

# INPLASY PROTOCOL

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## Corresponding author:

Lin Pei

peilin13831190309@126.com

## Author Affiliation:

Hebei University of Chinese Medicine. Hebei Province Academy of Chinese Medicine Sciences. Hebei Key Laboratory of Turbidity, Hebei Academy of Chinese Medicine Sciences.

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**Review Stage at time of this submission:** The review has not yet started.

## Conflicts of interest:

None declared.

## Efficacy and safety of scalp acupuncture in the treatment of depression: A protocol for systematic review and meta-analysis

Zhao, YN<sup>1</sup>; Wang, C<sup>2</sup>; Liu, J<sup>3</sup>; Lu, Y<sup>4</sup>; Sun, GQ<sup>5</sup>; Chu, L<sup>6</sup>; Pei, L<sup>7</sup>.

**Review question / Objective:** P: Patients with depression. I: Treatment intervention includes scalp acupuncture alone or scalp acupuncture combined with other treatments. C: Control group was treated with drugs or body acupuncture therapy and so on. O: The outcomes will include the Hamilton depression scale (HAMD), the effective, and the incidence of adverse events. S: This review included only randomized controlled trials. The aim of the study is to systematically evaluate the efficacy and safety of scalp acupuncture in the treatment of depression.

**Information sources:** We will search the publications by the following databases: PubMed, Embase, Cochrane Library, Web of Science, Chinese Biomedical Database (CBM), VIP Chinese Science, Wanfang Database, China national Knowledge Infrastructure (CNKI).

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 April 2022 and was last updated on 27 April 2022 (registration number INPLASY202240155).

## INTRODUCTION

**Review question / Objective:** P: Patients with depression. I: Treatment intervention includes scalp acupuncture alone or scalp acupuncture combined with other

treatments. C: Control group was treated with drugs or body acupuncture therapy and so on. O: The outcomes will include the Hamilton depression scale (HAMD), the effective, and the incidence of adverse events. S: This review included only

randomized controlled trials. The aim of the study is to systematically evaluate the efficacy and safety of scalp acupuncture in the treatment of depression.

**Condition being studied:** Depression is a common clinical emotional related mental disease, its representative clinical manifestations are low mood, sad to cry, silent, etc. In recent years, due to people's life and work pressure, the incidence of depression has gradually increased, and the suicide rate of patients with depression has also increased year by year. Depression has brought heavy burden to the society and family, and its diagnosis and treatment urgently need to be solved. At present, the treatment of clinical depression is still mainly western medicine, which has serious side effects, easy to appear truncation reaction, expensive and other shortcomings, acupuncture treatment has the advantages of small toxic and side effects, quick effect, cheap price and so on. Compared with ordinary acupuncture, scalp acupuncture has the advantages of fewer points to choose, safe operation and simple method, etc. Baihui, Yintang and Sishencong are commonly used. From case reports to clinical efficacy observation, the depth of research has been continuously expanded, and clinical research literature has gradually increased. But now rare head needle treatment of depression system analysis of related literature, this study search in recent 10 years at home and abroad to use the scalp acupuncture for the treatment of depression randomized controlled trials, and to assess the head needle treatment the clinical efficacy and safety of depression, lay a foundation for the clinical diagnosis and treatment of depression.

## METHODS

**Participant or population:** The subjects were participants with depression who were definitely diagnosed, regardless of gender, age, race, color of skin, and nationality.

**Intervention:** The intervention measures in the treatment group were scalp

acupuncture alone or scalp acupuncture combined with other treatments (There are no requirements on acupuncture point selection, acupuncture method, treatment course and electroacupuncture stimulation parameters in acupuncture operation).

**Comparator:** The control group was treated with drugs or body acupuncture therapy and so on.

**Study designs to be included:** This study will only include all published randomized controlled trials. The language will be limited to Chinese and English and there will be no regional restrictions.

**Eligibility criteria:** We abide by the Participants, Interventions, Comparisons, Outcomes and Study Design (PICOS) approach to established the eligibility criteria, which are as follows: P: The subjects were participants with depression who were definitely diagnosed, regardless of gender, age, race, color of skin, and nationality. I: The intervention measures in the treatment group were scalp acupuncture alone or scalp acupuncture combined with other treatments (There are no requirements on acupuncture point selection, acupuncture method, treatment course and electroacupuncture stimulation parameters in acupuncture operation). C: The control group was treated with drugs or body acupuncture therapy and so on. O: The primary outcomes will include the Hamilton depression scale (HAMD), the effective, and the incidence of adverse events. S: This study will only include all published randomized controlled trials. The language will be limited to Chinese and English and there will be no regional restrictions. Case reports, literature reviews, retrospective studies, animal studies, and studies with unbelievable or unavailable data will be excluded.

**Information sources:** We will search the publications by the following databases: PubMed, Embase, Cochrane Library, Web of Science, Chinese Biomedical Database (CBM), VIP Chinese Science, Wanfang

Database, China national Knowledge Infrastructure (CNKI).

**Main outcome(s):** The primary outcomes will include the Hamilton depression scale (HAMD), the effective, and the incidence of adverse events.

**Quality assessment / Risk of bias analysis:** Two reviewers will independently assess the risk bias of RCT using Cochrane Handbook, these items will be evaluated in three categories: low, unclear or high risk of bias. The main content of the Cochrane risk assessment tool includes the following 7 items: random method selection; allocation hiding; blind method, completeness of the result data; whether the evaluator is blind; selectively reporting results; other biases. If there is a disagreement during the evaluation process, find a third party for discussion.

**Strategy of data synthesis:** Meta-analysis was performed using Revman5.3 software provided by the Cochrane collaboration. The measurement indexes included in the literature were dichotomous variables and the relative risk (RR) will be used as a statistic and expressed by a 95% confidence interval (CI). The weighted mean difference (WMD) will be analysed for continuous variable acquisition.  $\chi^2$  test was used to evaluate the heterogeneity among the tests. The test level  $\alpha$  was 0.1, and the degree of heterogeneity was expressed as  $I^2$ . If  $P > 0.10$  and  $I^2 < 50\%$ , there was statistical homogeneity between studies, and the fixed-effect model was used to combine the effect size. If  $P \leq 0.10$  and  $I^2 \geq 50\%$ , there was statistical heterogeneity between studies, and random effect model was used for combined analysis. If the data provided by the included clinical trials could not be analyzed in combination, only descriptive analyses were performed.

**Subgroup analysis:** If the  $I^2$  value is equal or greater than 50%, subgroup analysis will be conducted to explore the main sources of heterogeneity. The grouping will base on the results of literature search.

**Sensitivity analysis:** Sensitivity analysis will be conducted to ensure the robustness of the results; the lower the sensitivity, the more robust and credible the results.

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

**Keywords:** Scalp acupuncture, Depression, Systematic review, Meta-analysis.

**Contributions of each author:**

Author 1 - Yanan Zhao.

Author 2 - Chi Wang.

Author 3 - Jia Liu.

Author 4 - Ye Lu.

Author 5 - Guoqiang Sun.

Author 6 - Li Chu.

Author 7 - Lin Pei.