

INPLASY PROTOCOL

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None declared.

Effectiveness and safety of acupuncture in the treatment of children with Tourette syndrome: a Protocol for Systematic Review and Meta-analysis

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Review question / Objective: Is acupuncture effective in the treatment of Tourette syndrome? A systematic review and Meta analysis of Randomized Controlled trials ?

Condition being studied: Acupuncture has been used as a complementary therapy for TS in children. At present, although a large number of clinical research results show that acupuncture is effective in treating children with Tourette syndrome, there are still some shortcomings. For instance, there are certain differences in the methodological design of each trial, some factors that interfere with the research results cannot be ruled out, and the results of a single study may not be applicable for the general population. Therefore, we have carried out a meta-analysis to include more research objects, systematically and comprehensively study all the literature on the treatment of children with Tourette syndrome by acupuncture alone, and evaluate the effectiveness and safety of acupuncture alone in the treatment of children with Tourette syndrome from an evidence-based perspective. This systematic review aims to evaluate the efficacy and safety of acupuncture for the treatment of TS in children.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 March 2023 and was last updated on 04 April 2023 (registration number INPLASY202330122).

INTRODUCTION

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METHODS

Search strategy: From the establishment of the databases to March 1, 2023, we will search RCTs of Acupuncture for the treatment of TS in children, and data sources include 3 English databases (PubMed, EMBASE, Cochrane Library) and 3 Chinese databases (CKNI, VIP and Wanfang).

Participant or population: Patients and the public will not be involved.

Intervention: Acupuncture combined with drug therapy.

Comparator: Drug therapy

Study designs to be included: RCTs of acupuncture combined with drug therapy for TS in children will be included.

Eligibility criteria: Type of studies. RCTs of acupuncture for TS in children will be included. Types of participants. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V), states that a healthcare clinician must rely on medical history and physical examination to diagnose TS, as there is no specific diagnostic test available. The tic severity value is assessed with the Tourette Disorder Scale (TODS), and the Yale Global Tic Severity Scale (YGTSS). Patients who are diagnosed as children with TS are not

limited by nationality, race, gender, or course of TS. Types of interventions. Treatment group: acupuncture combined with drug therapy. Control group: drug therapy. Outcome indicators. The outcome measures are the following: TODS and YGTSS.

Information sources: 3 English databases (PubMed, EMBASE, Cochrane Library) and 3 Chinese databases (CKNI, VIP and Wanfang).

Main outcome(s): Tourette Disorder Scale (TODS), and the Yale Global Tic Severity Scale (YGTSS).

Data management: Two researchers will independently extract data from the included studies, which will include information about the studies (year of publication, first author, sample size, age and sex of participants, duration of disease, interventions, primary and secondary outcomes, effectiveness, and adverse events). If there is any disagreement between the 2 reviewers during the screening process, they will consult a third reviewer to make a final decision.

Quality assessment / Risk of bias analysis: To evaluate the methodological quality of randomized controlled trials, the Cochrane Handbook's risk of bias assessment tool will be utilized. The tool assesses each randomized controlled experiment based on several factors, including random sequence generation, allocation concealment, blinding of outcome data, completeness of data, selective reporting, and any additional sources of bias. Based on the results of the evaluation, each factor is classified as low-risk, high-risk, or unclear.

Strategy of data synthesis: We will use RevMan V.5.4 for meta-analysis. Continuous outcome data will be presented as mean differences with 95% CI. We will determine whether to use a fixed-effects or random-effects model based on the results of the heterogeneity of research statistics,

and we will use descriptive analysis when quantitative analysis is not appropriate.

Subgroup analysis: According to the intervention methods, pure acupuncture and other therapies were analyzed in subgroups; according to the intervention time, subgroup analysis was performed; according to different courses of treatment, subgroup analysis was performed; according to the acupuncture points used, subgroup analysis was performed; according to the scale, it could be divided into simple motor tics, complex motor tics, simple vocal tics, complex vocal tics for analysis.

Sensitivity analysis: To ensure the stability and reliability of the combined results, we will perform a sensitivity analysis considering variables like sample size, methodological quality, and missing data.

Country(ies) involved: China.

Keywords: acupuncture, Tourette syndrome, protocol, meta-analyses.

Contributions of each author:

Author 1 - Kexin Lin - Author 1 drafted the manuscript.

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