INPLASY PROTOCOL

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Conflicts of interest: None declared.

Complementary and alternative therapies for perimenopausal insomnia

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Review question / Objective: The purpose of this study is to evaluate the effectiveness and acceptability of different CAM therapies, and to provide guidance for the rational selection of CAM therapy in the treatment of perimenopausal syndrome insomnia. CAM therapy in the treatment of perimenopausal syndrome insomnia.

Condition being studied: Perimenopausal syndrome insomnia. Information sources: PubMed, Cochrane Library, EMbase, China Knowledge Infrastructure, China Biomedical, China Scientific Journal Database and Wanfang database

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 September 2021 and was last updated on 19 September 2021 (registration number INPLASY202190061).

INTRODUCTION

Review question / Objective: The purpose of this study is to evaluate the effectiveness and acceptability of different CAM therapies, and to provide guidance for the rational selection of CAM therapy in the treatment of perimenopausal syndrome insomnia. CAM therapy in the treatment of perimenopausal syndrome insomnia. **Condition being studied:** Perimenopausal syndrome insomnia.

METHODS

Participant or population: Patients with perimenopausal insomnia.

Intervention: Complementary and alternative therapies.

Comparator: No treatment, sham/placebo or other conventional treatments.

Study designs to be included: RCT.

Eligibility criteria: The inclusion and exclusion criteria of this study are based on participant (P), intervention (I), comparator (C), outcome (O), and study design (S).

Information sources: PubMed, Cochrane Library, EMbase, China Knowledge Infrastructure, China Biomedical, China Scientific Journal Database and Wanfang database.

Main outcome(s): The PSQI is a self-rated questionnaire used to measure general sleep quality. It comprises 19 self-rated items and five other-rated items.

Quality assessment / Risk of bias analysis:

The methodologic quality of systematic review reflects the risk of bias or validity in its process and results. Methodologic quality will be assessed based on the Cochrane Collaboration's tool (Cochrane Handbook 5.1.0). Two trained researchers (XJL and YY) will independently evaluate the risk of bias of the included studies. In case of dispute, submit to corresponding author SJ for arbitration. Cochrane bias risk assessment tool will be used to assess the risk of RCTs being included in NMA, including: random sequence generation; allocation concealment; blinding of the subjects and researchers; blinding of outcome assessment: incomplete outcome data; selective reporting; and other bias.

Strategy of data synthesis: The Cochrane risk-of-bias tool with items of random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other biases will be used to assess the quality of included RCTs. Otherwise, the Newcastle-Ottawa Scale, which includes consideration of patient selection, study comparability and outcome assessment will be used to evaluate the quality of nonrandomised studies. We need to select a suitable scale according to the types of studies included. Subgroup analysis: "acupuncture," "electroacupuncture," "moxibustion," "aerobic exercise," "Cupping therapy, scraping, " "foot bath," "Chinese herbal medicines," "traditional Chinese medicine bath, " "meditation," "Yoga," "cupping therapy," "acupoints Embedding thread, " "ear acupoint pressure," "mind-body therapy," "Music therapy," and "Yi Jin Jing exercises".

Sensitivity analysis: If necessary, the sensitivity analysis will be used to assess the effect of each study on the random effects model. The sensitivity of the general combined effect of all outcome indicators is analyzed by the exclusion method. That is, each study is excluded, and the remaining studies will be reanalyzed to identify the stability of the results. If there is no qualitative change in the combined effect showed in the results, the results are stable.

Country(ies) involved: China.

Keywords: Complementary and alternative therapies; perimenopausal insomnia.

Contributions of each author:

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