

# INPLASY PROTOCOL

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**Corresponding author:**  
Min Li

mylittlefish66@163.com

**Author Affiliation:**  
Beijing Hospital of Traditional  
Chinese Medicine

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submission:** Preliminary  
searches.

**Conflicts of interest:**  
None.

## The effectiveness of acupuncture in the treatment of Tourette syndrome and other chronic tic disorders: a systematic review and meta-analysis of randomized controlled trials

Ai, H<sup>1</sup>; Li, M<sup>2</sup>; Chang, Y<sup>3</sup>; He, B<sup>4</sup>; Zhao, X<sup>5</sup>; Qi, Y<sup>6</sup>; Li, F<sup>7</sup>.

**Review question / Objective:** Participants are children or adolescents age under 18 with TS or other chronic tic disorders diagnosed by proper medical diagnosis criteria, such as the Diagnostic and Statistical Manual, fourth edition (DSM-IV), or the text revision of fourth edition (DSM-IV-TR), or the fifth edition (DSM-V). The Chinese Classification of Mental Disorders (CCMD) either measure with second revision version (CCMD-2R) or third version (CCMD-3). Interventions: Acceptable treatments only included manual acupuncture, electro-acupuncture or plum-blossom needling which regardless of needling techniques and stimulation method, combined routine treatment or alone. Auricular (ear) acupuncture, acupressure, acupoint application, catgut embedding, transcutaneous electrical acupoint stimulation, acupoint injection are excluded. Comparators: Treatments in the comparison groups can be sham-acupuncture, placebo, or no additional intervention to usual care. (e.g., psychoeducation, behavioral interventions or western medicine.) Studies compare different types of acupoint based therapy are included. Outcome: The main outcome is Yale Global Tic Severity Scale (YGTSS) which measured the mean overall change in tic symptoms from baseline to endpoint. Additional outcomes may include the incidence of adverse reactions, the recurrence rate and the improvement of comorbidities and TCM symptoms.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 January 2021 and was last updated on 16 January 2021 (registration number INPLASY202110062).

### INTRODUCTION

**Review question / Objective:** Participants are children or adolescents age under 18

with TS or other chronic tic disorders diagnosed by proper medical diagnosis criteria, such as the Diagnostic and Statistical Manual, fourth edition (DSM-IV),

or the text revision of fourth edition (DSM-IV-TR), or the fifth edition(DSM-V). The Chinese Classification of Mental Disorders (CCMD) either measure with second revision version (CCMD-2R) or third version (CCMD-3). Interventions: Acceptable treatments only included manual acupuncture, electro-acupuncture or plum-blossom needling which regardless of needling techniques and stimulation method, combined routine treatment or alone. Auricular (ear) acupuncture, acupressure, acupoint application, catgut embedding, transcutaneous electrical acupoint stimulation, acupoint injection are excluded. Comparators: Treatments in the comparison groups can be sham-acupuncture, placebo, or no additional intervention to usual care. (e.g., psychoeducation, behavioral interventions or western medicine.) Studies compare different types of acupoint based therapy are included. Outcome: The main outcome is Yale Global Tic Severity Scale (YGTSS) which measured the mean overall change in tic symptoms from baseline to endpoint. Additional outcomes may include the incidence of adverse reactions, the recurrence rate and the improvement of comorbidities and TCM symptoms.

**Condition being studied:** Based on several bibliographical databases, we will perform an elaborate and systematic search to identify the qualified Randomized controlled trials(RCTs) in which any acupuncture therapies for the treatment of TS and other chronic tic disorders are compared with other therapies or alone from the inception of each database up to 31th December 2020 without regional restriction. The main outcome is in accordance with Yale global tic severity scale(YGTSS) for evaluating the efficacy of acupuncture.

## METHODS

**Participant or population:** Participants are children or adolescents age under 18 with TS or other chronic tic disorders diagnosed by proper medical diagnosis criteria, such as the Diagnostic and Statistical Manual, fourth edition (DSM-IV), or the text revision

of fourth edition (DSM-IV-TR), or the fifth edition(DSM-V). The Chinese Classification of Mental Disorders (CCMD) either measure with second revision version (CCMD-2R) or third version (CCMD-3).

**Intervention:** Acceptable treatments only included manual acupuncture, electro-acupuncture or plum-blossom needling which regardless of needling techniques and stimulation method, combined routine treatment or alone. Auricular (ear) acupuncture, acupressure, acupoint application, catgut embedding, transcutaneous electrical acupoint stimulation, acupoint injection are excluded.

**Comparator:** Treatments in the comparison groups can be sham-acupuncture, placebo, or no additional intervention to usual care. (e.g., psychoeducation, behavioral interventions or western medicine.) Studies compare different types of acupoint based therapy are included.

**Study designs to be included:** The parallel-group RCTs including cross-over, parallel-group and cluster trials which published in Chinese or in English without any regional restrictions.

**Eligibility criteria:** The relevant randomized controlled trials (RCTs) which investigating the efficacy association between acupuncture and Tourette Syndrome or other chronic tic disorders.

**Information sources:** A comprehensive literature search will be carried out for identifying the relevant randomized controlled trials (RCTs) which investigating the efficacy association between acupuncture and Tourette Syndrome (TS) or other chronic tic disorders in the following electronic databases: Pubmed, the Cochrane Library, Web of science, and Chinese databases including Chinese National Knowledge Infrastructure(CNKI), Wanfang Database, VIP, Chinese Scientific Journal database, the Chinese Biomedical Literature Database, Chinese clinical trial registry, Clinical trials (www.clinicaltrials.gov) from their inception

to December 31th, 2020. Through the way that the Medical subject headings (MeSH) incorporated with free text terms by using the Boolean logical operators, an exhaustive search will be implemented by considering the following terms: “Tourette Syndrome”, “acupuncture”, “chronic tic disorders”, “tic disorders”, “electro-acupuncture”, “needle”, “plum-blossom needling”, “Randomized controlled trial”, “chronic motor or vocal tic disorders”. Consideration the omitting of the potentially eligible articles, the bibliographies of relevant meta-analyses and reviews will be additionally manual searched.

**Main outcome(s):** The main outcome is Yale Global Tic Severity Scale (YGTSS) which measured the mean overall change in tic symptoms from baseline to endpoint.

**Additional outcome(s):** Additional outcomes may include the incidence of adverse reactions, the recurrence rate and the improvement of comorbidities and TCM symptoms.

**Data management:** RevMan (V.5.3) software and the statistical software R will be used to perform data statistical analysis.

**Quality assessment / Risk of bias analysis:** Grading of Recommendations Assessment, Development, and Evaluation (GRADE) and ROBINS-II will be used to evaluate the quality of evidence. All the studies will be rated by two investigators independently in seven items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias; and each of the item will be respectively rated as unknown, low and high risk of bias. The disagreement will be addressed through joint discuss of the section to reach consensus.

**Strategy of data synthesis:** Two independent reviewers will extract information using a pre-designed form including: (1) identification information (publication year, first author); (2) general

information (country, study type, number of centers, sample size and study design); (3) participants (type of tic, age, sex and the score of YGTSS before treatment); (4) interventions (type of acupuncture, acupuncture points selection and treatment frequency/session/duration); (5) comparator (if there is any, details of the treatment including name, dosage, frequency and course); and (6) outcomes ( data and time points for each measurement, safety, the recurrence rate and the improvement of comorbidities and TCM symptoms). Meta-analysis including subgroup’s analysis will be carried out using “meta” package in R (The R Foundation for Statistical Computing, Vienna, Austria). For continuous variables, a mean difference (MD) with a corresponding 95% CI was calculated by using random effect models. Funnel plots, along with Begg’s and Egger’s test were used to address potential publication bias, were constructed when the number of included studies was more than 10. Any disagreements will be arbitrated by a third reviewer . Cross- check of all data will be done by two independent reviewers before transferring into RevMan software (V.5.3) and the statistical software R.

**Subgroup analysis:** A prespecified subgroup analysis will be done according to the type of comparisons between groups when there are two or more studies in a given subgroup. we may perform the subgroup analysis based on the type of intervention, the type of comparators, the needling techniques and stimulation methods, the age of the participants, and the total treatment period. Tests of interaction will be conducted to establish whether the subgroups differed significantly from one another.

**Sensibility analysis:** Not applicable

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

**Keywords:** Tourette syndrome, meta-analysis, tic disorders, acuapunctures, electro-acupuncture, plum-blossom needling.

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**Contributions of each author:**

**Author 1 - Haonan Ai.**

**Author 2 - Min Li.**

**Author 3 - Ying Chang.**

**Author 4 - Baixiang He.**

**Author 5 - Xiangrui Zhao.**

**Author 6 - Yaping Qi.**

**Author 7 - Fajun Li.**