [e]	Effect size
Sleep disruptive <u>activities</u>						
Noise	8.10 ±0.92	4.70 -9.00	6.66 ±1.46	2.50 -9.00	.001*	1.9
Clinical interventions (i.e. bath, vital signs, blood sample)	7.04 ±2.04	2.70 -9.00	6.07 ±2.4	2.00 -9.00	<.0005**	0.78
Light	2.43 ±1.15	1.00 -5.00	2.16 ±0.89	1.00 -4.50	.600	0.5
Noise sources						
Machines' alarm (i.e. heart monitor, ventilator, I.V. pump)	7.19 ±1.13	3.50 -9.00	4.68 ±1.37	2.50 -9.00	<.0005**	2.2
Talking	7.96 ±1.43	3.50 -9.00	7.55 ±1.70	2.50 -9.00	.300	0.4
Telephone	1.04 ±0.15	1.00 -1.70	1.02 ±0.15	1.00 -2.00	.625	0.07
Other <u>intrinsic factors</u> related to the patient						
Fear	6.32 ±1.81	3.00 -9.00	3.60 ±1.34	2.00 -6.50	<.0005**	2
Pain	2.90 ±0.96	1.50 -5.00	2.22 ±1.19	1.00 -6.00	<.0005**	0.6
Discomfort of being attached to the devices	3.24 ±1.84	1.00 -7.50	2.04 ±1.18	1.00 -5.00	<.0005**	1.4

[a] Sources of perceived sleep disruption, factors are rated on a scale of 1 to 10. 1 is no disruption, 2-4 mild disruption, 5-6 moderate disruption, 7-9 high disruption and 10 is significant disruption; [b] patients on mechanical ventilation; [c] patients after removal of ventilation; [d] mean ± standard deviation, [e] paired t test, *p< *.05 ; **p< .0005 is highly significant.

Overall, there was a trend toward a decrease in self-reported sleep disruptive factors after extubation. During ventilation, perhaps unsurprisingly, noise was rated as being the most common extrinsic sleep-disruptive factor, causing patients a high level of disturbance (8.10 ±0.92); this was followed by clinical interventions (7.04 ±2.04). Perhaps more surprisingly, the highest rated noise was still talking (7.96 ±1.43), followed by machine alarms (7.19 ±1.13). The fear

factor was rated highest as an intrinsic factor, causing a moderate level of disruption (6.32 ±1.81).

Following extubation, there was a significant decrease in reported noise and clinical interventions, which were then rated as causing moderate levels of sleep disruption with respective means of 6.66 ±1.46 ($p< 0.05$) and 6.07 ±2.34 ($p>.0005$) with large effect size, $d= 1.9$, and small effect size, respectively. Meanwhile, talking continued to be rated as causing a high level of disruption (7.55±1.70) and any differences were not statistically significant ($p=0.300$); the effect size was also small ($d=0.4$). On the other hand, the level of disruption caused by machine alarms was reduced significantly ($p>0.0005$), causing only a mild level of disruption to patients' sleep (4.68, ±1.37) with a large effect size of 2.2. The mean for the factor of fear also fell significantly to 3.60 ±1.34, ($p<0.0005$) with a large effect size ($d=2.2$). The significance of these changes in perceived sleep disruption, are shown in Figure 6-4.

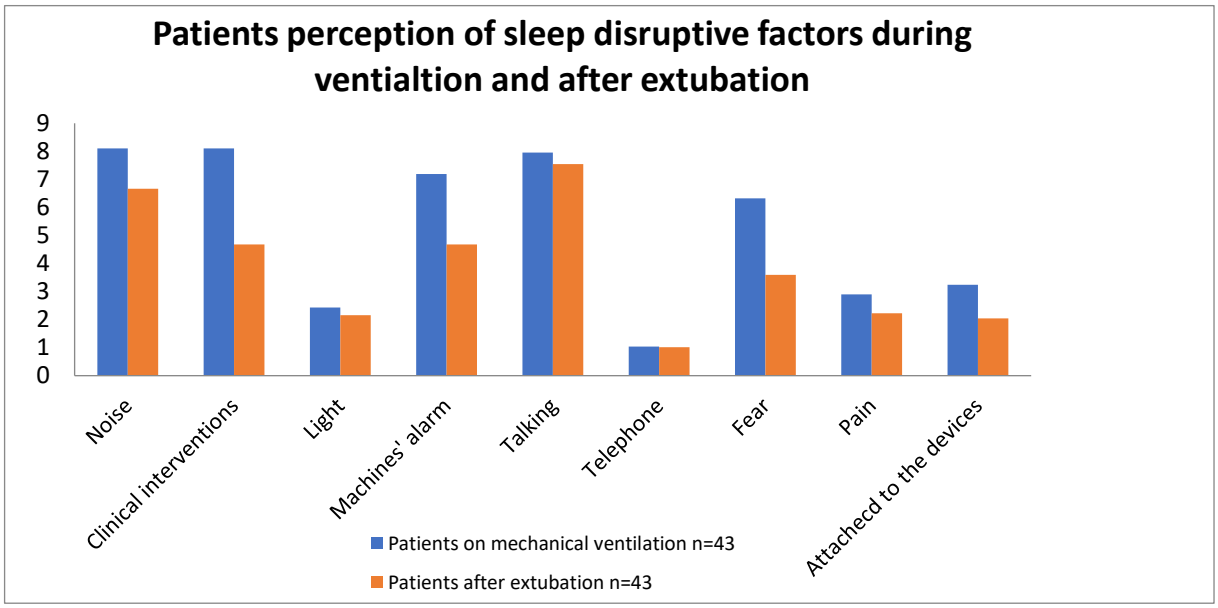

Figure 6-4 Changes in self-reported sleep disruptive factors during ventilation and after extubation

6.2.5.4 Factors associated with the quality of patients' sleep: multiple regression

A forward stepwise multiple regression was conducted to assess the association of each of independent variables with patients' sleep quality. The predictor independent variables included in the model were age, sex, daytime sleepiness, APACHE II score, baseline home sleep quality, length of ICU stay, analgesics, mechanical ventilation status (intubated, non-intubated), previously received sedation with Midazolam, Propofol or Precedex, noise, clinical interventions, talking, machine alarms, and fear. The dependent variable was total self-reported sleep quality. As there are no standard tables or standard methods of interpretation and presentation for multiple regression (Polit and Beck 2012), this section follows the example of regression interpretation provided by Polit and Beck (2012).

The results of the multiple regression model suggested several factors as significant predictors of patient sleep quality; a correlation between the independent variables and the dependent variable also emerged. It is worth noting, however, that while the results that can be inferred from the multiple regression reflect the relative importance of the independent variables in the prediction of the dependent variable, as well as whether these independent variables are significantly associated with the dependent variable, causality cannot be inferred from these correlations (Polit et al., 2013).

Table 6.8 offers a model summary, with details of the variations in sleep quality explained by the independent variables; it also presents the regression equation coefficients for all model variables. In this way, it describes the relationship

between the six independent variables and the dependent variable "total sleep quality". The stepwise regression analysis suggests that six independent variables, including Midazolam, Propofol, sex, noise, daytime sleepiness, and intubation status are significantly associated with total sleep quality. In Table 6.8, the full model of these six predictors is seen to explain 39.3% of the variance in total sleep quality, and this is statistically significant, with R^2 = 0.423, F (6.113) = 13.828, p < 0.0005. Interpretations of the correlations between predictors and total sleep quality are offered in more detail in the following paragraphs.

Table 6-8 Model summary of the predictor variables that associated with sleep quality (adjusted R2 = 0.393)

Total sleep quality, (n=120)						
Step	**Variable**	**B [a]**	**(95.0% CI) [b]**	**R^2**	**Adjusted R^2**	**F [c]**
1	Midazolam	-6.424**	(-8.99– -3.86)	0.222	0.222	33.719**
2	Propofol	-3.600*	(-5.71– -1.49)	0.287	0.065	23.541**
3	Gender	1.836*	(0.157– 3.52)	0.340	0.053	19.914**
4	Noise	-1.033*	(-1.70– -0.364)	0.373	0.033	17.097**
5	Daytime sleepiness	0.856*	(0.175– 1.54)	0.401	0.028	15.236**
6	Intubation status	-1.218*	(-2.36– -0.077)	0.423	0.023	13.828**

[a] B= unstandardized regression coefficients, [b] CI=confidence interval, [c] F=test of overall significance ** p <.0005 is highly significant; * p<.05

The first step of the stepwise regression analysis indicated that Midazolam sedation was significant predictor of sleep quality, accounting for 22.2% of the variance in sleep quality. There was negative and significant association between Midazolam sedation and sleep quality (B= -6.424, p<0.0005). Propofol sedation was also significant predictor in the model, added in step 2, accounting for an additional 6.5% of the variance in total sleep quality (p < 0.0005). There was, again, a negative and significant association between Propofol sedation and

sleep quality (B = -3.600, p = 0.001). This suggests that both Midazolam and Propofol sedation are associated with poorer patient sleep quality.

Another significant predictor was sex, as shown in step 3, which increased the variance in total sleep quality by 5.3% (p <0.0005). Total sleep quality was associated with differences in gender (B=1.836, p=0.032), and predicted total sleep quality for females was 1.836 greater than for males. This indicates that female patients report better sleep quality than male patients.

A similar improvement in the strength of the model was evidenced in step 4 of the analysis, where the significant predictor was noise. Noise created a further variance in total sleep quality of 3.3% (p < 0.0005), with the noise variable was negatively and significantly associated with the total sleep quality (B= -1.033, p=0.003), highlighting that more noise is associated with poorer sleep quality. Another significant predictor, daytime sleepiness, was found in step 5, and this accounted for an additional 2.8% of the variance in total sleep quality (p<0.0005). Daytime sleepiness was positively and significantly associated with total sleep quality (B=0.856, p=0.014). Thus, patients being alert and awake during the day was associated with better sleep quality. The final step in the model, intubation status (step 6) was a significant predictor when added to the five existing predictor variables, accounting for 2.3% (p<0.0005) of the variance in sleep quality. Being intubated was negatively and significantly associated with total sleep quality (B=-1.218, p=0.037), meaning that people who were intubated had a poorer sleep quality.

6.3 Summary

In this chapter, the results of both phases of this study were presented. The tests of internal consistency reliability and content validity in the sample of 57 medical and surgical ICU patients for the translated RCSQ-A in Phase 1 revealed that the RCSQ-A had good internal consistency. Content validity was also confirmed, based on the results of cognitive interviews with a subsample of 30 patients.

The results from Phase 2 indicated that the RCSQ-A was feasible and acceptable for ICU patients in daily use. However, many patients required a second person to note their responses on the measure, which may reduce its feasibility and acceptability for nurses in the ICU clinical practice. The data collected through the RCSQ-A and the SICQ revealed that participants in Stage 2 of this study (n=120) generally had a poor quality of sleep whilst in the ICU. The reported sleep patterns were generally very light and fragmented. Of the five items of sleep rated (sleep depth, falling asleep, wakefulness, returning to sleep, and overall sleep quality), sleep depth was rated worst. Multiple sleep disruptive factors were identified and evaluated by patients, and these differed from day to day. They including noise (talking, machine alarms, other patients' breathing) , clinical interventions, and fear. The findings also revealed that several factors were more significantly associated with patient self-reported sleep quality including Midazolam, Propofol, sex differences, noise, daytime sleepiness, and intubation status.

In next chapter, these findings are thus discussed in relation to the literature previously reviewed and the wider context of sleep in ICU settings.

Chapter 7 Discussion

This chapter offers an overall summary of the study's key findings as related to the research questions, allowing discussion of the results of the study in relation to the previous literature. This helps to identify the strengths and limitations of the study, and these, and the contribution to existing knowledge and other implications of the study are thus also presented.

This study aimed to develop and test the content validity, internal consistency reliability, and feasibility and acceptability of daily self-reported assessment of sleep quality in an ICU setting in Saudi Arabia using an Arabic version of the RCSQ (the RCSQ-A) and to thus report on sleep quality and sleep disruptive factors among ICU patients in Saudi Arabia. This study adopted a descriptive quantitative model in which an observational correlational research design was applied with repeated measures methods use to answer the research questions:

1. Can an Arabic version of the RCSQ (RCSQ-A) be developed for daily self-reported assessment of sleep quality in ICU settings in Saudi Arabia?
2. What is the content validity and internal consistency reliability of the resulting RCSQ-A in terms of daily self-reported assessment of sleep quality in ICU patients in Saudi Arabia?
3. What is the feasibility and acceptability of the RCSQ-A in terms of daily self-reported assessment of sleep quality in ICU patients in Saudi Arabia?
4. What is the self-reported quality of patients' sleep in an ICU setting in Saudi Arabia?
5. What factors related to patients' self-reported sleep quality arise in an ICU setting in Saudi Arabia?

To address these research questions adequately, this study was divided into two phases. Phase 1 addressed the first and second research questions, and involved translating the existing RCSQ into Arabic using the WHO translation and adaptation processes (World Health Organisation, n.d.), and then pilot testing the resulting RCSQ-A for internal consistency and reliability in 57 patients, and for content validity in a subsample of 30 ICU patients, using cognitive interviewing methods to assess understanding of the meaning of each item in the instrument.

Phase 2 of the study was a prospective repeated measures study, and this was carried out to address the third, fourth, and fifth research questions in the study, thus assessing the feasibility and acceptability of using the RCSQ-A in an ICU setting in Saudi Arabia for collecting data on sleep quality and sleep disruption factors in ICU patients. In Phase 2, the RCSQ-A was completed on a repeated daily basis from the point where patients were recruited until their date of discharge by 120 ICU patients, and correlations between sleep disruptive factors, demographic and clinical variables, and self-reported sleep quality were explored. An evaluation of the feasibility and acceptability of the RCSQ-A was also undertaken. The following sections thus present the general findings of the study and discuss these findings in relation to both the literature previously reviewed and the wider context of sleep in ICU settings.

7.1 Internal consistency reliability, content validity of the RCSQ-A

The RCSQ demonstrated evidence of simplicity and clarity on translation into Arabic in the current study, with no need for replication of any step of the translation process, which was therefore carried out according to WHO guidelines in a relatively straightforward manner (World Health Organisation, 2017). Further, the Arabic version RCSQ-A developed in this study showed evidence of translation validity based on comments from an expert panel formed of Arabic speaking medical staff specialising in the fields of sleep medicine and ICU. It further demonstrated evidence of content validity based on cognitive interviews with a subsample of 30 ICU patients who participated in the pilot test. These factors suggest that the RCSQ-A measures the various items of sleep in line with the intentions of the original RCSQ, in agreement with Chen et al. (2018), who indicated that, during the process of RCSQ translation into Chinese (RCSQ-C), the five items of the RCSQ were easy to translate and no RCSQ-C item required modification for the Chinese cultural context. They also indicated that the RCSQ-C showed good content validity according to an expert panel of five members (Chen et al 2018). However, they did not carry out cognitive interviews with the intended population for the RCSQ (ICU patients) to ensure there was no confusion about any items among respondents or to ensure content validation of the translated RCSQ in the new culture.

In a Japanese study, Murata et al. (2019) reported different findings in relation to the RCSQ translation into Japanese (J-RCSQ). They stated that, based on cognitive interviews with a sample of five Japanese patients, the Japanese version of J-RCSQ required rewording of certain phrases to improve comprehension. This may be due to the fact that none of the translators

involved in that translation process worked in the field of sleep medicine, and thus they may not have entirely grasped the concepts underlying the RCSQ, which may have affected the translation validity and necessitated further modifications (Murata et al., 2019). In the current study, some of the panel members involved in the Arabic translation process work in the field of sleep medicine; they were selected in order to provide a translation that more closely resembled the original RCSQ, a choice which appears to have been successful.

The translational validity of the RCSQ into Arabic must be compared with the studies by Chen et al. (2018) and Murata et al. (2019), as these were the only studies offering detailed information about RCSQ translation processes and content validity. While other studies that translated the RCSQ briefly described the translation process, no detail of the translation validity results was offered in any other cases (Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Naik et al., 2018, Nicolas et al., 2008, Ritmala-Castren et al., 2017). These studies did provide findings with regard to the translated RCSQs' internal consistency, however, which are discussed in relation to the current study in the following paragraph.

In the current study, the RCSQ-A showed good internal consistency reliability, with a Cronbach's alpha of 0.89 in the 57 medical and surgical ICU patients of the pilot phase; satisfying the criteria for internal consistency (Cronbach's alpha exceeding 0.70) (Tavakol and Dennick, 2011). This result is consistent with the results for the Spanish version of the RCSQ, which obtained a similarly good Cronbach's alpha of 0.89 in a sample of 104 non-mechanically ventilated surgical ICU patients (Nicolas et al., 2008), and the German version, which had a Cronbach's alpha of 0.88 in a sample of 51 patients in a mixed ICU (Krotsetis et

al., 2017), with six being mechanically ventilated; severity of illness was not reported in that case.

This is also consistent with other versions of the RCSQ, being only slightly lower than some. For example, the Swedish version, tested in 31 surgical ICU patients, had an excellent Cronbach's alpha of 0.92 (Frisk and Nordstrom, 2003), while the Finnish version also had an excellent Cronbach's alpha of 0.91 in 114 non-mechanically ventilated patients (Ritmala-Castren et al., 2017). An excellent Cronbach's alpha of 92.0 was also found for the Chinese version in a sample of 150 patients in mixed ICUs (Chen et al., 2018) and for the Japanese version in a sample of 45 non-mechanically ventilated patients (Murata et al., 2019). These slight differences in the results for RCSQ internal consistency may be due to explicit variations in sample characteristics, given that some studies included ventilated patients while others did not, as well as differences in sample size and ICU settings between studies. Overall, all translated versions of the RCSQ retain similar internal consistency to the original English version, which itself had an excellent Cronbach's alpha of 0.90 in non-mechanically ventilated 70 male medical ICU patients (Richards et al., 2000). The Arabic version RCSQ-A was thus found to be internally consistent in the pilot test, comparing well to both the original and other translated versions.

The results for internal consistency and reliability and the cognitive interviews conducted in Phase 1 of this study on the RCSQ-A were derived from a convenience sampling of 57 ICU patients. Thus, the results may not be generalisable to all ICU patient populations, particularly as none of the participants in the Phase 1 sample of this study was older than 66, with a mean age of 54±8.58 years. This differs from many previous studies in which the mean ages were greater, being between 57.72±14.81 and 64.74±16.16 (Chen et al., 2018, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Nicolas et al., 2008). Moreover, the current study's participants were not considered to be severely ill, with an average APACHE II score of only 17.80±4.48; this was similar to Ritmala-Castren et al. (2017), where participants had a mean APACHE II score of 16± 06, but much lower than Chen et al. (2018), who reported that their participants had a mean score of 26.04±04. Meanwhile, the rest of the studies did not use APACHE II to assess RCSQ internal consistency (Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Murata et al., 2019, Nicolas et al., 2008).

To ensure that the RCSQ-A is an appropriate tool for diverse populations of Arabic-speaking ICU patients, there was a need to assess the use of RCSQ-A in a wider range of ICU settings in Arabic-speaking countries; however, as this is the first study to assess the internal consistency of RCSQ-A, it only conducted a pilot test in medical and surgical ICU patients. The most important point to be considered in undertaking any further testing of the use of RCSQ-A in Arabic ICU clinical practice is that those assessing the ratings, who may be nurses, should understand how the RCSQ-A works and the terminology used in the scales to avoid any external effects on the reliability and validity of the results. According to McGoey et al. (2010), evaluators who participate in carrying out any

assessment should be adequately trained to administer and score the measures used in order to prevent measurement errors.

7.2 Feasibility and acceptability of the RCSQ-A in terms of daily assessment of ICU patients' sleep quality

The results of the current study demonstrate that daily self-reported assessments of sleep-quality using the RCSQ-A were acceptable and feasible to the majority of the participants. The majority of the eligible patients (n=130) who were invited to participate in the repeated measures study were willing to participate in daily sleep assessment using RCSQ-A 120 (92.3%). The number of withdrawals during the repeated measures study was very small at n=11 (9.2%); further, none of the reasons for withdrawal stemmed specifically from the use of RCSQ-A. The dropout rate was also very small, at 3 (2.5%), though no reasons for this cessation were provided. The majority of participants were thus able to participate fully in the study n=106 (88.4%).

These results are similar to those of most previous studies using RCSQ, where drop-out rates tend to be relatively low, ranging from 0 to 13% (Aitken et al., 2017, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Menear et al., 2017, Murata et al., 2019, Naik et al., 2018, Nicolas et al., 2008, Ritmala-Castren et al., 2017). Two studies contradict these findings, with high drop-out rates of 70% in Bourne et al. (2008), a small RCT study to examine the effects of exogenous melatonin medication on nocturnal sleep in 24 mechanically ventilated patients in a General ICU, and 35% in an experimental non-controlled pre-post study by Patel et al. (2014) to assess the effects of multicomponent interventions on sleep quality in medical and surgical ICU patients, which enrolled 338 patients into control (n=167) and experimental (n=171) groups.

However, unlike this study, in which RCSQ-A was the only sleep assessment tool used, Bourne et al. (2008) assessed patients' sleep using BIS along with RCSQ, which is likely to have affected patients' continued participation in the study. Certainly, the stated reasons for patients dropping out were not related to the RCSQ. Some patients also developed delirium and therefore were unable to complete the RCSQ in Bourne et al. (2008), while no reasons were provided in Patel et al. (2014). Overall, the majority of previous studies were cross-sectional and did not aim to assess the ICU patients' acceptance of completing the RCSQ on a daily basis during their ICU stays. Thus, comparability between the current study findings and those studies in relation to RCSQ feasibility and acceptability is limited.

The results of the current study demonstrate the acceptability and feasibility of daily self-report assessments of sleep-quality using the RCSQ-A among participants. In total, 381 reports were collected from 120 participants in repeated assessments, with participants each providing RCSQ-A data between one and six times, with the average being three times. The majority of participants, n=111 (92.5%), provided more than one RCSQ-A; only nine participants (7.5%) provided the RCSQ-A only once, for reasons not related to the RCSQ-A: four of the participants became delirious and agitated on the second day of the assessment, while three patients asked to stop taking part for personal reasons such as feeling tired or bored during the assessment; a further, two patients were discharged from the ICU on the second day of assessment. These results are comparable with those of previous repeated assessment studies that used RCSQ on multiple days in the ICU (Aitken et al., 2017, Kamdar et al., 2012, Menear et al., 2017). In Kamdar et al. (2012), 33 medical ICU patients

used RCSQ for a period of assessment longer than that used in this study (137 nights vs. 94 nights); there, overall, 33 patients completed 121 self-report RCSQs, a rate of 88% based on available days, with an average of three or four reports per patient. There were no reasons given for the 16 days on which RCSQs were not completed that related to the RCSQ itself. Reported reasons related to the patients' availability in the ICU during the assessment and changes in clinical status (e.g. developing delirium).

In Aitken et al. (2017), 151 medical and surgical ICU patients reported on their sleep using the RCSQ over an 18-night assessment, a much shorter period of assessment than in this study. Overall, they provided 356 RCSQs, with 50% of participants reporting on two or more days. However, no information was provided about reasons given by patients who provided RCSQ only once, and this information would be required to understand whether this was due to the burden of completing RCSQ or for other reasons not related to the RCSQ, such as patient discharge.

Menear et al. (2017) included 50 general ICU patients reporting on their sleep quality for multiple days; however, they did not specify the duration of this assessment. The RCSQ completion rate was nevertheless high, consistent with the current study at 72%. The rate of participants completing more than one RCSQ was much lower than in this study, however, at 42% as compared to 92.5%. The reason may simply be the small sample size of 50 ICU patients in Menear et al. (2017). Further, the stated reasons that repeated data were not collected from the remaining 29 (58%) participants were not related to RCSQ, consistent with this study.

There remains scant information and limited evidence for the feasibility and acceptability of RCSQ as a standard self-report tool for daily sleep assessment in ICU patients; the use of RCSQ for repeated assessment in ICUs is not frequently published. Only this Arabic study, two Australian studies (Aitken et al., 2017; Meaner et al., 2017) and one North American study (Kamdar et al., 2012) have used RCSQ for repeated measures in ICUs. Nevertheless, these studies' findings on the use of RCSQ for repeated assessment in the ICU (Kamdar et al.,2012, Aitken et al., 2017; Meaner et al.2017), together with the current study's findings, provide some evidence to support RCSQ feasibility and acceptability to patients for routine assessment of patient sleep in ICUs.

The current study also sought additional information about RCSQ-A feasibility and acceptability, including time taken to complete the RCSQ-A and patients' perception of completing daily self-report on their sleep quality using the RCSQ-A; such information was not reported in any previous studies. RCSQ-A was, however, shown in this current study to be a simple assessment tool, with time taken to complete each RCSQ-A being between two and three minutes; thus, patients were able to complete this regularly without excessive burden. The majority of the patients in this study (84%) even described their experience of completing the RCSQ-A during their stays positively. The patients were happy that various of their psychological and social needs were met by this method of assessment. For example, they felt a sense of security, enhanced communication levels, reduced feelings of loneliness, and a sense that someone respected and cared about their need for sleep. A few patients (16%) had some difficulties in completing the RCSQ-A at some point during the repeated assessment; however, the reasons provided by those patients for not completing RCSQ-A were personal and not related to the RCSQ-A, such as feeling tired or bored. This indicates that

acceptability of RCSQ-A may be reduced in tired patients, which might be expected in a critically ill population; however, the proportion of inability to complete the RCSQ-A remained relatively small both in this study and in previous repeated studies (Kamdar et al., 2012; Aitken et al., 2017; Meaner et al., 2017), suggesting that the RCSQ's five items structure is, overall, a non-burdensome tool acceptable to and feasible for the majority of ICU patients.

It is important to mention that more than half of the participants (56.7%) in the current study had physical issues; thus, while they were willing to complete the RCSQ-A, they were unable to complete the instrument themselves because of various barriers such as hand tremors and muscle weakness. These patients required external assistance to set a mark on the paper-based VAS for the RCSQ-A, being only able to point with the tip of their finger at their chosen spot on the VAS; in this study, the researcher then marked the scale accordingly. This is to be expected in a population of ICU patients, and it is consistent with previous studies which mention patients requiring assistance in marking the RCSQ (Aitken et al., 2017, Krotsetis et al., 2017, Ritmala-Castren et al., 2017).

It was not burdensome for the researcher to assist such patients in completing the simple and short five-item RCSQ-A. This is in agreement with previous studies, which reported that RCSQ is an easy to apply tool for sleep assessment in ICU patients (Aitken et al., 2017, Frisk and Nordstrom, 2003, Menear et al., 2017, Nicolas et al., 2008, Ritmala-Castren et al., 2017). Nonetheless, while this situation might be feasible for research, it is less likely to be feasible for everyday clinical use by ICU nurses. The nature of the busy ICU environment and the multiple clinical tasks required of ICU nurses may thus reduce RCSQ feasibility (Bourne et al., 2007). The feasibility and acceptability of repeated

use of the RCSQ-A for ICU nurses should be assessed and considered in future studies with this in mind, as, to date, no studies have provided information about RCSQ feasibility for nurses in ICU clinical practice.

Sekhon et al. (2017) argued that successful implementation of a new measure in the clinical practice depends on the acceptability of that measure to patients, researchers, and healthcare professionals. Thus, the current study considered the acceptability of the RCSQ-A among ICU patients as well as considering the RCSQ-A's feasibility for the researcher based on the effort required for scoring and interpretation. No previous studies had provided information about the feasibility of repeated use of the RCSQ by an evaluator based on effort required.

In the current study, the researcher did identify some burden with regard to the scoring of the five items of the RCSQ-A, as each VAS of the RCSQ-A had to be measured with a ruler from the 0 mm mark to the patient's mark (Richards et al., 2000). In addition, to derive the RCSQ-A total score, the method developed by Richards et al. (2000), involving summing the total scores of the five VAS lines and dividing this total by the number of the items, was applied. The burden experienced by the researcher in scoring the RCSQ-A in the current study can thus be explained by the fact that the researcher had to score multiple RCSQ-A questionnaires at the same time, a situation unlike that seen in real ICU clinical practice, where each nurse has only one patient in a shift during the day, thus achieving completion of only one RCSQ-A. The findings of the current study regarding the feasibility of the scoring the RCSQ-A might thus differ from the effects in ICU clinical practice, as reduced volume should make the task much easier for the nurses. This suggests a need for further studies to consider the

feasibility of the RCSQ-A in everyday clinical use by ICU nurses, based on effort required for scoring.

Additionally, the developers of the RCSQ indicate that higher scores indicate better sleep, but they did not set out cut-off scores to guide interpretation (Richards et al., 2000); thus, previous studies have attempted to set out cut-off scores for RCSQ to make the results of assessment easier to interpret and more meaningful and actionable for both clinical practice and research (Frisk and Nordstrom, 2003, Krotsetis et al., 2017, McKinley et al., 2013, Naik et al., 2018, Nicolas et al., 2008, Ritmala-Castren et al., 2017). In this study, 50 was used as the cut-off point between good and poor-quality sleep, based on Naik et al. (2018) who performed a sensitivity-specificity analysis test. This cut-off score was also used in (Aitken et al., 2017, Chen et al., 2018, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Menear et al., 2017). In contrast, Nicolas et al. (2008) and McKinley et al. (2013) used 70 as the cut-off point between good and poor-quality sleep, based on clinical experience; however, this has not been evaluated analytically, and may under- or over-estimate patients' sleep.

The differences in setting out the RCSQ cut-off scores between studies create an issue, as a valid and unified cut-off score is crucial for use in clinical practice, both to determine the intensity of poor sleep from patients' perspectives and to inform clinical decisions and actions (Machado, 2016, Streiner et al., 2015). As this is an important indication of the RCSQ's clinical utility in everyday practice, there is a need to further evaluate the cut-off scores used in both this study and previous studies (Aitken et al., 2017; Chen et al., 2018; Frisk and Nordstrom, 2003; Krotsetis et al., 2017; Naik et al., 2018).

Table 6- summarises the strengths and limitations of the RCSQ in relation to its use in ICU settings, based on the findings of the current study, as well as the findings from the review of previous studies discussed in Chapter 3 about the psychometric properties, feasibility and acceptability of the daily use of RCSQ in ICU. These strengths and limitations are further discussed in detail in sections 7.1,7.2 and 7.3.

Table 7-1 Summary of the strengths and limitations of the RCSQ in relation to its use in the ICU setting

Strengths	Limitations
It can facilitate the process of assessment of ICU patients' sleep and the effectiveness of the provided interventions. It helps ICU nurses to identify sleep aspects in conscious and oriented patients.	Cannot be used with cognitively impaired patients (sedated, delirious, neurological disorders).
It is a valid and reliable tool for self-reported sleep quality assessment where it can help nurses to identify sleep aspects and differentiate between good and poor sleep quality.	Although 50 was used as the cut-off point between good and poor-quality sleep in the majority of ICU-based sleep studies; there is no unified cut-off RCSQ score to make the assessment results easier to interpret and thus make it more meaningful and actionable for both clinical practice and research.
It is a promising tool for the routine assessment of patient sleep in ICUs. Low-cost, simple, short (five-items), only 2-3 minutes to complete, valid and reliable for patients' self-reporting.	ICU patients with physical stamina may be unable to complete it themselves, requiring external assistance to set a mark on the paper-based VAS for the RCSQ. No evidence about RCSQ feasibility for nurses in ICU clinical practice.
Many positive impacts can be generated when enquiring about patients' sleep using self-reported RCSQ in daily ICU clinical practice, including: patients' psychological and social needs such as feeling a sense of security; enhancing communication levels; reducing feelings of loneliness; a sense of respecting and caring about patient's need for sleep.	

7.3 Quality of ICU patients' sleep

The patients in this study rated their overall quality of sleep as poor and they claimed low sleep efficiency. Their sleep patterns were characterised by light sleep with frequent awakenings, and generally they had difficulty in falling asleep and returning to sleep once awake. These results are consistent with the reported findings of previous studies in populations of ICU patients (Aitken et al., 2017, Frisk and Nordstrom, 2003, Kamdar et al., 2012, Krotsetis et al., 2017, Li et al., 2011, Menear et al., 2017, Nicolas et al., 2008, Ritmala-Castren et al., 2017). However, at 34.41, the overall quality of sleep from patients' perspectives in this study was even lower than in previous studies, where the overall quality of sleep ranged from 42.39 ±19.51 in Murata et al. (2019) to 56±24 in Simons et al. (2018).

These differences may be due to differences in the clinical characteristics of the patients: the mean severity of illness APACHE II score among participants in this study was not very high at 15.78±2.606, while in Chen et al. (2018), the APACHE II score was 26.04±22, yet the overall sleep quality score was 44.76. The method of sleep quality assessment used could also be a reason for differences in the sleep quality results, as the current results are based on repeated measures during patients' stays in the ICU, while the majority of previous studies limited sleep assessment to a single night.

Only three previous studies assessed the quality of patients' sleep using repeated assessment methods (Aitken et al., 2017, Kamdar et al., 2012, Menear et al., 2017), and these studies also showed better self-reported sleep quality as compared to the current study (Aitken et al., 2017, Kamdar et al., 2012, Menear

et al., 2017). Importantly, however, these studies still differed from the current study in significant ways. Two of the studies included only non-intubated patients (Aitken et al.,2017; Kamdar et al.,2012), while in the other study, the majority of patients were not intubated, with only seven patients intubated (Meaner et al., 2017). In contrast, in the current study, 43 mechanically ventilated patients were included.

In addition, differences in the cultures and ICU settings between these studies and the current study, with previous studies carried out in ICU settings that may have guidelines for or better awareness or interest in patients' sleep quality; certainly, locally developed sleep promoting guidelines were in use by the time the studies were conducted by Meaner et al. (2017) and Kamdar et al. (2012). The findings of poor sleep quality in all participants in the current study may thus reflect the poor ICU environment, as there were no formal policies regarding patients' sleep quality within the hospital used for this study. In addition, this is the first study concerned with patients' perception of sleep in Saudi ICU setting, which may indicate a cultural lack of awareness or interest in patients' sleep quality, despite ICU based sleep studies attracting increasing interest in the Western health care context (Aitken et al., 2017, Chen et al., 2018, Krotsetis et al., 2017, Menear et al., 2017, Simons et al., 2018).

The findings of the current study suggested that, overall, patients had light sleep, with depth of sleep as rated in the RCSQ (item 1) rated lowest, with a mean of 31.82±7.03; this is similar to the findings of most previous studies, where the mean aspect of sleep depth is rated below 50 (Krotsetis et al., 2017; Aitken et al., 2017, Chen et al., 2017; Menear et al., 2017). However, in Nicolas et al. (2008), the state of wakefulness (item 3), was the lowest reported score,

being the only item averaging below 50, with a mean of 42 ±29.27 indicating some fragmented sleep in the study sample, but nevertheless showing better sleep depth than the mean reported awakenings in this study which was 35.06±5.76, indicating highly fragmented sleep. Further, the overall mean of self-reported sleep quality in Nicolas et al (2008) was not poor as measured by the cut off lines selected for this study, at 51.42 ±12.7, being better than both that reported in this study and in other studies (Aitken et al., 2017, Hu et al., 2015, Krotsetis et al., 2017). Nicolas et al. (2008) explicitly noted, however, that they observed nurses attempting to create an environment that promoted rest for the patients, which could have affected the results and may explain the better sleep quality seen there. In Frisk and Nordstrom (2003), the mean quality of sleep (item 5) among 31 patients in the general ICU was 39, the lowest among all sleep aspects; this varied from the findings of the current study and the majority of previous studies, where depth of sleep was the worst sleep aspect. Nevertheless, the mean depth of sleep was still rated low, at 40.2, in Frisk and Nordstrom (2003).

Although the variation in reported values of all sleep aspects from the patients' perspective between studies is wide, lack of sleep depth and light sleep are shown to be the main sleep problems for ICU patients both in this current study and in the majority of previous sleep studies. Thus, ICU patients appear to be at more risk of suffering harmful consequences from poor sleep quality, as they are deprived of the most important aspect of sleep (deep sleep), represented by the SWS stage in sleep architecture (Beltrami et al., 2015, Elliott et al., 2011, Delaney et al., 2015, Pisani et al., 2015). Previous studies utilising the gold standard PSG for sleep assessment similarly concluded that there is a predominance of light sleep stages N1 and N2 in ICU patients' sleep, with

corresponding decreases in the most restorative sleep stages, SWS and REM (Beecroft et al., 2008, Elliott et al., 2013, Freedman et al., 2001, Gabor et al., 2003, Trompeo et al., 2011).

The SEI derived from the RCSQ is not often reported; however, in this study, SEI emerged at 60.3%, indicating that patients had reduced sleep time, though this did not differ markedly from the normal range in healthy adults (70 to 85%) (Ohayon et al., 2017). This finding matched the results from a group of ICU patients in the United Kingdom used as a control, in which the SEI was 60.8% (Patel et al., 2014), slightly lower than that reported in a repeated self-report assessment study in Australia (65%) (Aitken et al., 2017), and much lower than that reported in the control group in Taiwan in a sample of non-mechanically ventilated surgical patients in an experimental pre-post study design (69%) (Li et al. (2011). These findings are supported by the findings of PSG sleep studies, which concluded that the mean TST of ICU patients frequently did not differ markedly from the normal range of sleep duration, being about 7 to 9 hours; however, wide individual variations are commonly reported with regard to TST (Boyko et al., 2017, Freedman et al., 2001, Elliott et al., 2013).

7.4 Factors associated with patients' self-reported sleep quality

The finding that patients reported good sleep quality prior the ICU as compared is consistent with previous studies (Bihari et al., 2012, Freedman et al., 1999, Elliott et al., 2014), with patients in the current study perceiving they had a good sleep quality at home prior to ICU admission. This indicates that there are factors within the ICU environment that lead to changes in, and disruption of, patients' sleep.

In contrast, a retrospective study including 56 medical and surgical ICU patients by Stewart et al. (2017) showed that 44% of patients rated their sleep in the ICU as better or unchanged. However, the patients in that study were asked to evaluate their perception of their sleep quality in the ICU and at home prior to hospitalisation on discharge from the ICU, which may have affected the patients' ability to remember their overall sleep quality prior to hospitalisation. The difference in results can further be explained by the different sample structure, as patients with sleep disorders and psychological problems prior to hospitalisation were recruited in Stewart et al. (2017), unlike in this study and most other studies. As patients with sleep disorders and psychological problems prior to hospitalisation are likely to have a reduced quality of sleep prior to hospitalisation, this may have affected the results in Stewart et al. (2017).

This study's findings also showed that patients had daytime sleepiness consistent with poor sleep quality overnight, with a mean daytime sleepiness score of 5.52± 1.52. This agrees with the results of a self-report study in Australia including medical ICU patients by Bihari et al. (2012), in which mean daytime sleepiness

was 5.0± 1.4. This result also in agreement with the polysomnographic studies that show that 40 to 50% of total sleep time in an ICU occurs during the day (Elliot et al., 2013; Freedman et al., 2001).

While daytime sleep could be a result of poor sleep quality, it could also be one of factors contributing to and associated with poor sleep quality (Elliot et al., 2013; Freedman et al., 2001). In this study's ICU environment, the windows in ICU patients' rooms were very small, and no care was taken to arrange a schedule of light to differentiate day and night. This could be a factor affecting patients' daytime sleepiness, which may have an association with sleep quality at night, as natural light can help maintain or restore the natural circadian rhythms by assisting daytime awakening and facilitating night-time sleep (Ohayon et al., 2017, Slater and Steier, 2012). Thus, daytime sleepiness as a factor may correlate with patients sleep quality, as in this study. A fuller discussion of the various factors associated with patients sleep quality is thus presented in the following paragraphs.

Multiple sleep disrupting factors were identified in the current study. In terms of extrinsic factors, patients rated noise as a major cause of high sleep disruption, with a mean score of 7.48 ±1.57. This result is in line with previous cross-sectional Australian studies by Elliott et al. (2014) in 57 general ICU patients and Bihari et al. (2012) in 100 medical ICU patients; these studies also used SICQ to assess patients' perceptions of factors disrupting their sleep, and they reported that noise factors were rated as the highest sleep disruptive factors by participants, with means of 5.70 ± 2.75 and 5.80± 2.70, respectively (Elliott et al., 2014; Bihari et al., 2012).

A Saudi study by Qutub and El-Said (2009) further supported the finding of this study; examining peak sound levels in a Saudi medical ICU setting over a 24-h period, they found that these were high during both day and night. The average daytime volume was 59.7 dB, while the night-time sound level was 58.8 dB. The current study did not objectively measure sound levels in the ICU; as the aim of this study was to identify sleep disrupting factors from the patients' perspective, it was instead the first study to consider such disruptions in terms of patients' perceptions and to assess self-reported sleep disruptive factors on a daily basis in an Arabic-speaking country. However, other studies in different countries have also reported high levels of noise, findings that support the results of this study. The average sound level reported in an Australian study was 52.85 dB (Delaney et al., 2017), and that in a similar American study was 57.58 dB (Scotto et al., 2009). All reported noise levels thus significantly exceed WHO recommendations for sound levels in ICUs, which should not exceed 35 dB during the day and 30 dB at night (Berglund et al., 1999, Darbyshire and Young, 2013). This indicates that high noise levels are an international problem in ICU settings.

The most significant source of noise reported by patients in the current study, was staff talking, with a mean of 6.80 ±1.25, followed by machine alarms at 4.31±2.35. This result contradicts the findings in the control group in the experimental study by Li et al. (2011) in Taiwan, which also used the SICQ questionnaire to assess patient perceptions of sleep disruptive factors. That study reported that machine alarms created the highest perceived level of disruption, with a mean of 6.59±2.66, while sleep disruption from staff talking was reported as having a mean of 4.82±1.04. This difference can arguably be accounted for by differences between ICU environments, as well as by differences in staff behaviours between ICU settings.

When the tool used for assessment lacks validity and reliability, it is well known that a source of measurement error can be generated. The present study used a modified SICQ to assess patients' perception of sleep disruptive factors, but this was only piloted with a panel of three experts who are recognised for their expertise in the study areas, the ICU and sleep medicine unit. In addition, it was tested and reviewed for content validity with the 57 ICU patients during the pilot test. This was to ensure that the modified SICQ was an appropriate fit for both patients' cultural backgrounds and the ICU environment in the Saudi context, as well as avoiding measurement errors as far as possible. The appropriateness and usefulness of the modified SICQ were confirmed in the pilot test with the target population.

Because the SICQ requires ICU patients' perception of a variety of sleep disruptive factors during their stay in the ICU; reliability and validity tests are not applicable and cannot be performed with SICQ. The nature of self-reported sleep disruptive factors within the ICU environment are multiple and vary among individual ICU settings, countries, patients' cultures or treatments and healthcare providers' behaviours. The sheer multitude of factors that contribute to sleep disturbances and the variations in reporting these factors among ICU sleep studies, indicates that sleep disrupting factors are not identical between ICU clinical settings. This highlights the importance of adapting and testing the SICQ within the target patients being studied in a specific ICU setting, which can be done by removing any items that do not apply in a given ICU environment or adding any items that the researcher deems necessary based on patients' answers (Bihari et al., 2012, Elliott et al., 2014, Li et al., 2011). The current study's findings showed a negative and significant correlation between noise and patients' self-reported sleep quality based on multiple regression (B= -1.033,

p=0.003). This finding is in agreement with a cross sectional study by Simons et al. (2018) in the Netherlands, which used regression analysis to assesses the associations between noise factors and patients' self-reported sleep quality using RCSQ in 64 patients from three different ICUs. Patients were also asked to indicate which noise they found the most disrupting during the night, and the majority of patients (n=49) cited monitor alarms as being the most disturbing, followed by staff speech (n=9), and staff activities (n=6). Regression analysis on that also data revealed that noise factors were negatively and significantly associated with patients' sleep ($\beta = -0.51$, $p < 0.05$).

According to the assessment of daily self-reports of sleep disruptive factors in the current study, other factors beside the noise factor were rated by the patients as disruptive; however, these factors were evaluated differently day-to-day and patient-to-patient, despite the constancy of the setting. This confirms that there are multiple sleep disrupting factors in addition to the impact of noise as identified by participants in this study. The study's findings thus do not support the hypothesis that ICU noise is the main factor responsible for sleep disturbance for all ICU patients as strongly as those of earlier studies (Aaron et al., 1996, Hilton, 1976, Falk and Woods, 1973).

Previous polysomnographic studies that correlated PSG data to environmental noise monitoring also support this study's findings that the noise factor is not solely responsible for the majority of sleep disturbances in ICU patients. Freedman et al. (2001), Cabello et al. (2008), and Gabor et al. (2003) all found that noise contributed directly to only 11.5% to 24% of arousals and awakenings. These findings provide evidence that other factors must be involved in interrupting the sleep of ICU patients.

The current study results support the idea that interruptions of sleep in the ICU are caused by clinical interventions during the night, with clinical interventions scoring relatively high on the SICQ with a mean of 5.95 ±1. This suggests that nurses' care activities contribute to patients lacking the necessary amount of sleep in ICU settings. This finding is supported by the results of a cross-sectional study in Turkey by Celik et al. (2005) which examined 60 patients in a medical ICU. Data regarding nursing care activities were gathered by means of retrospective examination of the nursing chart notes, and the researchers found that patients had their sleep interrupted by human-led interventions an average of 51 times each night.

In contrast, Gabor et al. (2003), who worked with seven medical and surgical ICU patients in Canada, reported that machine alarms and staff conversations were the most disruptive environmental factors for patients, with few sleep disruptions generated by nursing activities. The differences in the prevalence of care activities in that study and previous studies, and thus the discrepancies in their assessment of contributions to sleep disruption in ICU patients, can arguably be accounted for by differences in ICU design and nursing activities and workloads. In addition to these factors, however, psychological factors should not be ignored.

Patients reported fear as the most disruptive intrinsic factor in the current study; they also referred to nightmares and worries, corroborating previous studies' findings. In a German study by Krotsetis et al. (2017) featuring 51 patients from cardiac, surgical, and trauma ICUs, a predominance of worries and fears was a frequently reported reason for disrupted sleep (*n*=15), followed by arousal by staff (*n*=6) for care interventions, and the noisy environment (*n*=5).

An Australian study by Aitken et al. (2017) in 151 medical and surgical ICU patients also identified fear and worry as being prominent among the many factors reported by patients as disruptive to sleep, which otherwise included patient care activities, pain, discomfort, noise from staff and equipment, vivid dreams, and light levels. The results of the present study further identified that other variables were not associated with poor sleep quality, including the severity of illness, age and length of ICU stay, but this need to be adjusted unless it can be supported with individual correlational analyses data.

Patients' sleep quality was significantly associated with gender, with female patients experiencing better sleep than male patients (B=1.836, p=0.032). A polysomnographic study by Freedman et al. (2001), who assessed the sleep quality of 22 medical ICU patients in the USA for 48 hours, was in agreement with these findings, suggesting that length of stay in the ICU, severity of illness, and age did not correlate with patients' sleep quality.

Freedman et al. (2001) also reported that gender was also not correlated with patient sleep, however, though that study included only 12 males and 10 females, while the current study had a larger sample size featuring 72 males and 48 females. This larger sample size may have allowed the correlation between sleep quality and gender to emerge more obviously, though the sample characteristics could also have affected the correlation results. For example, the mean age of the current study's participants was 59.7±9.44, with ages ranging from 19 to 75; however, the majority (87%) of participants were aged between 50 and 75. In Freedman et al.'s (2001) study, the mean age was 61±16, with participants being between 40 and 62 years of age; none of their study sample was younger than 40 years old, and thus a relationship between age and sleep

was unlikely to emerge. Further, none of the participants in the current study had a high severity of illness as compared to ICU patients in general, with a mean APACHE II score of 15.78 ±2.606 based on scores ranging from 10.00 to 24.00; in contrast, none of the participants in Freedman et al's study had a low severity of illness, with the mean APACHE-II score being relatively high at 57±6, and scores ranging from 40 to 59.

The finding of the current study that gender difference is significantly correlated with patient sleep quality is in line with two previous self-report studies: Bihari et al. (2012), in 100 medical ICU patients, with a mean age of 63.2 ± 16.7 years; and Simon et al. (2019), in 64 patients with a mean age of 63.9± 11.7 years. These studies also used multiple regression analysis and reported that gender had significant relationship with patient sleep, with female patients experiencing better sleep than male patients (β = 1.25, $p < 0.01$, B=1.90, $p< 0.01$, respectively). Bihari et al. (2012) also found that neither length of stay in the ICU nor severity of illness correlated with patients' sleep quality, in agreement with the current study's findings. However, in contrast to the current study, Bihari et al. (2012) demonstrated that age had significant relationship with patient sleep quality, with older patients sleeping better in the ICU than younger patients. The differences in sleep disrupting factors between the current study and previous studies can be explained by the different nature of ICU environments, the duration of the study period, and by factor assessment, as the current study utilised repeated measures until patients were discharged from the ICU, while the majority of the previous studies have limited their assessment to shorter periods, often only one night (Elliott et al., 2014, Frisk and Nordstrom, 2003, Krotsetis et al., 2017, Nicolas et al., 2008, Simons et al., 2018).

Furthermore, the demographic and clinical characteristics of study participants affect their subjective perceptions of sleep quality and the factors they perceive as disruptive to their sleep, playing important role in the differences emerging between results. None of the patients were on sedation during the current study, though data on previously administered sedation was gathered. Overall, 54 (45%) patients had been prescribed Propofol, 40 (33.3%) benzodiazepines (Midazolam), and 26 (21.7%) dexmedetomidine (Precedex). The findings showed that previous use of both benzodiazepines and Propofol were significantly and negatively correlated with patients' sleep quality ($B= -6.424$, $p<.0005$; $B = -3.600$, $p = 0.001$, respectively). The adverse effects of sedatives, especially Midazolam and Propofol, in terms of suppressing SWS and REM sleep and increasing incidence of delirium have been well documented, and sedatives are thus not recommended for sleep promotion in ICU patients (Devlin et al., 2018); any patients receiving these medications should thus be particularly carefully monitored with regard to the quality of their sleep (Devlin et al., 2018, Bihari et al., 2012).

The data collected regarding sedatives prescribed to participants in this study reflected only previous receipt of sedatives, which means that patient sleep quality may have been different during the period of sedative administration. However, this was not possible to examine in this self-reported study, as sedatives are well known to affect cognitive abilities and concurrent use would therefore affect the validity of the results. This study did cover a very important period of patient sleep quality assessment, the time directly after sedative cessation, when sleep quality may be influenced by previously received sedation; assessment of sleep during this period was thus deemed a priority.

This study's findings regarding sedation correlation with patient sleep were supported by the results of a randomised double blinded trial in 66 surgical ICU patients carried out by Engelmann et al. (2014), who sought to compare the effects of Propofol and a benzodiazepine on ICU patients' sleep quality. The day after sedation cessation, once the patients were fully conscious, they were asked to judge several aspects of sleep quality. The results identified that the maximum a state of wakefulness at night reported by those in the Propofol group was significantly lower than that reported by the benzodiazepine group (6 vs 30; p >0.001); however, both groups reported poor ability to fall asleep, and total sleep duration was low for both groups (Engelmann et al., 2014), indicating adverse effects on patient sleep quality from previously received sedation.

In a polysomnographic study by Elliott et al. (2014) that measured sleep quality over a 24-hour period for 45 patients in the ICU, only lightly sedated patients were included; 53% of the sample were given benzodiazepine (Midazolam) or Propofol sedation during recording, with around half being on mechanical ventilation (54%) during recording. Elliott et al. (2014) reported that the mean arousal indices were significantly decreased in those patients receiving Midazolam or Propofol sedation (30.00 vs. 22.00; p=0.019), while the presence of mechanical ventilation during sleep monitoring was positively associated with PSG sleep data (p=0.004), indicating that patients' sleep may be improved in the presence of mechanical ventilation or when sedative medications are administered.

These results regarding the association of mechanical ventilation and sedation with patients' sleep quality contradict the current study's results, which indicate

that the presence of mechanical ventilation is negatively associated with sleep in ICU patients and that sedatives are also negatively correlated with patient sleep. However, Elliot et al. (2014) measured sleep only for a single 24-hour period during patients' ICU stays, with patients under sedation and mechanically ventilated. Thus, they did not develop an understanding of whether patients' sleep changed after discontinuation of sedative use or after the removal of mechanical ventilation. In the current study, 43 patients were on mechanical ventilation at some stage in their ICU stays, and their perceptions of sleep quality as well as their perceptions of sleep-disruptive factors were assessed on a daily basis both during intubation and after extubation, allowing investigation of whether the ventilator played a role in these patients' perceptions of sleep and the factors that disrupted their sleep.

This study's results showed that intubated patients reported better sleep quality following extubation and that the differences were statistically significant (31.88± 6.16 vs 35.04 ±6.47, $p < 0.0005$); however, although this difference had a large effect size ($d=1.9$), reported sleep was poor in both situations. To date, there is no information or guidance about assessing clinically important changes in RCSQ scores, and thus it is difficult to make much of this result. The participants in the current study did, however, report sleep fragmentation to be greater during intubation.

Furthermore, during ventilation, the factors of machine alarms, clinical-interventions, and fear were rated by the patients as being most disruptive, while after extubation, the level of disruption from all of these reduced significantly. One possible explanation for high sleep-fragmentation during intubation is thus the disruptive factors that arise from, or are increased by, the

presence of the ventilator, such as alarms, clinical interventions, and feelings of fear. During ventilation, noise was rated as being the most significant extrinsic sleep-disruptive factor, causing patients a high level of disturbance (8.10 ±0.92), followed by clinical interventions (7.04 ±2.04). The highest-rated noise disturbance was talking (7.96 ±1.43), followed by machine alarms (7.19 ±1.13). Fear was rated as the highest intrinsic factor, causing a moderate level of disruption (6.32 ±1.81). Following extubation, there was a significant decrease in all reported factors ($p > 0.05$).

The current work is the only self-report study thus far to have obtained data about patients' sleep quality and sleep disruptive factors both during ventilation and after extubation; thus, these findings are most comparable with those polysomnographic ICU sleep studies (Beecroft et al., 2008, Freedman et al., 2001, Gabor et al., 2003, Trompeo et al., 2011), which have documented the negative influence of mechanical ventilation on patients' sleep quality. In Freedman et al. (2001), sleep-wake patterns were characterised using a PSG sleep monitor for 48 hours in 22 medical ICU patients. The majority of patients were mechanically ventilated (n=20) and not sedated and were thus examined under similar circumstances to the current study. Freedman et al. (2001) demonstrated that patients' sleep was highly fragmented, while noting that environmental noise was only responsible for 17% of awakenings. The majority (71.5%) of arousals in participants were postulated by those researchers as being the result of patient-ventilator dyssynchrony in conjunction with the clinical interventions, such as suctioning and the administration of treatments, that are frequently required when mechanical ventilation is used (Freedman et al., 2001).

The findings of both Freedman et al. (2001) and the current study stress the need for additional attention to be paid to the sleep quality of mechanically ventilated patients. In particular, environmental factors such as noise from alarms should be carefully considered, and any impacts should be handled properly by following guidelines such as the Joint Commission (JCI) policies on safely managing clinical alarm systems to avoid false alarms (Sendelbach and Funk, 2013, Joint Commission, 2013). Furthermore, where mechanical ventilation is present, patients may experience additional distressing psychological side effects such as fear (McKinley et al., 2013), making it important to consider the individual patient's psychological needs. When considering the ICU patient population's sleep quality, particular attention should thus be paid to those who receive mechanical ventilation.

Although there are some differences between the outcomes of the current study and previous ICU-based sleep studies in terms of reported values of sleep quality and reported sleep disruptive factors, the results overall correspond with the conclusions in previous studies: ICU patients suffer from poor sleep quality and multiple factors disrupt their sleep, including environmental and clinical or demographic factors.

Overall, the full model of the six predictors (Midazolam, Propofol, gender differences, noise, daytime sleepiness and mechanical ventilation) is seen to explain 39.3% of the variation in the sleep quality. This means that many other factors in ICU are likely to be associated with patients' sleep quality; for example, light, clinical interventions and fear factors, which are not shown in the model. This may be due to the small sample size (n=120) and the diverse nature of participants' demographic and clinical characteristics, as well as sleep

disruption factors. Although the current study reached the pre-specified targeted sample size (n=120) based on the sample size calculation, a larger sample size might have yielded more reliable data. It is likely that patients' sleep disruption is influenced by several interrelated factors, which are not only diverse but also change constantly due to the dynamic nature of the ICU environment and patients' clinical situations, meaning that associations are difficult to assess and measure. Variations in sleep disruptive factors were clear, with different sleep disruptive factors reported by the participants from day-to-day, and recurring ones evaluated differently from patient-to-patient despite all patents staying in the same ICU. This highlights the importance of routinely enquiring about patents' perceptions of sleep disruptive factors and considering individual sensitivity to sources of sleep disruption when developing interventions or protocols for improving ICU patients' sleep quality.

Unfortunately, individual differences have not been considered in most recent intervention studies aiming to improve sleep in the ICU by developing and applying protocols (Hu et al., 2015, Li et al., 2011, Patel et al., 2014). Recent guidelines by SCCM (Devlin et al., 2018) also reveal problems with the methodology used in many intervention studies, highlighting the need for well-designed nonpharmacological measures to allow the implementation and assessment of interventions with individualised approaches.

7.5 Strengths of the study

The current study has several strengths. This is the first study to translate the RCSQ into Arabic (RCSQ-A), and the translation process strictly followed the

WHO’s gold standard protocol for tool translation and validation(World Health Organisation, 2017). What is more, the translation process was overseen and approved by experts in the appropriate medical fields at each stage. The report of the translation of the RCSQ-A derived from the current study has been now been published, showing that it has a place in the global context of the use of sleep assessment tools.

The current study is also one of the few international studies to use RCSQ in a repeated measures study throughout patients' stays in the ICU to report feasibility of use in practice (Aitken et al., 2017, Kamdar et al., 2012, Menear et al., 2017), as well as being the first study to assess ICU patients' acceptance of completing daily self-reports on the quality of their sleep. The repeated measures method applied in this study to determine patients' self-reported sleep quality and sleep disruptive factors simultaneously each morning facilitated the reduction of recall bias, as well as allowing the researcher to obtain a comprehensive picture of patients' sleep quality and to identify common sleep disruptive factors in the ICU; as results were not based on a single point assessment, the validity of the results was enhanced.

The data collection tools in this study were piloted on a sample of Arabic-speaking ICU patients. Thus, the appropriateness and usefulness of the tool with regard to patients' cultural backgrounds in the Saudi ICU context was assured and confirmed. Further, data acquisition was conducted by a single researcher within this study, ensuring that a similar approach was applied to all participants, reducing the possibility of performance bias and strengthening the validity of data collection.

The current study was the first study seeking data from patient's perspectives of their sleep quality and sleep disruptive factors in Saudi Arabia, despite sleep quality being highly subjective and patient experience affecting clinically meaningful outcomes (Aitken et al., 2017). Thus, it has established a baseline for examining patients' self-reported sleep quality and self-reported sleep disruptive factors in Saudi ICUs that should facilitate comparison across other Middle Eastern countries in the future. This addresses an important gap in current literature identified in this thesis's literature review.

In terms of the characteristics of ICU patients, unlike other self-report studies (Aitken et al., 2017, Frisk and Nordstrom, 2003, Kamdar et al., 2012, Krotsetis et al., 2017, Li et al., 2011, Nicolas et al., 2008), the current study assessed sleep quality and sleep disruptive factors both during periods of patient intubation and after extubation. This greatly improves the generalisability of the study findings s more than half of all ICU patients are intubated at ICU admission (Wunsch et al., 2010). This also addresses a key gap in the literature in terms of the understanding of self-reported sleep quality of patients whilst intubated. Results of self-reported sleep quality and self-reported sleep disruptive factors during intubation and after extubation in groups of intubated patients have not been offered in previous self-report studies, despite the inclusion of intubated patients (Chen et al., 2018, Frisk and Nordstrom, 2003, Hu et al., 2015, Krotsetis et al., 2017, Menear et al., 2017).

7.6 Study Limitations

As important as the study findings are in terms of contributing to the broader evidence base on sleep quality in patients in ICU settings, there are a number of limitations which must be acknowledged when considering these findings. The

current study was conducted in a mixed medical and surgical ICU in just one hospital in Saudi Arabia, and this restriction to a single hospital limits the generalisability of the findings to this specific ICU context. In future research, recruitment within a multicentre design should be considered to give advanced insight into patients' perceptions of sleep quality and sleep disruptive factors, as well as RCSQ-A reliability, validity, feasibility and acceptability in the context of other Saudi ICUs or those in other Middle Eastern countries more generally.

The results for internal consistency and reliability and the cognitive interviews conducted for Phase 1 of this study on the RCSQ-A were derived from a small sample of 57 ICU patients. Thus, the results may not be generalisable to all ICU patient populations, particularly as the majority (63%) of the patients evaluated were surgical ICU patients, none of them was over 66 years old and their severity of illness was not very high. Further work on the utility of the tool in broader populations such as older people and people with more severe illnesses would thus be welcomed.

The present study provided promising preliminary evidence of the reliability and validity of the Arabic version of the RCSQ-A for assessing sleep quality in Arabic-speaking ICU patients. The RCSQ-A criterion validity (the extent to which it correlates with the gold standard for sleep assessment PSG) and the RCSQ-A equivalence (patient-nurse inter-rater reliability when using the RCSQ) were not assessed in the current study, as the focus in the current study was to assess its internal consistency and content validity as properties that should be considered as first steps in the process of translation and adaptation of the original RCSQ in Arabic speaking ICU patients. It would thus be valuable to further validate the

RCSQ-A against the gold standard PSG monitoring to assess its inter-rater reliability in the Arabic speaking ICU populations.

The findings of phase two in the current study demonstrated that the RCSQ-A was feasible and acceptable to the majority of the participants; however, there were three patients who dropped out during the repeated measures phase, and reasons for these cessations are unknown, so they cannot be identified as being related to the RCSQ-A or to the patients themselves. Further, more than half of the participants were unable to complete the RCSQ-A themselves, requiring external assistance to complete it. While it was not burdensome for the researcher to assist such patients in completing the RCSQ-A, it was challenging for the researcher to measure and score the five items of the RCSQ-A for a number of patients each day, and both of these factors have implications for the practical utility of using RCSQ-A in clinical practice due to workload impacts on ICU nurses. This suggests a need for further studies to consider the feasibility and acceptability of the RCSQ-A in everyday clinical use by ICU nurses, as this was not assessed in the current study.

The 120 participants in phase two of this study were recruited consecutively, from all accessible and eligible patients over a long period (three months) in an attempt to reduce any potential recruitment bias while improving the sample size. However, selection bias cannot be completely ruled out as the sample was not gathered using probability sampling. Selection bias may also have occurred as all selected patients were non-sedated. While this was necessary, as sedatives affect cognitive abilities and would therefore, affect the validity of the results, it may mean that the results may not be generalisable to the whole ICU patient population. Despite this, an important patient population was studied, as this

study included patients just after sedation cessation, making regular assessment of sleep quality as affected by previously received sedation possible.

The other concern with the findings' generalisability includes the fact that patients with pre-existing sleep pathologies or neurosurgical issues were not included. This could be considered a study limitation, as such patients' perceptions of sleep may have been different.

Nevertheless, the risk of bias was limited by the application of strict inclusion and exclusion criteria. Although the study reached the pre-specified targeted sample size (n=120) based on the sample size calculation, a larger sample size might have yielded more reliable data. Due to the diverse nature of participants' demographic and clinical characteristics and sleep disruptive factors, when studying sleep in ICU patient populations, larger sample sizes are indicated. This study also did not control for underlying disease states, varying diagnoses, or general medications, as the researcher was interested in evaluating sleep quality in a heterogenous population of ICU patients. This meant, however, that the study was unable to study any correlations between patients' diagnoses and medications and patients' self-reported sleep quality; it was not possible to study the correlations of the medications either in combination or in terms of their individual associations with self-reported sleep quality.

7.7 Headline findings

This thesis developed an Arabic version of the most valid and reliable current tool for self-reporting on the quality of sleep in ICU patients, the RCSQ (RCSQ-A). The RCSQ-A showed evidence of content validity and internal consistency for self-reported sleep quality assessment in ICU patients. The RCSQ-A was shown to be feasible and acceptable for ICU patients, though self-completion of the RCSQ-A required external assistance. It is thus suggested that the instrument might be effective for daily routine use for self-reporting of sleep assessments in Saudi ICU clinical practice, and its feasibility and acceptability of repeated use among ICU nurses should thus be assessed and considered in future studies.

There was also evidence that ICU patients suffer from poor sleep quality, while the reported factors disrupting sleep were multiple and highly varied. The most highly rated factors included noise (e.g. talking, machine alarms), clinical interventions, and fear. Factors that were emerged from the multiple regression modelling that were associated with patient self-reported sleep quality, included previous receipt of Midazolam and Propofol sedation, daytime sleepiness, sex differences, noise, and the presence of mechanical ventilation.

However, this thesis should be viewed mainly as groundwork to be built upon; further research is required to strengthen, expand on, and confirm the findings contained herein.

7.8 Recommendations

7.8.1 Key recommendations for clinical practice

Based on the findings of this repeated measures study, there is evidence for poor sleep quality and poor ICU environments in terms of promoting sleep in current

ICU settings in Saudi Arabia. Some suggested strategies for daily practice in ICUs in Saudi Arabia are thus offered to help to evaluate and improve patients' sleep quality; these suggested strategies could also be adapted to other ICU settings.

- ICU nurses should routinely enquire about the patients' sleep using RCSQ-A and implement routine early documentation of patients' sleep in patient care plans.
- The evaluation of patients' sleep should be done alongside individual enquiries about patients' perceptions of any factors disrupting their sleep during the previous night. Further, patients should be involved in such assessment and in the resulting care, including the identification of specific needs to address any sleep disturbances arising from individual treatment decisions.
- Evaluation should follow the structure of the nursing process, including needs assessment, sleep assessment with individual identification of reasons for sleep disruption, sleep promoting interventions, and evaluation of the effects of such interventions.
- Various different interventions are required to improve the ICU environment in general. Promising interventions include those addressing of sleep hygiene factors, such as the provision of a quiet and dark environment at night (avoiding false machines alarms; avoiding conversations around the bed spaces; timed dimmers on the main lights between 23:00 and 07:00); more careful planning and clustering of night time nursing care; supporting comfortable bed positions; identifying patient's sleep habits, and enabling and supporting these; promoting daytime daylight exposure; and regularly orientating patients with regard to time, place, and date.

- Sleep evaluation practices in ICU settings should be included in hospital orientation programs to improve nurses' knowledge and practice with regard to sleep evaluation.

7.8.2 Key recommendations for future research

Notwithstanding the efforts of the current thesis to improve sleep evaluation in Arabic-speaking ICU patients by developing an Arabic version of a valid and reliable instrument to assess self-reported sleep quality in ICU patients, in terms of expanding knowledge about the feasibility and acceptability of the RCSQ-A in ICU clinical practice, and of developing knowledge about the quality of patients' sleep and the factors that disrupt that sleep in Saudi ICU clinical practice, several gaps persist. Several areas relating to evaluating or improving patients' sleep in ICU settings that require further research have thus emerged from this thesis.

This present study provided promising preliminary evidence of the reliability and validity of the Arabic version of the RCSQ-A for assessing sleep quality in Arabic-speaking ICU patients. There is a need for further studies with larger, more diverse samples to evaluate and expand on this finding in diverse ICU populations in various Arabic-speaking countries.

- Further studies are required to assess patients' self-reported sleep quality using the RCSQ-A alongside assessment of sleep disruptive factors in other ICU settings in Saudi Arabia to enhance knowledge of ICU patients' perceptions of sleep quality and sleep disruptive factors in Saudi Arabia, which is currently insufficient.

- This thesis suggests the adoption of a mixed quantitative and qualitative study designs using RCSQ in repeated measures studies to further evaluate the acceptability and feasibility of the repeated use of self-report RCSQs among ICU patients in general, and in Arabic settings using the RCSQ-A in particular for future studies. Evidence for such acceptability and feasibility remains limited and insufficient globally, and this would thus be useful in terms of gaining further understanding of patients' experience of providing daily self-report RCSQs about their sleep quality.
- Future studies should also consider the acceptability and feasibility of the daily clinical use of the RCSQ for nurses in ICU clinical practice, as the study findings here highlight potential implications for nurses' workloads, which have important ramifications for the successful implementation of the RCSQ in ICU clinical practice.
- Scoring and calculating the items of the RCSQ-A was challenging and this highlighted the need to think about how this can be better managed in ICU clinical practice, where time is strictly limited. One option might be to develop a computerised scoring algorithm that enables quick and accurate scoring in ICU clinical practice; however, this would then need to be assessed in future studies.
- In the current study, a cut-off score of 50 for the RCSQ-A was used to distinguish between good and poor-quality sleep, based on Naik et al. (2018), who performed a sensitivity-specificity analysis test. However, there is a need for further evaluation and validation of cut-off scores for RCSQ, as, to date, no unified and valid cut-off score has been produced for the RCSQ. This is an important issue that future studies must address

in order to make the results of RCSQ assessments easier to interpret and more meaningful and actionable in both clinical practice and research.

- The SEI has not been often reported in ICU sleep studies, and the formula used in the current study, derived from the RCSQ, was based on the initial validation of RCSQ against PSG in just 60 medical ICU patients. Thus, future studies need to report on the use of this formula for SEI and to evaluates its validity against PSG in diverse groups among ICU populations.

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Appendices

Appendix 1: Approval letter from King Abdul Aziz Hospital Research Ethics Committee

NGDOM OF SAUDI ARABIA
Ministry of Higher Education
NG ABDULAZIZ UNIVERSITY
Faculty of Medicine

المملكة العربية السعودية
وزارة التعليم العالي
جامعة الملك عبد العزيز
كلية الطب

FM: .....
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التاريخ : / / ١٤هـ
المرفقات: .....

UNIT OF BIOMEDICAL ETHICS
Research Committee

Initial Approval

TO: Principal Investigator and Local Supervisor: Dr. Faris AlHejaili
(Pulmonary and Sleep Medicine Consultant.)
Co-Investigator: Ghaida ALSulami
Co-Investigator: Joan McPeak
Co-Investigator: Dr.Ali Alfaidhi

From: Professor. Hasan Alzahrani
Co-Investigator: Ann Marie Rice
Co-Investigator: Prof.Siraj O. Wali

Date: Thursday, January 25, 2018
CC:Vice-Dean, University /Hospital Director & Academic Affairs & File & Mentoring Committee

RE: " Sleep quality and sleep disturbance factors in intensive care unit (Developing sleep enhancement protocol) in King Abdul-Aziz University hospital." Non Intervention / Cohort (Reference No 11-18)

The above titled research/study proposal has been examined with the following enclosures:

- Application for Research Unit of Biomedical Ethics. KAU FoM Form.
- Data Collection Sheet.

The REC recommended granting permission of approval to conduct the project along the following terms:

1. The PI and Investigators are responsible to get Academic Affairs, hospital and departmental approval. , according to bylaws they must get the administrative approval from organization collaborators outside KAUH .
2. Provide to committee" Continuing Review Progress Report "every 3 months.
3. The Investigators will conduct the study under the direct supervision Dr. Faris AlHejaili.
4. Any amendments to the approved protocol or any element of the submitted documents should NOT be undertaken without prior re-submission to, and approval of the REC for prior approval.
5. Monitoring: the project may be subject to an audit or any other form of monitoring by the REC.
6. The PI and Investigators are responsible for the storage and retention of original data of the study for a minimum period of five years.
7. The PI and Investigators are expected to submit a final report at the end of the study.
8. The PI and Investigators must provide to REC a conclusion abstract and the manuscript before publication.
9. To follow all regulations issued by the National Committee of Bio & Med ethics - King Abdul Aziz City for Science and Technology.

Kindly note that the committee does not disclose names of any of its members, however we confirm compliance with the above mentioned Saudi National Committee sections and we confirm that the PI is not part of the ethics committee.
The committee is fully compliant with the regulations as they relate to Ethics Committees and the conditions and principles of good clinical practice.
The Organization & operating procedure of the KAU. Faculty of Medicine - Research Ethics Committee (REC) are based on the Good Clinical Practice (GCP) Guidelines.
Please note that this approval is valid for one year commencing from the date of this letter.

Professor Hasan Alzahrani
Chairman of the Research Ethics Committee

(HA-02-J-008) No of Registration At National Committee of Bio.& Med. Ethics.
Mohammed S. ALsearee (Reference No 11-18)

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☎ : 6952063 / 6952063

Appendix 2: Permission letter from the medical director of the adult critical care unit

King Abdulaziz University Hospital
Jeddah

مستشفى جامعــة الملك عبد العزيز
جــدة

Ref. :

Date : January 19 , 2018

الإشارة :

التاريخ :

Permission Letter

Project Title: Sleep quality and sleep disturbance factors in intensive care unit (Developing Sleep Enhancement Protocol) in King Abdul Aziz University Hospital

The above titled research study had been examined with the following enclosures:

- [ ] Detailed protocol
- [ ] Data collection sheets
- [ ] Approval letter by Unit of Biomedical Ethics Research Committee KAU.

The detailed protocol and Data collection sheets have been read and understood and there will be no any effects on the treatment or recovery of the included ICU patients in the project.

I hereby to give a permission for this project to be conducted in Critical Care Unit (Medical ICU and Surgical ICU).

Thank you.

Sincerely Yours,

Dr. Ali Al Faydhi
Medical Director
King Abdulaziz University Hospital
Jeddah Saudi Arabia
Tel#: 640.1000 ext: 18335

ص.ب. 80215 ، جدة 21589 برقياً : جامعة الملك عبدالعزيز تلكس : 600800 يوني هوس فاكس : 6952538 ☎ 6952088 - 6401000
P.O. Box 80215, Jeddah 21589 Cable : Jameatabdulaziz Tlx : 600808 UNIHOS SJ Fax : 6952538 ☎ 6401000 / 6952088

Appendix 3: Approval letter from the University of Glasgow College of Medicine, Veterinary, and Life Sciences

University of Glasgow

Dear Dr Ann Marie Rice

MVLS College Ethics Committee

Project Title: *Sleep quality and sleep disturbance factors in intensive care unit in Saudi hospital*
Project No: 200170066

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. In reviewing the materials we note that approval for the clinical study has been given by a local Research Ethics Committee and that this application was around analysis of data in Glasgow. We are happy therefore to approve the project, subject to the following conditions:

- The data should be held securely for a period of **ten years after the completion of the research project** (*NB at the moment the materials describe storing the questionnaires for a shorter period, this should be amended to align with University policy*), or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research:
(http://www.gla.ac.uk/media/media_227599_en.pdf)

- The research should be carried out only on the sites, and/or with the groups defined in the application.

- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.

- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dr Terry Quinn

Terry Quinn
FESO, MD, FRCP, BSc (hons), MBChB (hons)
Senior Lecturer / Honorary Consultant

College of Medicine, Veterinary & Life Sciences
Institute of Cardiovascular and Medical Sciences
New Lister Building, Glasgow Royal Infirmary
GlasgowG31 2ER
terry.quinn@glasgow.gla.ac.uk
Tel – 0141 201 8519

Appendix 4: Regulation for research Furth of Glasgow to carry out the study in Saudi Arabia

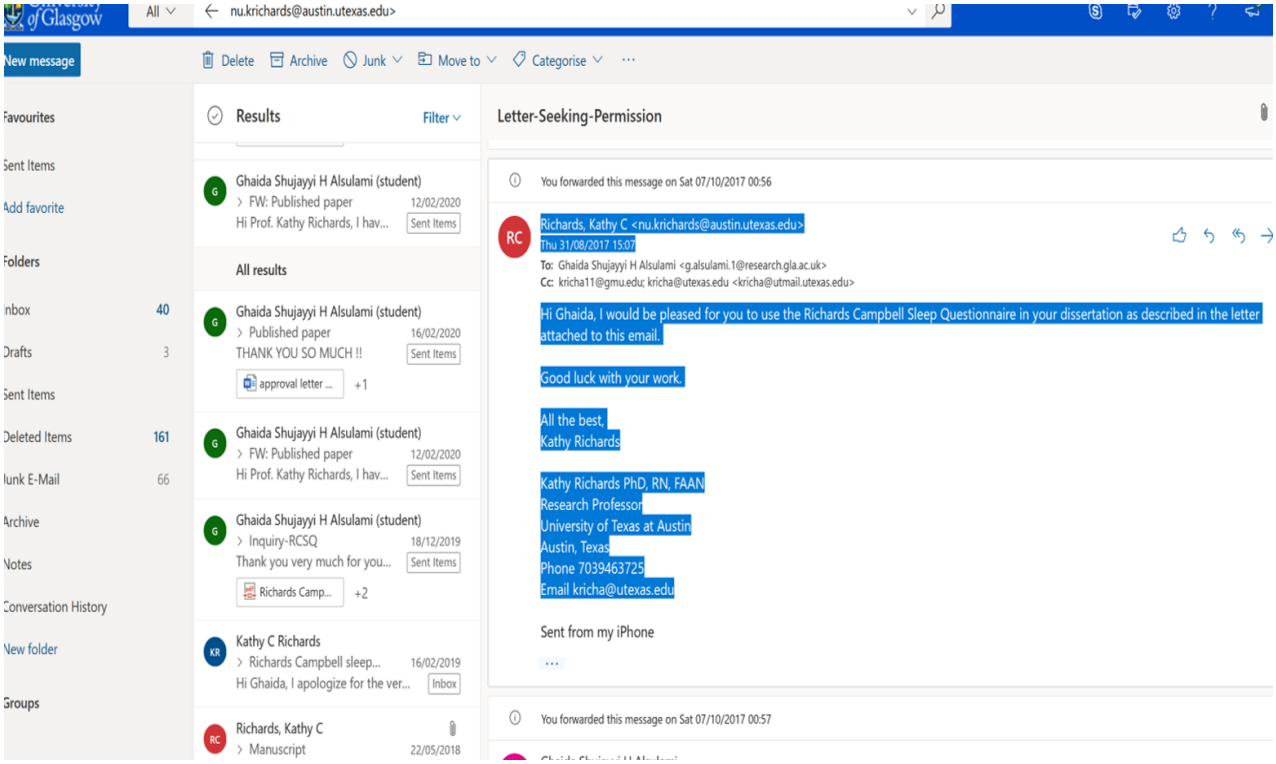
UNIVERSITY OF GLASGOW
Graduate School of Medical, Veterinary and Life Sciences

Application to Pursue Research Furth of Glasgow
Note: for fieldwork you **must** also attach a completed risk assessment form
All sections are mandatory

Student Name: Ghaida Shujayyi Alsulami	**Student Number: 2166896A**	
Academic group or MRes Course: MVLS		
Purpose and location of research furth (it must be justifiable as essential to your research degree or MRes placement work)	To start data collection. Participants will be ICU patients, researcher expects that it may be not easy to find patients meet this study's inclusion and exclusion criteria. Therefore, the researcher needs 3 months for the pilot study and main study as a maximum period for data collection to recruit a relatively large sample. Location : King Abdul Aziz University Hospital in Jeddah city . Saudi Arabia.	
Proposed dates of period away:	**From: 01/05/2018**	**To: 29/07/2018**
Full Contact Address of organisation, including Post Code:	Prince Majid Road , Alsulaymaniyah. 22252 Jeddah city- Saudi Arabia	
Contact Telephone Number of organisation:	Tel: 00966 6408222 Fax: 6952538	
Contact email address of organisation	unihos_sj@kau.edu.sa	
Arrangements for contact with GU Supervisor (*e.g. regular emails, visits, mobile phones, etc*):		
Baseline: Regular email as required Monthly video meeting with supervisors		
Emergency: Telephone contact : +966 555099824		
Arrangements for local Supervision/Support:		
Prof. Siraj Wali, Consultant in Respiratory and Sleep Medicine. Dr. Faris Alhejaili, Consultant in Respiratory and Sleep Medicine Dr. Ali Alfaidhi, Consultant Critical Care Medicine .		
Local Facilities available to student: Office space organized by student. Standard university facilities.		
Has a full risk assessment been completed? (*If the work is not being done in a University, research institute or company with safety systems comparable to GU, you should attach a Risk Assessment form*) (Note any special tasks related to lone fieldwork must be specifically detailed)	NO	
Have any local safety regulations been taken into account?	YES	
Has appropriate fieldwork training (including relevant first aid and emergency procedures) been identified and completed?	YES	
Has appropriate insurance been arranged? (through the Finance Office)	NO	

	Name (Print)	Signature	Date
Student	Ghaida Alsulami		
Supervisor	ANNEMARIE GRACE		
Institute or School Convenor	JA GRACIE		

Appendix 5: Permission to use and to translate the RCSQ into Arabic



Appendix 6: Richards Campbell Sleep Questionnaire (RCSQ)

Richards Campbell Sleep Questionnaire (RCSQ)

Code Number_____ Date_____

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. The following are examples of the type of questions you are to answer.

EXAMPLE A
Right now I feel:

Very Sleepy X_____***Not sleepy at all***

If you were very sleepy, you would place an "X" as is shown at the beginning of the line next to the words ***"Very Sleepy."***

EXAMPLE B
Right now I feel:

Very Sleepy_____X_____***Not sleepy at all***

If you were somewhat sleepy, you would place an "X" near the center of the line. Mark the answer line near the center to indicate the answer ***"Somewhat Sleepy."***

EXAMPLE C
Right now I feel:

Very Sleepy_____X ***Not sleepy at all***

If you were not sleepy at all, you would place an "X" at the end of the line next to the words ***"Not Sleepy At All."***

Please turn to next page

You are now ready to begin to answer the questions. Place your "X" ***anywhere*** on the answer 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 Almost Immediately _____ ***Just Never Could Fall Asleep***

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***

Optional Noise Item:

6. I would describe the noise level last night as:

Very Quiet _____ ***Very Noisy***

Appendix 7: Forward translation certificate of the RCSQ

Auz-IT

(A Division of Horizon Publishing Group™)
Interpreters & Translators
Expert Linguists – Editors
Cultural Advisers

ABN: 39 470 232 972

Certification

Assignment number
7120120/2017

I, Fayez P Hanna, an European and NAATI accredited Professional Interpreter and Translator, hereby certify that the attached text consisting of three (3) pages is a translation from the English Language into the Arabic Language.

I certify that as the documents to be translated relate to: Sleep Apnoea cases, the translations are not literal as this would have mislead the reader. Therefore, upon request, I used the background information about the conceptual basis of the measure rather than being literal in attempting to make the translation easily understood by the general lay patients.

Certified true (BUT NOT LITERAL) translation of the attached certified copies		
Translator ID No:	13.769	Date: 12 October 2017
Stamp & Signature of the Translator	NATIONAL ACCREDITATION AUTHORITY FOR TRANSLATORS AND INTERPRETERS ★ NAATI No. 13769 FAYEZ HANNA TRANSLATOR ARABIC <=> ENGLISH	Date: 12 October 2017

The Translator & Auz-IT give no warrant as to the authenticity or otherwise of the document(s) submitted for translation.
Any unsealed alteration to this translation renders it invalid.
Translation invalid without the official stamp of the Translator.

P.O. Box 275
Cherrybrook NSW 2126
Email: auz-it@horizonpg.net
editor@horizonpg.net

Back translation certificate of the RCSQ-A

GLOBAL
LANGUAGE SERVICES

Glasgow Office
HEAD OFFICE
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Glasgow G41 2SE
Tel: 0141 429 3429
Fax: 0141 465 8830
mail@globalglasgow.com

Edinburgh Office
Belgrave Business Centre
45 Frederick Street
Edinburgh EH2 1EP
Tel: 0131 220 0115
Fax: 0131 225 6574
mail@globaledinburgh.com

Highlands & Grampian Office
Fairways House
Fairways Business Park
Castle Heather
Inverness IV2 6AA
Tel: 01463 256839
Fax: 01463 258851
mail@globalinverness.com

Our ref: G171202
Please ask for: Riona Donowho

To whom it may concern,

RE: Translation of document requested by Ghaida Shujayyi H Alsulami

Please find enclosed the translation of the documents appended herein. We confirm that this is a true and accurate English translation of the document in the Arabic language.

This translation was undertaken by our qualified translator, details as follows:

Ms Verity Roat

- ***MA Applied Translation Studies (Pass with Distinction), awarded by University of East Anglia***
- ***BA Asian and Middle Eastern Studies: Arabic and French, awarded by University of Cambridge***

c/o Global Language Services Ltd., Craig House, 64 Darnley Street, Glasgow, G41 2SE

The enclosed translations have been stamped with our certified stamp and signed in confirmation hereof.

Please do not hesitate to contact us should you have any queries regarding this matter.

Yours faithfully,

Riona Donowho
Translation Project Manager

Appendix 8: Comparison between back translated versions of RCSQ-A and the original RCSQ

Table 1. *Comparison between back translated versions of the RCSQ-A and the original RCSQ*

Original item on the RCSQ	Back translated item form RCSQ-A	Comments
My sleep last night was: deep sleep /light sleep	My sleep last night was: deep sleep /light sleep	Original
Last night, the first time I got to sleep: **fell sleep almost immediately/ just never could fall asleep**	Last night, the first time I got sleep: **fell asleep immediately/ never could fall asleep**	Same meaning as the original instrument
Last night I was: **Awake Very Little/ Awake All night long**	Last night I was: **awake very little/ awake All night**	Same meaning as the original instrument
Last night, when I woke up or was awakened, I: **got back to sleep immediately/ couldn't get back to sleep**	Last night, when I woke up or was awakened : **got back to sleep immediately/ could not get back to sleep**	Original
I would describe my sleep last night as: **a good night's sleep / a bad night's sleep**	I would describe my sleep last night as: **A good night's sleep / a bad night's sleep**	Original

Appendix 9: Approval letter on the back translated RCSQ-A

From: Professor Kathy Richards

To: Ghaida Alsulami
PhD student; School of Medicine, Dentistry & Nursing | College of Medical, Veterinary & Life Sciences | University of Glasgow | 57-61 Oakfield Avenue | Glasgow | G12 8LL | United Kingdom

I am the author and holder of the copyright for the Richards Campbell Sleep Questionnaire (RCSQ). I declare I have granted a permission to Ghaida Alsulami to translate (RCSQ) into Arabic for her research study. And I have approved the back translated version of RCSQ.

Kathy Richards, PhD, RN, FAAN, FAASM
Research Professor
University of Texas at Austin
Austin, Texas

Appendix 10: Expert panel responses to a review of the consistency between the RCSQ-A and the original RCSQ

A four expert panel responses to a review of the consistency between the translated (RCSQ-A) and the original RCSQ

Item	Arabic and English version are			
	Similar	Somewhat similar	Different	Comments
RSCQ1 (sleep depth)	4			
RCSQ2 (ability to fall asleep)	3	1		
RCSQ3 (number of awakenings)	2	2		
RCSQ4 (ability to fall asleep when awake)	4			
RCSQ5 (quality of sleep)	4			

* Note: similar and somewhat similar are consistent/ acceptable, different and somewhat different'' responses are not consistent.

Appendix 11: The Arabic version of the RCSQ-A

إستبيان ريتشاردز كامبل (RCSQ)

الرقم الرمزي _____ التاريخ: _____

يتم الإجابة على كل سؤال من هذه الأسئلة بوضع علامة "X" على سطر الإجابة. يمكنك وضع علامة "X" في أي مكان من سطر الإجابة في المكان الذي يعبر عن حالة نومك خلال الليلة الماضية. فيما يلي أمثلة من هذا النوع من الأسئلة التي عليك الإجابة عليها.

المثال أ:

أشعر الآن:

أشعر بنعاس شديد X_____ لا أشعر بالنعاس على الإطلاق.

إن كنت تشعر بنعاس شديد، يجب عليك وضع علامة "X" في بداية السطر كما هو موضح أعلاه بجانب العبارة " **أشعر بنعاس شديد**".

المثال ب:

أشعر الآن:

أشعر بنعاس شديد _____X_____ لا أشعر بالنعاس على الإطلاق.

إن كنت تشعر بنعاس لحدٍ ما، يجب عليك وضع علامة "X" في منتصف السطر كما هو موضح أعلاه. يجب وضع العلامة في منتصف السطر لتبين أن إحساسك بالنوم هو "**أشعر بالنعاس إلى حدٍ ما**".

المثال ج:

أشعر الآن:

أشعر بنعاس شديد_____X لا أشعر بالنعاس على الإطلاق.

إن لم تكن تشعر بالنعاس على الإطلاق، يجب عليك وضع علامة "X" في نهاية السطر كما هو موضح أعلاه. يجب وضع العلامة في نهاية السطر لتبين أن إحساسك بالنوم هو " **لا أشعر بالنعاس على الإطلاق** ".

الرجاء الانتقال إلى الصفحة التالية

أنت الآن جاهزاً للبدء في الإجابة على الأسئلة. ضع علامة إجابتك "X" في أي مكان على خط الإجابة والذي تشعر أنه أفضل وصف لنومك الليلة الماضية.

١. نومي الليلة الماضية كان:

نوماً عميقاً ——————————————— نوماً خفيفاً

٢. الليلة الماضية، المرة الأولى التي نمت فيها، أنا:

نمت على الفور تقريباً ——————————————— أبداً لم أستطع الدخول في النوم بسهوله

٣. الليلة الماضية كنت:

أستيقظ قليلا جداً ——————————————— أستيقظ طوال الليل

٤. الليلة الماضية، عندما إستيقظت أو شيئاً أيقظني, أنا:

عدت للنوم فوراً ——————————————— لم أستطع العودة للنوم

٥. أود أن أصف نومي الليلة الماضية كالآتي:

ليلة نوم جيدة ——————————————— ليلة نوم سيئة

بند الضوضاء اختياري:

٦. أود أن أصف مستوى الضوضاء الليلة الماضية كالآتي:

جداً هادئ ——————————————— جداً مزعج

Appendix 12: A screening survey for recruitment process

Part I: Screening survey

Date ..... ID NO..... Date of ICU admission.....

Patient criteria	Yes	No	Comment
Adult patient ≥18 years			
Has been exposed to the ICU for more than 24 hours? *If no, please mention when the patient will complete 24hr in the ICU?			
Not sedated? If the patient is sedated, please mention if possible when the patient expected to be not sedated? In order to get back to the patient..			
Is the patient Conscious? And Oriented?			GCS= RASS score= CAM-ICU=

Do not proceed please if any of the above answers are 'No'. If answer of all above criteria is yes, proceed to the following and *eligibility criteria.*

Patient criteria	**Yes**	**NO**	**Comment**
1. Unable to interact and respond to Arabic commands?			
2. History of cognitive dysfunction? E.g. presence or history of dementia, traumatic brain injury, stroke or hepatic encephalopathy) or active delirium (positive CAM-ICU)?			
4. Neurologic impairment/Neuro-surgical?			
5. A history of sleep disorder/problem? (E.g. sleep apnoea, restless leg syndrome, insomnia, narcolepsy)?			
***The patient could be included if all the above 5 criteria are (No)**			

****Now, select one of the following:***

- A. The patient is conscious and oriented, will be able to read the participant information sheet and will be able to provide the consent form.
- B. The patient is not conscious or not oriented, will be unable to read the participant information sheet and will be able unable to provide the consent form.

- *If the selection is A, please, invite the potential patient to participate in the study and* ask the patient about his/her willingness to take part in this study. Please clarify to the patient that this study is for a PhD student and it is an external study, not related to the hospital. Also, inform the patient that this participation is voluntary and not obligatory. If they decided to take part, they are still free to withdraw at any time and without giving a reason, without any effect on their care and treatment.

- Please inform the patient that this is not final decision to take part in the study and he/she has an opportunity to ask any question before meeting the researcher. Inform Patients who are interested they will be contacted by the researcher, and they will be given the information sheets. After they read the information sheet, they have an opportunity to ask the researcher any question and the researcher will provide time

Appendix 13: Information sheet, phase one

Information sheet form for potential participants

Chief investigator: Mrs. Ghaida Alsulami
Co-investigators: Dr. Ann Marie Rice
Nursing & Health Care School
College of Medical, Veterinary & Life Science
University of Glasgow

1. **Research study title:**

Sleep quality and sleep disruptive factors in adult patients in the intensive care unit: Feasibility and acceptability of the daily use of self-report for sleep quality assessment in the ICU in Saudi Arabia.

2. Invitation

Dear sir/madam,

I am currently undertaking a research study as part of my PhD thesis in the Nursing & Health Care School, University of Glasgow. You are being invited to take part in the above research study. Before you decide it is important for you to understand why the research is being done Please take time to read the following information carefully and ask me if there is anything that is not clear or if you would like more information.

3. What is the purpose of the study?

This pilot test aims to develop an Arabic version of a questionnaire for sleep quality assessment in ICU patients. During this pilot test, you will be asked some questions to assess your understanding of the meaning of each item in the questionnaire attached to this information sheet.

4.Why have I been chosen?

Simply you have been chosen because you are a patient in the ICU. All ICU patients, who are conscious, oriented are invited to participate.

5.Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason, without any effect on your care and treatment.

6.What will happen to me if I take part?

You will be asked to complete the two questionnaires which attached with this information sheet, you will be asked for giving your feedback on the content and clarity of the questioners.

7. What are the possible disadvantage and risks of taking part?

Participation is not anticipated to cause any harm beyond that encountered in the setting, but that you might become bored or tired when completing the questionnaires. You are free to withdraw from the study for any reason at any time without any consequences

8. What are the possible benefits of taking part?

There are likely to be no direct benefits to your own health but that this would have wider benefits in terms of research and development in the health care service by assisting with improving sleep assessment in ICUs.

9. Will my taking part in this study is kept confidential?

All information that will be collected about you, or response that you provide, during the course of the research will be kept strictly confidential. All paper data collection materials for this current study will be coded with a unique identification numbers so that these are not linked in any way to identifiable information. Your anonymity in terms of demographic and clinical data will be assured, with such items collected from you medical records for the research purpose only

10. What will happen to the result of the research study?

Results of the research will be published in scientific journals. You will not be identified in any report or publication. If you wish to be given a copy of any reports resulting from the research, please ask me to put you on our circulation list.

11. Contact for further information

Mrs. Ghaida S Alsulami**,** Nursing & Health Care School , College of Medical, Veterinary & Life Sciences . University of Glasgow. Scotland.

Phone number: +966555099824 **E-mail:** G.alsulami.1@research.gla.ac.uk

Thank you for taking the time to read this information sheet. If you do decide that you would like to participate in this research study please read and sign the attached consent form.

***Yours sincerely*,**

Ghaida Alsulami, RN, MSc, BSc. PhD Candidate, Nursing & Health Care School ,University of Glasgow. Scotland, UK

Appendix 13: Information sheet, phase 2

Information sheet form for potential participants

Chief investigator: Mrs. Ghaida Alsulami
Co-investigators: Dr. Ann Marie Rice
Nursing & Health Care School
College of Medical, Veterinary & Life Science
University of Glasgow

2. Research study title:

Sleep quality and sleep disruptive factors in adult patients in the intensive care unit: Feasibility and acceptability of the daily use of self-report for sleep quality assessment in the ICU in Saudi Arabia.

2. Invitation

Dear sir/madam,

I am currently undertaking a research study as part of my PhD thesis in the Nursing & Health Care School, University of Glasgow. You are being invited to take part in the above research study. Before you decide it is important for you to understand why the research is being done Please take time to read the following information carefully and ask me if there is anything that is not clear or if you would like more information.

3. What is the purpose of the study?

This study aims to identify whether patients in the ICU are sleeping properly, and to understand some of the reasons why patients may not be able to get a good night's sleep. This study also aims to describe patients' ability in filling in a questionnaire for sleep assessment, to understand the feasibility for implementing this questionnaire in the ICU clinical practice. In order to help the nurses, assess patients' sleep.

4.Why have I been chosen?

Simply you have been chosen because you are a patient in the ICU. All ICU patients, who are conscious, oriented are invited to participate.

5.Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason, without any effect on your care and treatment.

6.What will happen to me if I take part?

You will be asked to complete the two questionnaires which attached with this information sheet, every morning during your stay in the ICU. At the end of the study, when you deemed fit to discharge from the ICU, you will be asked: "How did you find completing the sleep questionnaire on multiple days while you were an inpatient in the ICU?" The information collected from these surveys will be used to identify how patients are sleeping in the ICU, and to identify barriers to sleep that we may attempt to modify in order to improve the quality of patients' sleep.

7. What are the possible disadvantage and risks of taking part?

Participation is not anticipated to cause any harm beyond that encountered in the setting, but that you might become bored or tired when completing the

questionnaires. You are free to withdraw from the study for any reason at any time without any consequences

8. What are the possible benefits of taking part?

There are likely to be no direct benefits to your own health but that sharing their perceptions and experiences of sleep quality in the ICU and the utility of the RCSQ-A would help to improve assessment of sleep quality in the ICU setting and inform ways in which patients' quality of sleep could be improved during their stay in an ICU.

9. Will my taking part in this study is kept confidential?

All information that will be collected about you, or response that you provide, during the course of the research will be kept strictly confidential. All paper data collection materials for this current study will be coded with a unique identification numbers so that these are not linked in any way to identifiable information. Your anonymity in terms of demographic and clinical data will be assured, with such items collected from you medical records for the research purpose only

10. What will happen to the result of the research study?

Results of the research will be published in scientific journals. You will not be identified in any report or publication. If you wish to be given a copy of any reports resulting from the research, please ask me to put you on our circulation list.

11. Contact for further information

Mrs. Ghaida S Alsulami**,** Nursing & Health Care School , College of Medical, Veterinary & Life Sciences . University of Glasgow. Scotland.

Phone number: +966555099824 **E-mail:** G.alsulami.1@research.gla.ac.uk

Thank you for taking the time to read this information sheet. If you do decide that you would like to participate in this research study please read and sign the attached consent form.

***Yours sincerely*,**

Ghaida Alsulami, RN, MSc, BSc. PhD Candidate, Nursing & Health Care School ,University of Glasgow. Scotland, UK

University of Glasgow

ورقة المعلومات للمشاركين (مرضى العناية المركزة)

الباحث الرئيسي: غيداء شجيع السلمي

الباحث الثانوي: دكتورة أن ماري و دكتورة جوان ماكبيك

كلية التمريض والرعاية الصحية
جامعة غلاسكو/بريطانيا

1.موضوع الدراسة

نوعية نوم وعوامل اضطراب النوم في وحدة العناية المركزة (تطوير بروتوكول تعزيز النوم) في المستشفى السعودي.

2.الدعوة:

سيدي / سيدتي

أنا حالياً أجري دراسة بحثية كجزء من دراسة الدكتوراه. من كلية التمريض، جامعة غلاسكو في بريطانيا. "أنت مدعو للمشاركة في هذا الدراسة البحثية. قبل أن تقرر من المهم أن تفهم لماذا يتم إجراء هذا البحث. يرجى أن تأخذ الوقت الكافي لقراءة المعلومات التالية بعناية. اسألنا إذا كان هناك أي شيء غير واضح أو إذا كنت ترغب في مزيد من المعلومات. خذ وقتك الكافي لتقرر ما إذا كنت ترغب في المشاركة او لا.

3.ما هو الغرض من الدراسة؟

تهدف هذه الدراسة إلى وصف نوم مرضى العناية المركزة أثناء وجودهم في وحدة العناية المركزة و ما هي العوامل التي تؤثر على نوم المرضى.

4. لماذا تم اختياري؟

تم اختيارك لأنك مريض في وحدة العناية المركزة. جميع المرضى الواعين يتم دعوتهم للمشاركة في هذه الدراسة.

5. هل يلزم أن أشارك؟

الأمر متروك لك أن تقرر ما إذا ترغب بالمشاركة أو لا. سوف يطلب منك فقط تعبئة الاستبيانات وذلك بعد ان تتخذ القرار الأكيد في المشاركة سوف يطلب منك توقيع نموذج الموافقة للمشاركة في الدراسة. وبعد أن تقرر بالمشاركة فإنك لا تزال حر في الانسحاب في أي وقت ودون إبداء سبب.

6. ماذا سيحدث لي إذا شاركت؟

سوف نسألك لإكمال تقيمين عن طريق تعبئة استبيانات بعد الانتهاء من الاستبيان الأول، سيتم عرض عليك الاستبيان الثاني في التقييم الثاني

**إذا كان لديك أي صعوبات في استخدام القلم لتقييم هذه المقاييس، يمكنك بدلا من ذلك أن تشير إلى مقياس بأصبعك، أو سوف يدعمك الباحث ويساعدك.

**سيتم إجراء كل من هذه التقييمات يوميا، كل صباح، حتى تتلقى أمر طبي ليتم خروجك من الوحدة

7. ما هي العيوب والمخاطر المحتملة للمشاركة؟

وبما أن طبيعة هذه الدراسة ليست سوى دراسة وصفية، فمن غير المتوقع أن يسبب لك أي مخاطر. ولكن قد تشعر بالملل من ملء الاستبيانات، ولكن إذا رغبت في الانسحاب من الدراسة في اي وقت يمكنك ذلك.

8. ما هي الفوائد المحتملة للمشاركة؟

لن تتلقى أي فائدة مباشرة من المشاركة في هذه الدراسة. المعلومات التي تم جمعها خلال هذه الدراسة سوف تعطينا فهم أفضل

لنوعية نومك في وحدة العناية المركزة والعوامل التي تزعج نومك أثناء إقامتك في الوحدة. قد تحصل على فائدة من وجود فرصة لاستكشاف تجربة نومك وما هي العوامل التي تعطل النوم.

9. هل سيظل مشاركتي في هذه الدراسة سرية؟

جميع المعلومات التي يتم جمعها عنك، أو الاستجابة التي تقدمها، أثناء البحث سوف تبقى سرية للغاية. لديك الحق في الخصوصية، وسوف يتم تحديدها من قبل رقم الطبي الخاصة بك، وليس اسمك.

10. ماذا سيحدث نتيجة الدراسة البحثية؟

سيتم نشر نتائج البحث في المجلات العلمية. لن يتم التعرف عليك في أي تقرير أو منشور ولن تشمل المنشورات اسمك او رقمك السريري. إذا كنت ترغب في الحصول على نسخة من أي تقارير ناتجة عن البحث الرجاء ابلاغ الباحث بذلك.

11- بيانات التواصل للحصول على مزيد من المعلومات

الباحث الرئيسي: الأستاذة غيداء السلمي، كلية التمريض والرعاية الصحية، جامعة غلاسكو. اسكتلندا، المملكة المتحدة.

رقم الهاتف: 0555099824

البريد الالكتروني: g.alsulami.1@research.gla.ac.uk

نشكرك على وقتك لقراءة ورقة المعلومات هذه. إذا كنت ترغب في المشاركة في الدراسة أو لديك أي أسئلة أخرى ترغب في طرحها قبل اتخاذ قرار يمكنك ذلك. إذا قررت أنك ترغب في المشاركة في هذه الدراسة البحثية يرجى منك تعبئة الاستبيانات المرفقة.

تفضلوا بقبول فائق الاحترام،

غيدا السلمي طالبة دكتوراة: تمريض الحالات الحرجة

جامعة غلاسكو أسكتلندا، المملكة المتحدة

Appendix 14: English and Arabic versions of the consent form

University of Glasgow | College of Medical, Veterinary & Life Sciences

Centre Number:
Project Number:
Subject Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher(s):

Please initial box

I confirm that I have read and understand the information sheet dated _____ (version _____) for the above study and have had the opportunity to ask questions. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. ☐

I agree to take part in the above study. ☐

Name of subject	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

(1 copy for subject; 1 copy for researcher)

University of Glasgow | College of Medical, Veterinary & Life Sciences

نموذج الموافقة

عنوان المشروع:
أسماء الباحثين:

يرجى الإشارة للمربع

أؤكد أنني قرأت وفهمت المعلومات التي في الورقة المؤرخة_____ (نسخة _____) للدراسة المذكورة أعلاه، و أتيحت لي الفرصة لطرح الأسئلة. ☐

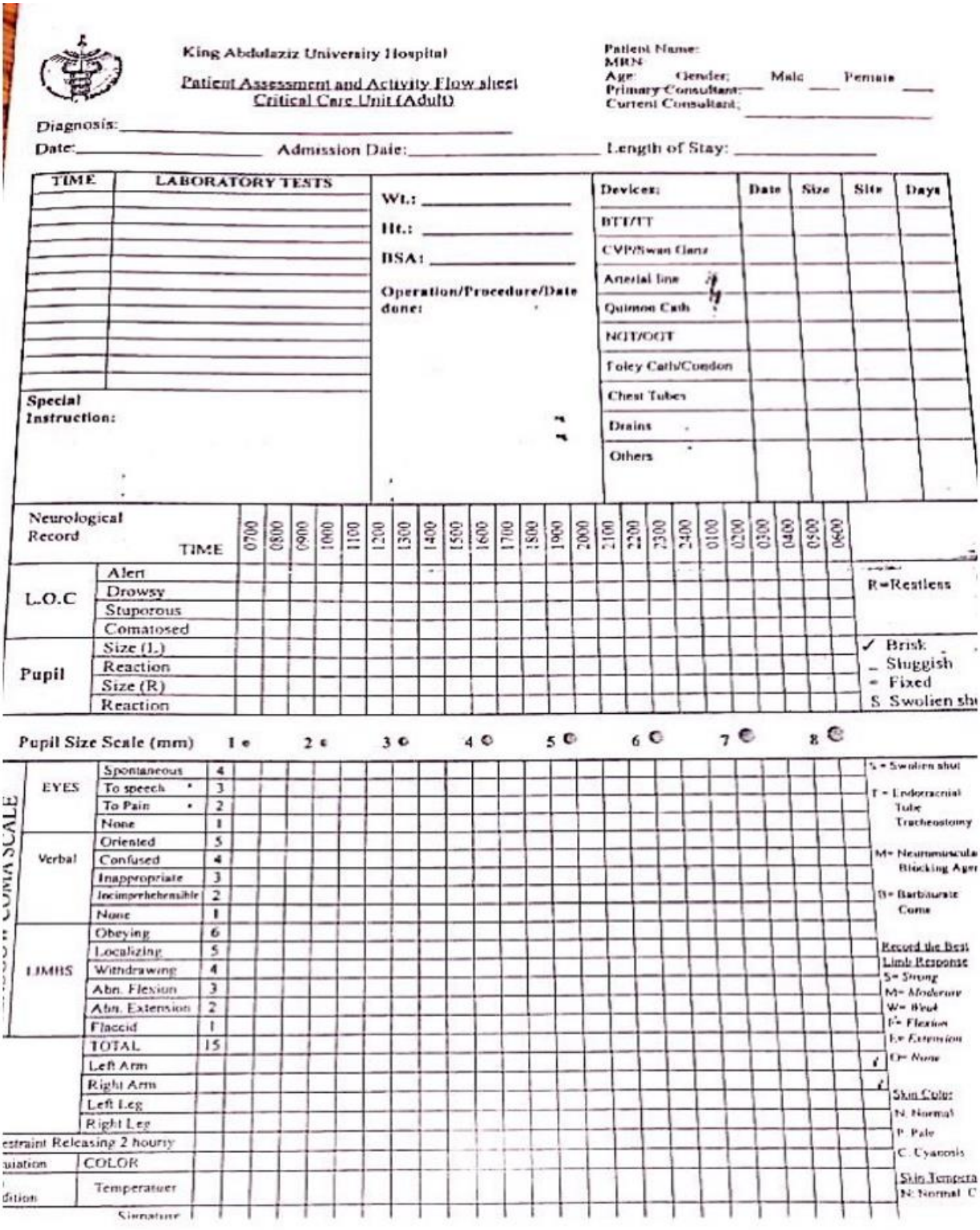
أفهم أن مشاركتي طوعية وأنني أستطيع الانسحاب في أي وقت، دون إبداء أي سبب، دون أن تتأثر حقوقي القانونية ☐

أوافق على المشاركة في الدراسة أعلاه ☐

_____	_____	_____
اسم المريض	التاريخ	التوقيع
_____	_____	_____
اسم الشخص الذي يأخذ الموافقة إذا كان مختلفاً عن الباحث	التاريخ	التوقيع
_____	_____	_____
الباحث	التاريخ	التوقيع

(1 نسخة للمريض , 1نسخة للباحث)

Appendix 15: Data collection sheet for GCS and RASS scores.



King Abdulaziz University Hospital

Patient Assessment and Activity Flow sheet
Critical Care Unit (Adult)

Patient Name:
MRN
Age: Gender: Male Female
Primary Consultant:
Current Consultant:

Diagnosis:
Date: Admission Date: Length of Stay:

TIME	LABORATORY TESTS

Wt.:
Ht.:
BSA:
Operation/Procedure/Date done:

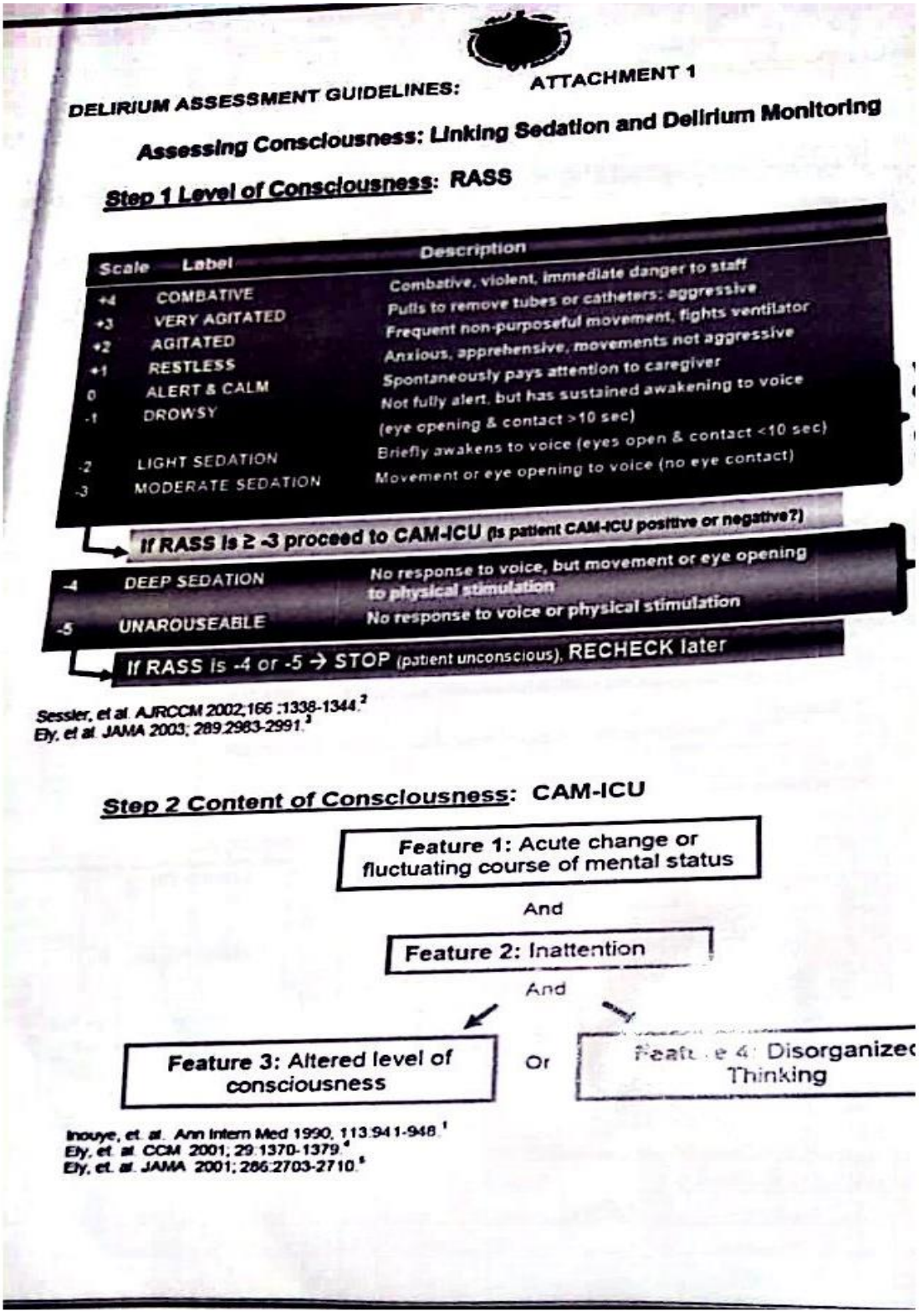
Special Instruction:

Devices:	Date	Size	Site	Days
BTT/TT				
CVP/Swan Ganz				
Arterial line				
Quinton Cath				
NGT/OGT				
Foley Cath/Condon				
Chest Tubes				
Drains				
Others				

Neurological Record TIME	0700	0800	0900	1000	1100	1200	1300	1400	1500	1600	1700	1800	1900	2000	2100	2200	2300	2400	0100	0200	0300	0400	0500	0600	
L.O.C: Alert																									R=Restless
L.O.C: Drowsy																									
L.O.C: Stuporous																									
L.O.C: Comatosed																									
Pupil: Size (L)																									✓ Brisk
Pupil: Reaction																									_ Sluggish
Pupil: Size (R)																									- Fixed
Pupil: Reaction																									S Swolien sh

Pupil Size Scale (mm) 1 2 3 4 5 6 7 8

GLASGOW COMA SCALE																									
EYES: Spontaneous	4																								S = Swolien shut
EYES: To speech	3																								T = Endotracheal Tube Tracheostomy
EYES: To Pain	2																								
EYES: None	1																								
Verbal: Oriented	5																								M= Neuromuscula Blocking Age
Verbal: Confused	4																								
Verbal: Inappropriate	3																								B= Barbaurate Coma
Verbal: Incomprehensible	2																								
Verbal: None	1																								
LIMBS: Obeying	6																								Record the Best Limb Response
LIMBS: Localizing	5																								S= Strong
LIMBS: Withdrawing	4																								M= Moderate
LIMBS: Abn. Flexion	3																								W= Weak
LIMBS: Abn. Extension	2																								F= Flexion
LIMBS: Flaccid	1																								E= Extension
TOTAL	15																								O= None
Left Arm																									
Right Arm																									
Left Leg																									Skin Color
Right Leg																									N. Normal
estraint Releasing 2 hourly																									P. Pale
uation: COLOR																									C. Cyanosis
dition: Temperature																									Skin Tempera
Signature																									N: Normal C



DELIRIUM ASSESSMENT GUIDELINES: ATTACHMENT 1

Assessing Consciousness: Linking Sedation and Delirium Monitoring

Step 1 Level of Consciousness: RASS

Scale	Label	Description
+4	COMBATIVE	Combative, violent, immediate danger to staff
+3	VERY AGITATED	Pulls to remove tubes or catheters; aggressive
+2	AGITATED	Frequent non-purposeful movement, fights ventilator
+1	RESTLESS	Anxious, apprehensive, movements not aggressive
0	ALERT & CALM	Spontaneously pays attention to caregiver
-1	DROWSY	Not fully alert, but has sustained awakening to voice (eye opening & contact >10 sec)
-2	LIGHT SEDATION	Briefly awakens to voice (eyes open & contact <10 sec)
-3	MODERATE SEDATION	Movement or eye opening to voice (no eye contact)

If RASS is ≥ -3 proceed to CAM-ICU (Is patient CAM-ICU positive or negative?)

-4	DEEP SEDATION	No response to voice, but movement or eye opening to physical stimulation
-5	UNAROUSEABLE	No response to voice or physical stimulation

If RASS is -4 or -5 → STOP (patient unconscious). RECHECK later

Sessler, et al. AJRCCM 2002;166 :1338-1344.[2]
Ely, et al. JAMA 2003; 289:2983-2991.[3]

Step 2 Content of Consciousness: CAM-ICU

Feature 1: Acute change or fluctuating course of mental status

And

Feature 2: Inattention

And

Feature 3: Altered level of consciousness

Or

Feature 4: Disorganized Thinking

Inouye, et. al. Ann Intern Med 1990; 113:941-948.[1]
Ely, et. al. CCM 2001; 29:1370-1379.[4]
Ely, et. al. JAMA 2001; 286:2703-2710.[5]

Appendix 16: CAM-ICU

CAM – ICU Worksheet

Patient Name: **MRN#:** **Date:** **Time:**

Feature 1: Acute Onset or Fluctuating Course	Score	Check here if present
Is the pt different than his/her baseline mental status? Or Has the patient had any fluctuation in mental status in the past 24 hours as evidenced by fluctuation on a sedation scale (i,e.,RASS), GCS, or previous delirium assessment?	Either question Yes →	☐
Feature 2: Inattention		
Letters Attention test (See training manual for alternate Pictures) **Directions:** Say to the patient," I am going to read you a series of 10 letters. Whenever you hear the letter ' A', indicate by squeezing my hand". Read letters from the following letter list in a normal tone 3 seconds apart. SAVEAHAART **Errors are counted when patient fall to squeeze o the letter "A" and when the patient squeezes on any letter other "A"**	Numbers of Errors > 2 →	☐
Feature 3: Altered Level of Consciousness		
Present if the actual RASS score is anything other than alert and calm(zero)	RASS Anything other than zero →	☐
Feature 4: Disorganized Thinking		
Yes/No Questions (See training manual for alternate set of questions**)** 1. Will a stone float on water? 2. Are there fish in the sea? 3. Does one pound weigh more than two pounds? 4. Can you use a hammer to pound a nail? **Errors are counted when the patient incorrectly answers a question.** **Command:** Say to patient "Hold up this many fingers" (Hold 2 fingers in front of patient) " Now do the same thing with the other hand" (Do not repeat number of fingers) * If pt is unable to move both arms, for 2nd part of command ask patient to " Add one more finger" **An error is counted if patient is unable to complete the entire command.**	Combined numbers of errors >1 →	☐

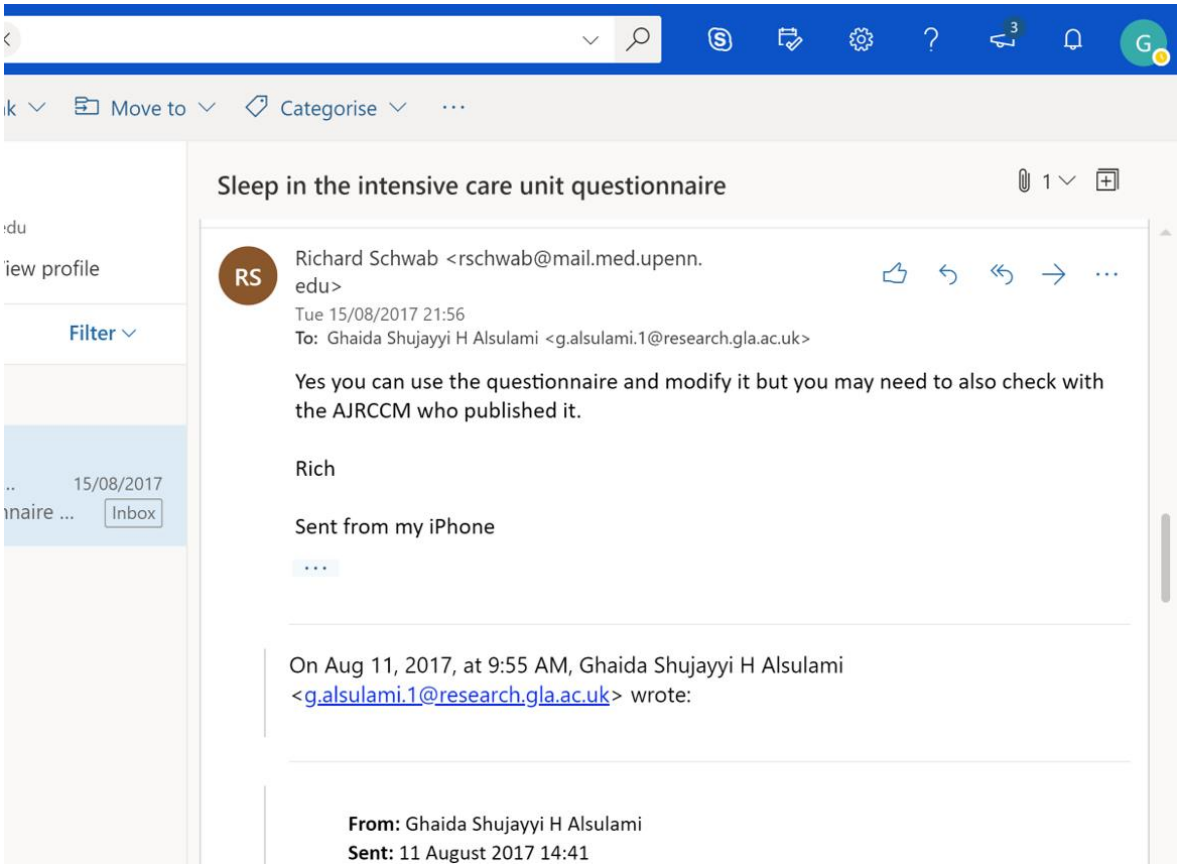
Overall CAM- ICU **Feature 1 plus 2 and either 3 or 4 present = CAM ICU positive**	Criteria Met →	☐ CAM- ICU Positive (Delirium present)
	Criteria Not Met →	☐ CAM- ICU Negative (No Delirium)

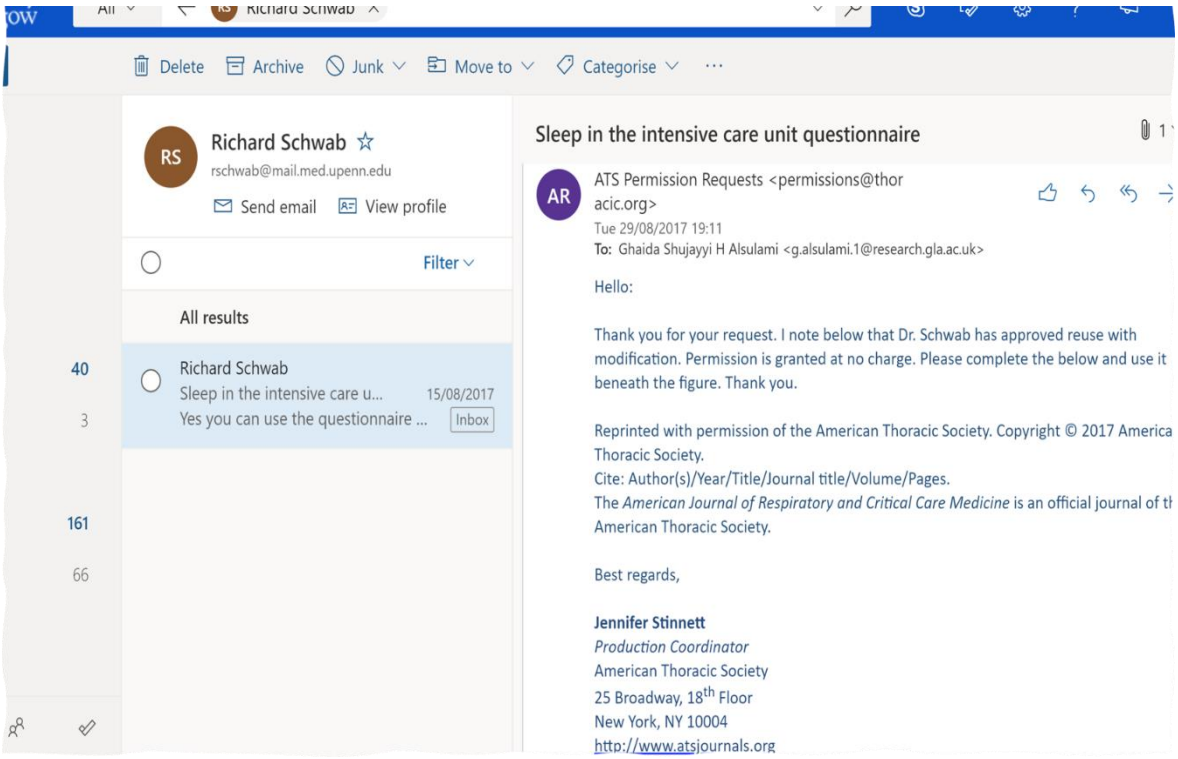
Appendix 17: Data collection form for cognitive interviews

Data Collection Form for Cognitive Interviews

Item	Number of corrected explanation	Number of wrong explanation	Recommendation/comments
RCSQ-item-1			
RCSQ-item-2			
RCSQ-item-3			
RCSQ-item-4			
RCSQ-item-5			

Appendix 18: Permission to use and to adapt the SICQ




Richard Schwab
Delete
Archive
Junk
Move to
Categorise
RS
Richard Schwab
rschwab@mail.med.upenn.edu
Send email
View profile
Filter
All results
40
Richard Schwab
Sleep in the intensive care u...
15/08/2017
3
Yes you can use the questionnaire ...
Inbox
161
66
Sleep in the intensive care unit questionnaire
AR
ATS Permission Requests <permissions@thoracic.org>
Tue 29/08/2017 19:11
To: Ghaida Shujayyi H Alsulami <g.alsulami.1@research.gla.ac.uk>
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Appendix 19: The modified SICQ

1. Rate how disruptive the following <u>activities</u> were to your sleep during the last night

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
- Clinical interventions (i.e. baths, vital signs, blood sample) 1 2 3 4 5 6 7 8 9 10

2. Rate how disruptive the following <u>noises</u> were to your sleep during the last night.

(1 is no disruption; 10 is significant disruption)

- Talking 1 2 3 4 5 6 7 8 9 10
- Machines' Alarm (Heart monitor, Ventilator, I.V. Pump) 1 2 3 4 5 6 7 8 9 10
- ICU Telephone 1 2 3 4 5 6 7 8 9 10

- **Rate how disruptive the following <u>other factors</u> were to your sleep during the last night.**

(1 is no disruption; 10 is significant disruption)

- Fear 1 2 3 4 5 6 7 8 9 10
- Pain 1 2 3 4 5 6 7 8 9 10
- Discomfort of being attached to the devices

1 2 3 4 5 6 7 8 9 10

Rate the overall degree of <u>daytime sleepiness</u>.

(1=is unable to stay awake; 10 fully alert and awake)

- Daytime sleepiness 1 2 3 4 5 6 7 8 9 10

- Other.....

The original SICQ

Sleep in the Intensive Care Unit (ICU) Questionnaire

1. **Rate the overall quality of your sleep at <u>home</u>.** 1 2 3 4 5 6 7 8 9 10
Use a scale of 1 to 10 (1 is poor; 10 is excellent)

2. **Rate the overall quality of your sleep in the <u>ICU</u>.** 1 2 3 4 5 6 7 8 9 10
Use a scale of 1 to 10 (1 is poor; 10 is excellent)

3. **Rate the overall quality of your sleep in the <u>ICU</u> 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 <u>daytime sleepiness</u> during your ICU stay:** 1 2 3 4 5 6 7 8 9 10
(1 is unable to stay awake; 10 is fully alert and awake)

5. **Rate the overall degree of <u>daytime sleepiness</u> during Your ICU stay on the following days:**
(1 is unable to stay awake; 10 is fully alert and awake)
   - 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

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 (i.e. baths) 1 2 3 4 5 6 7 8 9 10
   - Diagnostic Testing (i.e. 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.**
(1 is no disruption; 10 is significant disruption)
   - Heart Monitor Alarm 1 2 3 4 5 6 7 8 9 10
   - Ventilator Alarm 1 2 3 4 5 6 7 8 9 10
   - Ventilator 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
   - I.V. 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 Beepers 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

استمارة الاستبيانات أدناه لتحديد العوامل التي تؤثر على نومك في وحدة العناية المركزة رقم..... وحدة العناية المركزة الباطني والجراحي

1. قيم كيف تكون الأنشطة التالية معرقلة لنومك خلال الليلة الماضية

استخدم مقياس من 1 إلى 10 (1 لا يوجد عرقلة؛ 10 عرقلة بالغة)

- الضوضاء 1 2 3 4 5 6 7 8 9 10
- الضوء 1 2 3 4 5 6 7 8 9 10
- تداخلات التمريض : 1 2 3 4 5 6 7 8 9 10
(مثل الاستحمام، العمليات الحيوية، سحب عينات الدم....)

2. قيم كيف تكون الضوضاء التالية معرقلة لنومك خلال الليلة الماضية

(1 لا يوجد عرقلة؛ 10 عرقلة بالغة)

- إنذارات الأجهزة: 1 2 3 4 5 6 7 8 9 10
(مثل مراقب القلب, التنفس الصناعي, مضخة المحلول بالوريد...)
- الكلام 1 2 3 4 5 6 7 8 9 10
- تليفون وحدة العناية المركزة 1 2 3 4 5 6 7 8 9 10

3.قيم كيف تكون العوامل التالية الخاصة بك معرقلة لنومك خلال الليلة الماضية

(1 لا يوجد عرقلة؛ 10 عرقلة بالغة)

- الخوف 1 2 3 4 5 6 7 8 9 10
- الألم 1 2 3 4 5 6 7 8 9 10
- عدم الراحة بسب الأجهزة متصلة بي 1 2 3 4 5 6 7 8 9 10

4. قيم الدرجة الكلية للنعاس خلال النهار خلال الليلة الماضية

(1 غير قادر على البقاء مستيقظاً ؛ 10 جداً يقظ و مستيقظاً)

- النعاس أثناء النهار 1 2 3 4 5 6 7 8 9 10
- عوامل أخرى.....

Appendix 20: A data collection sheet for the collection of relevant demographic and clinical data

Data collection sheet (part I)

Q1. Eligible but declined participation? (no=0, yes=1); if yes, any reasons.....?
ID: ..... Age:..... Gender: .....APACHE-II .....

ICU admission date: ..... First assessment date: ..... ICU dismiss date: ....., ICU-LOS..... days

Q3: ICU admission diagnosis: .....

Q4: Current medications:.....

Q5: Previous sedation: .....

Ventilation status	1	2	3	4	5	6	7	8	9	10	11
Q6 Ventilation (I=extubated, II=NIV, III=IV)											
Q7 Delirium (no=0, yes=1)											
Q8 RASS score (no=0, yes=1)											
Q9 GCS score (no=0, yes=1)											

Date of intubation..... Date of extubation.....

Q3. Diagnosis	Medical cardiac	Medical respiratory	Medical Gastrointestinal	Surgical post-operative	Sepsis	Other
No=0, yes=1						

Q4. Current medication	Beta blocker	Anti-hypertensive	Analgesic: Opioids	Analgesic: Non-Opioids	Inotropic	Steroids	Other
No=0, yes=1							

Q5. Previous Sedation	Fentanyl	Propofol	Benzodiazepines	Midazolam	Other
No=0, yes=1					

Continue ⟶

Q10 Sleep quality assessment (RCSQ-A) Time taken to complete RCSQ-A (T)	1 T:	2 T:	3 T:	4 T:	5 T:	6 T:	7 T:	8 T:	9 T:	10 T:	11 T:	12 T:	AVERAGE
RCSQ1													
RCSQ2													
RCSQ3													
RCSQ4													
RCSQ5													
RCSQ_total/5													
Q11 Self-report sleep disruptive factors (SICQ)													
Light													
Noise													
Clinical interventions													
Machines alarm													
Talking													
Telephone													
Daytime sleepiness													
Fear													
Pain													
Being attached to machines													

Q2: How would you describe your sleep quality at home (1 very poor, 10 = excellent)

1 2 3 4 5 6 7 8 9 10

كيف تصف نومك في المنزل ؟

10 9 8 7 6 5 4 3 2 1

Appendix 21: Data collection sheet to collect information on the feasibility and acceptability of using the RCSQ-A

Data collection sheet for RCSQ-A feasibility and acceptability (part II)

12. Did the patient ask to stop taking part in the study? (no=0, yes=1) if yes , any provided reasons??	
13 Total number of completed RCSQ-A by the patient	
14 Number of days that patient was not able to complete the RCSQ-A	
15 Average time taken to complete the RCSQ-A	

Q16. How did you find completing the questionnaire on sleep quality on multiple days while you were an inpatient in the ICU?"

كيف وجدت اكمال استبيان النوم على عدة أيام خلال اقامتك بوحدة العناية المركزة؟