


BMJ Open Use of music to enhance sleep and psychological outcomes in critically ill patients: a protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Music listening is used as a non-pharmacological intervention in various populations with positive results; however, evidence for its effect on sleep and psychological outcomes in critically ill patients remains unclear. It is essential to understand the impact of music listening for critically ill patients to optimise care and minimise the risk for harm. We will assess whether music listening improves sleep and psychological outcomes in critically ill patients.

Methods and analysis We will systematically search scientific databases for relevant studies, including PubMed, Embase, CINAHL, PsycINFO, Web of Science, Scopus, ProQuest, the Cochrane Central Register of Controlled Trials, China Biological Medicine Database, China National Knowledge Infrastructure Library, Wan fang databases, VIP Database for Chinese Technical Periodicals and the Chinese Clinical Trial Registry. Databases will be searched for articles published from inception to 10 June 2020. Music therapy journals and reference lists in some articles will be hand-searched. Grey literature will also be searched. We will include randomised and quasi-randomised controlled trials that used music listening to improve sleep and psychological outcomes in critically ill patients. The primary outcomes will be sleep-related outcomes, and secondary outcomes will be anxiety and depression scores and physiological outcomes. Two reviewers will independently verify study eligibility and methodological quality; disagreements will be resolved by a third reviewer or through discussion. The risk of bias will be independently determined using the Cochrane Risk of Bias Tool. The Consolidated Standards of Reporting Trials checklist will be used to examine the quality of included papers. Data will be extracted from eligible studies by two researchers. RevMan V.5.3 will be used for meta-analysis.

Ethics and dissemination This work will review existing trial data and will not introduce new patient data or interventions; therefore, ethics committee approval is not required. We will disseminate this protocol in a related peer-reviewed journal.

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INTRODUCTION

Rationale

Sleep disturbance is a frequent problem among patients in the intensive care unit (ICU).^{1 2} Sleep quality and quantity are

Strengths and limitations of this study

- We plan to employ robust international gold-standard methodology and a comprehensive search strategy to reduce bias.
- We will assess the quality of included articles using a validated tool.
- Subgroup analyses will be performed when possible to elaborate intervention or participant characteristics correlated with increased effectiveness.
- High heterogeneity across studies may increase the difficulty in interpreting a meta-analysis.
- A limitation will be that the systematic review protocol will only include articles published in English and Chinese.

negatively affected by the ICU environment (eg, noise and lights),³ patient-care activities, symptoms of the patient's underlying illness and mechanical ventilation.^{4 5} In this context, sleep is characterised by prolonged sleep onset latency, short sleep duration, frequent awakenings, non-restorative sleep and decreased sleep efficiency (percentage of time in bed spent asleep). Sleep disturbance has been associated with numerous adverse consequences in critically ill patients, including impairments in immune function, memory, wound healing and inspiratory muscle endurance, along with higher rates of delirium and increased overall morbidity and mortality.⁶

An increase in psychological problems (eg, anxiety and depression) has also been found in critically ill patients.^{7 8} One study⁹ estimated that 70%–80% of critically ill patients experienced anxiety related to fear, sleeplessness, pain, discomfort, thirst and disease-related symptoms. That study also reported patients on assisted ventilation were especially prone to anxiety because of their need for frequent suctioning, inability to breathe independently



or talk and general discomfort. In addition, around half of patients experienced a high level of depression during their ICU stay.⁹ Unmanaged anxiety and depression have been associated with harmful effects on disease recovery and overall well-being, including prolonged weaning from ventilation and recovery time,¹⁰ increased work for breathing, fatigue,¹¹ acute elevated blood pressure¹² and an increased depression incidence in ICU survivors.¹³ Wewalka found that pre-existing depressive mood at the time of ICU admission was an independent risk factor for 28-day mortality among patients in the medical ICU.¹⁴

Sufficient evidence shows that sleep disturbance, anxiety and depression are detrimental to disease recovery and psychological well-being. Research has also reported an interplay of sleep disturbance, anxiety and depression.¹⁵ Anxiety and depression are both risk factors for sleep disturbance and disturbed sleep pattern increases emotional distress, which in turn lead to higher levels of anxiety and depression.^{9 16} Therefore, as key ICU staff, nurses need to provide effective interventions to address these issues.

Pharmacological and non-pharmacological interventions are used to manage sleep and psychological distress in the ICU. Pharmacological therapy is generally the first-line treatment.^{17 18} However, pharmacological therapy has been associated with numerous adverse effects and complications, including memory loss, prolongation of mechanical ventilation, altered sleep stages, longer length of hospitalisation, tolerance, bradycardia, hypotension, residual daytime effects, dysmotility, weakness and delirium.^{19 20} In addition, the medications used are expensive. To avoid these issues, researchers have developed alternative, non-pharmacological therapies to improve sleep, anxiety and depression among patients in the ICU, and positive results have been reported.²¹⁻²³ The results of recent music intervention studies have drawn attention to the relationship between music and sleep in various patient groups. This resulted in increased use of music therapy and music listening (sometimes called music medicine²⁴).

Music can be defined as the organisation of tone over the time, and it is one of the most pleasurable experiences for a human being. In the early 1800s, Florence Nightingale²⁵ described the importance of music and its healing effect on patients; the music first implemented in hospitals was live music. With the development of the music discipline and science, more recorded music was used and played to patients using musical equipment such as portable stereos, wall-mounted speakers or devices such as MP3 players.²⁶ Music as a non-pharmacological intervention has been adopted by medical staff, with these interventions involving different types of music, such as low volume, nature sounds, soothing music and Mozart piano recordings. As an intervention, music is relatively easy to implement, cost effective, safe and has no negative impacts.²⁷ Music therapy and music listening are common forms of music application that are similar but have distinct features. Music therapy is defined as the

clinical and evidence-based use of music to realise individualised clinical goals within a therapeutic relationship. It is conducted by certified music therapists, and centres on the dynamic musical interaction between the music therapist and the patient, verbal processing of the music experience, and implementation and alteration of music (tempo, volume and intensity) according to the patient's needs.^{28 29} Music therapy consists of active and passive forms. The active form refers to therapy that needs patient participation in the process, whereas the passive form refers to therapy that comprises listening to music without participation. Irrespective of whether it is active or passive, music therapy is an evidence-based practice conducted by certified music therapists. During therapy, music therapists consider elements of music such as melody, rhythm, tempo and harmony.³⁰ The use of environmental music therapy (EMT), which is type of music therapy, has increased in recent years.^{31 32} EMT involves trained, certified professionals using live music to address a chaotic intensive care environment and help to create a less tense atmosphere. They apply live music to meet the psychological, physical and cultural needs of caregivers, patients and staff in the hospital environment. A previous study verified the safety and effectiveness of EMT.³³

Music listening is defined as passive listening to recorded music via any form of music playback device (eg, earphones or speakers) or listening to live music without interacting with a music therapist or theoretical framework. It can be provided by medical or healthcare professionals or self-administered by a patient, and patients may or may not be involved in selecting the music.^{34 35} Although music-based applications are used in both music listening and music therapy, it is important to distinguish the two interventions in clinical practice³⁶ because of the varying levels of training in the fundamentals of music and its therapeutic applications. For example, music therapists have received specialised training in the aforementioned areas.²⁴ The effectiveness of music therapy is mostly attributable to the active musical interaction between the patient and the music therapist, which is why numerous studies suggest music therapy is more effective than music listening. However, most patients in the ICU are critically ill and weak, and they may not have enough energy to interact with a music therapist. Music listening may therefore be preferred, as compared with music therapy, it may be used by more patients. Music listening has also been widely used to assuage emotional, physiological and psychological symptoms in various diseases, such as Parkinson's disease,³⁷ Alzheimer's disease³⁸ and cancer.³⁹ A growing number of studies involving adults of all ages with various medical and surgical conditions have demonstrated the positive effects of music listening on anxiety, depression, stress and pain.^{40 41} Repeated studies have specifically reported music listening improved sleep in critically ill patients.^{23 42 43} Furthermore, music listening is inexpensive, relatively easy to implement and safe compared with pharmacological interventions²⁷; these benefits are favourably received by patients. Therefore,

music listening is a potentially viable alternative treatment option.

Clinical trials have provided support for the effectiveness of the application of music in the healthcare setting. Psychophysiological theory⁴⁴ also provides clues to its mechanism of action. Music comprises many key elements, including rhythm, pitch, harmony and melody. These elements play a comprehensive role in the degree to which music can promote sleep in patients.⁴⁵ Previous authors described that sleep improvement is mediated by the relaxing, distracting effect of ‘soothing’ music.⁴⁶ Music with a slow tempo (eg, 60–80 beats/min) mirrors the heart rate and reduces neuroendocrine and sympathetic nervous system activity, resulting in relaxation. Furthermore, the peaceful atmosphere created by soothing music in the ICU setting is a mood enhancer, reduces anxiety and depression and lowers treatment-related stress. Other authors described the effect of music in modulating mood and emotions at the cortical level through stimulation of self-image and intellect.⁴⁷ Clinical trials have also shown that listening to music reduced anxiety and stress responses, which can lead to greater relaxation and improved sleep.^{48 49}

Research on the impact of music listening for patients in the ICU has evolved over the past 20 years, and several researchers have studied the effects of music listening on sleep and psychological outcomes in critically ill patients. For example, recent studies reported that music listening may improve stress, anxiety,⁸⁵⁰ depression⁵¹ and sleep⁵²⁵³ in ICU patients. As an intervention, music listening involves using different types of music to improve sleep and psychological symptoms (eg, low volume, nature sounds, soothing music, classical music). Music listening can be provided by specific tools (eg, MP3 format via earphones or loudspeaker). The choice of music may be determined by the researcher or by participants themselves. The duration, frequency and timing of music exposure have also varied among studies. Although clinical trials have been performed to investigate the effects of music listening on sleep and psychological outcomes, their safety and efficacy for critically ill patients have not been established. In addition, most of these studies used small sample sizes,⁴³⁵⁴ making it nearly impossible to achieve statistically significant results. The impact of music listening may also differ because of different intervention designs (study design, method of intervention and type of music). A previous systematic review assessed the efficacy of music application for reducing anxiety among mechanically ventilated patients,³⁵ but only included mechanically ventilated patients. A recent systematic review also evaluated the effectiveness of music therapy to reduce stress and anxiety in critically ill patients.⁵⁵ In 2015, another review reported that music therapy appeared to be safe to improve sleep; however, that study did not perform a meta-analysis and noted further randomised controlled trials were required to assess efficacy.⁵⁶ The 2018 Pain, Agitation/sedation, Delirium, Immobility (rehabilitation/mobilization), and Sleep (disruption) (PADIS) guideline also suggests there

is no high-quality evidence to prove that music could improve sleep in critically ill adults.¹

Despite the large number of relevant studies, music listening has not been implemented as a therapeutic intervention in everyday critical care because information about its effectiveness has not been synthesised and disseminated universally. Therefore, we aim to assess the effectiveness of music listening in improving sleep, anxiety and depression in critically ill patients, and investigate relevant subgroups (ie, timing of intervention, type of intervention, severity of disease, mechanical ventilation status and study site).

OBJECTIVES

This systematic review and meta-analysis aims to integrate available scientific research on the use of music listening to promote sleep and reduce anxiety and depression for critically ill patients in the ICU. We will attempt to answer the following research questions.

1. What are the effects of music listening on sleep quality and quantity in critically ill patients?
2. What are the effects of music listening on anxiety, depression and physiological outcomes in critically ill patients?

METHODS AND ANALYSIS

This paper presents a quantitative systematic review protocol. We will follow the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines to complete and report the study protocol.⁵⁷ This systematic review protocol has been registered in PROSPERO.

Patient and public involvement

There is no patient or public involvement in this study.

Inclusion/exclusion criteria

Types of participants

Studies will be selected for inclusion if their participants meet specific criteria:

- ▶ Adult patients in the ICU (aged ≥18 years).
- ▶ Conscious and clear (Glasgow Coma Scale score ≥14).
- ▶ Ventilated or non-ventilated.
- ▶ Admitted to the ICU ≥24 hours.

We will exclude studies that included participants with:

- ▶ Hearing damage.
- ▶ A diagnosis of or overt signs or symptoms of obstructive sleep apnea.
- ▶ A diagnosis of dementia or neurological disease.
- ▶ Severe signs or symptoms of psychological illness, such as hallucinations, delusions and behavioural disorders.

Types of intervention and comparison

We will include any study that considered sleep or psychological variables as outcomes of music listening combined

with standard care versus standard care alone or standard care with other interventions in critically ill patients.

Types of outcome measures

At least one of the following outcomes must have been reported in the study.

Primary outcomes

Sleep outcomes

1. Sleep quality.
2. Sleep onset latency.
3. total sleep time.
4. Number of awakenings.
5. Sleep efficiency (percent of time in bed spent asleep).

Sleep outcomes may be measured using a variety of methods. Subjective perception of sleep is measured through validated self-report tools, including the Richards-Campbell Sleep Questionnaire,⁵⁸ Pittsburgh Sleep Quality Index⁵⁹ and the Verran and Snyder-Halpern Sleep Scale.⁶⁰ Objective measurement of sleep is performed with polysomnography, actigraphy, bispectral index monitoring or electroencephalography.

Secondary outcomes

Psychological outcomes

1. Anxiety.
2. Depression.

We will include trials that measured psychological outcomes using standardised questionnaires with established reliability and validity, including Hospital-based Anxiety and Depression Scales,⁶¹ the Visual Analogue Scale for Anxiety,⁶² the Spielberger State-Trait Anxiety Inventory⁶³ and the Beck Anxiety Inventory.⁶⁴

Physiological outcomes (heart rate, blood pressure and respiratory rate).

Types of study designs

We will include any interventional study, including randomised and quasi-randomised controlled trials.

Data source and search strategy

To identify eligible studies, we will search electronic databases, including PubMed, Embase, CINAHL, PsycINFO, Web of Science, Scopus, ProQuest, the Cochrane Central Register of Controlled Trials, China Biological Medicine Database, China National Knowledge Infrastructure Library, Wang Fang databases, VIP Database for Chinese Technical Periodicals and the Chinese Clinical Trial Registry. These databases will be searched from inception to 10 June 2020. In addition, we will hand-search music therapy journals and the reference lists of relevant articles, as well as grey literature.

A health sciences librarian will design the search. **Box 1** shows the search strategy with both keywords and Medical Subject Heading terms that will be used to search PubMed; this strategy will be adapted as appropriate for other databases.

Box 1 Search strategy for PubMed

Filter: Humans

1. music [Mesh] OR 'music therapy' [Mesh] OR music medicine OR music* OR listen*
2. sleep [Mesh] OR sleep Disorders, Circadian Rhythm [Mesh] OR sleep* OR insomnia* OR wakeful* OR sleepless*
3. anxiety [Mesh] OR fear [Mesh] OR stress OR psychological OR depression [Mesh] OR depress* OR mood disorders [Mesh]
4. 2 OR 3
5. critical illness [Mesh] OR critical care [Mesh] OR 'intensive care units' [Mesh] OR ventilators, mechanical [Mesh] OR respiration, artificial [Mesh] OR intensive care OR ICU
6. 1 AND 4 AND 5
7. infant* OR neonat* OR infant, premature [Mesh] OR infant, newborn [Mesh] OR Intensive Care Units, pediatric [Mesh]
8. 6 NOT 7

Selection of studies

All articles retrieved through the search of the selected databases will be imported into EndNote, and duplicate references will be removed. Two members of the research team (SQ and CH) will independently review the title/abstract of each article to verify that each study meets the inclusion criteria. If a title or abstract is unclear, the two researchers will review the full article. Disagreements will be resolved by a third researcher (LCh) or through discussion until consensus is reached. The reasons for all exclusions will be recorded.

Data collection and validation

Two researchers (JL and LCu) will independently extract data from the included studies using the Cochrane Collaboration Data Collection Form.⁶⁵ In the event of questions about or missing data in the original text, the researchers will contact the authors to obtain the relevant data. The results of data extraction will be compared to exclude any differences, and any disagreement will be resolved by a third researcher (LCh) or through discussion and consensus.

From all included studies, we will collect the following data.

1. Research and publication information, including the title, journal (volume, page number) or if unpublished, the author, year of publication, country, setting, language of publication and funding sources.
2. Study design, including the type of design, inclusion criteria, exclusion criteria, randomisation method (including concealment and blinding) and loss to follow-up.
3. Characteristics of the participants, including total sample size, number of participants in the intervention and control groups, gender, age, diagnosis, disease severity (Acute Physiology and Chronic Health Evaluation (APACHE) II scores), comorbidities and mechanical ventilation status.
4. Intervention details, including type of music, control of music selection (by participant or researcher), the

frequency, duration and timing of music listening and the format/devices used (eg, headphone and loud-speaker).

5. Outcomes, including the methods of assessment of sleep, anxiety and depression, pre-test and post-test means or change scores and SD.

Methodological quality assessment

The risk of bias and quality of the included studies will be evaluated using the Cochrane Collaboration Risk of Bias Tool,⁶⁵ which evaluates seven sources of study bias: (1) random sequence generation, (2) allocation concealment, (3) performance bias, (4) detection bias, (5) incomplete outcome data, (6) selective reporting and (7) other bias. Two researchers (LCh and XL) will independently grade each element as low risk, high risk or unclear risk.⁶⁶ Inconsistencies will be resolved through discussion and consensus, or by a third researcher (DJ). An appropriate assessment will be completed for the quality assessment of quasi-randomised controlled trials.

Data synthesis and analysis

A meta-analysis will be conducted when there are sufficient studies showing homogeneity. Statistical analyses will be performed using RevMan V.5.3.5 software. Continuous data will be expressed with ORs and 95% CIs. The level of heterogeneity of the included studies will be determined with the I^2 statistic and p value.⁶⁷ If there is statistical heterogeneity ($p > 0.1$ and $I^2 < 50\%$), a meta-analysis will be performed using a fixed-effects model. A random-effects model will be used to analyse clinical heterogeneity if $I^2 > 50\%$. Subgroup analyses will be performed by timing of intervention, type of intervention, severity of disease (APACHE II score < 25 , $25-35$, > 35), mechanical ventilation status (ventilated patients vs non-ventilated patients) and study site (surgical ICU patients vs medical ICU patients). Sensitivity analyses will be used to determine the stability of the results, and Egger's regression test and funnel plots will be used to assess potential publication bias. If data pooling is not possible, quantitative data will be presented in a narrative review using thematic summaries and tables.

Validity and reliability/rigour

The study protocol will use systematic review and meta-analytic methods and follow the Cochrane Collaboration recommendations for performing a systematic review. The results will be reported according to the PRISMA-P guidelines.⁶⁸ In addition, the Consolidated Standards of Reporting Trials checklist will be used to examine the quality of the included papers.

DISCUSSION

This paper presents the protocol for a systematic review of the literature examining the effects of music listening on sleep and psychological outcomes among critically ill patients. The study will be undertaken to answer

questions about the effectiveness of music listening in this population.

Properly powered, intervention studies provide strong evidence; therefore, this meta-analysis of existing evidence will permit conclusions about the efficacy of music listening on sleep, anxiety and depression among critically ill patients. Results from this study will provide recommendations for the use of music listening in this population and support nurses and other health practitioners in their promotion of mental health. In addition, by identifying existing lacunae in the literature, our results will prompt further research.

ETHICS AND DISSEMINATION

This work will review existing trial data and will not introduce new patient data or interventions; therefore, ethical committee approval is not required. This systematic review protocol will follow the PRISMA checklist. We will disseminate this protocol in a related peer-reviewed journal or at conferences.

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Contributors LCh, FW and LW were responsible for drafting the article or revising it critically for important intellectual content. JL and LCu conducted final approval of the version to be submitted. DJ, SQ and CH were responsible for the conception and design of the study, XL supervised the work. All authors approved the final version of the article.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

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