

# INPLASY

## Comparison of the efficacy of different types of TCM in the treatment of patients with subthreshold depression: a systematic review and a network meta-analysis protocol

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### ADMINISTRATIVE INFORMATION

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**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY2024120070

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 December 2024 and was last updated on 18 December 2024.

### INTRODUCTION

**Review question / Objective** The type of illness is Subthreshold depression. The interventions were different types of TCM treatments, including Chinese herbal medicine, acupuncture, moxibustion, Tuina, Tai Chi, Wu Bird Opera, and TCM Sentiment Therapy. Comparators were psychoeducation, placebo, no treatment, and usual care. Outcome types were divided into primary and secondary outcomes, with CES-D being used as the primary outcome, with higher CES-D scores indicating more severe depressive symptoms. Secondary outcomes were HAMD-17, HAMD-24, SDS, PHQ-9, and SCL-90, with higher scores indicating more severe depressive symptoms, with effect sizes of mean difference and 95% confidence interval for all outcomes. The method of study was a randomized controlled trial.

**Condition being studied** Subthreshold depression is a psychological sub-health state between

depression and health, with mild depressive manifestations, which is a high-risk stage for the development of major depressive disorder and a key stage for alleviating depressive symptoms, but there is no good treatment for it. A growing number of clinical studies have shown that TCM is safe and has no side effects in improving depressive symptoms, but the specific efficacy has not been effectively evaluated. Therefore, this study will conduct a systematic review and meta-analysis to evaluate the efficacy of different types of TCM treatments for patients with Subthreshold depression.

### METHODS

**Search strategy** Two review authors independently scanned titles and abstracts to confirm that they met the inclusion criteria, and conducted full-text reviews of all included studies. The following data were extracted using standard forms: first author name, year of publication, age

range of participants, sample size, diagnostic criteria, intervention in treatment and control groups, duration of treatment, outcome measures, and adverse events. If there are incompleteness or vague details, we will endeavour to contact the first author or corresponding author for clarification. If disagreements arise, a third reviewer will be consulted and a final decision will be made after discussion.

**Participant or population** Included patients met the following criteria: according to the Diagnostic and Statistical Manual of Mental Disorders criteria,  $CES-D \geq 16$ ,  $7 \leq HAMD-17 < 17$ , or  $8 \leq HAMD-24 < 20$ .

**Intervention** The interventions were different types of TCM treatments, including Chinese herbal medicine, acupuncture, moxibustion, Tuina, Tai Chi, Wu Bird Opera, and TCM Sentiment Therapy.

**Comparator** Comparators were psychoeducation, placebo, no treatment, and usual care.

**Study designs to be included** A randomized controlled trial.

**Eligibility criteria** Type of included studies: randomised controlled trials. The following studies were excluded: non-randomized controlled trials, single-arm design trials, animal experiments, conference abstracts, dissertations, systematic reviews, or meta-analyses.

**Information sources** PubMed, Web of Science, EMBASE, The Cochrane Library, CNKI, Wanfang Data Knowledge Service Platform, VIP, and CBM.

**Main outcome(s)** CES-D was main outcome, with higher scores indicating more severe depressive symptoms.

**Additional outcome(s)** The additional outcomes were HAMD-17, HAMD-24, SDS, PHQ-9 and SCL-90, with higher scores indicating more severe depressive symptoms.

**Quality assessment / Risk of bias analysis** Two review authors independently assessed the risk of bias of each included RCT using the Cochrane Handbook-recommended risk of bias tool, RoB1.0. The evaluation will cover the following aspects: 1. Random sequence generation; 2. Assign hidden; 3. Blinding of participants and staff; 4. Blinding of outcome assessments; 5. Incomplete result data; 6. Selective reporting; 7. Other potential sources of bias. Based on the assessment, each study will be classified as having high, low, or unclear risk of

bias. If there is a disagreement, a third reviewer will be involved to help reach consensus.

**Strategy of data synthesis** We will perform a meta-analysis using STATA. Each score is a numeric variable and may have different measures and scoring criteria. Therefore, we extracted the difference in scores before and after treatment, selected the standardised mean difference as the effect measure, and used the 95% confidence interval as the effect statistical test interval. Chi-square test and I-square test ( $I^2$ ) were used to evaluate the degree of heterogeneity. If the results of the study exhibit low heterogeneity ( $I^2 < 50\%$ ), a meta-analysis will be performed using a random-effects model and then further analysis will be performed to understand the source of the heterogeneity. If the data are not suitable for quantitative synthesis, a narrative summary will be provided to present the results for inclusion in the publication. For trials that only report pre-intervention and post-intervention values, the mean change will be calculated by subtracting the pre-measurement measurements from post-measurement. The standard deviation of change will be estimated accordingly.

**Subgroup analysis** In the presence of significant heterogeneity, subgroup analyses will be performed to explore potential sources of heterogeneity. The following aspects will be considered as potential subgroup factors: age, gender, mode of intervention, and degree of depression. If there are sufficient available data for each subgroup, a quantitative subgroup analysis will be performed to investigate the effect of these factors on treatment efficacy. However, if the data used for subgroup analysis are insufficient, a qualitative synthesis will be performed, in which the results of individual studies will be summarized and compared without the need for a formal quantitative combination.

**Sensitivity analysis** If significant heterogeneity remains after subgroup analysis is performed, sensitivity analysis will be performed. In sensitivity analyses, meta-analyses will be repeated after excluding low-quality studies or studies with potential sources of bias. By conducting sensitivity analyses and comparing the results of the two meta-analyses, we could assess the robustness and reliability of the findings. This process helps to assess the impact of individual studies on the overall outcome and provides a more comprehensive understanding of the results of the meta-analysis.

**Country(ies) involved** China.

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**Keywords** Traditional Chinese Medicine; Chinese herbal medicine; Acupuncture; Moxibustion; Massage; Tai Chi; five-animal boxing; Subthreshold depression; systematic reviews; Network meta-analysis.

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