INPLASY PROTOCOL

To cite: Gao et al. Treatment of Perimenopausal Depression with Acupuncture Combined with Chinese herbal medicine: A Systematic Review and Meta-Analysis. Inplasy protocol 202210122. doi: 10.37766/inplasy2022.1.0122

Received: 26 January 2022

Published: 26 January 2022

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Support: NCFC.

Review Stage at time of this submission: Completed but not published.

Conflicts of interest: None declared. Treatment of Perimenopausal Depression with Acupuncture Combined with Chinese herbal medicine: A Systematic Review and Meta-Analysis

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Review question / Objective: This study evaluated the clinical efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of perimenopausal depression by meta-analysis.

Condition being studied: Perimenopausal depression refers to women's menopause and one year before and after the menopause . The decline in estrogen levels causes persistent depression, anxiety, and autonomic disorders and other symptoms of emotional disorder. The risk for major depression appears twice as high in women relative to men, and the probability of perimenopausal women suffering from depression is about twice that of premenopausal women. According to the results of foreign epidemiological surveys, the prevalence of depression in perimenopausal women is as high as 36% . In recent years, Traditional Chinese medicine (TCM) has achieved significant effects in the treatment of perimenopausal period . Chinese herbal medicine and acupuncture have their own advantages and disadvantages. Combination of the two treatments can not only make up for the disadvantages of single treatment, but also show the multi-target, multi-channel and multi-level treatment advantages.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 January 2022 and was last updated on 26 January 2022 (registration number INPLASY202210122).

INTRODUCTION

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METHODS

Participant or population: The patient is diagnosed as perimenopausal depression, regardless of age or race. The diagnostic criteria for depression conform to the third edition of the Chinese Classification and Diagnostic Criteria for Mental Disorders (CCMD-3), DSM-5 (Diagnostic and Statistical Manual of Mental Disorders), and Perimenopausal diagnosis "Diagnostic Criteria for Gynecological Diseases".

Intervention: The experimental group was treated with a combination of acupuncture and Chinese herbal medicine.

Comparator: The control group was treated with antidepressant drugs or Chinese herbal medicine.

Study designs to be included: Randomized Controlled Trial (RCT), whether blinded or not.

Eligibility criteria: The PICOS (participant, intervention, comparison, and study

design) principle has been applied in the study design.

Information sources: Three major Chinese databases of CNKI, Wanfang, and Weipu, and three foreign databases of PubMed, Web of Science, and The Cochrane library were searched by keywords such as climacteric, perimenopause, depression, depressive symtoms, emotional depres, Chinese herbal medicine, Traditional Chinese Medicine, needle, electrostimulate, scalp acupuncture and acupuncture. The search time is from the establishment of the database to April 14, 2021.

Main outcome(s): Clinical effective rate; HAMD score (Hamilton Depression Scale); Kupperman index; estradiol content; SDS score.

Quality assessment / Risk of bias analysis: The six items of the risk of bias assessment tool recommended by Cochrane Handbook 5.2.3 were used to evaluate the included studies, and the RevMan 5.4 software was used to generate a risk of bias map. The content includes the generation of random sequence, allocation hiding, implementation of blinding method (subjects and implementers blinding and research results blinding), data integrity, selective publication and other biases, all of which can be classified as "low risk", There are 3 levels of "unclear" and "high risk". Cross-check the above results and discuss and resolve if there are differences.

Strategy of data synthesis: RevMan 5.4 software was used to analyze the data and Meta-analysis. For dichotomous data, use OR (odds ratio), RR (risk ratio) and 95% CI (confidence interval) as the statistical effect size. For Continuous data, use MD (mean difference) or SMD (standardized mean difference) and 95% CI as the statistical effect size.

Subgroup analysis: When the control group used different treatment methods, subgroup analysis was used. Sensitivity analysis: Sensitivity analysis was performed to exclude tests with quality defects and to ensure the stability of analytical results based on sample size, study design, heterogeneity, methodological quality, and statistical models.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Acupuncture, Chinese herbal medicine, perimenopausal period, depression, Meta-analysis, A Systematic Review.

Contributions of each author:

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