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Non-pharmacological interventions for sleep promotion in the intensive care unit (Review)

Hu RF, Jiang XY, Chen J, Zeng Z, Chen XY, Li Y, Huining X, Evans DJW, Wang S

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[Intervention Review]

Non-pharmacological interventions for sleep promotion in the intensive care unit

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ABSTRACT

Background

Adults in intensive care units (ICUs) often suffer from a lack of sleep or frequent sleep disruptions. Non-pharmacological interventions can improve the duration and quality of sleep and decrease the risk of sleep disturbance, delirium, post-traumatic stress disorder (PTSD), and the length of stay in the ICU. However, there is no clear evidence of the effectiveness and harms of different non-pharmacological interventions for sleep promotion in adults admitted to the ICU.

Objectives

To assess the efficacy of non-pharmacological interventions for sleep promotion in critically ill adults in the ICU.

To establish whether non-pharmacological interventions are safe and clinically effective in improving sleep quality and reducing length of ICU stay in critically ill adults.

To establish whether non-pharmacological interventions are cost effective.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, 2014, Issue 6), MEDLINE (OVID, 1950 to June 2014), EMBASE (1966 to June 2014), CINAHL (Cumulative Index to Nursing and Allied Health Literature, 1982 to June 2014), Institute for Scientific Information (ISI) Web of Science (1956 to June 2014), CAM on PubMed (1966 to June 2014), Alt HealthWatch (1997 to June 2014), PsycINFO (1967 to June 2014), the China Biological Medicine Database (CBM-disc, 1979 to June 2014), and China National Knowledge Infrastructure (CNKI Database, 1999 to June 2014). We also searched the following repositories and registries to June 2014: ProQuest Dissertations & Theses Global, the US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov), the metaRegister of Controlled Trials (ISRCTN Register) (www.controlled-trials.com), the Chinese Clinical Trial Registry (www.chictr.org.cn), the Clinical Trials Registry-India (www.ctri.nic.in), the Grey Literature Report from the New York Academy of Medicine Library (www.greylit.org), OpenGrey (www.opengrey.eu), and the World Health Organization International Clinical Trials Registry platform (www.who.int/trialsearch). We handsearched critical care journals and reference lists and contacted relevant experts to identify relevant unpublished data.

Selection criteria

We included all randomized controlled trials (RCT) and quasi-RCTs that evaluated the effects of non-pharmacological interventions for sleep promotion in critically ill adults (aged 18 years and older) during admission to critical care units or ICUs.

Data collection and analysis

Two authors independently screened the search results and assessed the risk of bias in selected trials. One author extracted the data and a second checked the data for accuracy and completeness. Where possible, we combined results in meta-analyses using mean differences and standardized mean differences for continuous outcomes and risk ratios for dichotomous outcomes. We used post-test scores in this review.

Main results

We included 30 trials, with a total of 1569 participants, in this review. We included trials of ventilator mode or type, earplugs or eye masks or both, massage, relaxation interventions, foot baths, music interventions, nursing interventions, valerian acupressure, aromatherapy, and sound masking. Outcomes included objective sleep outcomes, subjective sleep quality and quantity, risk of delirium, participant satisfaction, length of ICU stay, and adverse events. Clinical heterogeneity (e.g., participant population, outcomes measured) and research design limited quantitative synthesis, and only a small number of studies were available for most interventions. The quality of the evidence for an effect of non-pharmacological interventions on any of the outcomes examined was generally low or very low. Only three trials, all of earplugs or eye masks or both, provided data suitable for two separate meta-analyses. These meta-analyses, each of two studies, showed a lower incidence of delirium during ICU stay (risk ratio 0.55, 95% confidence interval (CI) 0.38 to 0.80, P value = 0.002, two studies, 177 participants) and a positive effect of earplugs or eye masks or both on total sleep time (mean difference 2.19 hours, 95% CI 0.41 to 3.96, P value = 0.02, two studies, 116 participants); we rated the quality of the evidence for both of these results as low.

There was also some low quality evidence that music (350 participants; four studies) may improve subjective sleep quality and quantity, but we could not pool the data. Similarly, there was some evidence that relaxation techniques, foot massage, acupressure, nursing or social intervention, and sound masking can provide small improvements in various subjective measures of sleep quality and quantity, but the quality of the evidence was low. The effects of non-pharmacological interventions on objective sleep outcomes were inconsistent across 16 studies (we rated the quality of the evidence as very low): the majority of studies relating to the use of earplugs and eye masks found no benefit; results from six trials of ventilator modes suggested that certain ventilator settings might offer benefits over others, although the results of the individual trials did not always agree with each other. Only one study measured length of stay in the ICU and found no significant effect of earplugs plus eye masks. No studies examined the effect of any non-pharmacological intervention on mortality, risk of post-traumatic stress disorder, or cost-effectiveness; the included studies did not clearly report adverse effects, although there was very low quality evidence that ventilator mode influenced the incidence of central apnoeas and patient-ventilator asynchronies.

Authors' conclusions

The quality of existing evidence relating to the use of non-pharmacological interventions for promoting sleep in adults in the ICU was low or very low. We found some evidence that the use of earplugs or eye masks or both may have beneficial effects on sleep and the incidence of delirium in this population, although the quality of the evidence was low. Further high-quality research is needed to strengthen the evidence base.

PLAIN LANGUAGE SUMMARY

Non-drug treatments for promoting sleep in adults in the intensive care unit

Review question

We reviewed the evidence on non-pharmacological interventions (i.e. non-drug treatments) for improving sleep in critically ill adults.

Background

Sleep is essential to enable adults in the intensive care unit (ICU) to recover from their illnesses. However, adults in the ICU often suffer from frequently disturbed sleep or a lack of sleep. The reasons for sleep disruption may include the underlying illness, uncomfortable therapy, psychological stress, or the ICU environment itself.

Interventions for sleep promotion include pharmacological treatments and non-pharmacological interventions. Medications may produce side effects, such as a reduced ability to think clearly and negative effects on breathing, and they can also interfere with normal sleep patterns and lead to a risk of tolerance or drug dependency . Therefore, non-pharmacological interventions, such as noise reduction, music therapy, alternative and complementary therapies, and social support, have been sought and are recommended for improving sleep in critically ill adults.

Search date

The evidence is current to June 2014.

Study characteristics

We found 30 trials, with a total of 1569 participants, and the interventions included changes to ventilator type and settings, earplugs and eye masks, relaxation therapy, sleep-inducing music, massage, foot baths, aromatherapy, valerian acupressure, sound masking, and changing the visiting times of family members. We assessed the effects of these interventions on sleep outcomes (e.g., quality and amount of sleep), length of stay in the ICU, the occurrence of delirium, other adverse events, and death.

Key results and quality of evidence

Overall, the quality of the evidence for an effect of the interventions on any of the outcomes was low or very low. Normally, we would try to pool findings from similar trials of each intervention, but this was difficult because the design of the trials varied greatly. We were able to combine the results from three trials of earplugs and eye masks and found that their use increased the number of hours slept and prevented delirium in adults in the ICU. However, we cannot be certain about these findings because of problems with how the trials were carried out.

There was also some low quality evidence from four studies that music may improve subjective sleep quality and quantity, but we could not pool the data. Similarly, a low number of studies found that relaxation techniques, foot massage, acupressure, nursing or social intervention, and sound masking can provide small improvements in participant-reported or nurse-assessed sleep quality and quantity, but the quality of the evidence was low. The effects of the interventions on objective sleep outcomes (e.g., sleep measured by a machine) varied: the majority of studies that looked at the use of earplugs and eye masks found no benefit, and although the results from six trials of ventilator modes suggested that certain ventilator settings might offer benefits over others, the results of the individual trials did not always agree with each other. Only one study measured length of stay in the ICU and found no significant effect of earplugs plus eye masks. None of the included studies looked at economic outcomes, risk of post-traumatic stress disorder, or deaths. The trials did not clearly report adverse effects, although there was very low quality evidence that ventilator mode might influence certain adverse effects that can happen when people are on a ventilator. In summary, further well-designed and conducted research is needed to strengthen the evidence for the use of these interventions for improving sleep in critically ill adults.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Non-pharmacological interventions for sleep promotion in ICU patients - narrative summary

Non-pharmacological interventions for sleep promotion versus usual care/no intervention

Patient or population: critically ill patients
Settings: ICU
Intervention: various non-pharmacological interventions for sleep promotion
Comparison: standard care or no intervention

Outcomes	Impact	Number of participants (studies)*	Quality of the evidence (GRADE)
Changes in objective sleep variables (SEI, SFI, REM sleep)	The evidence relating to effect of ventilator mode (89 participants; 6 studies) or type (40 participants; 2 studies) on objective sleep variables was inconsistent. The evidence relating to the use of earplugs or eye masks or both was also inconsistent (141 participants; 4 studies), with the majority of studies finding no benefit for this intervention type There was no evidence for an effect of relaxation via foot baths on objective sleep variables (6 participants; 1 study). There was no consistent effect of music intervention on objective sleep variables (58 participants; 2 studies). Only 1 study (69 participants) examined the effects of relaxation techniques on objective sleep variables, although a positive effect on SEI was noted	403 (16 studies)	⊕⊖⊖⊖ VERY LOW[2,3]
Length of ICU stay	No effect of a combination of earplugs, eye mask, and sleep-inducing music (45 participants; 1 study) was noted on length of ICU stay. No studies examined the effect of the other non-pharmacological interventions on this outcome	45 (1 study)	⊕⊖⊖⊖ VERY LOW[3,4,5]
Subjective sleep quality or quantity	No trials examined the effect of ventilator mode or type on subjectively measured sleep quality or quantity. Using various scales, 6 studies (395 participants) individually reported some benefit of earplugs or eye masks or both on subjective sleep quality; pooled analyses from 2 of these studies (116 participants) showed a benefit for the use of earplugs/eye masks compared with usual care. The mean difference in total sleep quantity versus usual care was **2.19 hours (95% CI 0.41 to 3.96)** although evidence of heterogeneity was observed **(I^2 statistic = 79%)** There was some evidence that music (350 participants; 4 studies) may improve subjective sleep quality and quantity, but we could not pool the data. Similarly, there was some evidence that relaxation techniques (102 participants; 2 studies), foot massage (110 participants; 2 studies), acupressure (85 participants; 1 study), nursing or social intervention (158 participants; 2 studies), and sound masking (40 participants; 1 study) can provide small improvements in various subjective measures of sleep quality and quantity. Aromatherapy (25 participants; 1 study) was not found to influence subjective sleep quality	1220 (18 studies)[1]	⊕⊕⊖⊖ LOW[3,6]
Risk of delirium	Data from 2 studies (177 participants) were pooled and showed a benefit of earplugs or eye masks or both versus usual care on the risk of delirium: the relative risk was **0.55 (95% CI 0.38 to**	177 (2 studies)	⊕⊕⊖⊖ LOW[3,5]

	0.80). Assumed risk[¶] was **489 per 1000** people, and the intervention reduced this risk to **269 per 1000** people (**95% CI 186 to 391**). No studies of other non-pharmacological interventions assessed this outcome		
Any adverse event	There was some evidence (72 participants; 5 studies) that ventilator mode influenced the incidence of adverse events, such as central apnoeas and patient-ventilator asynchronies: more adverse events were noted with PSV compared with ACV and PAV. No studies examined the effect of non-pharmacological interventions on other adverse events (including PTSD)	72 (5 studies)	⊕⊖⊖⊖ VERY LOW[3,5,7]
Mortality	None of the included studies examined the effect of non-pharmacological interventions for sleep promotion on the incidence of mortality	NA	NA
Economic outcomes	None of the included studies examined the cost effectiveness or health economic effects of non-pharmacological interventions for sleep promotion in ICU patients	NA	NA

[*]Number of participants refers to the number of participants analysed in each study.

[¶]The basis for the **assumed risk** is the median control group risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
ACV: assist-control ventilation;**CI:** confidence interval; **GRADE:** Grading of Recommendations Assessment, Development and Evaluation; **ICU:** intensive care unit; **NA:** non applicable;**PAV:** proportional assist ventilation; **PSV:** pressure support ventilation; **PTSD:** posttraumatic stress disorder; **RR:** risk ratio; **SEI:** Sleep Efficiency Index; **REM:** rapid eye movement sleep; **SFI:** sleep fragmentation index.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

General note: we assessed the effect of several interventions on each outcome; therefore, in some instances, the factors resulting in downgrading of the evidence varied by intervention type for a given outcome.
[1]Hu 2010 contributed data on the use of eye masks/earplugs as well as music as non-pharmacological interventions; the study and its 45 analysed participants were counted once towards the total number of studies and participants for this outcome.
[2]Evidence downgraded by 2 points (-2) for inconsistency. Although we could not perform meta-analysis because of clinical heterogeneity, reported treatment effects varied between individual studies.
[3]Evidence downgraded by 1 point (-1) for risk of selection bias. We rated a number of the studies contributing evidence as at an unclear or high risk of selection bias.
[4]Evidence downgraded by 1 point (-1) for indirectness as only a single study contributed data, and evidence was therefore based on a single patient population.
[5]Evidence downgraded by 1 point (-1) for imprecision as the confidence intervals were wide.
[6]Evidence downgraded by 1 point (-1) for either indirectness (data relevant to a single study population), inconsistency (findings across individual studies varied), or imprecision (confidence intervals were wide).
[7]Evidence downgraded by 1 point (-1) for indirectness as only studies of ventilator mode or type were considered, so the evidence would be unlikely to be applicable to other intervention types (e.g., eye masks).

BACKGROUND

Description of the condition

Sleep is a basic need for human survival and is essential for the recovery of critically ill adults. Normal human sleep is generally categorized as two states: non-rapid eye movement (NREM) and rapid eye movement (REM), which alternate cyclically across a sleep episode. The American Academy of Sleep Medicine Scoring Manual (Silber 2007) further subdivides NREM sleep into stages one to three. Sleep begins in NREM stage one (N1) and progresses through the deeper NREM stage two (N2) to NREM stage three (N3), which is also called delta sleep or slow-wave sleep (SWS). A progressive increase in the threshold required for arousal (e.g., by noise) accompanies the progression of sleep from stage N1 through to stage N3. NREM sleep normally cycles with REM sleep approximately every 90 minutes. Normally, REM sleep accounts for about 25% of sleep time, and adults spend up to 50% of the night in stage N2 sleep.

Adults in intensive care units (ICUs) often suffer from a lack of sleep or frequent sleep disruptions (Gabor 2003; Meyer 1994). Both subjective and objective studies have demonstrated significant sleep disruption in critically ill patients (Freedman 1999; Freedman 2001; Friese 2007; Gabor 2001; Parthasarathy 2004; Simini 1999). In one study, as many as 38% of ICU patients experienced difficulty in falling asleep, and 61% reported shorter periods of sleep than usual (Orwelius 2008). Several studies using polysomnography (PSG) have consistently demonstrated that the sleep of ICU patients is characterized by sleep fragmentation, poor sleep efficiency, an increase in light sleep, and a decrease in both REM sleep and SWS (Cooper 2000; Freedman 2001; Friese 2007). Moreover, about 50% of sleep occurs during the day in ICU patients (Cooper 2000; Freedman 2001; Gabor 2003; Hardin 2006).

PSG represents the gold standard for techniques used to monitor sleep and is the only method to identify the individual sleep stages. However, many centres lack the facilities required for PSG (in terms of equipment and staff). Therefore, some studies (especially those performed in critical care units) have adopted other techniques for measuring sleep, such as actigraphy, Bispectral Index (BIS) monitoring, and nurse/patient assessment (Le Guen 2014; Jaber 2007). An ActiGraph is a small wristwatch device that can monitor whether a patient is asleep or awake based on the levels of patient wrist motor activity. ActiGraphs have been used in studies of sleep and circadian rhythms in ICU patients. However, actigraphy does not provide any information regarding either the stage or quality of sleep and tends to overestimate total sleep time compared with PSG and BIS. BIS is calculated from multiple analyses of the raw electroencephalography (EEG) waveform that is capable of detecting sleep, but the overlap of BIS values between given sleep stages currently prevents its use as a depth-of-sleep monitor (Nieuwenhuijs 2006). Furthermore, BIS values potentially provide an inaccurate indication of patients' sleep characteristics when patients have neurological abnormalities. ICU studies have often used subjective measurements of sleep: several visual analogue scales (VAS), such as the Verran/Snyder-Halpern Sleep Scale (VSH) and the Richardson-Campbell Sleep Questionnaire (RCSQ), have been developed and used to assess patients' sleep perception. The RCSQ score accounted for approximately 33% of the variance in the PSG indicator Sleep Efficiency Index (SEI) in one critical care group (Richards 2000). However, a problem with VAS scales is that patients may be incapable of completing the questionnaire; one study excluded half of the recruited participants because of unconsciousness or delirium (Frisk 2003).

The reasons for sleep disruption are multifactorial and include underlying illness, uncomfortable therapy, psychological stress, age-related changes in sleep patterns, pain, mechanical ventilation, and the ICU environment (Drouot 2008; Friese 2008; Weinhouse 2006; Weinhouse 2009). Environmental stimuli are thought to be important factors. Light, noise, patient-care activities, and physician interventions all contribute to sleep deprivation; noise and patient-care activities are thought to account for approximately 30% of observed sleep disruption (Gabor 2003). Continuous exposure to light can also disrupt the patient's naturally occurring circadian rhythms (Czeisler 1986).

There are several adverse consequences of sleep disruption, which may include an impaired immune function (Benca 1997), reduced inspiratory muscle endurance (Chen 1989), an altered weaning process (Pandharipande 2006), a degeneration in the quality of life (Dignani 2015), and prolonged neurocognitive dysfunction (O'Donoghue 2012). Importantly, these adverse consequences may be associated with ICU delirium and severe morbidity (Eddleston 2000; Novaes 1999; Pun 2007; Weinhouse 2006).

Interventions for sleep promotion involve both pharmacological treatment and non-pharmacological interventions. Generally, pharmacological therapies are used for the treatment of sleep disturbances (Abad 2015). Pharmacological agents that induce sleep provide sedation and analgesia and are commonly used in the ICU setting. However, pharmacological interventions have potential side effects, including impaired cognitive function, risk of tolerance or dependency, depressed ventilation, and adversely affected normal sleep physiology (Mistraletti 2008). For example, benzodiazepines, opiates, or barbiturates disrupt normal sleep patterns and decrease REM activity and stage 3 sleep (Achermann 1987; Cronin 2001), whereas propofol leads to slow-wave activity that mimics slow-wave sleep and modifies circadian rhythms (Ozone 2000). Therefore, sedation in the ICU is both a cause and a potential treatment for sleep disruption in ICU patients (Weinhouse 2009). Additionally, induction of sleep by drugs is contraindicated in certain patient groups, such as non-ventilated patients suffering from hypercapnic lung disease (Shilo 1999). Therefore, non-pharmacological interventions have been sought, and a multifaceted approach is recommended to improve the sleep of critically ill patients (Jacobi 2002). In general, the efficacy of non-pharmacological interventions for improving sleep has been considered to be less than pharmacological methods while having no risk of drug-related tolerance or dependency (Hauri 1997; McClusky 1991).

Description of the intervention

A wide range of non-pharmacological interventions have been used to improve sleep in ICU patients. These can be broadly categorized as follows: psychological (cognitive or behavioural) interventions, complementary therapies (e.g., music therapy, aromatherapy, massage, guided imagery, acupressure), environmental interventions (e.g., synchronization of ICU activities with daylight, noise reduction), social interventions (e.g., family support), and equipment modification (e.g., optimizing ventilator modes or ventilator types). Cognitive behavioural therapy (CBT) has been used to treat insomnia in the ambulant setting by changing poor sleep habits and prompting sleep hygiene practices

(Gałuszko-Węgielnik 2012). A meta-analysis of 224 participants (aged > 60 years) who experienced insomnia in an ambulant setting indicated a mild effect of CBT for sleep problems and was best used for sleep maintenance insomnia (Montgomery 2003).

How the intervention might work

Complementary therapies, such as massage, music therapy, therapeutic touch, aromatherapy, relaxation, and mental imaginary, seem to comfort and reduce levels of stress and anxiety in critically ill patients, which in turn is likely to lead to improved sleep (Richards 2003). A combination of relaxation and imagery may be effective in improving the sleep of the critically ill adult (Richards 2003). Environmental interventions, such as reducing noise, controlling lighting, playing white noise, and adequate uninterrupted time for sleep, are safe and logical interventions to help patients sleep (Richards 2003). Several studies found that the use of earplugs and eye masks as methods of noise reduction and light control improved sleep quality (Koo 2008; Richardson 2007; Scotto 2009). Optimising modes of mechanical ventilation may also facilitate sleep, as some modes have been found to cause less arousals and awakenings per hour (Cabello 2008; Friese 2008; Parthasarathy 2004). However, the use of such non-pharmacological interventions in critical care needs to take account of environmental and patient considerations. Interventions must be easy to implement (i.e., practical) and must not harm or diminish patient safety.

Why it is important to do this review

Several systematic reviews have highlighted benefits of non-pharmacological interventions for improving sleep in different patient populations. Previous systematic reviews have assessed the efficacy of valerian and exogenous melatonin for improving sleep (Bent 2006; Buscemi 2005). Similarly, previous Cochrane reviews have examined the effects of bright light therapy, cognitive behavioural therapy, and acupuncture in improving sleep quality in patients with insomnia or elderly people (Cheuk 2012; Montgomery 2002; Montgomery 2003). However, there remains little clear evidence of the effectiveness of non-pharmacological interventions for improving sleep quality in critically ill patients residing in critical care units. An earlier systematic review examined the effects of massage on relaxation, comfort, and sleep in acute and critical care settings and concluded that the existing clinical data at that time were insufficient and further studies were required (Richards 2000a). A subsequent review of complementary and alternative therapies to promote sleep in critically ill patients concluded that techniques to promote sleep through muscle relaxation might be difficult for critically ill patients because of the need for patients to be conscious to receive the therapy. The review also reported that interventions such as music therapy, environmental interventions, therapeutic touch, and relaxing massage appeared to be safe but that further randomized controlled trials were required to assess efficacy (Richards 2003). Therefore, it was important to perform this review, which examined recent studies, particularly as there remains little guidance on the potential efficacy and harms of these interventions for adult patients in the critical care unit.

OBJECTIVES

To assess the efficacy of non-pharmacological interventions (Appendix 1) for sleep promotion in critically ill adult patients in the ICU.

To establish whether non-pharmacological interventions are safe and clinically effective in improving sleep quality and reducing length of ICU stay in critically ill adults.

To establish whether non-pharmacological interventions are cost effective.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) and quasi-RCTs that evaluated the effects of non-pharmacological interventions for sleep promotion in critical care units (CCU) or intensive care units (ICUs) for critically ill adult participants (aged 18 years and older).

We included all studies, published or unpublished, in any language.

Types of participants

Critically ill adult patients with stable haemodynamic status who were admitted to ICUs or critical care units and had a length of stay of more than 24 hours. We included studies of surgical or non-surgical patients with or without mechanical ventilation. We imposed no restrictions on gender or ethnicity. We excluded studies enrolling participants who were diagnosed with obstructive sleep apnoea or dementia or those who were terminally ill or required palliative care.

Types of interventions

We included any non-pharmacological intervention for improving sleep, such as those that examined one or a combination of interventions, and compared them with different non-pharmacological interventions, pharmacological interventions (e.g., sedation), or standard care (e.g., routine nursing care).

We included the following types of non-pharmacological interventions:

- psychological (cognitive or behavioural) interventions, such as music therapy, back massage, muscle relaxation, imagery, and therapeutic touch;
- environmental interventions, such as noise reduction, lighting control, and synchronization of ICU activities with daylight;
- social support interventions;
- equipment modification, including mechanical ventilation;
- complementary and alternative therapies: aromatherapy, herbs, acupuncture; and
- physical therapy modalities.

Types of outcome measures

Primary outcomes

- Changes in objective sleep variables (as measured by polysomnography, ActiGraph, or Bispectral Index), including

Sleep Efficiency Index (SEI), rapid eye movement (REM) sleep time, REM sleep latency, and sleep fragmentation index.
- Length of ICU stay.
- Mortality.

Secondary outcomes

- Any adverse reactions or events.
- Risk of delirium during ICU stay.
- Changes in subjective sleep quality or quantity, measured by participant report or medical or nursing observation.
- Risk of post-traumatic stress disorder (PTSD) once discharged from hospital.
- Participant satisfaction (as reported by the study authors).
- Economic outcomes.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, 2014, Issue 6), 2014, Issue 6) (Appendix 2), MEDLINE (OVID, 1950 to June 2014) (Appendix 3), EMBASE (1966 to June 2014), CINAHL (Cumulative Index to Nursing and Allied Health Literature, 1982 to June 2014), Institute for Scientific Information (ISI) Web of Science (1956 to June 2014) (Appendix 4) , CAM on PubMed (1966 to June 2014), Alt HealthWatch (1997 to June 2014), PsycINFO (1967 to June 2014), the China Biological Medicine Database (CBM-disc, 1979 to June 2014), and China National Knowledge Infrastructure (CNKI Database, 1999 to June 2014).

We searched for relevant ongoing trials up to June 2014 using the following websites.

- The World Health Organization International Clinical Trials Registry platform (WHO ICTRP) (www.who.int/trialsearch) - four WHO ICTRP Primary Registers.
- Chinese Clinical Trial Registry (www.chictr.org.cn).
- The metaRegister of Controlled Trials (ISRCTN Register) (www.controlled-trials.com).
- The US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov).
- Clinical Trials Registry-India (www.ctri.nic.in).

We searched for grey literature using the following websites.

- OpenGrey (www.opengrey.eu).
- Grey Literature Report from the New York Academy of Medicine Library (www.greylit.org).
- ProQuest Dissertations & Theses Global (www.search.proquest.com).

We modified the MEDLINE search strategy to search the other databases (Appendix 3).

Searching other resources

We handsearched appropriate journals and abstracts of relevant conference proceedings. We searched the reference lists of all retrieved articles. We did not limit the search by language or publication status.

We handsearched the following journals:

- *Critical Care Medicine* (1995 to May 2014);
- *Critical Care* (1997 to May 2014);
- *Journal of Critical Care* (1995 to May 2014); and
- *American Journal of Respiratory and Critical Care Medicine* (1995 to May 2014).

Data collection and analysis

Selection of studies

Two authors (HRF, CXY) independently examined the titles and abstracts identified from the search. We retrieved and evaluated the full text of potentially relevant studies. Two authors (HRF, ZZY) independently assessed their eligibility according to our inclusion and exclusion criteria, resolving any disagreements by discussion. A third author (CJM) settled any disagreements. Where appropriate, we corresponded with study authors by telephone or by email to clarify study eligibility. We recorded reasons for study exclusion in the 'Characteristics of excluded studies' tables.

Data extraction and management

Two authors (HRF, XHN) independently extracted data using a tool developed by the authors (Appendix 5). We resolved any disagreements by discussion with a third author (CJM). Two review authors entered the data into Review Manager software (RevMan 5.3), and a third author (JXY) checked the data.

Assessment of risk of bias in included studies

Two authors (HRF, LYP) independently assessed the quality of all included trials as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We assessed the methodological quality of all trials on the basis of the following six domains:

- random sequence generation;
- allocation concealment;
- blinding of participants, personnel, and outcome assessors;
- incomplete outcome data;
- selective reporting; and
- other sources of validity.

Measures of treatment effect

We calculated mean differences (MDs) with 95% confidence intervals (CI) for continuous data and standardized mean differences (SMDs) for outcome measures using results from different scales. Where possible, we obtained standard deviations from standard errors and confidence intervals. We analysed longer ordinal scales as continuous data. We combined adjacent categories together and made them into dichotomous data for trichotomous-type outcomes. Where trichotomous-type outcomes were summarized using methods for dichotomous data, we used risk ratios (RR) with 95% CIs to describe the intervention effect. We estimated heterogeneity using the I^2 statistic (Higgins 2011). In the case of significant clinical heterogeneity, we did not pool results.

Unit of analysis issues

We included both parallel and cross-over randomized controlled trials. The participants in each intervention arm were the unit of analysis in a single parallel group design. According to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011),

the recommended method for including multiple groups from one study is to combine all relevant experimental intervention groups from the study into a single group and combine all relevant control intervention groups into a single control group. Although we found an orphan study with more than a two-arm parallel intervention group and some cross-over trials with more than two intervention groups in this review, we could not include them in a meta-analysis. Considering the presence of carry-over, we had planned to analyse the data from only the first period in cross-over RCTs. However, only two cross-over RCTs reported data from the first period and the cross-over period, whereas the remaining studies only reported the whole period data. Thus, we took the decision to exclude cross-over studies from the meta-analyses.

Dealing with missing data

Whenever possible, we contacted the trial authors to request missing data. We calculated missing statistics (such as standard deviations or correlation coefficients) from other statistics, such as the standard error or confidence intervals.

Assessment of heterogeneity

We firstly explored clinical heterogeneity by assessing the clinical and methodological characteristics of the included studies (for example, trial design, participant characteristics, intervention, or outcome measurement). If we pooled data from multiple studies, we formally assessed heterogeneity using the I^2 statistic (Higgins 2011) and by visual inspection of the forest plots. We considered a Chi^2 statistic with a P value < 0.10 or an inconsistency between studies (I^2 statistic) greater than 50% as evidence of relevant heterogeneity.

Assessment of reporting biases

We assessed the scope for reporting bias by the absence of primary outcomes and by less detailed reporting of non-significant outcomes. Due to the small number of studies included in each category, we did not perform funnel plots for publication bias.

Data synthesis

We anticipated that studies would use different scales to measure the same outcomes. We calculated standardized mean differences (SMDs) from different scales. We made the following intervention comparisons using meta-analyses: use of earplugs or eye masks or both versus no use of earplugs or eye masks. We had planned to include the following additional treatment comparisons, but there were insufficient trials to do so, or the available trials had important clinical heterogeneity among them: acupressure versus other interventions or placebo, aromatherapy versus other interventions or placebo, back massage versus other interventions or placebo, foot baths versus other interventions or placebo, relaxation and imagery versus other interventions or placebo, foot massage versus other interventions or placebo, using sound masking versus other interventions or placebo, and social support intervention versus other interventions or placebo. Therefore, we included trials comparing these interventions with other therapies or placebo in the narrative but not the meta-analysis of this review.

Subgroup analysis and investigation of heterogeneity

We had planned to explore the following subgroups:

- age;
- sex;
- interventions (different methods, different duration, or difference frequency); and
- trial quality (e.g., RCT and quasi-RCT).

However, since we only pooled two studies for each meta-analysis in this review, we did not perform subgroup analyses (see Differences between protocol and review).

Sensitivity analysis

We did not perform sensitivity analyses due to the small number of studies included in each group (see Differences between protocol and review).

'Summary of findings' tables

We used the principles of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt 2008) to assess the quality of the body of evidence associated with specific outcomes. Because of the number of interventions considered, the heterogeneity between studies, and the lack of meta-analyses, we provided a narrative summary of findings: Summary of findings for the main comparison.

RESULTS

Description of studies

Please see the 'Characteristics of included studies' tables; the 'Characteristics of excluded studies' tables; the 'Characteristics of studies awaiting classification' tables; and the 'Characteristics of ongoing studies' tables.

Results of the search

Please see Figure 1.

Figure 1. Study flow diagram. CBM = China Biological Medicine Database; CENTRAL = Cochrane Central Register of Controlled Trials; CINAHL = Cumulative Index to Nursing and Allied Health Literature; CNKI = China National Knowledge Infrastructure; ISI = Institute for Scientific Information; PQDD = ProQuest Dissertations & Theses Global; RCT = randomized controlled trial; WHO ICTRP = the World Health Organization International Clinical Trials Registry

platform. *One trial examined music intervention and eye mask/earplugs and is counted under both categories. ** One trial examined relaxation interventions and is counted under both categories.

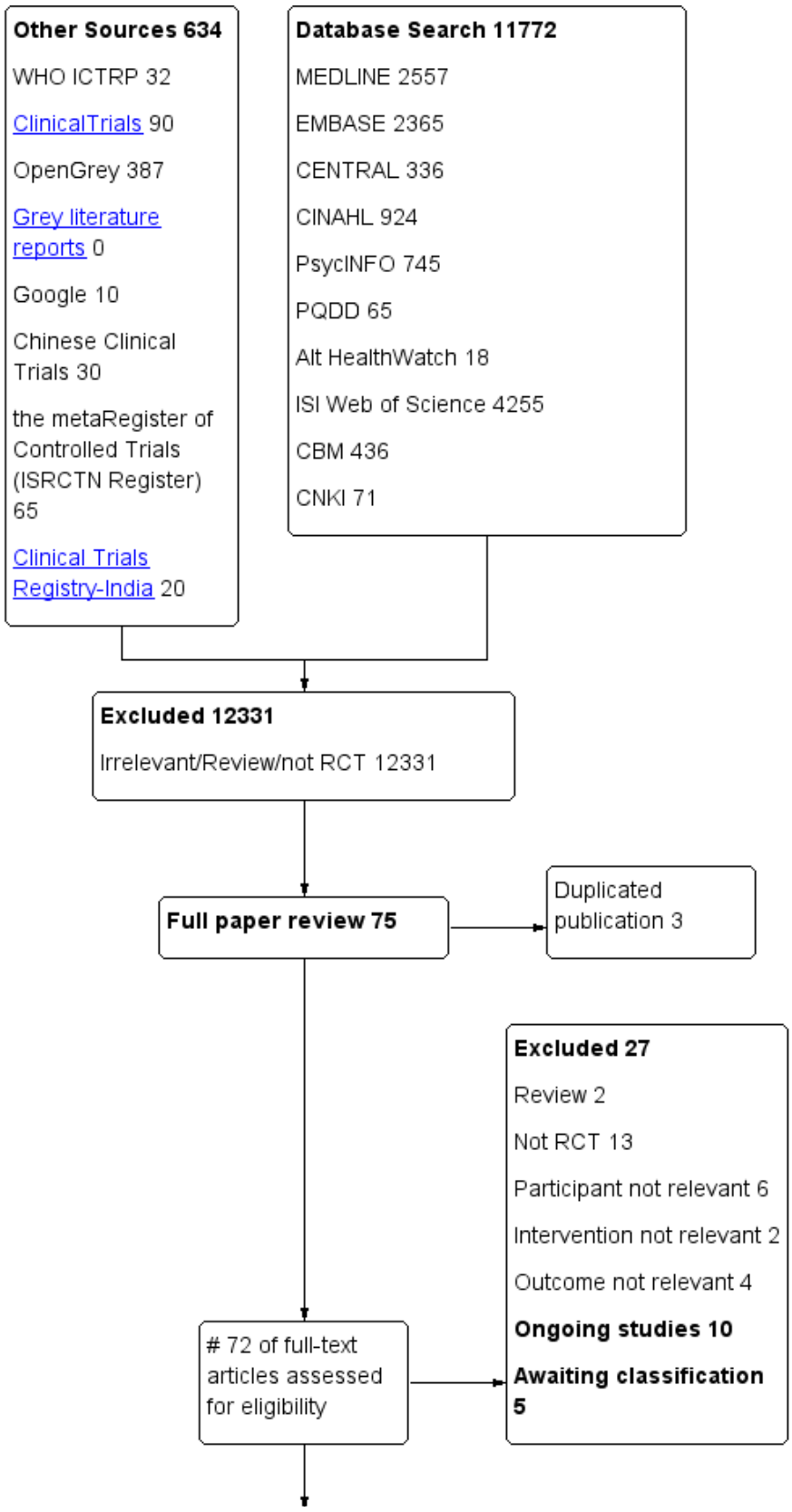
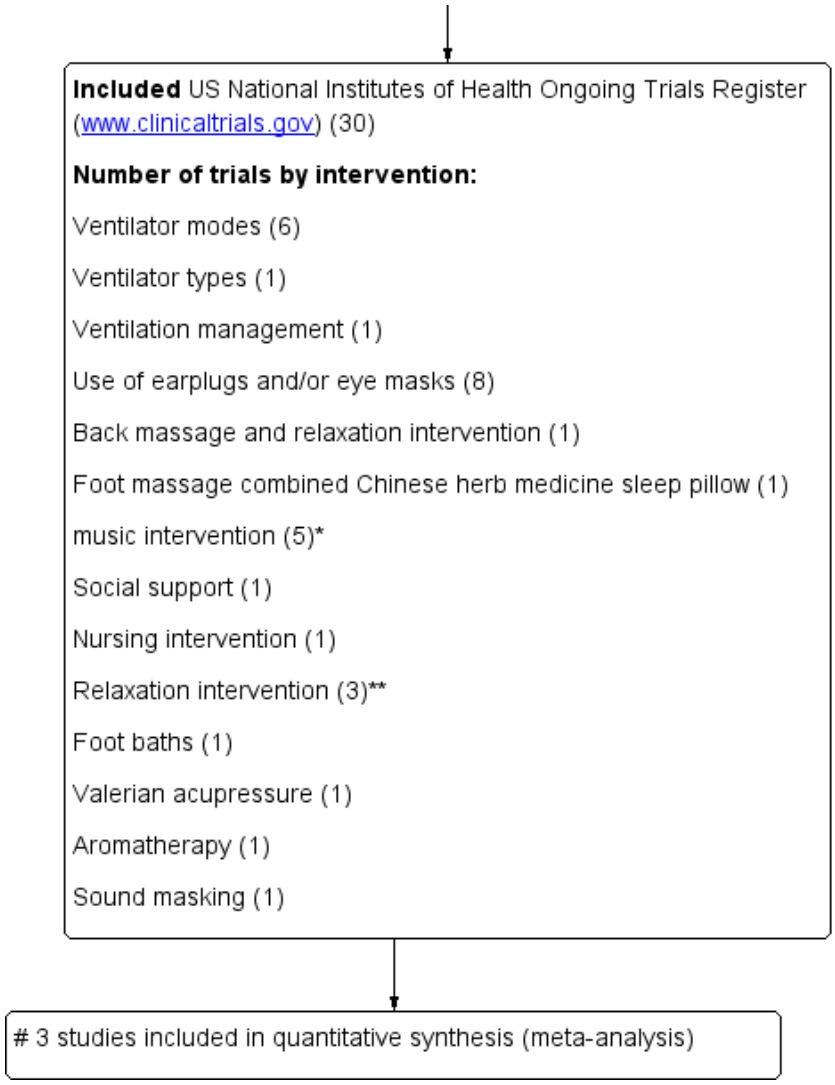


Figure 1. (Continued)



We identified 72 potentially relevant studies and retrieved them for further assessment. We included 30 studies (see the 'Characteristics of included studies' tables). We contacted the authors of five studies, Alexopoulou 2007; Andréjak 2013; Bosma 2007; Richards 1998; Wallace 1998, by email and retrieved details of study methods and data from them.

We excluded a total of 27 studies that did not meet the inclusion criteria (see the 'Characteristics of excluded studies' tables for detailed descriptions).

Ten trials registered on the US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov) are ongoing (see the 'Characteristics of ongoing studies' tables for detailed descriptions), and five studies are awaiting classification (see the 'Characteristics of studies awaiting classification' tables).

Included studies

In this review, we included 30 randomized controlled trials, with 1569 participants; 12 trials using cross-over design; and 18 trials using parallel group design. There were 29 randomized trials and one quasi-randomized trial. Eight trials were conducted in China, one was conducted in Korea, one was conducted in Japan, 11 were conducted in Europe, and nine were conducted in the United States (see the 'Characteristics of included studies' tables for detailed descriptions).

Participants

The number of participants per study ranged from a minimum of six to a maximum of 136. Ten trials included ventilated participants (Alexopoulou 2007; Andréjak 2013; Bosma 2007; Cabello 2008; Córdoba-Izquierdo 2013; Hu 2010; Jaber 2007; Parthasarathy 2002; Roche-Campo 2013; Wallace 1998); most of these studies ventilated participants through an endotracheal tube or tracheostomy, and only one of these trials, Córdoba-Izquierdo 2013, used non-invasive ventilation. One study included both ventilated participants and non-ventilated participants (Jaber 2007). Nine studies reported trials that were conducted in single-bed rooms in the critical care unit (Alexopoulou 2007; Andréjak 2013; Borromeo 1998; Gragert 1990; Richards 1998; Richardson 2003; Su 2013; Toublanc 2007; Wallace 1998). Seven trials were conducted in coronary care

units (Borromeo 1998; Gao 2008; Gragert 1990; Li 2011; Richards 1998; Ryu 2012; Wang 2012), one was performed in a cardiac surgical intensive care unit (Hu 2010), two were performed in a medicosurgical department of anaesthesia and resuscitation (Jaber 2007; Le Guen 2014), one was performed in a respiratory intensive care unit (ICU) (Toublanc 2007), one was performed in a pulmonary and critical care unit (Parthasarathy 2002), and the remaining studies were performed in medical ICUs.

Thirteen studies, Andréjak 2013; Bosma 2007; Córdoba-Izquierdo 2013; Foreman 2013; Gao 2008; Hu 2010; Le Guen 2014; Parthasarathy 2002; Ruan 2006; Su 2013; Sha 2013; Toublanc 2007; Wang 2012, reported that baseline characteristics did not differ significantly between the groups.

Interventions

We included six trials of ventilator mode, eight trials using earplugs or eye masks or both, five trials of music interventions (which included one trial, Hu 2010, using earplugs and eye masks combined with music intervention), three trials of relaxation and imagery (which included one trial of back massage and relaxation intervention (Richards 1998)), one trial of back massage and relaxation intervention, one trial of foot massage combined with the use of a Chinese herb sleep pillow (Wang 2012), one trial of a foot bath intervention (Namba 2012), one trial of social support intervention through changing the ICU visit time for family members (Gao 2008), one trial of a nursing intervention (Li 2011), one trial of valerian acupressure (Chen 2012), one trial of ventilator type (Córdoba-Izquierdo 2013), one trial of receiving mechanical versus spontaneous ventilation (Roche-Campo 2013), one trial of aromatherapy (Borromeo 1998), and one trial of sound masking (using USASI noise, namely a continuous sound occurring at the same level over a long period) (Gragert 1990).

The interventions included in this review were heterogeneous with respect to components, methods, content, and intensity of use. The duration of the interventions ranged from 10 minutes, Chen 2012, to seven days (Wang 2012). Most cross-over trials had no washout period between intervention periods (Alexopoulou 2007; Andréjak 2013; Bosma 2007; Cabello 2008; Jaber 2007; Martin 2008; Parthasarathy 2002; Roche-Campo 2013; Toublanc 2007); only two trials used a washout period (Borromeo 1998; Namba 2012).

1. Optimizing ventilator mode, type, or management strategy

Six trials examined the effect of ventilator mode on sleep, namely three trials of assist-control ventilation (ACV) versus pressure support ventilation (PSV) (Cabello 2008; Parthasarathy 2002; Toublanc 2007), two trials of proportional assist ventilation (PAV) versus PSV (Alexopoulou 2007; Bosma 2007), and one trial of pressure-controlled ventilation (PCV) versus low PSV (Andréjak 2013).

One trial, Córdoba-Izquierdo 2013, examined the effect of optimizing ventilator type on sleep.

One trial, Roche-Campo 2013, examined the effect of mechanical versus spontaneous ventilation on sleep.

2. Earplugs or eye masks or both

We included eight trials using earplugs or eye masks or both. Four of these trials compared the use of earplugs versus no use of earplugs during regular night-time sleeping hours (Martin 2008; Scotto 2009; Van Rompaey 2012; Wallace 1998). One trial compared the use of earplugs and eye masks combined with sleep-inducing music versus no use of earplugs, no eye masks, and no music (Hu 2010). Two trials compared the use of earplugs and eye masks versus no use of earplugs and eye masks during night-time (Le Guen 2014; Xie 2011). One trial compared oral melatonin, sound-reducing headphones, and eye covers versus standard care (Foreman 2013). The duration of the interventions varied from one night, Le Guen 2014; Martin 2008; Scotto 2009; Wallace 1998, to four nights (Van Rompaey 2012).

3. Music intervention

Five studies included in this review used music intervention with sleep-inducing or relaxing music, but the methods of the interventions, frequency and duration of music listening, and methods in the control group varied greatly between these trials. One trial compared earplug-delivered sleep-inducing music for 52 minutes versus control group (no music, but earplugs and eye shield worn) (Ryu 2012). One study compared a 45-minute music-listening intervention versus usual care without music (Su 2013). One trial combined the use of earplugs and eye masks with music listening versus no use of earplugs or eye masks and no music (Hu 2010). (We also counted this study under the eye mask/earplug category.) One trial compared a 20-minute relaxing music therapy versus sitting and uninterrupted resting (Jaber 2007). One trial compared an individualized music intervention (12.30 p.m. to 1.30 p.m. and 8.30 p.m. to 9.30 p.m.) versus usual care during the period of ICU stay (Sha 2013).

4. Relaxation techniques

Three trials used relaxation techniques: Richardson 2003 used a combination of relaxation and imagery (13 to 18 minutes in length); Ruan 2006 used a combination of relaxation, imagery, and relaxing music; Richards 1998 used a combination of muscle relaxation, mental imagery, and music (a 7.5-minute relaxation audiotape consisting of music; guided imagery; and muscle relaxation. We also included this trial under 'back massage' intervention below).

5. Massage

a) Back massage and relaxation intervention

Richards 1998 compared the effect of a back massage and relaxation intervention on sleep with two different groups: group one received a six-minute back massage; group two received a teaching session on relaxation and a 7.5-minute audiotape at bedtime consisting of muscle relaxation, mental imagery, and relaxing background music; group three received usual nursing care. The duration of the intervention was one night.

b) Foot massage or foot bath

Wang 2012 examined the effect of foot massage combined with use of a "sleep pillow" (ingredients: Chinese herbal medicine); the duration of the intervention was seven days.

Namba 2012 examined the efficacy of a foot bath intervention for sleep promotion.

6. Valerian acupressure

Chen 2012 compared valerian acupressure on the Shenmen, Neiguan, and Yongquan acupoints versus usual care; the duration of the intervention was one night.

7. Aromatherapy

Borromeo 1998 examined the effects of aromatherapy intervention on sleep.

8. Sound masking

Gragert 1990 compared sound masking (USASI noise) versus usual care.

9. Social support intervention and nursing intervention

Gao 2008 compared changing the ICU visit time for family members versus conventional care with standard visiting times.

Li 2011 compared a nursing intervention programme using the Roy Adaptation Model as a guide versus conventional care; the duration of the intervention was two weeks.

Outcomes

Not all trials measured all of the outcomes relevant for this review. Included studies examined objective sleep outcomes or subjective sleep outcomes or both.

Sleep was measured using polysomnography (Alexopoulou 2007; Andréjak 2013; Bosma 2007; Cabello 2008; Córdoba-Izquierdo 2013; Namba 2012; Parthasarathy 2002; Richards 1998; Roche-Campo 2013; Su 2013; Toublanc 2007 Wallace 1998), ActiGraph (Chen 2012; Le Guen 2014), Bispectral Index (BIS) (Jaber 2007), electroencephalography (EEG) and methods of muscle tension (Foreman 2013; Xie 2011), nurse observation (Chen 2012; Gragert 1990; Gao 2008; Ruan 2006), and participant assessment (Borromeo 1998; Gragert 1990; Hu 2010; Le Guen 2014; Martin 2008; Richardson 2003; Ryu 2012; Scotto 2009; Toublanc 2007; Sha 2013; Van Rompaey 2012; Wang 2012; Xie 2011).

Sixteen trials used subjective sleep scales to measure sleep quality on the day following the intervention, but the sleep scales varied among these trials: five trials, Richardson 2003; Martin 2008; Scotto 2009; Su 2013; Ryu 2012, used the Verran/Synder-Halpern (VSH (Snyder-Halpern 1987)) Sleep Scale (although the versions of the VSH Scale used differed between these trials, and the rating methods were different); three studies, Borromeo 1998; Gragert 1990; Hu 2010, used the Richardson-Campbell Sleep Questionnaire (RCSQ, a self-reported visual analogy instrument (Richards 2000)); three trials, Li 2011; Sha 2013; Xie 2011, used a Chinese version of the Pittsburgh Sleep Quality Index (PSQI) scale (Liu 1996); one trial, Chen 2012, used the PSQI and Stanford Sleepiness Scale (SSS (Fichten 1995)); one trial, Wang 2012, used the Athens Insomnia Scale (AIS (Soldatos 2000)) to measure subjective sleep quality; one trial, Le Guen 2014, measured self-assessment sleep quality by Spiegel score (Klimm 1987) and Medical Outcomes Study Sleep questionnaire (Hays 2005); and two trials, Toublanc 2007; Van Rompaey 2012, used participant-perceived measures of sleep quality.

Two trials reported outcomes relating to the incidence of delirium (Le Guen 2014; Van Rompaey 2012). Van Rompaey 2012 assessed delirium using the validated Neelon/Champagne Confusion (NEECHAM) scale (Milisen 2005), which was based on the nurses' 24-hour assessment of the level of processing information, the level of behaviour, and the physiological condition.

The majority of cross-over trials included in this review only reported the whole-period outcomes of the study. Two trials reported outcomes during the first period and the second period in addition to the whole period (Roche-Campo 2013; Toublanc 2007).

Excluded studies

We excluded 27 studies (see the 'Characteristics of excluded studies' tables). We excluded these studies for the following reasons: four trials did not have relevant outcomes; 13 trials were not randomized or quasi-randomized controlled trials; in six studies, the types of participants were not relevant; in two studies, the interventions were not relevant; and two articles were systematic reviews.

Studies awaiting classification

Five studies, NCT01607723; NCT01580956; NCT01343095; NCT01061242; Nerbass 2011, are awaiting classification. (Please refer to the 'Characteristics of studies awaiting classification' tables for more details.)

Ongoing studies

Ten studies, NCT02095496; NCT01082016; NCT01276652; NCT01284140; ChiCTR-TRC-14004405; IRCT2013030912749N1; NCT00638339; Qureshi 2014; NCT01523938; NCT01727375, are ongoing. (Please refer to the 'Characteristics of ongoing studies' tables for more details.)

Risk of bias in included studies

For details of the 'Risk of bias' rating for each study and the reasons for each rating, please see the 'Characteristics of included studies' tables. A summary of the 'Risk of bias' judgements by study and domain (sequence generation, allocation concealment, blinding, incomplete data, and selective reporting) can be found in Figure 2 and Figure 3.

Figure 2. 'Risk of bias' graph: review authors' judgements about each 'Risk of bias' item presented as percentages across all included studies.

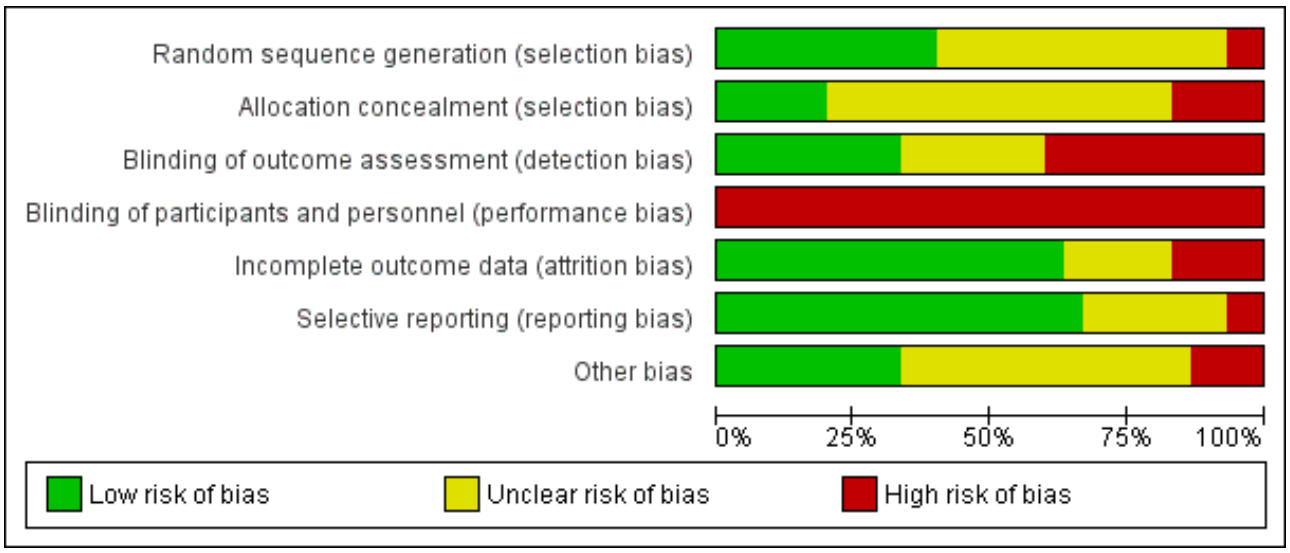


Figure 3. 'Risk of bias' summary: review authors' judgements about each 'Risk of bias' item for each included study.

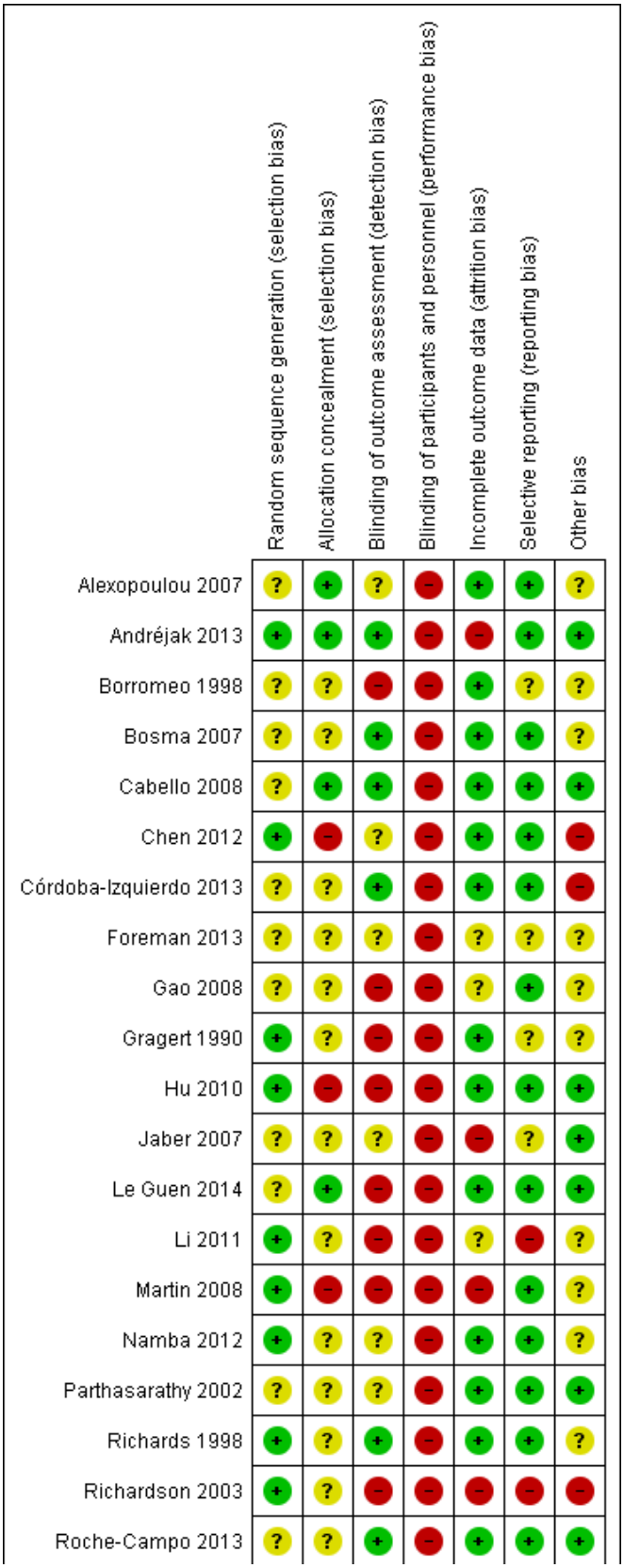
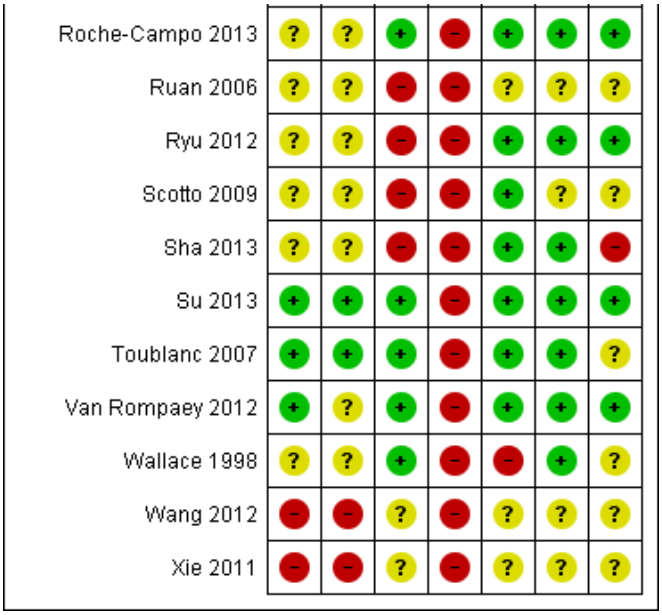


Figure 3. (Continued)



Allocation

The method of random sequence generation may have introduced bias into the studies analysed in this review. Twelve studies provided details of adequate methods for random sequence generation: Richards 1998 used a random number generator; Richardson 2003 used coin toss; two trials used a computer randomization method (Toublanc 2007; Van Rompaey 2012); and three trials used a random number table (Hu 2010; Li 2011; Namba 2012). Five trials used a method involving drawing lots/random numbers (Andréjak 2013; Chen 2012; Gragert 1990; Martin 2008; Su 2013). Sixteen studies stated that participants were "randomly allocated" but lacked description about the method of sequence generation. (Therefore, the risk of bias was unclear.) Two studies used inadequate methods of sequence generation and the risk of bias was considered high (Wang 2012; Xie 2011).

We considered allocation concealment to be adequate in six studies (Alexopoulou 2007; Andréjak 2013; Cabello 2008; Le Guen 2014; Su 2013; Toublanc 2007): all of them used a sealed-envelope technique. Five studies used inadequate methods of allocation concealment (Chen 2012; Hu 2010; Martin 2008; Wang 2012; Xie 2011), and it was unclear whether allocation concealment was adequate in the remaining 19 studies, so we considered that the risk of bias was unclear.

Blinding

Because of the nature of the interventions, it was not possible to blind personnel or participants or both to the intervention in any of the included studies. Therefore, we considered that all studies were at a high risk of performance and detection bias by participants and personnel, although we note that this was potentially less of a factor for the objective outcomes (e.g., mortality and objective sleep variables).

Seventeen studies considered objective sleep measures, and nine of these studies, Andréjak 2013; Bosma 2007; Cabello 2008; Córdoba-Izquierdo 2013; Richards 1998; Roche-Campo 2013; Su 2013; Toublanc 2007; Wallace 1998, were at a low risk of performance and detection bias by outcome assessors because polysomnography (PSG) sleep records (i.e., objective sleep measures) were scored by an expert who was blinded to the randomization assignment. The risk of bias for outcome assessors was unclear in six studies (Alexopoulou 2007; Chen 2012; Foreman 2013; Jaber 2007; Namba 2012; Parthasarathy 2002), and there was a high risk of bias for outcome assessors in one study (Le Guen 2014).

Incomplete outcome data

There was no risk of attrition bias in eight studies (Alexopoulou 2007; Cabello 2008; Chen 2012; Gragert 1990; Namba 2012; Parthasarathy 2002; Roche-Campo 2013; Su 2013) as there were no dropouts or losses to follow up in these studies. We rated a further 11 studies as at a low risk of attrition bias as the reasons for dropout or loss to follow up were documented and acceptable (Borromeo 1998; Bosma 2007; Córdoba-Izquierdo 2013; Hu 2010; Le Guen 2014; Richards 1998; Ryu 2012; Scotto 2009; Sha 2013; Toublanc 2007; Van Rompaey 2012). We considered five studies to be at a high risk of attrition bias (Andréjak 2013; Jaber 2007; Martin 2008; Richardson 2003; Wallace 1998). For six trials, it was unclear whether there were any participant withdrawals (Foreman 2013; Gao 2008; Li 2011; Ruan 2006; Wang 2012; Xie 2011).

Selective reporting

For two studies (Li 2011; Richardson 2003), it appeared that a degree of selective reporting had taken place, and we rated these studies as at a high risk of reporting bias. We considered 20 trials to be at a low risk of reporting bias, and it was unclear whether the remaining eight trials were at a risk of reporting bias.

Other potential sources of bias

Seven trials declared a conflict of interest; the other trials did not declare a conflict of interest, so we judged the potential bias

to be "unclear" as we had insufficient information to permit a judgement. Most trials did not report a sample size calculation. Other potential sources of bias were evident in one trial (Richardson 2003); the author did not report the mean sleep scores on day one, day two, and day three in both groups, but reported the mean sleep scores on day one, day two, and day three by gender. We then combined the male group and the female group into a single group and calculated the mean sleep scores in both groups. The results showed that the mean sleep scores of the first night (namely baseline) were significantly different between the two groups. In Chen 2012, the baseline mean age and mean Acute Physiology Score (APS) scores of the experimental group were higher than those of the control group. In Córdoba-Izquierdo 2013, the baseline Epworth Sleepiness Scale scores were higher in the NIV_D group than in the NIV_{ICU} group. Sha 2013 did not assess the baseline of PSQI scores.

Effects of interventions

See: **Summary of findings for the main comparison** Non-pharmacological interventions for sleep promotion in ICU patients - narrative summary

Please see Summary of findings for the main comparison.

There was considerable clinical heterogeneity across the included studies due to the wide range of scales used to assess outcomes, the different participant populations, and study designs used (e.g., duration, time points). We could not pool the majority of results for meta-analysis - in which case, we have presented measures of treatment effect. If the published results did not provide sufficient detail to calculate between-group differences and 95% confidence intervals, we present the data as reported in the study reports.

1 Primary outcome: objective sleep variables

In summary, the effects of non-pharmacological interventions on objective measurements of sleep quality and quantity were inconsistent across studies. Overall, we rated the quality of the evidence as very low. The reasons for downgrading the quality of the evidence varied by intervention type and are summarized at the end of each subsection below.

a) Ventilator mode or type

Six cross-over trials examined the effects of ventilator modes on objective sleep variables in ICU patients (Alexopoulou 2007; Andréjak 2013; Bosma 2007; Cabello 2008; Parthasarathy 2002; Toublanc 2007). All of these trials measured sleep using PSG, although there was inconsistency in the method of reporting outcomes between studies. Because of important clinical heterogeneity and missing data, we did not incorporate these studies into a meta-analysis. We summarize below findings for these individual studies measuring PSG sleep variables (as reported by the authors) and present them in Table 1, Table 2, and Table 3.

Three studies examined objective sleep variables in participants receiving ACV versus PSV (Cabello 2008; Parthasarathy 2002; Toublanc 2007).

i) One trial, Parthasarathy 2002, demonstrated a significant increase in Sleep Efficiency Index (SEI) in the ACV group (mean = 75, standard deviation (SD) = 5) compared with the PSV group (mean = 63, SD = 5) (P value < 0.05). However, no significant improvement in SEI was found by Cabello and colleagues (P value > 0.05; Cabello 2008).

ii) Two trials, Cabello 2008; Parthasarathy 2002, reported sleep fragmentation index, but only one, Parthasarathy 2002, indicated a significant reduction in sleep fragmentation index in the ACV group (mean = 54, SD =7) compared with the PSV group (mean = 79, SD = 7) (P value < 0.05). Cabello 2008 found no significant reduction in sleep fragmentation index (P value > 0.05).

iii) Toublanc 2007 reported no significant reduction in awakening index between ACV and PSV groups (P value > 0.05).

iv) Two trials, Cabello 2008; Parthasarathy 2002, measured the percentage of stage three and four sleep, but no significant difference was found between the PSV and ACV groups in either trial (P value > 0.05). However, during the second period of the cross-over study by Toublanc et al (Toublanc 2007), higher percentages of stage three sleep (mean = 6.3, SD = 7.7 versus mean = 0.3, SD = 1.0) (P value < 0.01) and stage four sleep (mean = 5.4, SD = 13.2 versus mean = 0, SD = 0) (P value < 0.05) were observed in the ACV group compared with those in the low PSV group.

Two studies compared PAV versus PSV (Alexopoulou 2007; Bosma 2007).

i) In Alexopoulou 2007, SEI was significantly higher in the PAV group (mean = 98.9, SD = 2.3) compared with the PSV group (mean =87.7, SD = 16.4) (P value < 0.05). Bosma 2007 found no significant difference in SEI (P value > 0.05).

ii) No significant reductions in sleep fragmentation index and slow-wave sleep (SWS) per cent were found in either trial (P > 0.05).

Only one study compared PCV versus PSV (Andréjak 2013).

i) SEI was significantly higher in the PCV group (mean = 61.5, SD = 25.1) compared with the PSV group (mean = 39.2, SD = 29.1) (P value < 0.01).

ii) A significant increase in the number of hours of REM sleep time was reported in the PCV group (mean = 3.4, SD=6.4) compared with the PSV group (mean = 0.8, SD = 2.1) (P value < 0.01).

iii) No significant difference in the percentage of stage three and four sleep was observed between groups (P value > 0.05).

Two studies examined the effect of ventilator type on objective sleep variables (Córdoba-Izquierdo 2013; Roche-Campo 2013). One study of 24 participants with acute hypercapnic respiratory failure requiring non-invasive ventilation, Córdoba-Izquierdo 2013, compared the use of conventional ICU ventilators versus dedicated non-invasive ventilators and found no significant difference between the groups in sleep fragmentation index, total sleep time (TST), stage one per cent, stage two per cent, SWS per cent, and REM per cent (P value > 0.05).

One cross-over study examined spontaneous ventilation versus mechanical ventilation at low levels of pressure support in 16 tracheostomized participants during weaning (Roche-Campo 2013). Total sleep time was greater during mechanical ventilation than during spontaneous ventilation (183 minutes versus 132 minutes, P value = 0.04). This study found no significant

difference between the groups in SWS time, REM time, and sleep fragmentation index (P value > 0.05).

We rated the quality of the evidence as low for the effect of ventilator mode or type on objective sleep variables, having downgraded once for inconsistency (findings differed between studies) and once for risk of selection bias.

b) Earplugs or eye masks or both

Two studies assessed the effect of eye masks or earplugs or both on objective sleep variables as measured using PSG (Foreman 2013; Wallace 1998). Due to clinical heterogeneity in study design, the results from these studies could not be combined statistically. Wallace 1998 reported significantly higher percentages of REM sleep during the night in the group assigned to earplugs compared with the control group (mean = 5.60, SD = 8.00 versus mean = 2.40, SD = 5.60) (P value = 0.04). No significant difference in other objective sleep variables (sleep period time, SEI, sleep maintenance efficiency index, number of awakenings) was found between the groups in this study (each P value > 0.05). Foreman 2013 examined objective sleep variables in 12 neurological ICU patients who received oral melatonin, sound-reducing headphones, and eye covers versus standard care, finding no significant difference between the groups in terms of sleep architecture (no P value or 95% CI reported).

One quasi-RCT of 75 ICU patients, Xie 2011, compared the use of earplugs and eye masks versus usual care on objective sleep variables, as measured by EEG. There was a greater improvement in the mean number of hours of SWS in the intervention group compared with the control group (SWS: post-test mean = 2.18, SD = 0.34 versus post-test mean = 1.43, SD = 0.28) (P value < 0.01) (REM: post-test mean = 2.09, SD = 0.28 versus post-test mean = 0.71, SD = 0.36) (P value < 0.01). A greater reduction in the mean number of hours of waking time was also reported in the intervention group compared with the control group (post-test mean = 1.79, SD = 0.75 versus post-test mean = 3.8, SD = 0.79) (P value < 0.01); no significant difference in NREM time was observed between groups (P value > 0.05).

One study of 41 postoperative patients compared the use of earplugs and eye masks versus usual care on objective sleep variables, as measured by ActiGraph (Le Guen 2014). This study found no significant between-group difference (P value > 0.05) in sleep variables, including sleep efficiency, sleep fragmentation, sleep disruptions, movement numbers, or activity scores.

We rated the quality of the evidence as very low for the effect of earplugs or eye masks or both on objective sleep variables, having downgraded twice for inconsistency (findings differed between studies) and once for risk of selection bias.

c) Music intervention

One study examined the effects of listening to music (versus usual care) on PSG sleep variables in 28 ICU patients (Su 2013). The authors reported that participants in the music group had shorter stage two sleep time (P value = 0.014) and longer stage three sleep time (P value = 0.008) in the first two hours of the nocturnal sleep as calculated by generalized estimating equation analysis. No statistically significant differences in the mean total sleep time, sleep efficiency, and stage one sleep times were reported between groups (P value > 0.05).

One study measured objective sleep variables as measured by BIS (Jaber 2007). The author reported a significantly greater reduction in BIS in the music intervention group (post-test mean = 81, SD = 10) compared with the control group (post-test mean = 94, SD = 5) (P value < 0.01).

We rated the quality of the evidence as very low for the effect of music on objective sleep variables, having downgraded once for inconsistency (findings differed between studies), once for indirectness (only two small studies included), and once for risk of selection bias in Jaber 2007.

d) Relaxation techniques

Richards 1998 compared a six-minute back massage versus relaxation intervention plus relaxing music (combined muscle relaxation, mental imagery, and audiotape) versus usual care (control). The study measured objective sleep variables using PSG in 69 older men with cardiovascular illness. Participants in the back-massage group slept more than one hour longer than those in the control group (mean = 319.82, SD = 48.45 versus mean = 257.33, SD = 108.22; no significance value reported). This study found a significant difference among the three groups in SEI (control group: mean = 62.84, SD = 24.46; back-massage group: mean = 77.32, SD = 10.53; relaxation group: mean = 73.13, SD = 15.66, F = 3.73) (P value = 0.03). No significant differences in other PSG sleep variables were found in this study.

We rated the quality of the evidence as very low for the effect of relaxation techniques on objective sleep variables, having downgraded once for risk of selection bias, once for indirectness (only one study population), and once for imprecision (large standard deviations).

e) Foot massage or foot bath

One study of six participants compared using foot baths at 40℃ for 10 minutes before sleep onset with usual care and measured PSG sleep (Namba 2012). There was no significant difference in total sleep time, sleep efficiency, time spent in REM or sleep stages, and sleep fragmentation (all P values > 0.05).

We rated the quality of the evidence as very low for the effect of foot massage/bath on objective sleep variables, having downgraded once for risk of selection bias, once for indirectness (only one study population), and once for imprecision.

f) Other interventions

None of the studies examined the effect of valerian acupressure, aromatherapy, sound masking, or nursing/social interventions on objective sleep variables.

2) Primary outcome: length of ICU stay

We rated the quality of the evidence as very low for this outcome, having downgraded once for risk of selection bias, once for indirectness (only one population considered), and once for imprecision (wide confidence intervals).

a) Earplugs or eye masks or both

Hu 2010 examined the effect of earplugs plus eye masks plus sleep-inducing music versus usual care on the length of ICU stay. No significant difference in the length of ICU stay was found between groups (MD = -5.90, 95% CI -16.42 to 4.62) (P value > 0.05).

b) Other interventions

No other trials examined the effect of the other non-pharmacological intervention types on the length of ICU stay.

3) Primary outcome: mortality

None of the included studies examined mortality.

4) Secondary outcome: adverse events

We rated the quality of the evidence as very low for this outcome, having downgraded once for risk of selection bias, once for indirectness (the evidence was based only on studies of ventilator mode or type), and once for imprecision (large standard deviations reported in individual studies).

a) Ventilator mode or type

Five trials assessed the effect of ventilator mode on adverse events, such as central apnoeas, patient-ventilator asynchronies, and ineffective efforts. In Bosma 2007, total patient-ventilator asynchronies per hour were more frequent during PSV than during PAV (53 ± 59 versus 24 ±15) (P value = 0.02); episodes of central apnoeas were observed during the night with PSV, whereas no participants showed central apnoeas during the night on PAV. In Cabello 2008, no apnoeas occurred during ACV, whereas nine of 15 participants presented sleep apnoeas during PSV, and the mean number of ineffective efforts per hour of sleep were similar with ACV, automatically adjusted pressure support ventilation (aPSV), and clinically adjusted pressure support ventilation (cPSV) (P value > 0.05). In Parthasarathy 2002, apnoeas occurred in six of 11 participants during PSV alone, but not during ACV; the use of PSV with dead space decreased the frequency of apnoeas significantly (P value < 0.05). In Alexopoulou 2007, the two modes (PAV and PSV) had comparable effects on respiratory variables, particularly at high assist, and a significant proportion of participants in both groups developed periodic breathing during sleep. In Roche-Campo 2013, one participant experienced periodic breathing and one participant experienced central apnoeas regardless of the ventilatory mode used; nobody exhibited ineffective efforts.

b) Other interventions

No trials of the other non-pharmacological interventions examined adverse events.

5) Secondary outcome: delirium

We rated the quality of the evidence as low for this outcome, having downgraded once for risk of selection bias and once for imprecision (wide confidence intervals - see Summary of findings for the main comparison).

a) Earplugs or eye masks or both

Two studies examined the effect of earplugs or eye masks or both on the risk of delirium (Le Guen 2014; Van Rompaey 2012). Van Rompaey and colleagues used the validated Neelon and Champagne Confusion Scale (NEECHAM) (Van Rompaey 2008). In Le Guen 2014, the author did not report the method of assessment of delirium. A meta-analysis of these two studies showed that use of earplugs or eye masks or both significantly decreased the risk of delirium or confusion (risk ratio (RR) 0.55, 95% CI 0.38 to 0.80) (P value = 0.002) (Analysis 1.1; Figure 4).

Figure 4. Forest plot of comparison: earplugs or eye mask or both versus usual care, outcome: 2.2 incidence of delirium and confusion.

b) Other interventions

No trials of the other non-pharmacological interventions examined delirium.

6) Secondary outcome: subjective sleep quantity or quality

Overall, we rated the quality of the evidence for this outcome as low. The reasons for downgrading the quality of the evidence varied by intervention type and are summarized at the end of each subsection below.

a) Ventilator mode or type

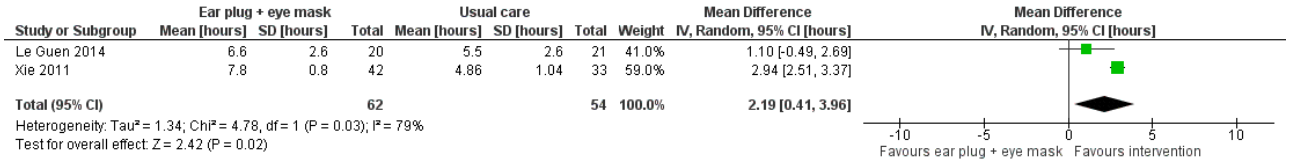
Toublanc 2007 reported that self-perceived quality of sleep in ICU patients was poor, but did not compare subjective sleep quality between the different ventilator modes.

b) Earplugs or eye masks or both

Six studies of earplugs or eye masks or both assessed sleep quality or quantity using subjective sleep scales (Hu 2010; Le Guen 2014; Martin 2008; Scotto 2009; Van Rompaey 2012; Xie 2011); the scales used varied among these trials.

Two studies, involving 120 participants, compared earplugs and eye masks versus usual care and assessed nurse-measured (subjective) sleep quantity (Le Guen 2014; Xie 2011). Meta-analysis of these two studies showed that total sleep time was significantly greater in the intervention group compared with the control group (MD 2.19 hours, 95% CI 0.41 to 3.96, two studies, 116 participants). However, there was evidence of heterogeneity between studies for this outcome (I^2 statistic = 79%; P value = 0.03) (Analysis 1.2; Figure 5).

Figure 5. Forest plot of comparison: Use of ear plugs and eye mask versus usual care, outcome: 2.3 subjective sleep quantity; total sleep time (hours).



Two studies, Hu 2010 and Xie 2011, compared the use of earplugs and eye masks versus usual care and assessed subjective sleep quality using the RCSQ and PSQI scales, respectively. As Hu 2010 combined music and the use of earplugs/eye masks in the intervention group whereas Xie 2011 examined earplugs plus eye masks only, we could not pool data from the two studies. Subjective sleep quality in the intervention group was greater in the intervention versus control groups of both studies. In Hu 2010, the mean difference in the Chinese version of RCSQ scores of perceived quality (0 = better sleep, 100 = poor sleep) for intervention versus control was -27.00 (95% CI -40.15 to -13.85). In Xie 2011, the mean difference in PSQI score (0 = best sleep, 21 = worst sleep) for intervention versus control was -7.25 (95% CI -8.46 to -6.04).

Le Guen 2014 evaluated subjective sleep quality using the Spiegel score for which higher scores indicate a better sleep quality; a total score below 15 signifies a pathological sleep, and a score above 20, good sleep. Postoperatively, the mean Spiegel score in the earplug and eye mask group was 20 (SD = 4) compared with 15 (SD = 5) in the control group (comparison P value = 0.006). Additionally, only 50% of the participants in the intervention group reported the need for a nap compared with 95% of those in the control group (P value = 0.001).

Martin 2008 reported no significant difference in VSH sleep scores between earplug and usual care groups (post-test mean = 56.7, SD = 25.6 versus post-test mean = 59.2, SD = 27.0; significance value not reported). Scotto 2009 also assessed sleep quality using the VSH sleep score. The author reported that use of earplugs improved the subjective sleep quality (P value < 0.05), but no mean scores were reported.

One study, Van Rompaey 2012, of 136 participants compared sleep perception using five dichotomous questions on the self-reported sleep quality of the participant, which they categorized as: bad sleep (sum < 2), moderate sleep (sum 2 < 4), and good sleep (sum ≥ 4). More participants perceived good sleep in the intervention group than those in the control group after the first night (P value = 0.042, no Chi^2 test value reported).

Overall, we deemed the quality of the evidence for the effect of earplugs or eye masks or both on objective sleep variables as low, having downgraded once for inconsistency (findings differed between studies) and once for risk of selection bias.

c) Music interventions

Four studies of music intervention reported subjective sleep quality. One study, Sha 2013, used the PSQI sleep scale, and one study, Hu 2010, used a Chinese version of RSCQ. We could not pool data from these studies as they reported no post-test PSQI total scores (Sha 2013), and the sleep quality scales were incompatible (Hu 2010). In Sha 2013, the subjective sleep quality, sleep time, sleep efficiency, and total PSQI scores were significantly improved in the intervention group compared with the control group (P value < 0.05). Additionally, the incidence of sleep disorder in the music intervention group was significantly lower than that in the control group (P value = 0.036).

Two studies examined subjective sleep quality using different versions of the VSH sleep scale (Ryu 2012; Su 2013). However, Ryu 2012 combined music with the use of earplugs and eye masks, whereas Su 2013 did not; for this reason, we could not combine the results in a meta-analysis. Ryu 2012 reported that participants receiving a music intervention had improved sleep quality versus those receiving usual care (standardized mean difference (SMD) 0.93, 95% CI 0.15 to 1.72; N = 28). Similarly, sleep quality was improved in participants receiving music intervention plus eye masks and earplugs versus usual care (SMD 1.37, 95% CI 0.79 to 1.94; N = 58; Su 2013).

Overall, we deemed the quality of the evidence for the effect of music interventions on objective sleep variables as very low, having downgraded once for inconsistency (findings differed between studies) and twice for a high risk of selection bias.

d) Relaxation techniques

One study measured perception of sleep quality using the VSH sleep scale (Richardson 2003). No differences were observed between control and experimental sleep scores on day one, two, and three (each P value > 0.05; no mean sleep score values were reported by group). We calculated mean sleep scores and used intention-to-treat (ITT) analysis; the results showed the intervention group (namely a combination of relaxation and imagery) exhibited significantly less change in sleep scores from the first night to the third night (MD -13.52, 95% CI -34.24 to 7.20), indicating better sleep in the intervention group (higher sleep scores indicated a perception of improved sleep in this trial). However, we also found the baseline of sleep scores in the intervention group was significantly higher than those in the control group, which resulted in a high risk of selection bias in the study, so it was difficult to ascertain if there was a real effect.

One study measured sleep quality and quantity by nursing observation (Ruan 2006). The main outcomes were trichotomous types; the study classified the outcome of the time taken to fall asleep into "less than 30 minutes", "0 to 60 minutes", or "greater than 60 minutes", and it classified the outcome of total nocturnal sleep time into "less than three hours", "three to five hours", or "greater than five hours". Using methodology recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), we transformed the published data into a dichotomous format by combining adjacent categories together, using "greater than 60 minutes" and "greater than five hours" as cut-off points. The results showed that it took significantly less time to fall asleep

in the intervention group than in the control group (RR 0.34, 95% CI 0.11 to 1.06), but there was no significant difference between the groups for total nocturnal sleep time (RR 0.26, 95% CI 0.09 to 0.74).

We deemed the quality of the evidence for the effect of foot massage/bath on objective sleep variables as very low, having downgraded once for indirectness (evidence based on two small populations), once for risk of selection bias, and once for precision (wide confidence intervals).

e) Foot massage or foot bath

In Namba 2012, the participants claimed that they slept well the night after receiving a foot bath. One study, Wang 2012, of 104 participants with sleep problems in a coronary critical care unit compared foot massage plus 'sleep pillow' (ingredients: Chinese herbal medicine) and measured perceived sleep quality using the Athens Insomnia Scale (AIS). This study found that the mean change scores of AIS in the intervention group were higher than those in the control group (mean = 1.06, SD = 0.72 versus mean = 0.74, SD = 0.61) (P value < 0.05). We deemed the quality of the evidence for the effect of foot massage/bath on objective sleep variables as low, having downgraded once for indirectness (evidence based on two small populations) and once for risk of selection bias.

f) Valerian acupressure

One study of 85 ICU patients, Chen 2012, compared valerian acupressure on the Shenmen, Neiguan, and Yongquan acupoints versus usual care and measured subjective sleep quality using the Stanford Sleepiness Scale (SSS). This study found that, compared with the control group, the acupressure group had lower SSS ratings (i.e., better sleep; mean = 2.5, SD = 0.5 versus mean = 3.4, SD =1.1) (P value < 0 .001) and a greater number of hours sleep as observed by nursing staff (mean = 3.4, SD = 1.7 versus mean = 2.6, SD = 1.5) (P value < 0.05). We calculated the mean changes and the standard deviations in each group from baseline and calculated the mean difference. We found evidence of a difference between the two groups for number of hours of sleep (MD 0.7, 95% CI 0.29 to 1.11) (P value = 0.0008) and waking frequency (MD -4.30, 95% CI -6.36 to -2.24) (P value < 0.0001), but not for SSS ratings (MD -0.10, 95% CI -0.35 to 0.15) (P value = 0.44). We deemed the quality of the evidence for the effect of valerian acupressure on objective sleep variables as low, having downgraded once for indirectness (evidence based on one small population) and once for risk of selection bias.

g) Aromatherapy

One study compared aromatherapy intervention versus usual care and measured perceived sleep quality by RCSQ (Borromeo 1998). The study indicated no significant between-group differences in sleep scores (intervention group: mean = 59.84, SD = 2.91; control group: mean = 63.28, SD = 2.48) (P value > 0.05). We deemed the quality of the evidence for the effect of aromatherapy on objective sleep variables as low, having downgraded once for indirectness (evidence based on one small population) and once for risk of selection bias.

h) Sound masking

One study of 40 older patients in a critical care unit assessed the effect of sound masking on subjective sleep quality measured by RCSG and nursing observation (Gragert 1990). The results indicated a significant difference in mean SEI between the intervention group and the control group (75% versus 61%; P value = 0.016), a greater total sleep time (308.70 minutes versus 249.5 minutes, P value = 0.012), and a reduced sleep latency time (35.12 minutes versus 102.60 minutes, P value = 0.000). No standard deviations were provided. No significant difference was seen in the number of awakenings (P value = 0.60). The following six variables were scored from 0 to 100 mm using the RCSQ: sleep depth, falling asleep, awakenings, returning to sleep, quality of sleep, and noise level (0 represented the best possible score, and 100 represented the worst possible score). The results showed that there was greater sleep depth (81.55 versus 54., P value = 0.001), less sleep latency (79.80 versus 56.15, P value = 0.002), and fewer awakenings (79.40 versus 56.20, P value = 0.002) in the intervention group compared with the control group. Subjective sleep quality was greater (81.20 versus 54.60, P value = 0.002); participants had less difficulty returning to sleep (79.90 versus 58.35, P value = 0.005) and lower subjective impressions of the noise level during the night-time (90.85 versus 38.40, P value = 0.000) in the intervention group compared with the control group. We deemed the quality of the evidence for the effect of sound masking on objective sleep variables as low, having downgraded once for indirectness (evidence based on one small population) and once for risk of selection bias.

i) Nursing intervention or social intervention

One study, Gao 2008, compared changing the ICU visiting time for family members versus conventional care and demonstrated a significant increase in hours of total sleep time in the intervention group (post-test mean = 6.7, SD = 1.1 versus post-test mean = 3.6, SD = 2.4) (P value < 0.05).

One study, Li 2011, compared a nursing intervention programme with the Roy Adaptation Model as a guide versus conventional care and measured subjective sleep quality by PSQI (0 = better sleep, 21 = worse sleep). The author reported a significantly higher subjective sleep quality in the intervention group than in the control group (post-test mean = 5.57, SD = 2.62 versus post-test mean = 10.03, SD = 2.62) (P value < 0.05).

7. Secondary outcome: PTSD

None of the included studies examined PTSD.

8. Secondary outcome: participant satisfaction

a) Music interventions

One trial reported that five participants did not complete the study because they refused or resented the music therapy (Jaber 2007).

b) Other interventions

No trials examined the effect of the other non-pharmacological intervention types on participant satisfaction.

9. Secondary outcome: economic outcomes

None of the included studies examined economic outcomes.

DISCUSSION

Summary of main results

We included non-pharmacological interventions, such as ventilator modes and type, earplugs or eye masks or both, massage, relaxation techniques, foot baths, music interventions, nursing interventions, valerian acupressure, aromatherapy, and the use

of sound masking, in this review. Thirty studies, with a total of 1569 adult participants, were eligible for inclusion, three of which provided data suitable for meta-analysis (all three studies assessed the use of earplugs or eye masks or both). Outcomes included objective sleep outcomes (as measured by polysomnography (PSG), Bispectral Index (BIS), or ActiGraph), subjective sleep quality and quantity by participant assessment or nursing observation, risk of delirium during intensive care unit (ICU) stay, participant satisfaction, length of ICU stay, and adverse events.

We considered the overall quality of the evidence for an effect of non-pharmacological interventions on objective sleep variables in ICU patients as very low. Clinical heterogeneity prevented meaningful meta-analysis of data from individual studies that examined the same intervention, and findings across studies of the same intervention were often inconsistent; the following text discusses our findings for this outcome by intervention type.

Four included studies examined the effect of earplugs or eye masks or both on objective sleep variables, all versus usual care (i.e., without using earplugs or eye masks). Individual studies provided some evidence that the use of earplugs or eye masks or both may increase rapid eye movement (REM) sleep time (Wallace 1998; Xie 2011) and non-REM (NREM) 3˜4 time (Xie 2011). However, the trials contributing evidence for this outcome were potentially at a risk of selection bias, and there were inconsistent findings between studies (Le Guen 2014). Therefore, our overall rating of the evidence for an effect of earplugs or eye masks or both on objective sleep variables was very low. Mechanical ventilation has been cited as an important contributing factor to sleep disruption, and the optimization of ventilator mode is recommended for sleep promotion in ICU patients (Friese 2008; Parthasarathy 2004). Six randomized cross-over studies also examined the effect of ventilator mode or type on objectively measured sleep variables (Alexopoulou 2007; Andréjak 2013; Bosma 2007; Cabello 2008; Parthasarathy 2002; Toublanc 2007). Clinical heterogeneity in the types and methods of interventions assessed and the specific outcomes measured meant that it was not possible to pool data from these studies.

Results from individual studies suggested that optimizing ventilator modes may improve sleep quality and reduce patient–ventilator asynchrony. In particular, pressure-controlled ventilation mode (PCV), assist-control ventilation mode (ACV), and proportional assist ventilation (PAV) mode appeared to offer some benefit in terms of sleep quantity or quality or both compared with pressure support ventilation mode (PSV). For example, in one study, Toublanc 2007, participants on ACV had lower wakefulness and longer stage one and two NREM sleep than participants on PSV. In a separate study (Parthasarathy 2002), differences in respiratory rate, mechanical expiratory time, mechanical inspiratory time, and end-tidal CO_2 between sleep and wakefulness were greater during PSV than during ACV. However, we considered many of the included studies to be at a risk of selection bias, and findings were inconsistent between studies. For example, Parthasarathy 2002 reported that participants with ACV had a higher Sleep Efficiency Index (SEI) and lower sleep fragmentation than those during PSV, whereas Cabello 2008 reported no significant difference in SEI and sleep fragmentation. In addition to ventilator mode, the effect of ventilator type was also examined. One included study, Córdoba-Izquierdo 2013, examined the effects of dedicated non-invasive ventilators versus conventional ICU ventilators on sleep and reported no significant difference between groups. Similarly, another included study, Roche-Campo 2013, reported that sleep quality was similar during mechanical ventilation (MV) and spontaneous ventilation (SV), but noted a greater quantity of sleep during MV than during SV in tracheostomized participants with prolonged weaning. Both studies were of an unclear risk of selection bias and represented only small populations of participants. Overall, we rated the quality of the evidence for the effect of ventilator mode or type on objective sleep variables as low. Similarly, the quality of evidence for an effect of music interventions on objective sleep variables was very low, with only two studies contributing relevant data, which we could not pool because of clinical heterogeneity. The two included studies reported contrasting findings: in one study, Jaber 2007, music interventions appeared effective in reducing the BIS with a difference of 13 points between groups. However, Su 2013 reported no effect of music interventions on PSG sleep outcomes.

Only one included study, Hu 2010, incorporated length of ICU stay as an outcome (a secondary outcome for this review). No significant effect of earplugs plus eye masks was found on length of ICU stay. We rated the overall quality of the evidence for this outcome as very low. None of the interventions examined in this review were assessed in relation to effect on mortality.

In terms of the review's secondary outcomes, few included studies assessed the effect of the interventions on adverse events in ICU patients. There was some evidence that ventilator mode influenced the incidence of adverse events, such as central apnoeas and patient-ventilator asynchronies. Generally, more adverse events were noted with PSV compared with ACV or PAV. For example, two included studies reported that no central apnoeas occurred during ACV whereas more than 50% of participants had apnoeas during PSV (Cabello 2008; Parthasarathy 2002). However, clinical heterogeneity between studies prevented meta-analysis, and we rated the quality of the evidence for this outcome (and thus the effect of ventilator mode on adverse events) as low.

Two included studies examined the incidence of delirium in ICU patients (Le Guen 2014; Van Rompaey 2012). Both of these studies examined the effect of earplugs or eye masks or both, and we pooled data from these studies for meta-analysis. In participants using earplugs or eye masks or both, the risk of delirium was lower than for participants in the control group (risk ratio (RR) 0.55, 95% confidence interval (CI) 0.38 to 0.80). Assuming an incidence of delirium of 489 per 1000 people in the ICU with usual care, we estimated that 220 fewer people per thousand would experience delirium if using earplugs or eye masks or both (CI 98 to 303 fewer people per thousand). However, we rated the quality of the evidence for this finding as low.

Several studies assessed subjective sleep quantity or quality with the various non-pharmacological interventions in ICU patients (Borromeo 1998; Chen 2012; Gao 2008; Gragert 1990; Hu 2010; Le Guen 2014; Li 2011; Martin 2008; Namba 2012; Richardson 2003; Ruan 2006; Ryu 2012; Scotto 2009; Sha 2013; Su 2013; Toublanc 2007; Van Rompaey 2012; Wang 2012; Xie 2011). Overall, we rated the quality of the evidence for objective sleep quality/quantity as low. Using various subjective scales, six studies individually reported some benefit of earplugs or eye masks or both on subjective sleep quality (Hu 2010; Le Guen 2014; Martin 2008; Scotto 2009; Van Rompaey 2012; Xie 2011). Pooled data from two of these studies showed a benefit for the use of earplugs/

eye masks compared with usual care (Le Guen 2014; Xie 2011; 116 participants). The mean difference in total sleep quantity versus usual care was 2.19 hours (95% CI 0.41 to 3.96) although we observed evidence of heterogeneity (I^2 statistic = 79%). The quality of the evidence for the effect of this intervention on sleep quantity (assessed subjectively) was low due to heterogeneity and an unclear or high risk of selection and detection bias in these studies. Individual studies also provided some evidence that music interventions may improve subjective sleep quantity or quality (Ryu 2012; Sha 2013; Su 2013). However, findings were inconsistent across studies, and the studies had a high risk of selection bias. Therefore, we considered the quality of the evidence for an effect of music intervention on subjective sleep quantity/quality as very low. Several included studies examined alternative and complementary therapies; relaxation techniques (Richardson 2003; Ruan 2006), foot massage or foot bath (Namba 2012; Wang 2012), acupressure (Chen 2012), nurse or social intervention (Gao 2008; Li 2011), and sound masking (Gragert 1990) may offer some benefit in terms of subjectively measured sleep quantity or quality. However, the number of studies per intervention type was minimal (i.e., one or two studies), and the studies had an unclear or high risk of selection bias. Therefore, we rated the quality of the evidence for an effect of these interventions on subjectively measured sleep quantity/quality as low.

None of the interventions examined in this review were assessed in relation to mortality, risk of post-traumatic stress disorder, or economic cost.

Overall completeness and applicability of evidence

The review included 29 randomized controlled trials (RCTs) and one quasi-RCT. Because of the small number of studies per intervention and the different outcomes used across studies, we could not incorporate many studies into meta-analyses in this review.

We found very limited evidence supporting non-pharmacological interventions, such as massage, acupressure, imagery relaxation, nursing intervention, and social support. Most of these trials had small sample sizes, and none of the trials measured longer-term clinical outcomes.

Interestingly, we found that ongoing studies are assessing several other non-pharmacological interventions, including environmental modification, behavioural interventions, massage therapy, and 'device modifications' (see Ongoing studies). The excluded studies also examined several other non-pharmacological interventions; these included aromatherapy (Cho 2013), use of earplugs and eye protective devices (House 2003; Koo 2008), an ICU-wide quality improvement intervention (Kamdar 2013), therapeutic touch (Cox 1999), a postoperative pain treatment programme (Diby 2008), a sedation wake-up trial and spontaneous breathing trial (Figueroa-Ramos 2010), and implementing a "quiet time" protocol to reduce ICU environmental stimuli (Olson 2001). We excluded the majority of these trials as they were not RCTs, and most used non-equivalent group designs.

The frequency and duration of the interventions varied widely across the trials. There were relatively small numbers of participants in all of the included studies, and few studies used power analysis, thereby, limiting study power. It was often difficult to collate and interpret information from the included studies due to inconsistency in the outcomes studied between the included trials. For example, few studies reported the same sleep outcomes or type of data with respect to PSG sleep variables. Similarly, few studies that assessed subjective sleep outcomes used the same sleep scales to measure subjective sleep quality. All of these factors contributed to our overall rating of the quality of the evidence using Grading of Recommendations Assessment, Development and Evaluation (GRADE). None of the included trials provided data on the effects of the non-pharmacological interventions on mortality, risk of post-traumatic stress disorder (PTSD), and cost effectiveness in ICU patients.

Quality of the evidence

A large number of the included studies had an unclear or high risk of allocation bias as methods of random sequence generation or allocation concealment or both were often inadequately reported or inappropriate. Furthermore, blinding of participants and personnel was often not possible for non-pharmacological treatments, such as massage, use of earplugs and eye masks, imagery, relaxation, music therapy, or social support. As many of the trials in this review included subjective outcomes, such as subjective sleep scores, there was a high risk of performance bias associated with many of the studies. For many of the included studies, there was a need for additional methodological and statistical information, which if available, could have improved the quality of the evidence in the review. Additionally, many of the included studies provided insufficient information about general characteristics before randomization, and the majority of included studies had relatively small numbers of participants (most trials did not use power analysis), thus, limiting the power of the trials. Finally, due to substantial clinical heterogeneity, it was generally not possible to pool data across studies of the same intervention type, and findings from individual studies of the same intervention type were often inconsistent. In summary, all of these factors provided rationale for rating the quality of the evidence as low or very low (Summary of findings for the main comparison).

Potential biases in the review process

Our goal was to determine whether a range of non-pharmacological interventions were effective for sleep promotion in ICU patients. We developed our search strategy to cover as many terms as possible. We searched all available databases, checked the reference lists of all relevant trials, and included trials without restricting language for both published and unpublished studies. Where necessary, we contacted the authors for additional unpublished information. However, it remains possible that we missed some published and unpublished trials. In the several instances where we contacted lead authors to request additional data and detailed information regarding research practice, we often failed to receive a reply from the authors (See Characteristics of included studies).

Agreements and disagreements with other studies or reviews

Music interventions have been cited as helpful measures to improve mood and reduce anxiety in coronary heart disease patients (Bradt 2009) and mechanically ventilated patients (Bradt 2010) and to reduce pain in cancer patients (Bradt 2011). In a systematic review (de Niet 2009), music-assisted relaxation had a moderate effect on the sleep quality of participants with sleep complaints, possibly via effect on psychological outcomes (e.g., by assisting the relaxation for ICU patients). These findings

are supported by those of a Cochrane systematic review, which suggested that music listening may have a large anxiety-reducing effect on mechanically ventilated patients (Bradt 2014). These reviews reported no adverse reactions or outcomes relating to participant satisfaction.

An earlier systematic review by Richards and colleagues, Richards 2000a, examined the effects of massage on relaxation, comfort, and sleep in acute and critical care settings. In agreement with our findings, the review concluded that the clinical data were insufficient and further studies were required. Another systematic review, Richards 2003, presented the complementary and alternative therapies for promoting sleep in critically ill patients. The review searched the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and MEDLINE databases and limited to papers in the English language from 1982 to 2002. Therapies included massage, relaxation technique, aromatherapy, therapeutic touch, environmental interventions, music therapy, and alternative sedatives. Although this review focused on the interventions and did not assess quality of the evidence, the authors conclusions were similar to those that we obtained: that there is currently insufficient evidence relating to the efficacy of non-pharmacological interventions for sleep promotion in critically ill patients. A more recent systematic review, Tamrat 2014, identified non-pharmacologic interventions for improving sleep quality and quantity of non-intensive care unit inpatients. Again, this review found insufficient evidence to support the use of any non-pharmacologic intervention for improving sleep quality or quantity in general inpatients. Finally, it will be interesting to examine our findings alongside those of a future Cochrane systematic review, which plans to evaluate the use of pharmacological agents for the promotion of sleep in the intensive care unit (Evans 2016).

AUTHORS' CONCLUSIONS

Implications for practice

Mechanical ventilation is an important contributing factor to sleep deprivation. In this review, several studies investigated the effects of ventilator modes on sleep outcomes, although we were unable to perform meta-analysis of these studies. There was some evidence from individual studies to suggest that pressure-controlled ventilation mode, assist-control ventilation mode, and proportional assist ventilation mode may all improve sleep quantity or quality or both compared with pressure support ventilation mode. However, we noted some inconsistent findings between studies, and we rated the overall quality of the evidence as very low.

Our findings suggest that non-pharmacological interventions, such as the use of earplugs or eye masks or both, may have some beneficial effects on sleep promotion and potentially decrease the risk of delirium in intensive care unit (ICU) adult patients. However, again, the quality of the evidence was generally low due to inconsistency in the findings of the contributing studies and the risk of bias associated with these studies. If using earplugs and eye masks, careful consideration should be given to implementation. For example, Scotto 2009 reported that some ICU patients were unwilling to use earplugs or eye masks or both because they found them uncomfortable or they fell out during sleep. Therefore, it may be important to provide alternative designs of earplugs or eye masks, or for clinical staff to help with the correct insertion of the earplugs.

Implications for research

The quality of existing evidence relating to the use of non-pharmacological interventions for sleep promotion in ICU patients is low or very low. Whilst these interventions are often difficult to assess in the ICU setting and some of the methodological difficulties (e.g., blinding) relate to the nature of the interventions, we have several recommendations for future research in this area.

Generally, future studies should ensure the following:

1. Provide power calculations so that adequate sample sizes are used and where possible use as large a sample size of participants as is feasible.
2. Ensure low risk of bias through rigorous methodological development and reporting. For example, trials need to use reliable methods of allocation concealment, and methods of blinding should be as robust as possible. It is essential that trial design methods and outcomes are better reported, including randomization methods, loss to follow up, and details of prespecified outcomes measures.
3. Include an assessment of sleep-related outcomes using polysomnography, which represents the gold standard of sleep measurement; relatively few published studies use this technique.
4. Outcomes should focus not only on sleep outcomes but also on the clinical outcomes, such as mortality, incidence of adverse events, or the risk of delirium or PTSD. Greater inclusion of outcomes relating to participant satisfaction, length of ICU stay, or health economics would also be desirable.
5. Include a validated sleep scale to measure subjective sleep quality. (A validated consensus instrument is required for comparison of studies in different countries.)

Specifically, we would recommend that more research is needed to test the effects of music intervention on objective sleep outcomes, ideally using polysomnography (PSG). A greater volume of research is needed for interventions, such as massage, acupressure, music therapy, environmental intervention, behaviour therapy, and psychological support, all in the ICU setting. (These interventions are used widely for sleep promotion in other clinical settings.)

Finally, we note that the analysis of data from cross-over trials is critical for systematic reviews in this area. Therefore, a consensus in the method of reporting outcomes from cross-over trials is required (e.g., reporting first period data and full period data separately). We also recommend that cross-over trials include an adequate washout period between interventions; an inadequate washout period could potentially confound the findings of studies where the intervention serves to improve sleep via anxiolytic effects.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Alexopoulou 2007

Methods	Design: cross-over RCT Setting: single-bed rooms in an intensive care unit, Greece
Participants	**Inclusion criteria** • Good patient–ventilator synchrony with PS mode

Alexopoulou 2007 *(Continued)*

	• Haemodynamically stable without vasoactive drugs • Ventilated with PS through cuffed endotracheal or tracheostomy tubes **Exclusion criteria** • Had significant patient–ventilator dyssynchrony during PS, "as indicated by the occurrence of ineffective efforts, excessive triggering delay or apneas, Glasgow Coma Scale < 11 and acute physiology score > 13" 17 participants (received mechanical ventilation for at least 48 hours) were studied Age: 63.9 ± 16.7 years Sex: 6 women, 11 men Number included: 17 Number analysed in protocol A (sedated): 11 Number analysed in protocol B (without sedation): 9 3 participants were studied in both protocols
Interventions	• PSV versus with PAV+ at 2 levels of assist: baseline and high ($PAV+_{base}$, $PAV+_{high}$, PSV_{base}, PSV_{high}) "PS_{high} was obtained by increasing the pressure assist level by 40-50% or until Paw reached 30 cm H_2O. $PAV+_{high}$ was obtained by increasing the percentage of unloading by 40-50% or until the assist reached a value of 85%" Intervention duration: 2.5 hours for each period in protocol A (from 9:00 p.m. to 7 a.m. over 1 night) and at least 3 hours in protocol B (from 11.00 p.m. to 6.00 a.m. over 2 consecutive nights) There was no washout between cross-over periods
Outcomes	**Primary outcomes** 1. Sleep recordings by PSG: arousals per hour; awakenings per hour; total sleep fragmentation (calculated as the sum of arousals and awakenings per hour of sleep); sleep efficiency; per cent of stage 1, stage 2, SWS, and REM; central apnoeas per hour; breath components; periodic breathing during NREM sleep **Secondary outcomes** 1. Ineffective efforts 2. Respiratory variables Protocol A: sedated participants Protocol B: non-sedated participants
Notes	Author Georgopoulos D provided additional data and the study protocol via email Only the whole period of the cross-over study was analysed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Each participant was randomized (concealed envelopes) to receive each mode Comment: insufficient details were provided

Alexopoulou 2007 *(Continued)*

Allocation concealment (selection bias)	Low risk	The trial used concealed envelopes (emailed author response)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	The participants were ventilated randomly either with pressure support or with PAV+ mode, so it was not possible to blind personnel
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the study
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Unclear risk	In 2006, Dimitris Georgopoulos received 4500 euros as a lecture fee (honoraria) from the company TYCO

Andréjak 2013

Methods	Design: randomized, cross-over study to compare the impact of pressure-controlled ventilation (PCV) with spontaneous ventilation with 6 cm H_2O inspiratory pressure (low PSV) on sleep Setting: isolated single rooms, respiratory ICU, France
Participants	ICU patients with acute-on-chronic respiratory failure and near to being weaned off mechanical ventilation **Inclusion criteria** • Orally intubated with a tube and had to have been mechanically ventilated for an episode of acute or chronic respiratory failure • Near the end of their weaning period • Patients were invited to participate in the study on the night preceding their planned extubation, when respiratory failure was controlled and when participants were able to sustain low levels of PSV (absence of respiratory acidosis in arterial blood gases sampled after 1 hour of low PSV levels) • Haemodynamically stable without any vasopressive, sedative, narcotic, or analeptic drugs administered in the previous 48 hours **Exclusion criteria** • Participants with central apnoea syndrome, narcolepsy, or metabolic encephalopathy • Participants considered unstable, with asthma or interstitial lung disease Age: 67 ± 11 years Sex: 23 men, 3 women Number included: 35 Number analysed: 26 Number of assessable participants in PCV first/low PSV first arms: 13/13

Andréjak 2013 *(Continued)*

Interventions	• PCV versus low PSV PCV: inspiratory pressure support was set at 20 cm H_2O with the respirator-frequency set to provide complete disappearance of spontaneous inspiratory efforts. Inspiratory time was set to provide an I/E ratio of between 1/1.2 and 1/1.5 Low PSV: participants breathed spontaneously via the respirator's circuitry, with a pressure-support level of 6 cm H_2O and a trigger sensitivity of 0.5 cm H_2O Intervention duration: 13 participants received PCV first (10 p.m. to 2 a.m.) and then low PSV (2 a.m. to 6 a.m.); 13 participants received low PSV first and then PCV There was no washout between cross-over periods
Outcomes	**Primary outcomes** 1. PSG sleep data - polysomnographic recordings were performed from 10 p.m. to 6 a.m.
Notes	The 2 groups were similar in terms of anthropometric data, pulmonary function tests, and arterial blood gas data sampled before randomization Only the whole period of the cross-over study was analysed Sample size calculation: a power of 80% and an alpha risk of 5% We contacted the author via email and acquired additional information

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random sequence was generated through lots
Allocation concealment (selection bias)	Low risk	The trial used the closed-envelope method
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The physician who scored the polysomnographic recordings was not aware of the randomization
Blinding of participants and personnel (performance bias) All outcomes	High risk	The personnel were not blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	35 participants were included; 9 were discarded
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	No other bias was described

Borromeo 1998

Methods	Design: randomized cross-over trial

Borromeo 1998 *(Continued)*

	Settings: coronary care unit with 20 beds, single room for each bed, USA
Participants	All participants were diagnosed with 1 of the following diseases: chest pain, R/O MI, unstable angina **Inclusion criteria** • Participants admitted to the CCU of a large tertiary hospital • With ischaemic heart disease or unstable angina • 21 years of age or older • Willing to participate in the study • Able to speak, read, and understand English; • With an intact olfactory sense tested by the Smell Test **Exclusion criteria** • Chronic sleep problems • Any condition that has been reported to affect the sense of smell like Parkinson's, sinusitis, allergic rhinitis, nasal polyps, and diabetes • Reported to be day sleepers or declined to participate in the study Total number randomized: 25 Total number analysed: 25 Age: from 38 to 82 years old, 62 ± 3 years Sex: 18 men, 7 women
Interventions	• Intervention group: a passively-diffused 9-hour lavender aromatherapy treatment, 1 drop of lavender oil to cotton balloon participants' pillow case for 1 night • Control group: no aromatherapy treatment, 1 drop of distilled water (same protocol) Study duration: 1 night for the aromatherapy treatment, 1 night for the control treatment, 15 hours for washout Washout period = 15 hours
Outcomes	**Primary outcomes** 1. Subjective sleep quality, using RCSQ (depth, latency/onset, awakenings, time asleep, sleep quality each assessed on 0 to 100 VAS scale: 0 indicating optimal sleep, 100 indicating poor sleep) daily at 6 a.m. 2. Anxiety level: using the Spielberger State-Trait Anxiety Inventory (STAI) before the treatment at 9 p.m., 30 minutes to an hour after the treatment, and at 10 p.m.
Notes	We were unable to contact the author by email A power calculation was used for the sample size Only the whole period of the cross-over study was analysed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The treatment order was randomized. There was insufficient detail of the sequence generation method
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described

Borromeo 1998 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported measures were used for subjective sleep quality
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was reported
Selective reporting (reporting bias)	Unclear risk	There was insufficient information to permit judgement
Other bias	Unclear risk	There may have been some confounding variables, such as medication and ICU environment, which may have disturbed the effects

Bosma 2007

Methods	Design: randomized, cross-over clinical trial to assess quality and quantity of sleep during PSV and PAV Setting: a 12-bed ICU, arranged as a row of 3 rooms with 4 participants per room, Italy
Participants	"Patients during weaning from mechanical ventilation, between 18 and 75 yrs of age, mechanically ventilated for ≥ 3 days and sedated with midazolam, lorazepam, or propofol according to the daily interruption protocol at doses not higher than 0.05, 0.01, and 2 mg/kg/hr, respectively, were eligible to participate in the study" **Inclusion criteria** • "An intact respiratory drive with a maximal inspiratory pressure > 20 cm H_2O • A PaO_2/FIO_2 ratio > 200 on positive end-expiratory pressure (PEEP) ≤ 5 cm H_2O • A PH of 7.35-7.45 • Sedation had been discontinued for a minimum of 36 hrs for propofol and 72 hrs for lorazepam • Analgesia was provided solely with morphine at a dosage ≤ 0.01 mg/kg/hr • The participant was fully alert and cooperative with a Glasgow Coma Scale score ≥ 10" **Exclusion criteria** • "Successfully completed a spontaneous breathing trial • Had an abnormal electroencephalogram performed 24 hrs before study entry • Had a history suggestive of central sleep apnoea or drug or alcohol abuse or had general anaesthesia within 72 hrs from study entry • Requiring haloperidol > 10 mg/24 hr • Were haemodynamically unstable or had infection, sepsis, severe sepsis, or septic shock" Participants were withdrawn from the study at any time for the following a priori defined conditions: "a) need for inotropic support, sedation, or analgesia with morphine at a dosage > 0.01 mg/kg/hr; b) readiness for extubation; c) haemodynamic instability, arrhythmia, PaO_2/FIO_2 ratio less than 200, PH less than 7.35 or less than 7.45, or temperature > 37.5 °C" Total number randomized: 16 Total number analysed: 13

Bosma 2007 *(Continued)*

	Numbers of assessable participants in PAV first/PSV first arms: 7/6 Mean age: 63 ± 13 years Sex: 3 women, 10 men
Interventions	• Pressure support (PSV) versus proportional assist ventilation (PAV) "Patients were randomized to receive PSV or PAV on the first night and then crossed over to the alternative mode for the second night" Study duration: 1 day for each period. There was no washout between cross-over periods
Outcomes	**Primary outcomes** 1. PSG sleep variables including total sleep time (TST), total sleep period (TSP), per cent of sleep efficiency (SE%), per cent of sleep maintenance efficiency (SME per cent), REM per cent, SWS per cent, arousals per hour, awakenings per hour **Secondary outcomes** 1. Respiratory variable 2. Patient-ventilator asynchrony 3. Numbers of central apnoeas per night 4. Environmental light and noise intensity "All data were recorded from 10:00 PM to 8:00 AM for the two consecutive study nights"
Notes	On the first study nights, baseline values of PaO_2, $PaCO_2$, and arterial pH did not differ between PAV and PSV. Maximum and mean environmental noise and light did not differ between PSV and PAV Author Bosma K provided additional data via email Only the whole period of the cross-over study was analysed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Details of the randomization method were not described
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	An expert blinded to respiratory signals manually scored all polysomnography records
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel
Incomplete outcome data (attrition bias) All outcomes	Low risk	Incomplete outcome data were described in detail. 16 participants met enrolment criteria; 3 participants were withdrawn because of sepsis (2 participants) and severe hypoxaemia (1 participant)
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes

Bosma 2007 *(Continued)*

Other bias	Unclear risk	Università di Torino (grant PR60ANRA02) and Regione Piemonte (grant CEPAN-MAS03) supported, in part, the trial "Dr. Ranieri is on the advisory board for Maquet and received unopposed research grants from Tyco, Draeger, and Hamilton. The remaining authors have not disclosed any potential conflicts of interest"

Cabello 2008

Methods	Design: randomized, cross-over clinical trial to compare the influence of 3 ventilatory modes on sleep Setting: a 24-bed medical ICU, France
Participants	**Inclusion criteria** • "Conscious • Free from sedation and opiate analgesia for ≥ 24 hrs • Ventilated in PSV with an FIO_2 less than 60% and SpO_2 ≥ 90%" "All were ventilated through an endotracheal tube or a tracheostomy" **Exclusion criteria** • "Presence of a central nervous system disorder • An abnormal Glasgow Coma Scale score • Haemodynamic instability • Renal and/or hepatic insufficiency • Ongoing sepsis" Number randomized: 15 Number analysed: 15 Ages: range from 47 to 84 years, mean ages = 70 ± 13 years old Sex: 11 men and 4 women During the first study stage, there were 4 participants in ACV, 5 in aPSV, and 6 in cPSV During the second study stage, there were 5 participants in each ventilatory mode During the third study stage, there were 6 participants in ACV, 5 in aPSV, and 4 in cPSV
Interventions	• Assist-control ventilation (ACV) versus clinically adjusted pressure support ventilation (cPSV) versus automatically adjusted pressure support ventilation (aPSV) Participants were successively ventilated with ACV, cPSV, and aPSV in a randomized order during 3 successive periods of 6 hours: a daytime period from 2 p.m. to 8 p.m., a first nocturnal period from 8 p.m. to 2 a.m., and a second nocturnal period from 2 p.m. to 8 a.m. Study duration: 6 hours for each period There was no washout between cross-over periods
Outcomes	**Primary outcomes** 1. PSG sleep recordings from 2 p.m. to 8 a.m. **Secondary outcomes**

Cabello 2008 *(Continued)*

	1. Apnoeas (number of apnoeas per hour of sleep) and ineffective efforts (number of ineffective efforts per hour of sleep) 2. Noise levels
Notes	Sleep variables were expressed as a median (25th–75th percentile) Only the whole period of the cross-over study was analysed We attempted to contact author Dr Cabello via email; however, we received no response

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomized order" was mentioned, but there was a lack of description about the randomization procedure or method
Allocation concealment (selection bias)	Low risk	The trial used a closed-envelope technique
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessor was blinded. A neurologist blinded to the study manually scored sleep recordings
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were successively ventilated with ACV, cPSV, and aPSV; it was not possible to blind the personnel
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts were reported. All participants completed the study and were included in analyses
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	Grants from the Instituto de Salud Carlos III (expedient CM04/00096, Ministerio deSanidad) and the Instituto de Recerca Hospital de la Santa Creu Sant Pau (BC) in part supported the study

Chen 2012

Methods	Design: randomized clinical trial to test the effectiveness of valerian acupressure on the sleep of participants in the ICU Settings: a 42-bed adult intensive care unit, 28 single-bed rooms and a 24-bed ward, Taiwan, China
Participants	**Inclusion criteria** • "Participants were patients who were conscious, literate, communicable, and had agreed to participate, with an acute physiology score (APS, part of APACHE II) of lower than 15" **Exclusion criteria** • Hand or foot amputees • Diagnosed with bilateral paralysis or convulsions • Sedative users or had been consuming sleeping pills or over a month

Chen 2012 *(Continued)*

	Number randomized: 85 (41 in the experimental group and 44 in the control group) Number analysed: 85 Mean ages: 72.1 years old in the experimental group, 69.1 years old in the control group Sex: 30 men/41 women in the experimental group, 35 men/9 women in the control group

Interventions	• Valerian acupressure versus usual care
	  ○ Intervention group: received valerian acupressure (applied 2.5% valerian essential oils) on the participants' Neiguan, Shenmen (both located near the inner side of the wrist), and Yongquan points (located on the foot) between 7 p.m. and 10 p.m. Pressure was continuously applied to each acupoint for 3 minutes; the total time for 1 intervention on the 6 acupoints was 18 minutes
	  ○ Control group: usual care without valerian acupressure

Outcomes	**Primary outcomes** 1. Sleep quantity and quality: used the ActiGraph GT1M activity monitor as a sleep measurement tool; sleep data included daily hours of sleep, time spent awake, and waking frequency 2. Sleep observation checklists: sleep observations by nursing staff from 10 p.m. to 6 a.m. 3. Subjective sleep assessments: used Stanford Sleepiness Scale, which comprises 7 levels, with Level 1 the highest level of wakefulness and Level 7 the highest level of sleepiness **Other outcome** 1. Heart rate variability
Notes	As for baseline, the mean age and mean APS scores of the experimental group were higher than those of the control group; the 2 groups did not show any statistically significant differences in their baseline observed sleep and sleep measurements (the first night) Sample size calculation was used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants randomly selected a numbered (1 to 10) stick from a bin. Participants who had selected odd numbers were assigned to the control group, and the participants who had drawn even numbers were assigned to the experimental group
Allocation concealment (selection bias)	High risk	Allocation was not concealed as the investigator knew the relevance of an odd or even draw
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	The study was unable to blind participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the study and were included in analyses
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes

Chen 2012 *(Continued)*

Other bias	High risk	The mean age and mean APS scores of the experimental group were higher than those of the control group. SSS ratings in the baseline (namely first night) were significantly lower in the intervention group than the control group (P value < 0.01)

Córdoba-Izquierdo 2013

Methods	Design: RCT, 2-arm, parallel group design Setting: medical ICU, France
Participants	24 participants admitted for acute hypercapnic respiratory failure requiring non-invasive ventilation **Inclusion criteria** • AHRF over a 1-year period and requiring NIV for > 1 day were eligible **Exclusion criteria** • Hypercapnic coma • Use of medications that could alter sleep • Previous home treatment with NIV or with continuous positive airway pressure • The presence of central neurological disease • Haemodynamic instability Total number randomized: 25 (12 in the NIV_{ICU} group and 13 in the NIV_D group) Total number analysed: 24 (12 in both groups) Age: mean age: 69 years, range from 65 to 77 years Sex: 14 men, 10 women

Interventions	• Conventional ICU ventilators versus dedicated non-invasive ventilators
	  ○ Group 1: using conventional ICU ventilators for non-invasive ventilation
	  ○ Group 2: using dedicated non-invasive ventilators for non-invasive ventilation
	
	Study duration: 1 night

Outcomes	**Primary outcomes** 1. PSG sleep data from 11 p.m. to 7:30 a.m.: TST, SWS per cent, stage 1%, REM, stage 2%, sleep fragmentation **Secondary outcomes** 1. Respiratory parameters
Notes	There were no differences between groups, including the time under NIV previous to the study inclusion. The only difference was a higher Epworth Sleepiness Scale score in the NIV_D group than in the NIV_{ICU} group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The trial was randomized, but sequence generation was not described

Córdoba-Izquierdo 2013 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The sleep scorer was blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 participant was excluded from the analysis as a result of technical problems during the recordings
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	High risk	The baseline Epworth Sleepiness Scale scores significantly differed between the 2 groups

Foreman 2013

Methods	Design: 2-arm, parallel group design RCT Setting: neurological ICU
Participants	Adult neurological ICU patients undergoing continuous electroencephalography Total number randomized: 12 participants (6 in each arm) Mean age: 57.9 years old
Interventions	• Oral melatonin, sound-reducing headphones, and eye covers versus standard care
Outcomes	1. Sleep was measured by electroencephalography, including total sleep time
Notes	There were no significant differences between those who received the intervention and those who did not regarding illness severity, intubation, or neurological exam As this was a conference abstract, we could not access the original full paper and contact author The sample size was small

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The trial was randomized, but there was no description of the randomization
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias)	Unclear risk	Blinding of outcome assessment was not described

Foreman 2013 *(Continued)*

All outcomes		
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	This was a conference abstract, so there was insufficient information to permit judgement of risk of bias
Selective reporting (reporting bias)	Unclear risk	There was insufficient information to permit judgement of risk of bias
Other bias	Unclear risk	There was insufficient information to permit judgement of risk of bias

Gao 2008

Methods	Design: 2-arm, parallel RCT Settings: coronary care unit, China
Participants	**Inclusion criteria** • Elderly participants with coronary artery diseases admitted to the CCU **Exclusion criteria** • Expected length of CCU stay less 7 days Total number randomized: 106 (53 in each group) Total number analysed: 106 Mean age: 54.94 ± 10.51 years Sex: 63 men, 43 women
Interventions	• Intervention group: the relatives of the participants were allowed to visit the participants at dinner time • Control group: the relatives visited the participants only in the afternoon Study duration: 7 days
Outcomes	**Primary outcomes** 1. Daily accumulative sleeping time by nurse's observation **Other outcome** 1. Anxiety level
Notes	The general characteristic of the 2 groups before randomization did not differ

Risk of bias

Bias	Authors' judgement	Support for judgement

Gao 2008 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Random sequence generation was not described
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	The daily cumulative sleeping time was measured by unblinded nurses' observation
Blinding of participants and personnel (performance bias) All outcomes	High risk	The trial was unable to blind participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participant flow was not described
Selective reporting (reporting bias)	Low risk	The stated outcomes were all addressed in the report
Other bias	Unclear risk	COIs were not provided

Gragert 1990

Methods	Design: 2-arm, parallel RCT Settings: an 11-bed coronary care unit, single bedrooms, USA
Participants	**Inclusion criteria** • Elderly participants in a coronary care unit (31 with cardiac diseases; 5 participants were diagnosed with the following: spine cancer, adrenal insufficiency, pulmonary infiltrate, chronic obstructive pulmonary disease, and post-respiratory arrest; 4 participants had surgical diagnoses) **Exclusion criteria** • Unable to read or speak the English language • Had a serious neurological impairment, were not alert, rational, and oriented • Were either drug or alcohol abusive • If they professed a major hearing impairment Total number randomized: 40 (20 in each group) Total number analysed: 40 Sex: 20 men and 20 women Ages: ≥ 65 years of age, mean age = 72.9 ± 7.09 years
Interventions	• Intervention group: using a masking signal; the masking signal was set at 52 to 54 dB • Control group: not using a masking signal, the usual critical care noise; the average background noise level was 42 to 44 dB Study duration: 1 night
Outcomes	**Primary outcomes**

Gragert 1990 *(Continued)*

	1. Sleep monitored for 1 night by the investigator using continuous observation and anecdotal notes from 10 p.m. to 6 a.m. 2. Subjective sleep quality: used the Richards Campbell Sleep Questionnaire at 6 a.m., sleep scores ranged from 100 (indicating optimal sleep) to 0 (indicating poor sleep), and measured sleep depth, falling asleep, awakenings, returning to sleep, and quality of sleep
Notes	The author used 2-way ANOVAs with noise, gender, and sleep outcomes as factors to analyse the effects and their interactions, without providing the detail of mean and SD of sleep outcomes in each group; we were unable to make contact with the author to acquire the additional data

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomized by drawing a random number
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported measures were used for subjective sleep quality (non-blinded)
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind participants and personnel
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no incomplete outcome data
Selective reporting (reporting bias)	Unclear risk	There was insufficient information to permit judgement of risk of bias
Other bias	Unclear risk	There was insufficient information to permit judgement of risk of bias

Hu 2010

Methods	Design: 2-arm, parallel RCT Settings: a cardiac surgical intensive care unit with 17 beds, open room, China
Participants	Adult cardiac surgical participants **Inclusion criteria** • No history of cardiac surgery • Age > 40 years • No history of mental diseases • The length of ICU stay was more than 48 hours • Alert and able to answer the questionnaire **Exclusion criteria** • Use of sedatives during the period postoperation

Hu 2010 *(Continued)*

	• Unstable of hemodynamic status Number randomized: 50 Number analysed: 45 (25 in the intervention group, 20 in the control group) Mean age: 56.7 years Sex: 27 men, 18 women
Interventions	• Intervention group: used earplugs and eye masks combined with sleep-inducing music on nights during the ICU stay from 10 p.m. to 7 a.m. • Control group: usual care without earplug, eye masks, and music therapy Study duration: 3 days
Outcomes	1. Subjective sleep quality: used the Richards-Campbell Sleep Questionnaire, a self-report visual analogue instrument, on the day following discharge from ICU to assess the nights' sleep during ICU 2. Length of ICU stay 3. Nocturnal melatonin and cortisol secretion levels before and after 1 and 2 days of cardiac surgery
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The trial used block randomization; a random number table was used to select the blocks
Allocation concealment (selection bias)	High risk	The trial used the closed-envelope technique, but the researcher was also the person responsible for recruitment
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report measures were used for subjective sleep quality
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	Less than 15% of participants were excluded (N = 5)
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	There were no conflicts of interest

Jaber 2007

Methods	Design: cross-over design RCT Setting: ICU, medicosurgical department of anaesthesia and resuscitation, 16 beds, France

Jaber 2007 *(Continued)*

Participants	30 participants were included: 15 non-intubated participants and 15 intubated participants during weaning from mechanical ventilation **Inclusion criteria** • Age older than 18 years • Absence of sedation • Absence of administration of pressor amines • Coherent response to simple commands **Inclusion criteria specific for the intubated group** • Assisted ventilation through an endotracheal tube or tracheostomy • With pressure support ventilation • An average level between 10 and 15 cm H_2O • FiO_2 below 50% • A positive expiratory pressure of less than 5 cm H_2O Number randomized: 35 Number analysed: 30 Ages: 57.5 ± 12 years Sex: 17 men, 13 women

Interventions	• Received 20 minutes of relaxing music therapy or sitting and uninterrupted resting
	  ○ Intervention group: 20 minutes of music therapy. Music therapy took place during the day from 10 a.m. to 8 p.m.; the music style was first chosen based on musical tastes of the participant. The participant listened to the music with a helmet, lying or half-sitting, eyes closed
	  ○ Control group: no music, 20 minutes of uninterrupted rest
	
	Music therapy was not performed in 5 participants (5/35 = 14%)

Outcomes	**Primary outcomes** 1. Heart rate, systolic blood pressure, respiratory rate, and Bispectral Index (BIS score) were recorded at 5-minute intervals throughout both periods (rest and music) 2. State-agitation: assessed by behavioural scale RASS before and after each session 3. Pain: evaluated by digital visual analogue scale before and after each session
Notes	Only the whole period of the cross-over study was analysed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	There were insufficient details
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not described

Jaber 2007 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel and participants to the intervention
Incomplete outcome data (attrition bias) All outcomes	High risk	5 participants did not have music therapy (5/35 = 14%)
Selective reporting (reporting bias)	Unclear risk	Results were reported for all stated outcomes
Other bias	Low risk	There were no conflicts of interest

Le Guen 2014

Methods	Design: 2-arm, parallel design RCT Setting: Paris, France, a 1200-bed university-based teaching hospital, postanaesthesia care units (PACUs), an L-shaped open ward
Participants	"46 patients without any neurological or respiratory failure undergoing major non-cardiac surgery were included" **Inclusion criteria** • Participants had undergone a scheduled major surgery under general anaesthesia with the previous night in hospital and an expected postoperative night in the PACU related to comorbidities or surgery **Exclusion criteria** • Participants with bilateral deafness, blindness, severe sleep disorder requiring daily treatment and neurological disorders with shaking or cognitive preoperative dysfunction measured by mini-mental state evaluation and day-case surgery • After surgery, additional exclusio criteria were intrathecal morphine related to sedative effects and a need for postoperative non-invasive ventilation • Re-operation or transfer to another unit during the night Number randomized: 46 Number analysed: 41 (20 in the intervention group, 20 in the control group) Mean age: 60.5 years Sex: 34 men, 7 women

Interventions	• Use of earplugs and eye mask versus usual care (without earplugs and eye mask) during the first postoperative night
	  ◦ Intervention group: use of earplugs and eye mask during 1 night (from about 10 p.m. to 6 a.m.)
	  ◦ Control group: usual care without earplugs and eye mask
	
	Study duration: 1 night of using earplugs, 1 night without earplugs

Outcomes	**Primary outcomes** 1. Sleep quality was simultaneously measured by sleep quality scales (Spiegel score and Medical Outcomes Study Sleep) for 2 nights (the nights before and after surgery), by nurses' assessment, and through a wrist ActiGraph

Le Guen 2014 *(Continued)*

2. The MOSS Questionnaire consists of 12 items leading to 6 subscales or domains: sleep disturbance, sleep adequacy, daytime sleepiness, "supposed or known" snoring, being awakened by shortness of breath or by a headache, and quantity of sleep
3. Spiegel score: 6 questions about sleep, the maximum score is 30 and impaired sleep is defined as a score < 24, a pathological sleep pattern exists if the score is < 15
4. Wrist ActiGraph: placing at 8 p.m. and set to monitor movements every 5 seconds for a period of 12 hours
5. Occurrence of early delirium

Secondary outcomes

1. Nocturnal care activity
2. Total morphine consumption during the first 24 postoperative hours through PCA
3. Acceptance of devices

Notes	Sample analysis was used; no difference was shown in participant characteristics

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	This was a randomized study. There were insufficient details of sequence generation
Allocation concealment (selection bias)	Low risk	Sealed envelopes were used
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported measures were used for subjective sleep scores. Participants were not blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind the participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	46 participants were included; 5 participants were excluded from the final analysis (3 in the intervention group, 2 in the control group)
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	No COIs were declared

Li 2011

Methods	Design: 2-arm, parallel RCT Settings: coronary care unit, China
Participants	**Inclusion criteria** • Medical diagnosis of cardiovascular illness • Hospitalized in the CCU for no more than 2 weeks • Alert and able to read, speak, and hear

Li 2011 *(Continued)*

	Number randomized: 52 (26 in both groups) Mean age: 64 years Sex: 29 men, 23 women
Interventions	• Experimental group: nursing intervention with the Roy Adaptation Model as a guide • Control group: conventional care Study duration: 2 weeks
Outcomes	1. Subjective sleep quality: sleep scores were measured by Pittsburgh Sleep Quality Index (PSQI) scale 2. Quality of life: SF-36
Notes	There was no provided information about general characteristics before randomization between the groups

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The trial was randomized (used a table of random numbers)
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported measures were used for subjective sleep quality. Participants were not blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind the personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participant flow was not described
Selective reporting (reporting bias)	High risk	The trial did not provide information about general characteristics before randomization between the groups or the baseline sleep scores
Other bias	Unclear risk	Baseline sleep scores were not reported

Martin 2008

Methods	Design: randomized, cross-over trial Settings: ICU and telemetry unit at St. Vincent Healthcare in Billings, Montana, USA
Participants	**Inclusion criteria** • At least 18 years of age • Oriented to time and place • Had 1 previous night on the unit during this hospital stay • Able to read, speak, and hear English

Martin 2008 *(Continued)*

- Be at least 48 hours postoperative, if a surgical patient
- Able to consent to participate in the study

Exclusion criteria

- History of brain damage (traumatic or pathologic) or chronic sleep problems
- Ear injury or hearing impairment requiring use of aids
- Allergy to polyurethane

Number randomized: 14

Number analysed: 10

Mean age: 66 ± 11.29 years

Sex: 6 men, 4 women

Interventions	• Use of earplugs versus usual care
	  ○ Intervention group: use of earplugs during 1 night (from about 10 p.m. to 6 a.m.)
	  ○ Control group: usual care without earplugs
	Study duration: 1 night of using earplugs, 1 night without earplugs

Outcomes	1. Subjective sleep quality: using the Verran/Snyder-Halpern Sleep Scale 2. Qualitative data: participant comments or verbal responses
Notes	Sample size calculation was used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to earplug use on either the first or second night. The researcher selected 1 of 2 folded pieces of paper. 1 piece read control and 1 read earplugs
Allocation concealment (selection bias)	High risk	The researcher generated the random sequence and did the research by herself. See above - the paper was folded but not sealed
Blinding of outcome assessment (detection bias) All outcomes	High risk	The researcher generated the random sequence and administered the VSH Sleep Scale questionnaire by herself
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	High risk	10 of the 14 participants were able to complete the 2 nights of study
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Unclear risk	There was insufficient information to permit judgement of risk of bias

Namba 2012

Methods	Design: randomized, cross-over trial to examine the effects of foot baths on sleep outcomes Settings: ICU, Okayama University Hospital, Japan
Participants	6 ICU patients **Exclusion criteria** • Head injury/neurotrauma participants • Burn participants • Comatose participants Mean age: 65 years Sex: 3 women and 3 men
Interventions	• Intervention group: received a foot bath at 40℃ for 10 minutes before sleep onset on 1 night • Control group: non-foot bath before sleep onset Study duration: a foot bath night and a non-foot bath night Washout duration: at least 1 non-foot bath day was provided between foot bath days
Outcomes	**Primary outcomes** 1. PSG sleep recordings: total sleep time (TST); duration of rapid eye movement (REM); duration of sleep stages 1, 2, 3 and 4; arousal and awake times; and oxygen saturation (SpO_2) PSG was performed from 9 p.m. to 6 a.m. on both days **Secondary outcomes** 1. Subjective evaluations with regard to sleep
Notes	"Two patients had been prescribed sedatives which affected sleep directly. Three patients had been prescribed sleep medications"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was generated using a random number table
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts were reported

Namba 2012 *(Continued)*

Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Unclear risk	No COIs were declared

Parthasarathy 2002

Methods	Design: randomized, cross-over clinical trial to assess the quality and quantity of sleep during ACV, PSV alone, and PSV with dead space Setting: pulmonary and critical care unit, USA
Participants	11 male mechanically ventilated participants (ventilated through an endotracheal tube or tracheostomy) were recruited, aged 49 to 90 years All were receiving sedatives **Exclusion criteria** • Comatose • Receiving vasopressors • Recovering from general anaesthesia • Drug overdose or alcohol intoxication • Were considered unstable by their primary physician Total number randomized: 11 Total number analysed: 11 Mean age: 67 years Sex: all men
Interventions	• Pressure support ventilation (PSV) versus assist-control ventilation (ACV) "Patients were randomized to receive at least 2 hours each of the following three modes: assist-control ventilation, pressure support alone, and pressure support with dead space" ACV: the ventilator was initially set in the assist-control mode with a backup rate of 4 breaths per minute and tidal volume (Vt) of 8 ml/kg. The backup rate on assist-control ventilation was then set at 4 breaths below the participant's respiratory rate and kept at that setting for the rest of the study PSV: pressure support was adjusted to achieve a Vt equivalent to that during assist-control ventilation, namely 8 ml/kg Study duration: at least 2 hours for each period between 10:00 p.m. and 06:00 a.m. There was no washout between cross-over periods
Outcomes	**Primary outcomes** 1. PSG sleep recordings: number of apnoeas, arousals, and awakenings that occurred per hour of sleep; total sleep time; stages of sleep; the efficiency of maintaining sleep; total sleep fragmentation (sum of arousals and awakenings per hour of sleep) **Secondary outcomes** 1. Breath components and respiratory mechanics: elastance and resistance of the respiratory system, mechanical inspiratory time (Ti), expiratory time (Te), total respiratory cycle time (Ttot), and Vt 2. Gas exchange: end-tidal CO_2, oxygen saturation

Parthasarathy 2002 *(Continued)*

Notes	The 2 groups were similar in terms of anthropometric data, pulmonary function tests, and arterial blood gas data sampled before randomization ACV: assist-control mode with a backup rate of 4 breaths per minute and tidal volume (Vt) of 8 ml/kg PSV: pressure support was adjusted to achieve a Vt equivalent to that during assist-control ventilation, namely 8 ml/kg Only the whole period of the cross-over study was analysed We attempted to contact author Dr Tobin via email; however, we received no response

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The trial was randomized, but sequence generation was not described
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind participants and personnel
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses were reported
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes. The authors did not report the number of participants in each period
Other bias	Low risk	Funds from medical groups/charities only (i.e., not manufacturers) supported the trial

Richards 1998

Methods	Design: 3-arm, parallel group design RCT Setting: medical CCU, single-bed rooms, veterans medical centre in America
Participants	**Inclusion criteria** • "Male, 55 to 79 years old • Medical diagnosis of cardiovascular illness • Alert and oriented as determined by a brief examination of mental status • Able to read, speak, and hear conversational English • Stable hemodynamic status (defined as a systolic blood pressure greater than 90 mm Hg, a diastolic blood pressure less than 120 mm Hg, the absence of life-threatening dysrhythmias of chest pain, and infrequent need for adjustments in doses of vasopressors) • Hospitalized in the CCU for no more than 48 hours before selection for the study

Richards 1998 *(Continued)*

	• No prior diagnosis of obstructive sleep apnoeas or overt signs or symptoms of the disorder" Total numbers randomized: 71 Total numbers analysed: 69 (24 in group 1, 28 in group 2, and 17 in group 3) Age: 55 to 79 years old; the mean age was 65.8 years Sex: all were men
Interventions	• Group 1: received a 6-minute back massage • Group 2: received a teaching session on relaxation and a 7.5-minute audiotape at bedtime consisting of muscle relaxation, mental imagery, and relaxing background music • Group 3: received usual nursing care Study duration: 1 night
Outcomes	**Primary outcomes** 1. PSG sleep parameters: including sleep efficiency; REM sleep latency; REM sleep time; total sleep time; latency to sleep onset; arousals index; percentage of stage 1, 2, 3, and 4. "PSG was used to measure 1 night of sleep for each patient"
Notes	Power analysis was used to determine the numbers of participants Intention-to-treat analysis was not performed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The trial used a random number generator (author Richards KC provided the detail via email)
Allocation concealment (selection bias)	Unclear risk	No details about allocation concealment were reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinding of scoring of sleep studies was performed
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	Less than 15% of participants were excluded Quote: "Seventy-one patients were randomized, one subject did not complete the study because his condition became unstable, one member of the back-massage group was excluded because he met the criteria for an outlier (3 or more standard deviations from the group means for sleep efficiency index), 69 patients were analyzed"
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Unclear risk	There was insufficient information to permit judgement of risk of bias

Richardson 2003

Methods	Design: 2-arm, parallel group design RCT Setting: 3 intensive care units, single-bed rooms in 2 teaching hospitals, USA
Participants	**Inclusion criteria** • "Adults (18 years or older) admitted to ICU with nurse-patient acuity ratio of 1:1 or 1:2" **Exclusion criteria** • "Unstable patients with an acuity ratio of 2:1 or more (such as patients on an intraaortic balloon pump or a left ventricular assist device) • Patients with a history of Alzheimer's disease, dementia, psychoses, central neurological impairment (cerebrovascular accident, head injury, cranial surgery, coma), severe bradycardia, or severe hypotension • Non-English-speaking patients" Total numbers randomized: 36 Total numbers analysed: 29 (17 in the control group and 12 in the experimental group) Sex: 17 men, 19 women Mean age: 58.4 years
Interventions	• Experimental group: a combination of relaxation and imagery; the participant received the intervention for 2 evenings, between the hours of 5 p.m. and 7 p.m.. The investigator designed the intervention to be from 13 to 18 minutes in length, and the intervention was delivered in person • Control group: usual care without relaxation and imagery Study duration: 2 days
Outcomes	**Primary outcome** 1. Subjective sleep scores: used the Verran/Snyder-Halpern (VSH) Sleep Scale, an 8-item visual analogue instrument using a 100 mm response line, to measure the sleep quality; 3 items were added to the tool for this study, and 1 item was revised, resulting in an 11-item visual analogue instrument. These 11 items were numbers of awakenings, hours awake, hours of sleep, concern with interruptions, time to first sleep, concern with time to first sleep, depth of sleep, sufficiency of sleep, refreshment upon awakening, number of naps taken during the previous day, and good or bad night. Higher sleep scores indicated a perception of improved sleep
Notes	There were no significant differences between groups for any demographic variable There was no pattern of administration of medications that could have affected sleep over time for any participant The paper did not report the results of sleep scores on day 1, day 2, and day 3 The mean sleep scores of the baseline night were as follows: control group was 57.85 ± 44.1, intervention group was 82 ± 44.6, showing a significant difference between them We attempted to contact author Dr S Richardson via email; however, we received no response

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was generated using a coin toss

Richardson 2003 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "The investigator was responsible for recruitment and was the individual who presented the tool to the subject on day 1. The research assistant, without knowing group membership of the subject, presented the tool to the subject on days 2 and 3" Comment: however, self-report measures were used for subjective sleep data, and participants were not blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind participants and personnel to the intervention
Incomplete outcome data (attrition bias) All outcomes	High risk	The refusal rate for participation was 16% (n = 6); 36 were randomized; 29 were analysed 19.4% of participants dropped out
Selective reporting (reporting bias)	High risk	The results of sleep scores on day 1, day 2, and day 3 in both groups were not reported
Other bias	High risk	The mean sleep scores of the first night (namely baseline) were significantly different between the 2 groups

Roche-Campo 2013

Methods	Design: randomized, cross-over clinical trial to evaluate the direct impact of mechanical ventilation on sleep quantity and quality Setting: a 24-bed medical ICU, Henri Mondor teaching hospital, France
Participants	**Inclusion criteria** • All tracheostomized participants able to breathe spontaneously for more than 5 continuous hours were eligible for inclusion if they were conscious and non-sedated with a Richmond Agitation-Sedation Scale (RASS) score of 0 **Exclusion criteria** • Encephalopathy (RASS ≤ -1), agitation (RASS ≥ +1) • Need for supplemental administration or introduction of sedative, opioid, or neuroleptic drugs within the last 48 hours (except for chronic or dependent medication) • Central neurologic disease • Chronic psychiatric disorders • Ongoing sepsis Total numbers randomized: 16 Total numbers analysed: 16 Sex: 11 men, 5 women Median age: 68 years, from 25 to 86 years old

Roche-Campo 2013 *(Continued)*

Interventions	• Spontaneous ventilation versus mechanical ventilation at low levels of pressure support
	  ○ received either spontaneous ventilation or mechanical ventilation at low levels of pressure support (a PS level of 10 cm H_2O)
	  ○ for 2 cross-over periods of 5 hours' duration each, from 10 p.m. to 8 a.m. (from 10 p.m. to 3 a.m. and from 3 a.m. to 8 a.m.)

Outcomes	1. Polysomnography sleep outcomes 2. Basal data
Notes	Only the whole period of the cross-over study was analysed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random sequence generation was not described
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The sleep scorer was blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses were reported
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	There were no conflicts of interest

Ruan 2006

Methods	Design: 2-arm, parallel RCT Settings: ICU, China
Participants	A total of 73 ICU patientswere divided into 2 groups, chronic hypercapnic respiratory failure participants in stable conditions
Interventions	• Intervention group: used a synthesized psychologic intervention (relaxation and imagery) before sleep • Control group: usual care Study duration: 1 day
Outcomes	**Primary outcomes**

Ruan 2006 *(Continued)*

	1. The time falling to sleep and the total sleep time during night, scored by nurses' observation
Notes	The general characteristics of the 2 groups before randomization were not different

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The "randomized order" was mentioned, but there was a lack of description about the randomization procedure or method
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Nurses (unblinded) measured subjective sleep quantity and quality
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Incomplete outcome data were not described
Selective reporting (reporting bias)	Unclear risk	There was insufficient information to permit judgement of risk of bias
Other bias	Unclear risk	There was insufficient information to permit judgement of risk of bias

Ryu 2012

Methods	Design: 2-arm, parallel group design RCT Setting: cardiac care unit (CCU), K University D hospital, South Korea
Participants	**Inclusion criteria** • "At least 20 years of age • Diagnosis of coronary artery disease • Admittance to CCU after PTCA • Occurrence of ABR immediately after angiocatheter removal in the CCU" **Exclusion criteria** • "Use of ventilators • Diagnosed [with] dementia, neurologic disease, or sensory disorder • Use of sleep-inducing drugs or sedative medications • History of sleeping problem before admittance to CCU" Numbers randomized: 60 Numbers analysed: 58 (29 in both group)

Ryu 2012 *(Continued)*

Interventions	• Experimental group: listened to sleep-inducing music and wore an eye shield; the sleep-inducing music included nature sounds, Delta wave control music, Goldberg Variations BWV, MP3 music through earphones from 10 p.m. to 10.53 p.m. • Control group: no music, but earplugs and eye shield were applied from 10 p.m. to 5 a.m. the next morning Study duration: 1 night
Outcomes	**Primary outcomes** 1. Quantity of sleep: using quantity of sleeping questionnaire 2. Quality of sleeping: using the modified Verran/Synder-Halpern (VSH) Sleep Scale, The VSH includes 8 questions regarding the frequencies of awakening while sleeping, depth of sleep, and self-evaluation of sleep. The VSH is a Likert scale that ranged from 0 to 10 for each question, with total possible points ranging from 0 to 80. Lower scores indicated poorer sleep quality The quantity and quality of sleep were measured using questionnaires at 7 a.m. the next morning
Notes	Power analysis was used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...randomly assigned using card number, the participants having an even number were assigned to experimental group, and those with odd number were assigned to control group" Comment: but there was a lack of description of the methods of card number generation
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Although blinding of outcome assessor was performed, self-reported measures were used for subjective sleep quality, and participants were unblinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 participants dropped out: 1 for having taken a sleep-inducing drug, and 1 transferred to another unit
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	There were no COIs

Scotto 2009

Methods	Design: 2-arm, parallel group design RCT

Scotto 2009 *(Continued)*

	Settings: 2 critical care units of a Midwestern US teaching hospital, USA
Participants	**Inclusion criteria** • "People who were alert and oriented, able to understand the study, give informed consent, and mark the tool" **Exclusion criteria** • "With diagnosed sleep disorders or hearing loss • Those who received sedation or anesthesia in the previous 12 hours • Those who required mechanical ventilation" Number randomized: 100 Number analysed: 88 (39 in the control group, 49 in the intervention group) Mean age: 63.1 years Sex: 53 men, 35 women
Interventions	• Intervention group: used earplugs during regular night-time sleeping hours for 1 night • Control group: no earplugs The duration of intervention: 1 night
Outcomes	1. Subjective sleep quality and quantity: used the Verran/Snyder-Halpern Sleep Scale before noon on the day following the intervention
Notes	We attempted to contact author CJ Scotto via email; however, we received no response Only t-scores were provided

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The paper mentioned "randomly assigned", but there was a lack of description about the randomization procedure or method
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported measures were used for subjective sleep quality, and participants were not blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Low risk	Less than 15% of participants were excluded (N = 12) "100 participants were randomly assigned to earplug intervention or control, with 88 completing the study"
Selective reporting (reporting bias)	Unclear risk	The authors did not report the value of mean sleep scores in both groups, even though they stated 'statistically significant difference'
Other bias	Unclear risk	There was insufficient information to permit judgement of risk of bias

Sha 2013

Methods	Design: 2-arm, parallel group design RCT Settings: ICU, cancer hospital of Tianjin Medical University, China
Participants	Lung cancer participants in ICU after thoracotomy **Inclusion criteria** • Age > 18 years old • With primary school degree or above • No history of sleep disorders and neurologic disease • ICU stay time more than 7 days • With general anaesthesia in thoracic operation • No hearing loss • Able to give informed consent and mark the tool • Alert and oriented **Exclusion criteria** • Had serious complication during operation or postoperation • Unable to listen to the music Number randomized: 240 (120 in each group) Number analysed: 112 in the control group, 107 in the intervention group Mean age: 55.5 years Sex: 146 men, 73 women
Interventions	• Control group: received routine postoperative care • Intervention group: received increasing individualized music intervention based on the routine post-operative care for at least 30 minutes, twice every day (12:30∼13:30, 20:30∼21:30) Study of duration: more than 7 days
Outcomes	1. Sleep quality: assessed with Pittsburgh Sleep Quality Index (PSQI) on the day of the ICU discharge
Notes	The general characteristic of the 2 groups before randomization was not different

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The paper mentioned "randomly assigned", but there was a lack of description about the randomization procedure or method
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported measures were used for subjective sleep quality, and participants were not blinded
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind personnel or participants

Sha 2013 *(Continued)*
All outcomes

Incomplete outcome data (attrition bias) All outcomes	Low risk	Less than 15% of participants were excluded (N = 21 - 13 in the intervention group, 8 in the control group)
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	High risk	The PSQI scores before admission to the ICU were not provided

Su 2013

Methods	Design: 2-arm, parallel group RCT to test the effects of non-commercial music on quality of sleep and relaxation indices Settings: a 45-bed medical ICU, a 650-bed multispecialty teaching hospital located in Taipei, single-bed rooms, Taiwan
Participants	**Inclusion criteria** • Age > 18 years old • APACHE II score ≦ 25 • Ability to communicate in either Mandarin or Taiwanese • Conscious and clear • Having a length of residency in the ICU of more than 24 hours • Having an arterial catheter inserted **Exclusion criteria** • Hearing impairment • Physical restraint • Alcoholism • Infectious disease • Haemodynamic instability Total number randomized: 28 (14 in both groups) Total number analysed: 28 Mean age: 61.68 ± 9.82 Sex: 17 men, 11 women
Interventions	• A 45-minutes sedating-music listening intervention versus usual care Music intervention consisted of 4 pieces of sedating piano music composed by 2 of the authors; the music was played on a Sony (CFD-S07CP) CD player
Outcomes	**Primary outcomes** 1. PSG sleep was recorded for the first 2 hours of the nocturnal sleep between the hours of 9.30 p.m. to 11.30 p.m. **Secondary outcomes**

Su 2013 *(Continued)*

1. Subjective sleep quality: using the Verran/Synder-Halpern Sleep Scale (VSH sleep scale) Chinese version; this VSH consists of 15 self-reported scales with each visual analogue scale running from 0 to 100 mm. The sum of the scores provided a global sleep quality score ranging from 0 to 1500
2. Relaxation indices: including heart rate, mean arterial blood pressure, and respiratory rate, with a 5-minute interval between each recording

Notes	Power analysis was used There were no statistically significant pretest differences between the music and control groups in terms of participants' demographics and diagnoses and also no statistically significant differences in baseline subjective and objective PSG sleep parameters and heart rate, mean arterial pressure, and respiratory rate

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Lots were drawn to determine the group
Allocation concealment (selection bias)	Low risk	Quote: "All lots (labels) were packed in a jar that was prepared by another person"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers responsible for statistical analysis were not aware of which group participants were assigned, and the sleep technician scored blindly The authors who composed the music were blind to the procedures and not involved in data collection
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no losses
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	There were no conflicts of interest

Toublanc 2007

Methods	Design: randomized, cross-over study to compare the impact of assist-control ventilation (ACV) and pressure support ventilation with 6 cm H_2O inspiratory pressure (low PSV) on sleep quality Setting: respiratory ICU, single-bed rooms, France
Participants	"Adult patients with chronic lung disease, intubated, and mechanically ventilated for an episode of acute respiratory failure of their chronic condition (I. e., chronic obstructive or restrictive pulmonary diseases). Near-to-wean ICU patients with acute on chronic respiratory failure. Patients were invited to participate in this study at the end of their weaning period, during the last night preceding the planned extubation, when the cause of respiratory failure was controlled, and when patients were able to sustain low levels of PSV. Patients also needed to be haemodynamically stable without any sedative, narcotic, or analeptic drugs administered for the previous 48 hour"

Toublanc 2007 *(Continued)*

	Total number included: 22 Total number analysed: 20 Numbers of assessable participants in ACV first/low PSV first arms: 10/10 Sex: 15 men, 5 women Mean age: 65 ± 10.9 years

Interventions	• ACV versus low PSV
	  • ACV: started with a tidal volume of 10 ml/kg and a respirator frequency of 12 cycles/min, and these parameters were increased until complete disappearance of spontaneous inspiratory efforts
	  • Low PSV: breathed spontaneously via the respirator's circuitry, with an inspiratory pressure support of 6 cm H_2O and a trigger sensitivity of 0.5 cm H_2O for 7200 PB and 5 L/min
	
	Study duration: 4 hours for each period (from 10 p.m. to 6 a.m.)
	
	There was no washout between cross-over periods.

Outcomes	1. Objective sleep data: PSG sleep recordings were performed from 10 p.m. to 6 a.m. 2. Sleep variables: sleep structure, the number of arousals per hour of sleep, total sleep time 3. Self-perceived sleep quality (assessed by participants' self-perception of the global quality of their night) 4. Sleep scored: 0 = not slept at all, 1 = poor sleep quality, and 2 = slept well
Notes	The 2 groups were similar in terms of anthropometric data, pulmonary function tests, and arterial blood gas data sampled before randomization The whole period, the first period, and the second period of the cross-over study were analysed Considering the whole night, no significant differences in sleep architecture were observed. There was significantly lower wakefulness with ACV than in low PSV (30.8 ± 28.2% versus 69.0 ± 26.2%, P value < 0.05) In the first 4-hour period and significant increases in stages 3 and 4 NREM sleep in the second part of the night

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computer randomization method was used
Allocation concealment (selection bias)	Low risk	The trial used the closed-envelope method
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessor was blinded; a neurologist blinded to the study manually scored sleep recordings
Blinding of participants and personnel (performance bias) All outcomes	High risk	The personnel were not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Two patients were not analyzed, one because of excessive electrical artefacts on polysomnographic records and the other because of onset of respiratory distress during the sleep study"

Toublanc 2007 *(Continued)*

Selective reporting (reporting bias)	Low risk	Although the author did not report the mean scores of self-perceived sleep quality in both groups, the author tested the correlations between self-perceived sleep quality and sleep stages
Other bias	Unclear risk	The study report did not provide funding information or a conflict of interest statement

Van Rompaey 2012

Methods	Design: 3-arm, parallel group RCT Setting: ICU, Antwerp University Hospital, Belgium
Participants	**Inclusion criteria** • Age > 18 years old • The expected length of stay in the ICU was more than 24 hours • Speaking Dutch or English • Scoring a minimum Glasgow Coma Scale of 10 **Exclusion criteria** • Participants with known hearing impairment • Using sedation • Dementia, confusion, or delirium at admission Total number randomized: 136 (69 in the experimental group, 67 in the control group) Total number analysed: 136 in night 1, 71 in night 2, 27 in night 3, and12 in night 4 Mean age: 59 years (range = 18 to 84) Sex: 66% were men
Interventions	• Experimental group: participants sleeping with earplugs during the night • Control group: participants sleeping without earplugs during the night Study duration: 4 days
Outcomes	1. Assessment of delirium and confusion: using the NEECHAM scale based on the nurses' 24-hour assessment of the level of processing information, the level of behaviour, and the physiological condition, rating the participant on a 30 to 0 scale 2. Subjective sleep perception: using 5 dichotomous questions on the self-reported sleep quality of the participant; a higher total sum score on 5 questions showed a better sleep perception. The scores were categorized as bad sleep (sum < 2), moderate sleep (2 ≤ sum < 4), and good sleep (4 ≤ sum)
Notes	Sample size calculation was used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random sequence generation was achieved using a computer program
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described

Van Rompaey 2012 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	The research nurse and the critical care nurse scoring the NEECHAM scale had no information on the use of earplugs
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Low risk	136 participants were included and randomized and included in the analyses
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Low risk	There was no COI

Wallace 1998

Methods	Design: randomized, cross-over study to measure the effect of earplugs during the night-time hours on the quality and quantity of sleep in ICU patients Settings: ICU with 60 beds, private rooms, tertiary care hospital providing level I trauma services and comprehensive heart services, USA
Participants	**Inclusion criteria** • Likely to remain in ICU for ≥ 3 additional days • Age ≥ 18 • Mechanically ventilated **Exclusion criteria** • History of current alcohol or drug abuse, sleep medication abuse, current psychiatric illness or anxiety disorder, and brain disorder • Inability to pass hearing screening test or documented history of hearing problems • History of sleep disorder or failed sleep disorders screening Number enrolled: 17 Number randomized: 13 Number analysed: 13 Numbers of assessable participants in treatment first/control first arms: 7/6 Sex: 5 men and 8 women Mean ages: 56.9 ± 20 years
Interventions	• Intervention group: wore earplugs on 1 night • Control group: no use of earplugs on 1 night Study duration: 1 night for each period, 1 night for washout.
Outcomes	**Primary outcome**

Wallace 1998 *(Continued)*

1. PSG sleep data
2. Night-time PSG sleep data from 10.30 p.m. to 6 a.m.
3. ICU length of stay
4. Hospital length of stay
5. Survival of hospital discharge
6. Length of time on ventilator (without providing these outcomes in each group)

Secondary outcome

1. Participants' satisfaction (earplug feasibility sleep questionnaire)

Other outcomes

1. Environmental variables (noise, lighting levels, and temperature)
2. Care content variables: intensity of care, medications, and surgical procedures
3. Care process variables: pain, opportunity for sleep, sleep position, and anxiety
4. Physiologic variables: circadian rhythm, medications circadian rhythm, and body temperature

Notes	The general characteristics of the 2 groups before randomization were not different Sound pressure levels, intensity of care, the verbal pain assessment scale or morphine equivalents, sensory alteration scores, the skin temperature data, and lighting levels were not significantly different between the 2 nights Only the whole period of the cross-over study was analysed Days in ICU at enrolment = 12.6 ± 8.3 Sample size calculation was used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The paper mentioned "randomly assigned", but there was a lack of description about the randomization method
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The sleep scorer was blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel and participants were not blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Thirty-three eligible subjects were approached for consent, 16 declined to participate, 17 were enrolled, and 13 completed the study"
Selective reporting (reporting bias)	Low risk	Results were reported for all stated outcomes
Other bias	Unclear risk	There was insufficient information to permit judgement of risk of bias

Wang 2012

Methods	Design: 2-arm, parallel RCT Setting: cardiac care unit, China
Participants	**Inclusion criteria** • Medical diagnosis of cardiovascular illness • Alert • Hospitalized in the CCU for more than 7 days Numbers randomized: 104 (52 in both group) Mean ages: 56 ± 0.5 years Sex: 56 men, 48 women
Interventions	• Experimental group: received foot massage and use of sleep pillow (ingredients: Chinese herbal medicine) • Control group: usual care (no massage, no use of sleep pillow) Study duration: 7 days
Outcomes	1. Subjective sleep quality: measured by AIS
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	This was a quasi-RCT; participants were allocated to the intervention group based on the hospital orders
Allocation concealment (selection bias)	High risk	Allocation concealment was inadequate
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participant flow was not described
Selective reporting (reporting bias)	Unclear risk	Results were reported for all stated outcomes, but the trialists did not provide measures of statistical significance for sleep outcomes, even though they stated "statistically significant difference in sleep quality between the control and experimental groups"
Other bias	Unclear risk	The trialists provided the preparation

Xie 2011

Methods	Design: 2-arm, parallel quasi-RCT Settings: medical intensive care unit, China
Participants	**Inclusion criteria** • No prior diagnosis of obstructive sleep apnoea or overt signs or symptoms of the disorder • Alert, without ventilation **Exclusion criteria** • Use of sedative and hypnotic drugs • Severe pain or anxiety Numbers randomized: 75 (42 in the experimental group, 33 in the control group) Mean ages: 56.4 ± 10.2 years Sex: 43 men, 32 women
Interventions	• Experimental group: used earplugs and eye masks • Control group: did not use earplugs and eye masks Study duration: 3 days
Outcomes	**Objective sleep outcomes** 1. Used EEG monitoring 2. Measured muscle tension 3. Subjective sleep quality: sleep scores were measured by Pittsburgh Sleep Quality Index (PSQI) scale (before and after 3 days of intervention)
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	This was a quasi-RCT; participants were allocated to the intervention group based on the hospital orders
Allocation concealment (selection bias)	High risk	Allocation concealment was inadequate
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind personnel or participants
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Incomplete outcome data were not described

Xie 2011 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	The authors did not report the test statistic value for sleep outcomes between the 2 groups, even though they stated "statistically significant difference"
Other bias	Unclear risk	Information about general characteristics before randomization between the groups was not provided

ACV = assist -control ventilation.
AIS = Athens Insomnia Scale.
AHRF = acute hypercapnic respiratory failure
ANOVA = analysis of variance.
APACHE II = Acute Physiology and Chronic Health Evaluation.
APS = Acute Physiology Score.
aPSV = automatically adjusted pressure support ventilation.
BIS = Bispectral Index.
BWV = Bach Werke Verzeichnis.
CCU = critical care unit.
COI = conflict of interest.
cPSV = clinically adjusted pressure support ventilation.
EEG = electroencephalogram.
Hr = hour.
I/E = inspiration/expiration.
ICU = intensive care unit.
MI = myocardial infarction.
MOSS = medical outcomes study sleep.
NEECHAM = Neelon/Champagne Confusion Scale.
NIV = non-invasive ventilation.
NIV_D = dedicated non-invasive ventilator
NIV_{ICU} = non-invasive ICU ventilator
NREM = non-rapid eye movement.
PACUs = postanaesthesia care units.
PAV = proportional assist ventilation.
$PAV+_{base}$ = proportional assist ventilation with baseline level of assist.
$PAV+_{high}$ = proportional assist ventilation with level of assist.
PB = Puritan Bennett.
PCA = patient-controlled analgesia.
PCV = pressure-controlled ventilation.
PEEP = positive end-expiratory pressure.
pH = potential hydrogen.
PS = pressure support.
PS_{high} = pressure support ventilation with high pressure support.
PS_{base} = pressure support ventilation with baseline pressure support.
PSG = polysomnography.
PSQI = Pittsburgh Sleep Quality Index.
PSV = pressure support ventilation.
PTCA = percutaneous coronary intervention.
R/O = rule out.
RASS = Richmond Agitation-Sedation Scale.
RCSQ = Richards-Campbell Sleep Questionnaire.
RCT = randomized controlled trial.
REM = rapid eye movement.
SD = standard deviation.
SE = standard error.
SF = short form.
SME= seep maintenance efficiency.
SSS = Stanford Sleepiness Scale.
STAI = Speilberger State-Trait Anxiety Inventory.
SWS = slow-wave sleep.
Te = expiratory time.

Ti = time.
TSP = total sleep period.
TST = total seep time.
Ttot = total respiratory cycle time.
VAS = visual analogue scale.
VSH = Verran/Snyder-Halpern.
Vt = tidal volume.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Barnason 1995	The outcomes were not relevant (blood pressure and heart rate, anxiety level (using Spielberger's State-Trait Anxiety Inventory))
Chen 2009	There was no randomization
Cho 2013	This was a non-equivalent control group, non-synchronized quasi experiment designed to test the effects of a lavender, roman chamomile, and neroli oil blend aromatherapy on anxiety, sleep, and blood pressure in coronary artery disease participants with ischaemic heart diseases in ICU
Cox 1999	This was a 1-group pretest-post-test experimental study, with a time series design
Diby 2008	This was 1-group pretest-post-test experimental study, with a quasi-experimental study design
Dunn 1995	The outcomes were not relevant: physiological variables (systolic and diastolic blood pressure, heart rate and rhythm, and respiratory rates) and participants' evaluation of their anxiety levels, mood, and ability to cope with their intensive care experience
Elliott 1994	The outcomes were not relevant (anxiety level and physiologic variables (systolic and diastolic blood pressure and heart rate))
Fang 2006	This was a case report study
Fietze 2008	The participants were not relevant. Participants with stable, pharmacologically treated CHF in the sleep centre
Figueroa-Ramos 2010	This was a non-randomized trial, with a historical control. The US National Institutes of Health On-going Trials Register (www.clinicaltrials.gov) identifier for the study is NCT00714194
Gardner 2009	The participants were not relevant. The participants were admitted to orthopaedic wards
Gunnarsdottir 2007	The outcomes were not relevant (anxiety and physiological variables)
House 2003	There was no randomization; this was a before-after study in 2 participants
Kamdar 2013	There was no randomization; this was a before-after study in different participants
Koo 2008	This was a non-equivalent control group, non-synchronized quasi-experiment trial
Nunes 2008	The intervention was not relevant (participants received 3 mg melatonin or placebo), and the participants were not relevant (COPD participants attending the respiratory outpatient clinic)
Olson 2001	There was no randomization; this was a before-after study in different participants
Richards 2000a	This was a systematic review

Study	Reason for exclusion
Richards 2003	This was a systematic review
Richardson 2007	This was a non-randomized trial; participants were self selected into either an intervention or non-intervention group
Robinson 2005	This was described as a study, but there was no control group
Shilo 2000	The intervention was not relevant. Participants received either 3 mg of controlled-release melatonin or a placebo
Walder 2000	The outcomes were not relevant (light level and noise level in an ICU)
Williamson 1992	The participants were not ICU patients; they were postoperative coronary artery bypass graft (CABG) participants after transfer from an intensive care unit
Winck 2004	The participants were not relevant; they had COPD and CVF and were admitted for pulmonary rehabilitation
Young 2008	The participants were not relevant. Participants were recruited from a cross-sectional study of 60 consecutive adult CF outpatients with mild to severe lung disease
Zimmerman 1996	The participants were not relevant; all participants were moved out of the critical care unit before the sessions were initiated

CABG = coronary artery bypass graft.
CF = cystic fibrosis.
CHF = congestive heart failure.
COPD = chronic obstructive pulmonary disease.
CVF = chronic ventilatory failure.
ICU = intensive care unit.

Characteristics of studies awaiting assessment *[ordered by study ID]*

NCT01061242

Methods	2-arm, parallel trial
Participants	**Inclusion criteria** • >=18 years old • Spent at least 1 full night (i.e., 7 p.m. to 7 a.m.) in the Johns Hopkins Hospital (JHH) Medical Intensive Care Unit (MICU) • Discharged directly from MICU to an inpatient medical step-down or ward bed at JHH
Interventions	• Group 1: no Intervention • Group 2: sleep-promoting interventions (a multifaceted, staged sleep-promoting intervention as part of a pre-existing sleep quality improvement project)
Outcomes	1. Digit span test score 2. Sleep in the ICU questionnaire 3. Trail-making test times 4. Delirium status
Notes	This study has been completed. No data are presently available

NCT01343095

Methods	3-arm, parallel trial
Participants	Adult participants who are admitted to the MICU for at least 24 hours with at least 72 hours' additional expected stay in the ICU, and who are mechanically ventilated
Interventions	• No intervention: usual care • Active comparator: earplugs (application of earplugs from 10 p.m. to 6 a.m. nightly for 7 nights or until ICU discharge) • Active comparator: earplugs and headphones (earplugs and noise-cancelling headphones applied from 10 p.m. to 6 a.m. nightly for 7 nights or until ICU discharge)
Outcomes	1. Days free of delirium or coma 2. Noise attenuation 3. Sleep efficiency and architecture 4. Amount of sedative use 5. Amount of analgesic use
Notes	This study was suspended because of a lack of study staff (last status update May 2014)

NCT01580956

Methods	Cross-over trial
Participants	**Inclusion criteria** • Ventilation planned for more than 48 hours • Participant alert and calm corresponding to a Richmond Agitation-Sedation Scale (RASS) between -2 and 0 • Age ≥ 18 • Surrogate decision maker's consent **Exclusion criteria** • Clinical instability for any reason • Life support withdrawal code • Participant under tutelage • Pregnancy • No French health insurance
Interventions	• Group 1: variable-PSV ventilatory mode • Group 2: standard-PSV ventilatory mode
Outcomes	1. Oxygenation in each ventilatory mode 2. Ventilatory comfort 3. Feasibility 4. Participant-ventilator asynchronism 5. Ventilatory effects
Notes	The study was completed in August 2012. No results are presently available

NCT01607723

Methods	Cross-over trial
Participants	**Inclusion criteria** • An estimated remaining duration of mechanical ventilation of more than 2 days • Participant alert and calm • Surrogate decision maker's consent **Exclusion criteria** • Clinical contraindication for the use of NAVA: contraindications for an EAdi catheter placement (e.g., oesophageal varices, upper gastrointestinal bleeding, gastroesophageal surgery) • Clinical instability for any reason • Contraindications for continuing intensive care treatment • Participant under tutelage • Age < 18 years • Pregnancy • No French health insurance
Interventions	• Group 1: NAVA ventilatory mode • Group 2: PAV+ ventilatory mode
Outcomes	1. Oxygenation in NAVA and in PAV+ 2. Ventilatory comfort 3. Participant-ventilator asynchronies 4. Ventilatory parameters 5. Sleep pattern
Notes	The study was completed in March 2014. No results are presently available

Nerbass 2011

Methods	2-arm, parallel trial
Participants	**Inclusion criteria** • Participants of both genders, between 40 to 80 years of age who were waiting for coronary artery bypass graft surgery
Interventions	• Group 1: massage therapy • Group 2: control group
Outcomes	1. Quality of sleep 2. Pain 3. Fatigue complaints
Notes	This study has been completed; data are published (Nerbass 2011)

ICU = intensive care unit.
JHH = Johns Hopkins Hospital.
MICU = Medical Intensive Care Unit.
NAVA = neurally adjusted ventilatory assist.
PAV+ = proportional assist ventilation+.

PSV = pressure support ventilation.
RASS = Richmond Agitation-Sedation Score.

Characteristics of ongoing studies *[ordered by study ID]*

ChiCTR-TRC-14004405

Trial name or title	Study on the affection of sleeping quality with non-pharmacological intervention for cardiac valve voice improvement
Methods	2-arm parallel trial
Participants	**Inclusion criteria** • Participants with MVR only • Less than a 48-hour stay in the ICU • Haemodynamic stability after operation, personal report of good sleeping without regular sleep pills taken • Fully conscious, can communicate with writing • No severe complication on the brain, liver, or kidney • Between 18 to 65 years old • Participants or relatives willing to join the study
Interventions	• Non-pharmacological intervention (acoustic optic protection measures) versus usual care
Outcomes	1. Sleep quality
Starting date	January 2014
Contact information	ChiCTR-TRC-14004405
Notes	This study is currently recruiting participants

IRCT2013030912749N1

Trial name or title	The effect of foot massage on the quality of sleep in patients with ischemic heart hospitalized in intensive care unit at the Ekbatan Hospital
Methods	2-arm parallel trial
Participants	Participants with ischaemic heart hospitalized in the intensive care unit **Inclusion criteria** • Being conscious • Having a sleep quality score of at least 8 • No diabetes or risk of deep vein thrombosis • No drug and alcohol addiction • Lack of sensitivity to the massage **Exclusion criteria** • Sick • Sick leave • History of chronic sleep disorders
Interventions	• Intervention group: foot massage

IRCT2013030912749N1 *(Continued)*

	• Control group: receives the routine nursing care in the CCU ward
Outcomes	1. Quality of sleep: measured using the SMSHQ sleep quality questionnaire before massage at 9 p.m. and the next morning 2. Blood pressure and heart rate; measured before the intervention and 1 minute after the intervention
Starting date	May 2013
Contact information	Dr Khodayar Oshvandi Email: oshvandi2004@yahoo.com
Notes	This study is currently recruiting participants

NCT00638339

Trial name or title	Effects of invasive and non-invasive mechanical ventilation on sleep In the ICU
Methods	Prospective case control
Participants	18 years and older, critically ill participants undergoing invasive or non-invasive mechanical ventilation in the medical ICU and CCU at Tufts New England Medical Center
Interventions	• Group 1: critically ill participants undergoing invasive mechanical ventilation in the medical ICU and CCU • Group 2: critically ill participants undergoing non-invasive mechanical ventilation in the medical ICU and CCU
Outcomes	**Primary outcome** 1. Sleep characteristics and total sleep time
Starting date	November 2006
Contact information	Nicholas S Hill, MD Email: nhill@tufts-nemc.org
Notes	This study is currently recruiting participants

NCT01082016

Trial name or title	Sleep promotion in critically ill and injured patients cared for in the intensive care unit
Methods	Interventional study
Participants	**Inclusion criteria** • Received care in ICU for at least 3 days • Received care in ICU for no longer than 14 days • Score of 3 to 5 on the Riker Sedation-Agitation Scale (SAS) • Aged 18 years to 55 years • Able to tolerate PO or have gastric access present (nasogastric/orogastric/PEG)

NCT01082016 *(Continued)*

	Exclusion criteria • Pregnancy • Incarceration • Admission diagnosis of closed head injury or traumatic brain injury • Evidence of delirium on Confusion Assessment Method (CAM-ICU) Score • Haemodynamic instability • Sepsis • Multiple organ dysfunction • Acute renal failure • Known history of sleep disorder • Known psychiatric disorder
Interventions	• Experimental: sleep promotion • No intervention: control
Outcomes	**Primary outcomes** 1. Polysomnography during sleep promotion protocol. 2. Time in rapid eye movement (REM) Sleep 3. Time in slow-wave sleep **Secondary outcomes** 1. Systemic inflammatory mediators (cytokines) 2. Safety profile
Starting date	April 2010
Contact information	Randall S Friese, MD University of Arizona College of Medicine
Notes	"Status unknown" (last update 2010)

NCT01276652

Trial name or title	Sleep and circadian rhythms in mechanically ventilated patients: a feasibility and mechanistic study
Methods	Randomized controlled trial (parallel design, phase I)
Participants	18 years and older, undergoing mechanical ventilation in the medical intensive care unit; estimated enrolment is 25
Interventions	• Intervention group: environmental modification (reducing exposure to environmental light and sound) • Control group: delivering routine care according to classic day/night routines
Outcomes	**Primary outcome** 1. Feasibility of studying sleep and circadian rhythms, utilizing continuous bedside polysomnography and the collection of urinary samples for 6-sulfatoxymelatonin analysis
Starting date	November 2011

NCT01276652 *(Continued)*

Contact information	-
Notes	This study is currently recruiting participants

NCT01284140

Trial name or title	Improving the sleep and circadian rhythms of mechanically ventilated patients
Methods	2-arm parallel trial
Participants	**Inclusion criteria** • Aged 18 years or older • Receiving mechanical ventilation and intravenous sedation
Interventions	• Experimental group: sleep promotion protocol • Control group: usual care
Outcomes	1. Circadian timing 2. Circadian amplitude 3. Spectral edge frequency 4. Delirium
Starting date	January 2011
Contact information	The US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov) identifier: NCT01284140
Notes	This study is currently recruiting participants

NCT01523938

Trial name or title	Influence of perioperative hypnotherapy on postoperative improvement in cognitive performance. A randomized-controlled open clinical monocentric interventional study
Methods	2-arm parallel trial
Participants	**Inclusion criteria** • Participants aged 18 years and older • Participants scheduled for open heart surgery or spinal column surgery • Offered participant information and written informed consent • Mini-Mental State > 23 • American Society of Anesthesiologists physical status classification system (ASA) 1 to 3
Interventions	• Experimental: hypnotherapy • Control: no hypnotherapy
Outcomes	1. Incidence of postoperative cognitive dysfunction at the time of discharge 2. Incidence of postoperative cognitive dysfunction 3 months after surgery 3. Postoperative delirium 4. Reduction in pre- and postoperative agitation and anxiety

NCT01523938 *(Continued)*

	5. Reduction of pain 6. Reduction of stress 7. Reduction of holding time 8. Reduction of hospital stay 9. Reduction of intensive care unit stay 10.Readmission rate 11.Emotional status 12.Functional status 13.Subjective evaluation of sleep quality 14.Perioperative assessment of sleep stage
Starting date	March 2012
Contact information	The US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov) Identifier: NCT01523938
Notes	This study is active and not currently recruiting participants

NCT01727375

Trial name or title	Prevention of delirium with light in the intensive care unit
Methods	Interventional, parallel RCT
Participants	**Inclusion criteria** • Men and women aged 18 years and above • Intensive care unit stay ≥ 48 hours • Invasive mechanical ventilation or non-invasive mechanical ventilation (with positive ventilation pressure > 6 hours/day and high flow > 30 litres) on the day of intensive care unit admission **Exclusion criteria** • Participants with a history of intensive care unit stay during the actual hospital stay • Participants with delirium on the day of intensive care unit admission • Participants with psychiatric diseases • Participants with a history of stroke and known cognitive dysfunctions • Participation in other clinical studies 10 days before study inclusion and during the study period • Psychiatric disease • History of stroke with known residual cognitive deficits • History of asystole or pulseless electric activity with cardiopulmonary resuscitation during entire hospital stay • Analphabetism • Unable to use the German language • Anacusis or Hypoacusis with hearing aid device • Amaurosis • Allergies to any ingredient of the electrode fixing material • Lacking willingness to save and hand out data within the study • Accommodation in an institution due to an official or judicial order • The informed consent of the participant or the participant's legally acceptable representative can not be obtained in time • Participant has a power of attorney or patient's provision, where he/she refuses participation in any clinical trial

NCT01727375 *(Continued)*

Interventions	• No intervention: standard light, participants receive standard lightening conditions • Experimental: circadian light, participants receive artificial ceiling light (circadian light) at the bedside
Outcomes	1. Prevalence of delirium 2. Severity of delirium 3. Duration of delirium 4. Severity of anxiety 5. Cognitive dysfunction 6. Post-traumatic stress disorder 7. Sleep quality 8. ICU length of stay 9. Duration of mechanical ventilation 10. Hospital length of stay 11. Level of sedation 12. Pain level 13. Amount of administered opioids 14. Mortality
Starting date	July 2013
Contact information	Claudia Spies, MD, Prof Email: claudia.spies@charite.de
Notes	The US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov) identifier: NCT01727375 This study is currently recruiting

NCT02095496

Trial name or title	Contribution to the understanding of the involvement of mechanical ventilation in ICU patients sleep disorders
Methods	Interventional cross-over RCT
Participants	**Inclusion criteria** • Participant under invasive mechanical ventilation for at least 6 hours and for an expected duration of at least 48 hours, including a continuous period of 24 hours, from 2 p.m. to 2 p.m. the next day • Aged > 18 years • Body mass index < 40 • Informed consent signed by the family **Exclusion criteria** • Participant requiring neuromuscular-blocking agent or deep sedation enough to abolish spontaneous ventilatory effort • Participant with encephalopathy regardless of origin • Participant with Glasgow Coma Scale score < 8 • Participants abusing drugs or alcohol

NCT02095496 *(Continued)*

	• Participant with a contraindication for placement of a nasogastric tube, such as sufferers of oesophageal or gastric ulcer, tumours, diverticulitis or bleeding varices, or participants with sinusitis epistaxis or those that have recently had an operation on the nose or pharynx • Participant with bleeding disorders • Participants with unstable respiratory situation as defined by an arterial oxygen partial pressure and inspired oxygen fraction ratio (PaO_2/FiO_2) < 100 mmHg with positive end expiratory pressure (PEEP) > 12 cm H_2O • Participants with unstable haemodynamic situation as defined by Systolic Blood Pressure (SBP) < 75 mmHg despite a therapeutic optimization • Inclusion in another research protocol submitted to consent
Interventions	• Experimental: IntelliVent-ASV • Control group: conventional ventilation
Outcomes	1. Sleep fragmentation index 2. Duration of sleep episodes 3. Distribution of the sleep 4. Sleep's architecture 5. Number of asynchronies and apnoeas and ventilatory variability 6. Circadian rhythm
Starting date	May 2014
Contact information	Emilie Bialais, PhD student Email: bialais@uclouvain.Be
Notes	The US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov) identifier: NCT02095496 This study is not yet open for participant recruitment

Qureshi 2014

Trial name or title	A study to assess the effectiveness of using earplugs and eye masks during night on perceived quality of sleep among participants in intensive care units of AIIMS
Methods	Randomized cross-over trial
Participants	**Inclusion criteria** • Participants admitted in intensive care units of AIIMS and Jai Prakash Narayan Apex Trauma centre of AIIMS • People who are conscious and able to communicate in English and Hindi • People who are willing to participate • People who are hospitalized for more than 2 days **Exclusion criteria** • With ear injury, hearing impairment, eye disease or injuries, phlebitis or cellulitis, blood clots, contagious skin conditions, eczema and other skin lesions, high fever, mental impairment, chronic condition, or who are unconscious • On mechanical ventilators • Not willing to participate in the study • Taking medication for sleep

Qureshi 2014 *(Continued)*

Interventions	• Intervention group: earplugs and eye mask • Control group: without intervention (routine environment)
Outcomes	1. Quality of sleep
Starting date	January, 2014
Contact information	Ms Ashia Qureshi Email: qureshi.ashia@gmail.com Koushal Dave Email: qureshi.ashia@gmail.com
Notes	CTRI/2014/01/004320 This study is open to recruitment

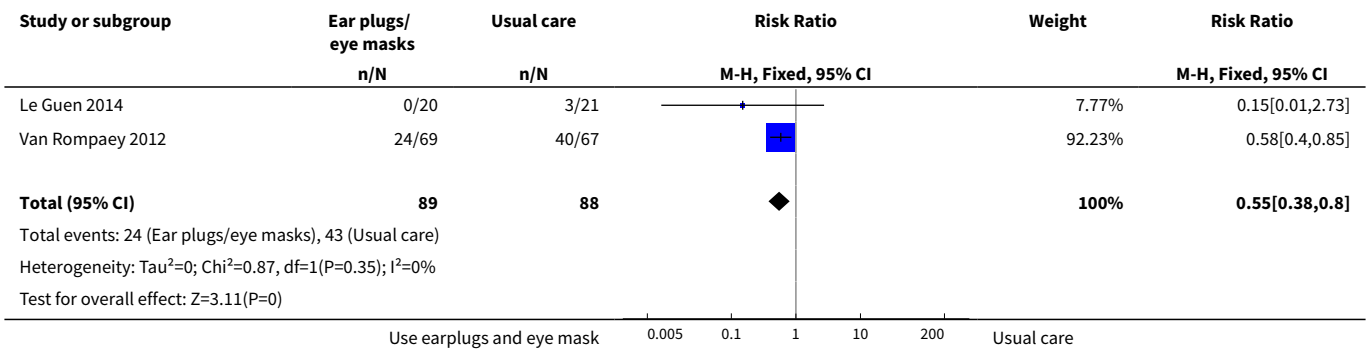
AIIMS = All India Institute of Medical Sciences.
ASA = American Society of Anesthesiologists.
ASV = adaptive support ventilation.
CAM-ICU = confusion assessment method for ICU.
CCU = critical care unit.
MVR = mitral valve replacement.
PEEP = positive end-expiratory pressure.
PEG = percutaneous endoscopic gastrostomy.
PO = oral administration.
RCT = randomized controlled trial.
REM = rapid eye movement.
SAS = sedation-agitation scale.
SBP = systolic blood pressure.

DATA AND ANALYSES

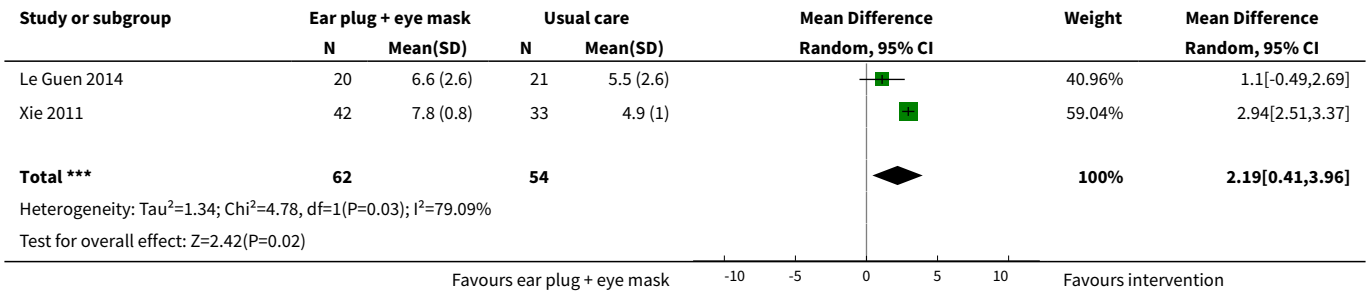
Comparison 1. Ear plugs or eye mask versus usual care or both

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of delirium and confusion	2	177	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.38, 0.80]
2 Total sleep time	2	116	Mean Difference (IV, Random, 95% CI)	2.19 [0.41, 3.96]

Analysis 1.1. Comparison 1 Ear plugs or eye mask versus usual care or both, Outcome 1 Incidence of delirium and confusion.



Analysis 1.2. Comparison 1 Ear plugs or eye mask versus usual care or both, Outcome 2 Total sleep time.



ADDITIONAL TABLES

Table 1. Comparison of sleep quantity between ACV versus PSV

Toublanc 2007	ACV group			PSV group		
Sleep outcomes	**Whole night (n = 20)**	**1st period (n = 10)**	**2nd period (n = 10)**	**Whole night (n = 20)**	**1st period (n = 10)**	**2nd period (n = 10)**
Stage 1, %	No report[b]	34.8 ± 18.6[a]	No report[b]	No report[b]	17.1 ± 15.0[a]	No report[b]
Stage 2, %	No report[b]	33.0 ± 24.6[a]	No report[b]	No report[b]	11.4 ± 15.9[a]	No report[b]
Stage 3, %	No report[b]	No report[b]	6.3 ± 7.7[a]	No report[b]	No report[b]	0.3 ± 1.0[a]
Stage 4, %	No report[b]	No report[b]	5.4 ± 13.2[a]	No report[b]	No report[b]	0.0 ± 0.0[a]
Wakefulness, per cent	35.4 ± 25.6	30.8 ± 28.2[a]	No report	50.7 ± 35.7	69.0 ± 26.2[a]	No report[b]
REM, per cent	No report[b]	No report[b]	No report[b]	No report[b]	No report[b]	No report[b]
Awakening index	7.1 ± 5.0	No report	No report	6.5 ± 4.9	No report[b]	No report[b]

Table 1. Comparison of sleep quantity between ACV versus PSV *(Continued)*

Parthasarathy 2002

Sleep outcomes	ACV (n = 11)	PSV alone (n = 11)	PSV with Dead space (n = 11)	P value
Total sleep time, minutes	90 ± 6	75 ± 6	82 ± 7	-
Sleep efficiency, per cent	75 ± 5	63 ± 5	81 ± 7	P value < 0.05
Fragmentation index, n/hour	54 ± 7	79 ± 7	No report	P value < 0.05
Arousals/hour	35 ± 7	39 ± 6	No report	P value = 0.8
Awakenings/hour	19 ± 3	39 ± 7	No report	P value < 0.01
REM, %[c]	-	-	-	-

Cabello 2008

Sleep outcomes	ACV (n = 15)	cPSV (n = 15)	aPSV (n = 15)	P value
Sleep efficiency, per cent	58 (44 to 82)	44 (29 to 80)	63 (29 to 80)	P value = 0.15
Fragmentation index, n/hour	30 (17 to 41)	28 (17 to 53)	23 (21 to 45)	P value = 0.62
Stage 1, %	8 (1 to 15)	7 (1 to 23)	5 (0 to 11)	P value = 0.62
Stage 2, %	54 (47 to 79)	67 (54 to 84)	39 (52 to 62)	P value = 0.02
SWS, minutes	37 (4 to 62)	26 (0 to 68)	24 (0 to 51)	P value = 0.79
REM, per cent	7 (0 to 13)	4 (0 to 10)	1 (0 to 7)	P value = 0.54

ACV = assist-control ventilation.
aPSV = automatically adjusted pressure support ventilation.
cPSV = clinically adjusted pressure support ventilation.
PSV = pressure support ventilation.
REM = rapid eye movement.
SWS = slow-wave sleep.
Data sourced from Toublanc 2007 and Parthasarathy 2002 are expressed as mean ± standard deviation. Data sourced from Cabello 2008 are expressed as median (25th to 75th percentile).
[a]P value < 0.05 compared ACV with PSV.
[b]Data were expressed in the source articles using figures; no numerical sleep data were provided: comparisons showed no significant difference for ACV versus PSV.
[c]4 participants achieved REM sleep; only 1 participant achieved REM sleep with all 3 modes.

Table 2. Comparison of sleep quantity between PAV versus PSV

Alexopoulou 2007	PAV group		PSV group	
Sleep outcomes	**$PAV+_{base}$**	**$PAV+_{high}$**	**PS_{base}**	**PS_{high}**

Table 2. Comparison of sleep quantity between PAV versus PSV *(Continued)*

Sleep efficiency, per cent	98.9 ± 2.3	98.1 ± 4.7	93.3 ± 10.8	87.7 ± 16.4[a]
Protocol A	75.6 ± 10.8	70.7 ± 21.0	68.1 ± 19.2	71.6 ± 14.9
Protocol B				
Stage 1, per cent	40.5 ± 41.5	39.4 ± 35.8	50.6 ± 40.5	55.2 ± 41.3
Protocol A	55.0 ± 38.1	33.0 ± 30.4	52.0 ± 39.9	35.3 ± 34.7
Protocol B				
Stage 2, per cent	50.5 ± 42.3	48.1 ± 35.5	39.4 ± 37.7	35.0 ± 34.9
Protocol A	36.3 ± 32.1	61.2 ± 27.6	42.5 ± 34.9	43.6 ± 31.6
Protocol B				
SWS, per cent	9.9 ± 29.5	12.9 ± 28.3	11.01 ± 29.9	10.6 ± 24.3
Protocol A	2.6 ± 7.4	4.1 ± 9.4	2.1 ± 3.9	1.8 ± 4.9
Protocol B				
REM, per cent	-	0.88 ± 2.7[b]	-	-
Protocol A	6.2 ± 13.9	1.7 ± 4.2	3.5 ± 6.2	19.3 ± 23.3
Protocol B				
Arousals/hour	4.6 ± 4.9	7.4 ± 10.7	5.4 ± 3.6	6.5 ± 6.7
Protocol A	12.2 ± 8.0	11.4 ± 7.6	8.4 ± 4.8	10.5 ± 9.9
Protocol B				
Awakenings/hour	0.6 ± 1.4	0.8 ± 1.5	1.3 ± 1.4	2.7 ± 3.1
Protocol A	4.0 ± 3.0	4.3 ± 3.2	3.6 ± 3.1	3.9 ± 3.4
Protocol B				
Fragmentation index, n/hour	5.2 ± 5.1	8.3 ± 11.1	6.8 ± 4.5	9.2 ± 8.5
Protocol A	17.5 ± 8.2	16.8 ± 8.9	13.0 ± 5.5	15.3 ± 10.6
Protocol B				

Bosma 2007

Sleep outcomes	**PAV (n = 13)**	**PSV (n = 13)**
Total sleep time, minutes	334 ± 124	314 ± 140
Total sleep period, minutes	451 ± 99	484 ± 63
Sleep efficiency, per cent	60 ± 23	58 ± 25
Sleep maintenance efficiency, per cent	69 ± 22	68 ± 21
Arousals, n /hour	12.8 ± 10.3	25.6 ± 23.2[c]

Table 2. Comparison of sleep quantity between PAV versus PSV *(Continued)*

Awakenings, n/hour	5.2 ± 6.1	8.3 ± 7.5
Fragmentations index, n/hour	18.0 ± 10.4	33.9 ± 28.9
REM, per cent	9 (0 to 3)	4 (0 to 23)
SWS, per cent	3 (0 to 16)	19 [0 to 10)

n = number.
PAV = proportional assist ventilation.
$PAV+_{base}$ = proportional assist ventilation with baseline level of assist.
$PAV+_{high}$ = proportional assist ventilation with level of assist.
PS_{high} = pressure support ventilation with high pressure support.
PS_{base} = pressure support ventilation with baseline pressure support.
PSV = pressure support ventilation.
REM = rapid eye movement.
SWS = slow-wave sleep.
All data sourced from Alexopoulou 2007 are expressed as mean ± standard deviation. Data sourced from Bosma 2007 are expressed as mean ± standard deviation or median (range).
Protocol A: sedated participants.
Protocol B: non-sedated participants.
[a]Statistically significantly different from $PAV+_{mode}$.
[b]REM was observed in 1 participant.
[c]P value < 0.05 compared PAV with PSV.

Table 3. Comparison of sleep quantity between PCV versus PSV

Andréjak 2013	PCV (n = 26)	Low PSV (n = 26)	P value
Sleep outcomes			
Stages 1, %	15 ± 14	15 ± 10	P value > 0.05
Stage 2, %	35.3 ± 23.3	20 ± 21.9	P value < 0.01
Wakefulness, per cent	37.7 ± 24.7	58.3 ± 28.8	P value < 0.01
REM, per cent	3.4 ± 6.4	0.8 ± 2.1	P value < 0.01
Sleep efficiency, per cent	61.5 ± 25.1	39.2 ± 29.1	P value < 0.01
SWS, per cent	8.9 ± 10.1	3.5 ± 8.9	P value < 0.01

PCV = pressure-controlled ventilation.
PSV = pressure support ventilation with 6 cm H_2O inspiratory pressure.
REM = rapid eye movement.
SWS = slow-wave sleep.
All data are expressed as mean ± standard deviation (Andréjak 2013).

APPENDICES

Appendix 1. Interventions

01 Psychological interventions, cognitive or behavioural therapy such as music therapy, back massage, muscle relaxation, imagery, therapeutic touch.

02 Environmental interventions, such as noise reduction, lighting control, synchronization of ICU activities with daylight.

03 Social support interventions

04 Physical therapy modalities

05 Equipment modification, including mechanical ventilation.

06 Comentary therapy such as aromatherapy, herbs, acupuncture, acupressure.

Appendix 2. Search strategy for CENTRAL

#1	MeSH descriptor Complementary Therapies explode all trees
#2	MeSH descriptor Music Therapy explode all trees
#3	MeSH descriptor Massage
#4	MeSH descriptor Muscle Relaxation explode all trees
#5	MeSH descriptor Imagery (Psychotherapy) explode all trees
#6	MeSH descriptor Cognitive Therapy explode all trees
#7	MeSH descriptor Behavior Therapy explode all trees
#8	MeSH descriptor Social Support explode all trees
#9	MeSH descriptor Physical Therapy Modalities explode all trees
#10	MeSH descriptor Aromatherapy explode all trees
#11	MeSH descriptor Sleep explode all trees
#12	((Music or complementary or alternative or cognitive or behavioural) near therap*):ti,ab
#13	(imagery or massage or muscle relaxation or therapeutic touch or aromatherapy):ti,ab
#14	((environmental or cognitive or behavioural or interventions or social support) near intervention*):ti
#15	(nighttime light or noise level*):ti,ab
#16	(sleep near (promot* or help* or support* or Initiat*))
#17	sleep:yi,ab
#18	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17)
#19	MeSH descriptor Critical Illness explode all trees

(Continued)

#20	MeSH descriptor Critical Care explode all trees
#21	MeSH descriptor Intensive Care explode all trees
#22	MeSH descriptor Intensive Care Units
#23	((intensive or critical) near unit*)
#24	(critical* near ill*)
#25	(#19 OR #20 OR #21 OR #22 OR #23 OR #24)
#26	(#18 AND #25)

Appendix 3. Search strategies

01 Search Strategy for MEDLINE (via OVID 1950 to May 2014)

1. Complementary Therapies/ or Music Therapy/ or Massage/ or Muscle Relaxation/ or "Imagery (Psychotherapy)"/ or Cognitive Therapy/ or Behavior Therapy/ or Social Support/ or Physical Therapy Modalities/ or Aromatherapy/ or ((Music or complementary or alternative or cognitive or behavioural) adj3 therapy*).ti,ab. or (imagery or massage or muscle relaxation or therapeutic touch or aromatherapy).ti,ab. or ((environmental or cognitive or behavioural or interventions or social support) adj3 intervention*).ti,ab. or (nighttime light or noise level*).ti,ab.
2. exp Sleep/ or (sleep adj3 (promot* or help* or support* or Initiat*)).mp. or sleep.ti,ab.
3. 1 or 2
4. exp Critical Illness/ or exp Critical Care/ or exp Intensive Care/ or exp Intensive Care Units/ or (((intensive or critical) adj3 unit*) or (critical* adj3 ill*)).mp.
5. 4 and 3
6. ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or clinical trial.af. or randomly.ab. or trial.ti.) not (animals not (humans and animals)).sh.
7. 6 and 5

02 Search Strategy for EMBASE <1980 to April 2014>

#1 (((Music or complementary or alternative or cognitive or behavioural) adj3 therap*) or (imagery or massage or muscle relaxation or therapeutic touch or aromatherapy) or ((environmental or cognitive or behavioural or interventions or social support) adj3 intervention*) or (nighttime light or noise level* or melatonin)).ti,ab. or (sleep adj3 (promot* or help* or support* or Initiat*)).mp. or sleep.ti,ab.
#2 alternative medicine/ or music therapy/ or massage/ or muscle relaxation/ or imagery/ or cognitive therapy/ or behavior therapy/ or social support/ or physiotherapy/ or aromatherapy/ or exp sleep/
#3 #1 or #2
#4 intensive care unit/ or ((intensive or critical) adj3 unit*).ti,ab.
#5 #3 and #4
#6 (controlled study.ab. or random*.ti,ab. or trial*.ti,ab.) not (animals not (humans and animals)).sh.
#7 #5 and #6
#8 from #7 keep #1

03 Search Strategy for CINAHL via EBSCO host <1982 to July 2013>

#S1 (MH "Alternative Therapies")
#S2 (MM "Music Therapy")
#S3 (MH "Massage")
#S4 (MH "Muscle Relaxation")
#S5 (MH "Cognitive Therapy")
#S6 (MH "Behavior Therapy")
#S7 (MH "Social Support (Iowa NOC)") or (MH "Social Support Index")
#S8 (MH "Physical Therapy")
#S9 (MH "Aromatherapy")
#S10 (MH "Sleep")

#S11 AB ((Music or complementary or alternative or cognitive or behavioural) and therap*)
#S12 AB imagery or massage or muscle relaxation or therapeutic touch or aromatherapy
#S13 AB ((environmental or cognitive or behavioural or interventions or social support) and intervention*)
#S14 AB nighttime light or noise level*
#S15 AB ((sleep and (promot* or help* or support* or Initiat*))) or TI sleep
#S16 #S1 or #S2 or #S3 or #S4 or #S5 or #S6 or #S7 or #S8 or #S9 or #S10 or #S11 or #S12 or #S13 or #S14 or #S15
#S17 (MM "Critical Illness") or (MM "Critically Ill Patients")
#S18 (MM "Critical Care")
#S19 (MH "Intensive Care Units")
#S20 AB ((intensive or critical) and unit*) or AB (critical* and ill*)
#S21 #S17 or #S18 or #S19 or #S20
#S22 #S16 and #S21
#S23 (MM "Random Assignment")
#S24 AB random* or AB controlled trial*
#S25 #S23 or #S24
#S26 #S22 and #S25

Appendix 4. Search strategy for ISI Web of Science

#1 Topic=(Critical Illness or Critical Care or Intensive Care or Intensive Care Units or critical* ill*)
#2 Topic=(Sleep or sleep promot* or help* or support* or Initiat*)
#3 Topic=(randomized controlled trial or controlled clinical trial or placebo or clinical trial or randomly or trial)
#4 Topic=(Music or complementary or alternative or cognitive or behavioural therap* or imagery or massage or muscle relaxation or therapeutic touch or ventilation or aromatherapy or environmental or cognitive or behavioural or interventions or social support intervention* or nighttime light or noise level*)
$5 #4 AND #3 AND #2 AND #1

Appendix 5. Data Extraction Form

CARG 200 Non-pharmacological interventions for sleep promotion in intensive care unit

Data Extraction Form

Reviewer _____

Reference number _____

Study ID _____

Date of review _____

First author	Journal/Conference Proceedings, etc.	Year/language
title		

Study eligibility form

RCT/Quasi/CCT? (delete as appropriate)	**Relevant participants**	**Relevant interventions**	**Relevant outcomes**
	Adult critically ill patients admitted to the intensive or critical care unit	Complementary and alternative therapies (music, therapy, back massage, muscle relaxation, imagery, therapeutic touch, aromatherapy, herbs, etc.), physical therapy modalities, environmental interventions,social support interventions, equipment modification.	Changes in objective and subjective sleep variables, length of stay in ICU, patient satisfaction, any adverse reactions or events, mortality, risk of delirium during ICU stay, risk of PTSD, cost

(Continued)

Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear	Yes/No*/Unclear

I f issue relates to selective reporting (i.e. when authors may have taken measurements for particular outcomes, but not reported these), reviewers should contact trialists for information on possible non-reported outcomes & reasons for exclusion from publication. Study should be listed in 'Studies awaiting assessment' until clarified. If no clarification is received after three attempts, study should then be excluded.

Final decision: Include ☐ Unclear ☐ Exclude ☐

Do not proceed if any of the above answers are 'No'. If study to be included in 'Excluded studies' section of the review, record below the information to be inserted into 'Table of excluded studies'

Freehand space for comments on study design and treatment:

References to trial

Check other references identified in searches. If there are further references to this trial link the papers now and list below. All references to a trial should be linked under one *Study ID* in RevMan.

Code each paper	Author(s)	Journal/Conference Proceedings, etc.	Year
A	The paper listed above		
B	Further papers		

Participants and trial characteristics

Participant characteristics	
	Further details
Age (mean, median, range, etc.)	
Sex of participants (numbers/%, etc.)	

(Continued)

Disease status/type, etc. (if applicable)
Settings
Other

Trial characteristics	
	Further details
Single centre/multicentre	
Country/Countries	
How was participant eligibility defined?	
How many people were randomized?	
Number of participants in each intervention group	
Number of participants who received intended treatment	
Number of participants who were analysed	
Treatment(s) used	
Dose/frequency of administration	
Duration of treatment (State weeks/months, etc., if cross-over trial, give length of time in each arm)	
Median (range) length of follow-up reported in this paper (state weeks, months, or years or if not stated)	
Time points when measurements were taken during the study	
Time points reported in the study	
Time points you are using in RevMan	
Trial design (e.g., parallel/cross-over*)	
Other	

Methodological quality

Allocation of intervention	
State here method used to generate allocation and reasons for grading	Grade (delete as appropriate)

(Continued)

Note reason for allocation:	Adequate (Random)
	Inadequate (e.g., alternate)
	Unclear

Concealment of allocation	
Process used to prevent foreknowledge of group assignment in a RCT, which should be seen as distinct from blinding	
State here method used to conceal allocation and reasons for grading	Grade (delete as appropriate)
Note reason for allocation:	Adequate
	Inadequate
	Unclear

Blinding	
Person responsible for participant's care	Yes/No
Participant	Yes/No
Outcome assessor	Yes/No
Other (please specify)	Yes/No
Note reason for blinding:	

Intention-to-treat

An intention-to-treat analysis is one in which all the participants in a trial are analysed according to the intervention to which they were allocated, whether they received it or not.

All participants entering trial
15% or fewer excluded
More than 15% excluded
Not analysed as 'intention-to-treat'
Unclear

Were withdrawals described? Yes ☐ No ☐ not clear ☐

Discuss if appropriate

Data extraction

Outcomes relevant to your review	
	Reported in paper
Outcome 1 Changes in objective sleep variables including sleep efficiency index and/or REM sleep latency and/or REM sleep time and/or arousals index and/or latency to sleep onset and/or total sleep time and/or percentage of stage 1, 2, 3, 4	Yes/No Specify:
Outcome 2 Changes in subjective sleep quality and quantity	Yes/No Specify:
Outcome 3 Length of stay in ICU	Yes/No Specify:
Outcome 4 Cost	Yes/No Specify:
Outcome 5 Patient satisfaction	Yes/No
Outcome 6 Adverse reactions or events	Yes/No Specify:
Outcome 7 Mortality	Yes/No Specify
Outcome 8 Risk of delirium during ICU stay	Yes/No Specify
Outcome 9 Risk of PTSD once discharged from hospital	Yes/No Specify

For continuous data

Code of paper	Outcomes (rename)	Unit of measurement	Intervention group		Control group		Details if outcome only described in text
			n	Mean (SD)	n	Mean (SD)	
A etc	Objective sleep variables, such as REM sleep latency and/or REM sleep time and/or total sleep time and/or latency to sleep onset and/or sleep period time	Minute					
	Objective sleep variables, such as sleep efficiency index and/or arousals index and/or percentage of stage 1, 2, 3, 4 and/or numbers of awakenings						
	Subjective sleep quality						
	Subjective sleep quantity	Minute					
	Length of stay in ICU	hour					
	Patient satisfaction						
	Cost	dollar					

For dichotomous data			
Code of paper	Outcomes (rename)	Intervention group (n) n = number of participants, not number of events	Control group (n) n = number of participants, not number of events
A	Adverse reactions or events		
B	Mortality		
C	Risk of delirium during ICU stay		
D	Risk of PTSD once discharged from hospital		
E			

Other information which you feel is relevant to the results

Indicate if: any data were obtained from the primary author; if results were estimated from graphs etc; or calculated by you using a formula (this should be stated and the formula given). In general if results not reported in paper(s) are obtained this should be made clear here to be cited in review.

Freehand space for writing actions such as contact with study authors and changes

References to other trials

Did this report include any references to published reports of potentially eligible trials not already identified for this review?

First author	Journal/Conference	Year of publication

Did this report include any references to unpublished data from potentially eligible trials not already identified for this review? If yes, give list contact name and details

WHAT'S NEW

Date	Event	Description
17 December 2018	Amended	Editorial team changed to Cochrane Emergency and Critical Care

CONTRIBUTIONS OF AUTHORS

Conceiving the review: Rong-Fang Hu (HRF).
Co-ordinating the review: HRF.
Undertaking manual searches: HRF.
Screening search results: HRF and Xiao Y Chen (CXY).
Organizing retrieval of papers: HRF and CXY.
Screening retrieved papers against inclusion criteria: HRF.
Appraising quality of papers: HRF and Yueping Li (LYP).
Extracting data from papers: HRF and CXY.
Writing to authors of papers for additional information: HRF.
Providing additional data about papers: HRF.
Obtaining and screening data on unpublished studies: Xiao-Ying Jiang (JXY).
Data management for the review: HRF and JXY.
Entering data into Review Manager (1): HRF.
RevMan statistical data: HRF and Junmin Chen (CJM).
Other statistical analysis not using RevMan: LYP.
Double entry of data: (data entered by person one: HRF; data entered by person two: Xin Huining (XHN)).
Interpretation of data: HRF, CJM, and Zhiyong Zeng (ZZY).
Statistical inferences: LYP.
Writing the review: HRF and David Evans (DE).
Guarantor for the review (one author): HRF.
Person responsible for reading and checking review before submission: CJM, HRF, and DE

DECLARATIONS OF INTEREST

Rong-Fang Hu: nothing to declare.
Xiao-Ying Jiang: nothing to declare.
Junmin Chen: nothing to declare.
Zhiyong Zeng: nothing to declare.
Xiao Y Chen: nothing to declare.
Yueping Li: nothing to declare.
Xin Huining: nothing to declare.
David Evans: nothing to declare.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

1. In the protocol (Hu 2010), we planned to synthesize data using Review Manager software (RevMan 5); in the review, we used RevMan 5.3.
2. *At least one o utcome listed under 'Criteria for considering studies for this review' was a criteria for including studies; this was not pre-specified in the protocol.*
3. In the protocol, we originally specified the inclusion of studies of critically ill adult patients who were admitted to the intensive or critical care units, where the length of intensive care unit (ICU) stay was more than 48 hours, having stable hemodynamic status without any sedative, narcotic drugs administered in the 24 hours prior to recruitment. During the review, we did not restrict the length of ICU stay because several trials included participants where the expected length of stay in the ICU was more than 24 hours.

4. We added two additional authors to the team: Xin Huining was responsible for entering data, and David Evans was responsible for checking the review against peer review comments and revising the review for language.
5. We changed the Allied and Complementary Medicine Database (AMED) to Alt HealthWatch from May 2011, because we were then unable to access the AMED database.
6. We had planned to include the following additional treatment comparisons, but there were insufficient trials to do so, or the available trials had important clinical heterogeneity among them: acupressure versus other interventions or placebo, aromatherapy versus other interventions or placebo, back massage versus other interventions or placebo, foot baths versus other interventions or placebo, relaxation and imagery versus other interventions or placebo, foot massage versus other interventions or placebo, using sound masking versus other interventions or placebo, and social support intervention versus other interventions or placebo. Therefore, we included trials comparing these interventions with other therapies or placebo in the narrative but not the meta-analysis of this review.
7. Considering the presence of carry-over, we had planned to analyse the data from only the first period in cross-over RCTs. However, only two cross-over RCTs reported data from the first period and the cross-over period, whereas the remaining studies only reported the whole period data. Thus, we took the decision to exclude cross-over studies from the meta-analyses.
8. We planned to test the robustness of the evidence by sensitivity analyses according to sequence generation, allocation concealment (adequate or unclear or inadequate), and blinding (adequate or unclear or inadequate or not performed). We intended to compare the fixed-effect model results with the random-effects model results. We planned to undertake sensitivity analyses to examine the effects of excluding study subgroups. None of these actions were performed due to the heterogenous nature of the included studies.
9. We planned to perform subgroup analyses. However, as we only pooled two studies for each meta-analysis in this review, subgroup analyses were not performed,
10. We replaced the outcome of arousal index with the sleep fragmentation index in the 'Summary of findings' table as the majority of trials reported the sleep fragmentation index and did not report the arousal index.
11. We originally included the following statements in the protocol but did not implement these plans during the review owing to the types of data available; we removed these methods from the current methods section, but they may be relevant to future updates.
    - Effect measures for dichotomous outcomes: we will calculate odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous outcomes.
    - Dealing with missing data: we will extract data regarding intention-to-treat (ITT). If the researchers did not perform ITT and participants lost to follow up are less than 20%, but sufficient raw data are available, we will conduct an ITT analysis prior to data entry into RevMan 5.0. If more than 20% of the data are missing from the study, we will exclude the study from the meta-analysis and perform an available case analysis.
    - 'Summary of findings' tables: we intend to include seven outcomes, such as sleep efficiency index; rapid eye movement (REM) sleep time; REM sleep latency; arousal index; mortality; length of ICU stay; and risk of delirium during ICU stay.

INDEX TERMS

Medical Subject Headings (MeSH)

*Intensive Care Units; *Sleep; Delirium [*prevention & control]; Ear Protective Devices; Eye Protective Devices; Length of Stay; Music; Randomized Controlled Trials as Topic; Sleep Wake Disorders [*therapy]; Ventilators, Mechanical

MeSH check words

Adult; Humans