

# INPLASY

## Clinical evidence of acupuncture as an adjuvant treatment for primary depression: A systematic review and meta-analysis with meta-regression

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### ADMINISTRATIVE INFORMATION

**Support** - No.

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202420002

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 February 2024 and was last updated on 01 February 2024.

### INTRODUCTION

**Review question / Objective** To estimate the efficacy and safety of acupuncture adjuvant treatment on primary depression compared with SSRIs/SNRIs alone control groups and to determine the moderating effects acupuncture of on depression and the presence of publication bias.

**Condition being studied** Depression is a prevalent and disabling disorder associated with reduced quality of life, medical comorbidity and mortality. Over 300 million people live with depressive disorder, equating to approximately 4.4% of the world's population. The prevalence of depression has increased during the COVID-19 pandemic by an estimated 27.6%. highlighting the need for appropriate. Currently, recommended treatments include psychotherapy and antidepressant

medication (or a combination of both). However, psychotherapy achieves remission rates of only 50% while typically being cost-intensive. Side effects and relapses from antidepressant medication commonly occur as can withdrawal symptoms. Importantly, about two thirds of adults with depression do not receive . Untreated depression often leads to intensification of the illness including the development. This attests to the need for rapid and readily available alternative treatment options.

Acupuncture therapy has been practiced in China for thousands of years for disease prevention and treatment. Previous evidence-based studies have indicated that acupuncture is associated with a decrease in the severity of depression when compared with usual care alone, control acupuncture (invasive, non-invasive sham controls), no treatment/wait list/treatment as usual, or SSRI/SNRI medication alone. Although

acupuncture dose has been found to be associated with symptom, reduction in MDD by linear regression. However, some of these meta-analyses found moderate, weak or no effects of acupuncture and moxibustion, while others reported greater effects. These mixed results stem from methodological and conceptual differences regarding inclusion criteria and analytical approaches. For example, some studies focus on individuals diagnosed with major depressive disorder (MDD) and exclude studies evaluating the presence of depression based on effective screening measures. This creates the potential for bias. Importantly, some reviews have proposed a reason for concern, that is, when restricted to "high bias risk" randomized controlled trials (rct), acupuncture and has no significant impact. Therefore, extant meta-analyses have failed to provide convincing evidence to enable clinicians globally to implement acupuncture as an evidence-based effective treatment option for depression. A meta-analysis solved the shortcomings of these methods, focusing on the use of verified depression samples and diagnostic tools to diagnose MDD diagnosis samples, and only included the control study of acupuncture and moxibustion assisted drug comparison drugs alone. We excluded the placebo controlled study of acupuncture and moxibustion in the treatment of depression, and then we excluded the control study of non primary depression. In addition, in the past few years, a large number of studies have been published, which requires an updated meta-analysis of the antidepressant effect of acupuncture and moxibustion, and solves the shortcomings of previous reviews. The purpose of this meta-analysis is to update the current evidence on the role of acupuncture and moxibustion in reducing the elevation of clinical depression in adults, and to compare acupuncture and moxibustion adjuvant treatment with drug treatment alone. In addition, our aim is to investigate the potential regulatory factors of acupuncture and moxibustion's antidepressant effect and the existence of publication bias.

## METHODS

**Participant or population**(1) Investigated participants aged 18 years or older with a primary diagnosis of depression defined by the Research Diagnostic Criteria, Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or DSM-5 or International Classification of Diseases (ICD-10) or Hamilton Rating Scale for Depression (HAM-D)).

**Intervention** A kind of acupuncture assisted intervention for depression was studied, in which

acupuncture and included manual acupuncture , electronic acupuncture and laser acupuncture. The control group includes medication alone treatment (such as SSRIs and SNRIs). Excluding other treatment methods (traditional Chinese medicine, psychological therapy).

**Comparator** The control group includes medication alone treatment (such as SSRIs and SNRIs). Excluding other treatment methods (traditional Chinese medicine, psychological therapy).

**Study designs to be included** Randomized controlled trials.

**Eligibility criteria** To structure the eligibility criteria, the PICOS (Patient/Population; Intervention; Comparison, Outcome; Study design) approach was used. Eligible for this meta-analysis included studies that: (1) Investigated participants aged 18 years or older with a primary diagnosis of depression defined by the Research Diagnostic Criteria, Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or DSM-5 or International Classification of Diseases (ICD-10) or Hamilton Rating Scale for Depression (HAM-D)). A kind of acupuncture assisted intervention for depression was studied, in which acupuncture and included manual acupuncture , electronic acupuncture and laser acupuncture. The control group includes medication alone treatment (such as SSRIs and SNRIs). Excluding other treatment methods (traditional Chinese medicine, psychological therapy). (4) Use validated scales to evaluate the impact on depression patients before and after intervention. (5) Randomized controlled trials.

**Information sources** An electronic search of the following databases was conducted: Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, MEDLINE, Embase, PsycINFO, CNKI, Wanfang without any (eg, language or date) restrictions from inception to December 2023.

**Main outcome(s)** The primary outcome was the mean change in depressive in the acupuncture compared with the control group from baseline to postintervention (HAM-D).

**Additional outcome(s)** SERS, TESS.

**Quality assessment / Risk of bias analysis** Selected studies were assessed by three independent authors given an overall estimation of risk of bias (ie, low risk, some concerns or high risk) according to the revised Cochrane risk-of-bias

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tool for randomised trials (RoB2).According to RoB2, the following domains were considered for the assessment of risk of bias: randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported result.

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**Strategy of data synthesis** A random effects meta-analysis was calculated due to expected heterogeneity. The standardised mean difference (SMD) and 95% CIs were used as the effect size (ES) measure. All results were calculated on an intention-to-treat basis. Heterogeneity was calculated using the I<sup>2</sup>. Sensitivity analyses were further calculated excluding one study due to unequal distribution of psychotherapy among the intervention and control group and excluding studies with high risk for bias. Potential moderators of the antidepressant effects of Acupuncture were investigated using linear meta-regression analyses for all studies and, separately, for studies including only patients with a diagnosis of depression. The meta regression hypothesis was tested in SPSS. Subgroup analysis was calculated to assess the impact of cross bias risk, different languages, types of drugs, and types of acupuncture . Publication bias was assessed with visual inspection of funnel plots and with the Begg-Mazumdar Kendall's tau and Egger bias test.Whenever significant, the Duval and Tweedie Trim and Fill was applied. Fail safe number of negative studies that would be required to nullify (ie, make  $p>0.05$ ) the ES were calculated. All analyses were performed using Comprehensive Stata software.

**Subgroup analysis** Calculate subgroup analysis to assess the impact of cross bias risk, different languages, types of drugs, and types of acupuncture and moxibustion.

**Sensitivity analysis** Sensitivity analyses were further calculated excluding one study due to unequal distribution of psychotherapy among the intervention and control group and excluding studies with high risk for bias.

**Language restriction** No.

**Country(ies) involved** China.

**Keywords** Depression, acupuncture , Meta analysis, meta-regression, adjuvant therapy.

#### **Contributions of each author**

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