The Impact of Music Intervention on COVID-19 Patients with Mental Disorders: A Protocol for a Systematic Review and Meta-analysis

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Protocol

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Abstract

Background: The COVID-19 pandemic caused by the SARS-CoV-2 virus is a major health crisis that is affecting countries across the world. Patients infected with COVID-19 are often associated with mental health disorders, such as anxiety, depression, and sleep disorders. As a non-drug therapy applied in clinics for many years, music intervention is safe, effective, inexpensive, and devoid of side effects. Yet, there is a distinct lack of evidence to support the use of this technique. In this study, we aim to collect and evaluate the clinical evidence, in order to provide a basis for the efficacy and safety of music intervention in the treatment of COVID-19 patients with mental disorders.

Methods: We plan to search a range of electronic databases from inception to the May 2021, including PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Wanfang Database, Chinese Biomedical Literature Database, and Chinese Science and Technology Periodical Database (VIP). All randomized controlled trials featuring music intervention to treat mental disorders such as anxiety, depression, or sleep disorders, for patients with COVID-19, will be included. The primary outcomes will be quantitative scores for anxiety, depression, and sleep disorder. The secondary outcomes will be quality of life and the safety profile of music intervention, including adverse events. Two reviewers will carry out the selection of studies, data extraction independently. The Cochrane risk of bias tool will be used to evaluate the risk of bias for the studies. We will use Review Manager V.5.3 software for data analysis. Subgroup analyses and sensitivity analyses are planned to assess the heterogeneity and reliability.

Discussion: This is an up-to-date systematic review and meta-analysis of the efficacy and safety of music intervention on mental disorders (anxiety, depression, or sleep disorder) in COVID-19 patients, in order to provide clinicians, researchers, and policy makers, with powerful reference guidelines to facilitate treatment and improve the quality of life in COVID-19 patients with mental disorders.

Systematic review registration: OSF 10.17605/OSF.IO/9RCX5

Background

The COVID-19 pandemic has created an unprecedented global public health crisis and represents a serious threat to public health [1]. At the time of writing, more than 163 million cases of COVID-19 infection have been reported; thus, epidemic prevention and control remains a major challenge across the world [2,3]. COVID-19 is a highly infectious respiratory infection caused by the SARS-CoV-2 virus, that is associated with a range of clinical manifestations, including fever, cough, dyspnea, and chest pain [4]. This virus can cause a number of physical, respiratory, and psychological disorders [5]. Worldwide, COVID-19 has resulted in 163,896,992 confirmed cases and 3,396,433 deaths as of 17 May 2021 [6]. The COVID-19 outbreak therefore poses a major threat to international health, the economy, psychological stress, and global mental health [7].

Case reports and observational studies on COVID-19 patients have shown that they are more likely to be affected by anxiety, depression and sleep disorder [8–10]. In addition, coronaviruses can induce psychopathological sequelae by directly infecting the central nervous system or in an indirect manner via immune responses [11]. Coronaviruses also have the potential for neurotropic effects that can induce neuronal damage [12]. In addition, the psychosocial impacts of infection represent an important underlying component of the mental health of patients, including fear of the strong pathogenicity and rapid transmission of the virus [13], uncertainty with regards to the future, traumatic memory of severe diseases, and social isolation [14,15]. A previous study of COVID-19 sequelae found that COVID-19 patients experienced a series of persistent or manifested psychiatric symptoms in the months following the first infection. Furthermore, 30–40% of COVID-19 survivors suffered from anxiety, depression, sleep disorders, and post-traumatic stress disorder [16,17]. Previous studies have also shown that SARS survivors experience severe mental sequelae and high levels of psychological stress, manifesting in excessively high levels of depression, anxiety, and post-traumatic symptoms [18]. Therefore, the psychological impact brought about by exposure to public health emergencies such as SARS [19], earthquakes [20] and Ebola epidemics [21], have been shown to evolve into long-term health problems that cannot be ignored. Effective mental health services clearly play an important role in the rehabilitation of such patients [22]. Therefore, it is necessary to pay close attention to the mental health problems of patients with COVID-19 by adopting global health measures, such as the promotion of community-supported psychological interventions [23], improvements in mental health and psychological resilience [24], and improvements in the quality of life of patients with COVID-19.

The combination of routine treatments with antidepressants, anxiolytics, or moderate psychological intervention, is the basic principle used to treat COVID-19 patients with mental disorders [25]. However, psychotropic drugs have many limitations. For example, benzodiazepines are not suitable for COVID-19 patients due to the fact that they can inhibit the respiratory system although these drugs do have significant anti-anxiety effects [26]. On the other hand, music intervention is a safe and effective psychological intervention measure that is becoming increasingly popular across the world and accepted by an increasing body of people [27]. Music-based interventions can be divided into two broad categories: music therapy and music medicine. Music therapy is offered as a professional qualification course and refers to individualized therapy provided by a certified music therapist. According to the American Music Therapy Association, “music therapy is the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program” [28]. These guidelines emphasize a systematic therapeutic process that is created by a certified music therapist and goes beyond just listening to music. Instead, patients are encouraged to play or compose music and interact with pre-recorded or live music. However, music medicine is performed independently by professionals, such as relaxation therapists and physicians, rather than professional music therapists [29]. If a subject listen to their favorite music, this can be considered as a form of musical medicine. In other words, music medicine is about using music as a medicine to treat diseases. The two music interventions are similar in that they both focus on

scientific, artistic, or clinically based methods, to study music [30]. The main difference is that the focus of music therapy is active music therapy while the other is passive music listening [31,32].

Since ancient times, music has been a beautiful and sacred medium for expressing emotions and feelings, such as joy, despair, blessing, or love. Nowadays, music is not only an artistic expression and cultural phenomenon but is also used as a therapeutic intervention. The effects of music on the body and mind are multi-modal and act at multiple levels, including difficult-to-quantify changes in subjective emotional and sensory states, as well as measurable neurological, endocrine, and structural changes [33]. Inner peace, the activation of self-treatment potential and the harmonization of body and spirit, are key to the overall effect of music intervention. In other words, music has both artistic and neuropsychological value [34].

Music intervention has been proven to be a safe and effective as it is a non-invasive treatment with no known side effects. Studies have shown that music intervention has a wide range of physiological effects on the human body, including heart rate [35], blood pressure [36,37], respiration [38], and changes in biochemical reactions [39]. Music intervention has obvious effects on the improvement of symptoms associated with mental disorders, such as depression, anxiety, and sleep disorders [40–42]. Recent research on the effects of music on neurochemistry and neurophysiology has also highlighted the ability of music to induce structural changes in the brain as well as its ability to alter the secretion of neurochemicals and neurohormones. For example, reduced sympathetic nerve activity triggers the release of endorphins in the limbic system of the brain [43]. Moreover, music is beneficial to the self-regulation of emotions [44], in which the central function of music is to induce emotional expression [45]. Music can also help subjects to turn their attention to pleasant and soothing events [46]; this is an aesthetic experience that can provide comfort and calm. Previous studies of patients in palliative care, showed that music intervention produced positive changes in anxiety and other emotional states, pain, social interaction, and mental health [47]. Music intervention can also improve cognitive, psychological, and behavioral disorders in patients with Alzheimer's disease [48], and has been shown to have a positive impact on the quality of life of patients after long-term depression [49]. Music intervention is also beneficial for depressive patients experiencing sleep disorders and has been shown to be comparable to hypnotic drugs in terms of improving sleep quality [50].

Research on mental health during the COVID-19 pandemic has shown that certain family activities, such as music and yoga, can promote mental health and minimize potential risks [51,52]. A survey from Italy, Spain, and other countries, showed that people who were isolated at home during COVID-19 lockdowns played music and sang together from open windows or balconies to help cope with emotional distress and social isolation [53]. Music intervention is safe, non-invasive, inexpensive, and devoid of any known side effects. However, there has been no systematic review of music intervention in the treatment of COVID-19 patients with mental disorders. Therefore, this systematic review and meta-analysis aimed to collect and evaluate all available evidence and evaluate the efficacy and safety of music intervention in the treatment of COVID-19 patients with mental disorders. Our goal was to provide clinicians, researchers,

and policy makers, with powerful reference guidelines to facilitate treatment and improve the quality of life in COVID-19 patients with mental disorders.

Patients, Interventions, Comparisons, And Outcome Strategy

Patients:

We included patients who had been diagnosed as COVID-19 with mental disorders, such as anxiety, depression, or sleep disorders.

Interventions:

Music intervention alone or combined with other interventions.

Comparisons:

Placebo, conventional western medicine, no music intervention, traditional Chinese medicine, no treatment.

Outcomes:

Self-rating Anxiety Scale (SAS), Hamilton Anxiety Scale (HAMA), Self-rating Depression Scale (SDS), Hamilton Depression Scale (HAMD), Pittsburgh Sleep Quality Index (PSQI), quality of life (QOL), and the safety profile of music intervention, including adverse events.

Methods

This protocol will be performed in accordance with the guidelines of Preferred Reporting Items for Systematic Review and Meta- Analysis Protocols (PRISMA- P) 2015 [54] (Additional file 1).

Inclusion criteria

Types of studies

Only randomized controlled trials (RCTs) of music intervention for COVID-19 with mental disorders will be included. Quasi-randomized controlled trials, reviews and animal experiments will be excluded. Only articles that were published in English or Chinese will be included.

Types of participants

We will only include patients diagnosed as COVID-19 with mental disorders, such as anxiety, depression, or sleep disorder. No limitations relating to age, gender, nationality, ethnicity, and education level.

Types of interventions and controls

The treatment group will be treated with music intervention, including music therapy or music medicine, regardless of duration and frequency. The control group will receive a placebo treatment, conventional western medicine, no music intervention, traditional Chinese medicine, or even no treatment. The curative effects of the two groups will then be compared.

Types of outcomes

As this study aims to systematically evaluate the effects of music intervention on COVID-19 patients with mental disorders such as anxiety, depression, and sleep disorders. The primary outcomes of our study are the scores of questionnaires relating to anxiety, depression, and sleep disorder, and reflect the level of anxiety, depression and sleep quality, from the related scales. The anxiety score will be measured by the SAS and the Hamilton HAMA. The score for depression will be assessed by the SDS and the HAMD. The score for sleep quality will be assessed by the PSQI. The secondary outcomes will be the quality of life and safety. Quality of life will be measured by the MOS Item Short from Health Survey (SF-36), while safety will be measured by the incidence of adverse events.

Data collection and analysis

Search strategy

We plan to search a range of electronic databases from inception to the May 2021, including PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Wanfang Database, Chinese Biomedical Literature Database, and Chinese Science and Technology Periodical Database (VIP). We will include all RCTs that were written in English or Chinese that are associated with music intervention for COVID-19 patients with mental disorders. We will also search the reference lists of the all selected articles to identify relevant trails and reviews, and manually search the gray literature, such as trail registries. Further details of the PubMed search strategy are shown in Table 1.

Table 1

Search strategy for PubMed

Number	Search terms
#1	“COVID-19”[Mesh Terms]
#2	“2019-nCoV”[Title/Abstract]OR“coronavirus”[Title/Abstract] OR“COVID19”[Title/Abstract]OR“COVID-19”[Title/Abstract] OR“SARS-CoV-2”[Title/Abstract]OR“coronavirus covid-19”[Title/Abstract]OR“SARSCoV-2”[Title/Abstract]OR“COVID-19 pneumonia”[Title/Abstract]OR“novel coronavirus”[Title/Abstract] OR“new coronavirus”[Title/Abstract]OR“coronavirus covid-19”[Title/Abstract]OR“nCoV-2019”[Title/Abstract]OR“SARS-CoV”[Title/Abstract]OR“novel coronavirus pneumonia”[Title/Abstract] OR“novel coronavirus 2019”[Title/Abstract]
#3	#1OR#2
#4	“Anxiety”[Mesh Terms] OR“anxieties”[Title/Abstract] OR“anxious symptom”[Title/Abstract]OR“nervousness”[Title/Abstract]
#5	“Depression”[Mesh Terms] OR“depressions”[Title/Abstract] OR“depressive symptom”[Title/Abstract] OR“emotional depression”[Title/Abstract]
#6	“Sleep disorder”[Mesh Terms]OR“sleep disorders”[Title/Abstract] OR“sleep disturbance”[Title/Abstract] OR“sleep disturbances”[Title/Abstract] OR“insomnia”[Title/Abstract] OR“somnipathy”[Title/Abstract] OR“sleeplessness”[Title/Abstract]
#7	#4OR#5OR#6
#8	“Music intervention”[Mesh Terms] OR“music therapy”[Title/Abstract] OR“music medicine”[Title/Abstract]OR“music”[Title/Abstract] OR“music listening”[Title/Abstract]OR“singing”[Title/Abstract] OR“song”[Title/Abstract]
#9	“Randomised controlled trial”[Publication Type] OR“randomised”[Title/Abstract] OR“placebo”[Title/Abstract]
#10	#3AND#7AND#8AND#9

Study selection

Endnote V.X9 software will be conducted to manage literature. After reading the titles and abstracts, two independent investigators (SP and ZX) will search and screen for appropriate studies. Any differences will be submitted to a third researcher (X-YZ). The protocol to be used is shown in Additional file 2.

Data extraction and management

Two reviewers (SP and ZX) will use a predefined extraction template to extract data independently, including: (1) general information [the first author, journal, year, country, and funding information]; (2)

patient characteristics [sample size, average age, gender, anxiety score, depression score, sleep quality, and comorbidity]; (3) treatment-protocol for music interventions [types, duration and frequency] and protocols for comparators [types, duration and frequency]; (4) study design [random sequence generation, allocation concealment, blinding, and follow-up]; (5) outcomes [primary, secondary and other outcomes, including scores for anxiety, depression, and sleep quality; adverse events]. The extracted information will be cross-checked by SP and ZX, and any differences will be discussed and resolved with a third reviewer (X-YZ). When necessary, the author will be contacted for more relevant information.

Assessment of risk of bias

Two investigators (CX and GX) will assess the risk of bias independently according to the Cochrane Collaboration's Risk of Bias tool [55]. The following items will be examined: random sequence generation, allocation concealment, incomplete data, blinding, selective reporting, and other bias. The results will be evaluated systematically and any disagreements will be resolved by the third reviewer (X-YZ). The grades derived from these evaluations will be given as 'low', 'high', or 'unclear' risk of bias.

Measures of treatment effect

We will calculate the risk ratio (RR) for dichotomous data with 95% confidence intervals (CIs) and the mean difference (MD) will be included in our study for continuous data. As all outcomes (scores for anxiety, depression, and sleep quality; safety) are continuous variables, the MD and 95% CIs will be calculated by two authors (CX and GX) independently.

Dealing with missing data

If important data is missing in the selected article, or the reported details are insufficient, we will contact the author via various means to supplement and complete the content. If the information is not available, then sensitivity analyses will be performed to address missing data.

Assessment of heterogeneity

Clinical heterogeneity refers to the variation caused by interventions, different participants, and different end-point indicators. The heterogeneity will be assessed by calculating the I^2 value. If $I^2 \leq 50\%$ for a given study, then the study will not show statistically significant heterogeneity and will be considered in the study. Studies with an $I^2 > 50\%$, will be deemed to show statistically significant heterogeneity and will not be included in our meta-analysis.

Assessment of publication bias

When the meta-analysis contains 10 or more RCTs, we will use funnel plots and Egger's test to evaluate any publication bias.

Data synthesis

We will use Review Manage software V.5.3.5 to analyze all data. Since all of the outcomes arising from this meta-analysis will be continuous variables, we will calculate MD and 95% CIs. If the included studies are sufficiently homogeneous, we will use the fixed-effect model to process the data. While subgroup analyses or sensitivity analyses will be used in studies with significant heterogeneity.

Subgroup analysis

To explore the potential sources of heterogeneity in a given study, subgroup analysis will be used according to the following factors:

1. Different age groups.
2. Gender.
3. The type of mental disorders (anxiety, depression, or sleep disorders).
4. The type of music intervention.
5. Differences in duration and frequency.
6. The types of control group (placebo, conventional western medicine, no music intervention, traditional Chinese medicine, no treatment).

Sensitivity analysis

Sensitivity analysis is an important method that can be used to assess the robustness and reliability of the combined results in meta-analysis. Sensitivity analysis will determine whether there is any change in the results by including or excluding a specific study. If the results are unstable, we can then remove research studies with a high risk of bias or check the missing data.

Evaluating the evidence

The quality of evidence will be evaluated according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guideline. We will evaluate the five factors of risk of bias, heterogeneity, inaccuracy, indirectness, and publication bias, and divide the results into 'high', 'moderate', 'low', and 'very low' levels of quality.

Discussion

Studies have shown that one third of COVID-19 survivors have been diagnosed with mental health or nervous system problems within the first 6 months after infection. The most common symptoms are anxiety, depression, and sleep disorder. Furthermore, the incidence of disorders associated with psychological factors and the nervous system of COVID-19 patients is higher than that for other respiratory infections [56]. Therefore, it is critical that we pay attention to the mental health problems of COVID-19 patients, adopt appropriate global health measures, and promote community supportive psychological intervention measures.

Musical intervention has been shown to be beneficial for symptoms of mental disorders, including anxiety and depression. Music intervention is a safe, effective, non-invasive, inexpensive form of therapy that is devoid of side effects. Music intervention is also easy to manage and promote. Although music intervention has been used widely for many years, there has been no systematic review or meta-analysis that attempted to assess the advantages as well as disadvantages of this approach for COVID-19 patients with mental disorders. Therefore, we designed a systematic evaluation and meta-analysis to evaluate the evidence put forward by published RCTs, evaluate the efficacy and safety of music intervention in the treatment of COVID-19 patients with mental disorders, and provide powerful reference guidelines for clinicians, researchers, and policy makers. Only papers that were written in Chinese and English studies will be included in this study. Studies that were written in other languages will be omitted. Consequently, we need to consider the fact that our study may include some language bias, thus limiting the scope of our meta-analysis.

Abbreviations

OSF: Open Science Framework; VIP: Chinese Science and Technology Periodical Database; RCTs: Randomized Controlled Trials; SAS: Self-rating Anxiety Scale; HAMA: Hamilton Anxiety Scale; SDS: Self-rating Depression Scale; HAMD: Hamilton Depression Scale; PSQI: Pittsburgh Sleep Quality Index; QOL: Quality of Life; PRISMA-P: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols; GRADE: Grading of Recommendations Assessment, Development and Evaluation.

Declarations

Acknowledgements

Not applicable.

Authors’ contributions

SP and JK helped to conceive this study. The draft of this paper was conceived and prepared by SP and revised by HY and GX. SP and ZX will independently screen potential studies and extract relevant data. The assessment of bias risk will be carried out by CX and GX. Any differences will be settled by consultation with X-YZ. HY and X-GZ will evaluate the quality of evidence by using the GRADE approach.

YL will supervise every procedure of the review to avoid errors. All authors have read and approved the publication of this protocol.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

The ethical approval is not required for this study because we will use data from published papers. The results arising from this study will be reported in peer-reviewed journals.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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