

# INPLASY PROTOCOL

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**Corresponding author:**  
Jie Ding

602042542@qq.com

**Author Affiliation:**  
Jiangxi University of Chinese  
Medicine, Nanchang, China.

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None declared.

## Effectiveness and safety of music therapy for insomnia disorder patients: A systematic review and meta-analysis protocol

Ding, J<sup>1</sup>; Yuan, F<sup>2</sup>; Huang, T<sup>3</sup>.

**Review question / Objective:** Music therapy has been widely used clinically to relieve insomnia disorder patients. However, the efficacy of Music therapy in the treatment of insomnia disorder patients is uncertain. The purpose of this study is to determine the effectiveness and safety of Music therapy in the treatment of insomnia disorder patients.

**Information sources:** The following electronic databases will be searched: PubMed, Embase, the Cochrane Library, the China National Knowledge Infrastructure, Chinese Science and Technology Periodical Database, Wanfang Database, and Chinese Biomedical Literature Database. We will search the databases from the beginning to January 2021. Search terms consist of disease (Disorders of Initiating and Maintaining Sleep, Early Awakening, Primary Insomnia, Sleep Initiation Dysfunction and Chronic Insomnia) and intervention (Music Therapy, Acoustic Stimulation, music-supported therapy) and research types (randomized controlled trial, controlled clinical trial, random trials). The PubMed search strategy will be shown in Table 1.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 May 2021 and was last updated on 24 May 2021 (registration number INPLASY202150087).

### INTRODUCTION

**Review question / Objective:** Music therapy has been widely used clinically to relieve insomnia disorder patients. However, the efficacy of Music therapy in the treatment of insomnia disorder patients is uncertain. The purpose of this study is to determine the effectiveness and safety of Music

therapy in the treatment of insomnia disorder patients.

**Condition being studied:** Insomnia is a condition characterized by both nocturnal and diurnal symptoms, one of the most prevalent health concerns in the population and in clinical practice<sup>5</sup>. The main clinical characteristic is difficulty falling asleep or

difficulty maintaining sleep; frequent awakenings, difficulty returning to sleep after awakenings, or awakening too early with inability to return to sleep; and is accompanied by fatigue, decreased energy, mood disturbances and reduced cognitive functions, such as impaired attention, concentration and memory below. The prevalence of insomnia symptoms in the general worldwide prevalence ranges from 35% to 50%, and the prevalence of insomnia disorder ranges from 12% to 20%, and according to epidemiological studies show that the prevalence among the adolescent population is increasing. The insomnia with its effects on quality of life (QOL), occupational functioning and physical and psychological health means that the disorder inflicts a heavy burden on individuals and the broader community. The etiology and pathophysiology of insomnia involve genetic, environmental, behavioral, and physiological factors culminating in hyperarousal. Study shows that Insomnia is more prevalent in women than in men and is also more commonly diagnosed in people with medical or psychiatric disorders than in the general population. Insomnia treatment includes 2 broad categories, cognitive-behavioral treatment and medication treatment. Treatment for patients with insomnia who do not have a co-occurring illness should begin with patient education regarding sleep hygiene and education to improve sleep. Hypnotic medications are also efficacious, but the long-term side effects of sedative, hypnotic drug use are obvious. Music-supported therapy (MST) is a promising new treatment, and extensive research suggests that music therapy increased the sleep quality of insomnia disorder patients. Music easily elicits movements that stimulate interactions between the perception and action systems, Insomnia patients may sensitive to the music, and listening to music has been considered as a therapeutic strategy for insomnia patients' treatment. The focus of this study is the efficacy of Music therapy for insomnia disorder patients. Therefore, we conducted this study to systematically evaluate the impact of music therapy on insomnia disorder patients. It can provide a

basis for the diagnosis and treatment of MST for insomnia disorder.

## METHODS

**Participant or population:** Inclusion criteria for study populations will be all patients with insomnia disorder. No restrictions will be applied in terms of gender, age, race, condition duration or intensity.

**Intervention:** The treatment group will only receive Music therapy alone, without any restrictions on music material, type or treatment process.

**Comparator:** The control group will receive an internationally recognized therapy such as pharmacological therapies. Placebo, no treatment, and Sound wave will also be included. Studies that compare the effect of different types of music will be excluded.

**Study designs to be included:** All RCTs of Music therapy for the insomnia disorder patients will be included without language restriction. Non-RCTs, observational studies, cross-over studies, uncontrolled trials, animal trials, and reviews will be excluded.

**Eligibility criteria:** All RCTs of Music therapy for the insomnia disorder patients will be included without language restriction. Non-RCTs, observational studies, cross-over studies, uncontrolled trials, animal trials, and reviews will be excluded.

**Information sources:** The following electronic databases will be searched: PubMed, Embase, the Cochrane Library, the China National Knowledge Infrastructure, Chinese Science and Technology Periodical Database, Wanfang Database, and Chinese Biomedical Literature Database. We will search the databases from the beginning to January 2021. Search terms consist of disease (Disorders of Initiating and Maintaining Sleep, Early Awakening, Primary Insomnia, Sleep Initiation Dysfunction and Chronic Insomnia) and intervention (Music Therapy, Acoustic Stimulation, music-supported therapy) and research

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types (randomized controlled trial, controlled clinical trial, random trials). The PubMed search strategy will be shown in Table 1.

**Main outcome(s):** Sleep quality will be accepted as the primary outcomes, measured by the Pittsburgh Sleep Quality Index (PSQI); can also be evaluated using the Athens Insomnia Scale.

**Additional outcome(s):** The sleep onset latency (in minutes) and sleep efficiency (%) and safety assessment will be considered a secondary outcomes.

**Quality assessment / Risk of bias analysis:** Two independent authors will evaluate the risk of bias among the final included studies using the risk of bias assessment tool by the Cochrane Collaboration. The contents will include: (1) random sequence generation; (2) allocation concealment; (3) blinding of participants and personnel; (4) blinding of outcome assessment; (5) incomplete outcome data; (6) selective reporting; and (7) other sources of bias. Each study will be evaluated as High, Low, or Unclear risk of bias for each item. Discrepancies will be resolved through further discussion with the third author.

**Strategy of data synthesis:** We will conduct statistical analysis through RevMan 5.3 software. For Categorical data, we will calculate with the risk ratio (RR) and 95% confidence intervals (CIs). For continuous variables, mean difference (MD) will be included in the meta-analysis. If outcome variables are measured on different scales, results will be reported as standardized mean differences (SMDs) with 95% CI.

**Subgroup analysis:** If the included studies have significant heterogeneity, we will perform subgroup analysis based on different control groups.

**Sensitivity analysis:** When sufficient studies are available, sensitivity analysis will be used to assess the robustness of the meta-analysis based on methodological quality, sample size and missing data.

**Country(ies) involved:** China.

**Keywords:** Music therapy, insomnia disorder, protocol, systematic review.

**Contributions of each author:**

Author 1 - Jie Ding.

Author 2 - Fuqiang Yuan.

Author 3 - Tianqi Huang.