

INPLASY PROTOCOL

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None declared.

Effectiveness and safety of music- supported therapy on mood in post-stroke rehabilitation patients: A systematic review and meta- analysis protocol

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Review question / Objective: 2.1.1. Types of studies. All RCTs of acupotomy for the third lumbar vertebrae transverse process syndrome will be included without language restriction. Non-RCTs, observational studies, cross-over studies, uncontrolled trials, animal trials, and reviews will be excluded. 2.1.2. Types of Participants. Inclusion criteria for study populations will be all patients with third lumbar vertebrae transverse process syndrome. No restrictions will be applied in terms of gender, age, race, condition duration or intensity. 2.1.3. Types of interventions 2.1.3.1. Experimental interventions. The treatment group will only receive acupotomy therapy alone, without any restrictions on needle material, shape or treatment process. 2.1.3.2. Control interventions. The control group will receive an internationally recognized therapy such as pharmacological therapies. Placebo, no treatment, and acupuncture will also be included. Studies that compare the effect of different types of acupotomy will be excluded. 2.1.4. Types of outcome measures. 2.1.4.1. Primary outcomes. Visual analogue scale (VAS) and Percentage of Clinical Effectiveness will be accepted as the primary outcomes. 2.1.4.2. Additional outcomes. The safety assessment will be considered a secondary outcomes.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 February 2021 and was last updated on 03 February 2021 (registration number INPLASY202120011).

INTRODUCTION

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Condition being studied: Music-supported therapy has been widely used clinically to relieve post-stroke rehabilitation. However, the efficacy of Music-supported therapy in the treatment of Mood in post-stroke rehabilitation Patients is uncertain. The purpose of this study is to determine the effectiveness and safety of Music-supported therapy in the treatment of Mood in post-stroke rehabilitation Patients.

METHODS

Search strategy: Search PubMed, Cochrane Library, Embase, China National Knowledge Infrastructure Database, Wanfang Database, China Science and Technology Journal Database, China Biomedical Literature Database, and search related randomized controlled trials. Two reviewers will independently select studies, collect data, and evaluate methodological quality through the Cochrane Deviation Risk Tool. Revman V.5.3 will be used for meta-analysis.

Participant or population: Inclusion criteria for study populations will be all patients

with Anxiety and depression in post-stroke rehabilitation Patients. No restrictions will be applied in terms of gender, age, race, condition duration or intensity.

Intervention: The treatment group will only receive Music-supported 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-supported therapy for the post-stroke rehabilitation 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-supported therapy for the post-stroke rehabilitation 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: Electronics searches. 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 May 2020. Search terms consist of disease (third lumbar vertebrae transverse process syndrome, third lumbar transverse process syndrome, third lumbar, low back pain) and intervention (acupotomy, needle knife, acupotomology, needle scalpel) and research types (randomized controlled trial, controlled clinical trial, random trials). The PubMed search strategy is shown in Table 1. 2.2.2. Search for other resources. We will also retrieve the relevant conference papers, and search for new trials related to

acupotomy treatment of the third lumbar vertebrae transverse process syndrome on the WHO International Clinical Trials Registration Platform (ICTRP) and the Clinicaltrial.gov.

Main outcome(s): Mini mental status examination(MMSE) score and he Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI), Percentage of Clinical Efectiveness will be accepted as the primary outcomes.

Additional outcome(s): The 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-supported therapy, stroke, Anxiety, depression, protocol, systematic review.

Contributions of each author:

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