## INPLASY PROTOCOL

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### Corresponding author: Ping Rong

erke2007@163.com

### **Author Affiliation:**

Department of Paediatrics, First Teaching Hospital of Tianjin University of Traditional Chinese Medicine

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### **Conflicts of interest:**

The authors declare that they have no conflicts of interest.

# Acupuncture for treating tic disorders in children: A protocol for systematic review and meta analysis

Fu, Qf<sup>1</sup>; Zhang, Xl<sup>2</sup>; Yan, Hh<sup>3</sup>; Xu, Jb<sup>4</sup>; Liu, H<sup>5</sup>; Yang, Lb<sup>6</sup>; Zhao, Sy<sup>7</sup>; Ma, R<sup>8</sup>; Rong, P<sup>9</sup>.

Review question / Objective: This study aims to explore the efficacy and safety of acupuncture for TDs in children. Condition being studied: Tic disorders (TDs) are very common neuropsychiatric disorders in children. Pharmacotherapy as the main treatment is often associated with various side effects, thus significantly affecting patients' quality of life. Clinical studies have found acupuncture shows certain advantages in the treatment of TDs. However, there is no high level of evidence about the efficacy and safety of acupuncture for TDs in children.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 November 2020 and was last updated on 12 November 2020 (registration number INPLASY2020110050).

#### INTRODUCTION

Review question / Objective: This study aims to explore the efficacy and safety of acupuncture for TDs in children.

Condition being studied: Tic disorders (TDs) are very common neuropsychiatric disorders in children. Pharmacotherapy as the main treatment is often associated with various side effects, thus significantly affecting patients' quality of life. Clinical studies have found acupuncture shows

certain advantages in the treatment of TDs. However, there is no high level of evidence about the efficacy and safety of acupuncture for TDs in children.

### **METHODS**

Participant or population: Patients with a clinical diagnosis of TDs who met the definitions in the following guidelines: (1) the Diagnostic and Statistical Manual of Mental Disorders-III (DSM-III), DSM-IV, DSM-IV Text Revision or DSM-V; (2) the International Classification of Diseases-10 (ICD-10); and (3) the Chinese Classification and Diagnostic Criteria of Mental Disorders (CCMD). The inclusion criteria required patients enrolled to be younger than 18 years.

Intervention: Any type of acupuncture treatment will be included, such as body acupuncture, dermal needle, auricular acupuncture, scalp acupuncture, warm needling, fire needling and electroacupuncture, regardless of frequency, intensity and duration. Point injection, acupoint application, acupressure, laser acupuncture, cupping and moxibustion considered to be another part of TCM will be excluded. Acupuncture combined with other therapies will also be included.

Comparator: No treatment, placebo, false acupuncture, and other interventions (e.g., drug treatment, other active therapies) will be included as control interventions.

Study designs to be included: All randomized controlled trials evaluating the efficacy and safety of acupuncture treatment for TDs will be included without publication type restriction. The language will be limited to English and Chinese. Conference papers, protocol, case report, review, animal study, comments, supplementary issue will be excluded.

Eligibility criteria: Types of studies: All randomized controlled trials evaluating the efficacy and safety of acupuncture treatment for TDs will be included without publication type restriction. The language will be limited to English and Chinese.

Conference papers, protocol, case report, review, animal study, comments, supplementary issue will be excluded. Types of participants: Patients with a clinical diagnosis of TDs who met the definitions in the following guidelines: (1) the Diagnostic and Statistical Manual of Mental Disorders-III (DSM-III), DSM-IV, DSM-IV Text Revision or DSM-V; (2) the **International Classification of Diseases-10** (ICD-10): and (3) the Chinese Classification and Diagnostic Criteria of Mental Disorders (CCMD). The inclusion criteria required patients enrolled to be younger than 18 years. Types of interventions and controls: Any type of acupuncture treatment will be included, such as body acupuncture, dermal needle, auricular acupuncture, scalp acupuncture, warm needling, fire needling and electroacupuncture, regardless of frequency, intensity and duration. Point injection, acupoint application, acupressure, laser acupuncture, cupping and moxibustion considered to be another part of TCM will be excluded. Acupuncture combined with other therapies will also be included. No treatment, placebo, false acupuncture, and other interventions (e.g., drug treatment, other active therapies) will be included as control interventions. Types of outcome measures: The primary outcome is reduction rate (amount) of tic symptom scores measured by related scales. In order of preference, the scales include Yale Global Tic Severity Scale, Tourette Syndrome Global Scale, The Gilles de la Tourette Syndrome-Quality of Life Scale, Shapiro Tourette Syndrome Severity Scale and other methods. The secondary outcomes include recurrence rate and adverse events (AEs).

Information sources: We will search PubMed, EMBASE, Cochrane Library, Web of Science, World Health Organization International Clinical Trials Registry Platform, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Chinese Scientific Journal Database (VIP), Wan-fang database. The temporal interval is limited from the databases inception until November 2020. In addition, We will search

the Chinese Clinical Trial Registry Centers and grey literatures. Authors will be contacted for further information if essential data are missing. The following literatures, earlier than the database above mentioned will also be searched: "China Rehabilitation Medicine Journal""Chinese Acupuncture and Moxibustion""Chinese Acupuncture""Journal of Traditional Chinese Medicine""Chinese Journal of Physical Medicine and Rehabilitation" "Acupuncture Research""Acupuncture Clinical Journal", and "Shanghai Acupuncture Journal".

Main outcome(s): The primary outcome is reduction rate (amount) of tic symptom scores measured by related scales. In order of preference, the scales include Yale Global Tic Severity Scale, Tourette Syndrome Global Scale, The Gilles de la Tourette Syndrome-Quality of Life Scale, Shapiro Tourette Syndrome Severity Scale and other methods.

Additional outcome(s): The secondary outcomes include recurrence rate and adverse events (AEs).

### Quality assessment / Risk of bias analysis:

Two authors will perform the assessment of risk of bias independently adopting the Cochrane Collaboration's risk of bias tool. For each item, risk of bias will be divided into 3 levels: high, low or unclear. Conflicts will be resolved first by discussion and then by seeking the judgement of a third author.

Strategy of data synthesis: We will analyse the data using RevMan V.5.3.0. For dichotomous data, the risk ratio (RR) with 95% confidence intervals (CIs) will be calculated, and for continuous variable outcome, mean difference (MD) or standardized mean difference (SMD) with 95% CIs will be recorded, depending on whether different scales are used to measure an outcome. A P-value <.05 will be defined as statistically significant. Two a uthors will perform this work independently to reduce inaccuracy in the extracted data.

Subgroup analysis: A subgroup analysis will be conducted to explore the differences in acupuncture methods, treatment frequencies, control group and follow-up duration.

Sensibility analysis: Sensitivity analysis will be applied to evaluate the stability of the meta-analysis results according to the following criteria: the quality of studies, sample size, missing data, heterogeneity qualities, and statistical model (fixedeffects or random-effects model).

Country(ies) involved: China.

Keywords: acupuncture, tic disorders, systematic review, meta analysis.

### Contributions of each author:

Author 1 - Qianfang Fu.

Email: 1728020603@qq.com

Author 2 - Xilian Zhang.

Author 3 - Haihong Yan.

Author 4 - Jiabao Xu.

Author 5 - Hui Liu.

Author 6 - Libin Yang.

Author 7 - Shuyi Zhao.

Author 8 - Rong Ma.

Author 9 - Ping Rong.