INPLASY PROTOCOL

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Support: TCM S&TDPP of Shandong.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None.

The efficacy and safety of acupuncture for perimenopausal insomnia: a network meta-analysis protocol

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Review question / Objective: The efficacy and safety of acupuncture for perimenopausal insomnia.

Condition being studied: As a common symptom of perimenopausal period, perimenopausal insomnia brings great pain to many women and families. Acupuncture has been accepted by people as the incidence rate of this disease increases. The purpose of this study is to systematically compare the safety and efficacy of various acupuncture treatments for perimenopausal insomnia through network meta-analysis.

Information sources: We will search Web of Science, PubMed, The Cochrane Library, Embase, Chinese National Knowledge Infrastructure (CNKI), Wan Fang Date and VIP database. Meanwhile, conference papers and grey literature will be searched to get RCTs of acupuncture for perimenopausal insomnia. Relevant studies published before October 2020 will be included. If the information is incomplete, we will contact author by email or telephone.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 November 2020 and was last updated on 11 November 2020 (registration number INPLASY2020110047).

INTRODUCTION

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METHODS

Participant or population: Women who meet insomnia in perimenopause, and are clearly diagnosed as peimenopausal insomnia will be included without restrictions on race, nationality, education and economic incomes.

Intervention: All randomized controlled trials with acupuncture therapy (without restriction on form, acupoint selection, operation method, etc.) will be included.

Comparator: The control group with other treatment (sham acupuncture, placebo, drugs, etc.) will be included.

Study designs to be included: All relevant Randomized controlled trial (RCT) using acupuncture for perimenopausal insomnia will be included.

Eligibility criteria: According to a prepared date extraction form, two reviewers will independently search and screen date including studies' characteristics (title, authors, journal, publication time, method of randomization and blinding), participants' characteristics(age, duration of disease, diagnostic criteria and sample size), interventions and controls, outcomes. Any disagreement will be resolved through discussion with a third reviewer.

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Main outcome(s): Main outcome is sleep quality measured by the Pittsburgh Sleep Quality Index Scale (PSQI).

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk of bias of included studies according to The Cochrane Handbook for systematic Review of Interventions. Seven domains will be included, random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome date, selective outcome reporting and other bias. Each item will be judged as high, low and unclear.

Strategy of data synthesis: Revman5.3 will be used to evaluate the bias risk. Heterogeneity test depends on P and I2. Stata 15.0 and WinBUGS 1.4.3 software will be used to perform this network meta-analysis.

Subgroup analysis: If there is heterogeneity, a subgroup analysis would be conducted to analyze the source of heterogeneity.

Sensibility analysis: We will conduct sensitivity analysis of main outcomes to ensure reliability of conclusion, including risk of bias, missing state and methodological quality.

Country(ies) involved: China.

Keywords: acupuncture, network meta-analysis, perimenopausal insomnia, protocol.

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