INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy and safety of Complementary and Alternative Medicine for the treatment of insomnia: A protocol for systematic review and meta analysis

Wang, Z[1]; Li, H[2]; Wang, Y[3].

Review question / Objective: **To explore the effectiveness and safety of Complementary and Alternative Medicine for the treatment of insomnia.**
Condition being studied: **Insomnia is a common clinical condition characterized by difficulty initiating or maintaining sleep, accompanied by symptoms such as irritability or fatigue during wakefulness. The prevalence of insomnia disorder is approximately 10% to 20%, with approximately 50% having a chronic course.Patients experiencing insomnia symptoms frequently self-treat their symptoms with sleep medications. However, there remains concern regarding the short- and long-term health impacts of sleep medications. In view of the health hazards of insomnia and the shortcomings of western medicine, Complementary and Alternative Medicine (CAM) should be considered in the management of insomnia. CAM for insomnia has made some progress, but high quality evidence-based medical evidence is still needed to provide guidance for clinical application.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 May 2021 and was last updated on 23 May 2021 (registration number INPLASY202150085).

INTRODUCTION

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METHODS

Participant or population: Adults with primary insomnia (as diagnosed by a clinician, or using any recognized diagnostic criteria) will be included.

Intervention: Conventional treatment drugs or placebos.

Comparator: Use complementary and alternative therapies, including exercise, acupuncture, moxibustion, herbal medicine, behavioral intervention, topical heat, dietary supplements, etc.

Study designs to be included: We will include randomized controlled trials (RCTs). Quasi-RCTs will also be included.

Eligibility criteria: In this review, only randomized controlled trials evaluating CAM for adults with insomnia (as diagnosed using any recognised diagnostic criteria) were eligible for inclusion, regardless of publication status or language.

Information sources: We will search the following sources without restrictions for date, language, or publication status: PubMed, Web of Science,Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Library, EMBASE and China National Knowledge Infrastructure.We will apply a combination of Medical Subject Heading (MeSH) and free-text terms incorporating database-specific controlled vocabularies and text words to implement search strategies. We will also search the ongoing trials registered in the World Health Organization's International Clinical Trials Registry Platform. Besides, the previous relevant reviews conducted on CAM for insomnia and reference lists of included studies will also be searched.

Main outcome(s): Changes in the Pittsburgh Sleep Quality Index (PSQI) total score.

Additional outcome(s): Total effective rate (assessed by PSQI), Sleep disorders scale (SDRS), difficulty falling asleep score, change in number of awakenings, change in actual sleep time, and adverse reactions.

Quality assessment / Risk of bias analysis: The methodological quality of eligible studies will be assessed by two review authors independently according to the the Cochrane Handbook for Systematic Reviews of Interventions. The following characteristics will be assessed: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), other bias. Based on the assessments of the studies against these seven domains, they will be classified as being of "low risk", "high risk" or "unclear risk" of bias. Any disagreements will be resolved by discussion or discussed with another reviewer if necessary.

Strategy of data synthesis: Meta-analysis was conducted using Review Manager software (version 5.3). Odds ratio (OR) with 95% confidence intervals (CI) was reported for the dichotomous data, and mean differences (MD) with 95% CI for the continuous data. Statistical heterogeneity between studies was tested by calculating Higgins I^2 values or using the χ^2 test. $I^2 > 25\%$, $I^2 > 50\ \%$, and $I^2 > 75\ \%$ were respectively defined to indicate moderate, substantial, and considerable heterogeneity. When the P-value of χ^2 test was < 0.1, an I^2 test was carried out. If the

I^2 test showed a value > 50 %, a random effects model was carried out. Otherwise, a fixed effects model was carried out. A Pvalue lower than 0.05 was considered to be statistically significant.

Subgroup analysis: If results of the meta analysis are significantly heterogeneous, subgroup analyses of the control groups might be performed.

Sensitivity analysis: If sufficient trials are identified, we plan to conduct a sensitivity analysis comparing the results using all trials with high methodological quality: studies classified as having a 'low risk of bias' versus those identified as having a 'high risk of bias'.

Language: No restriction.

Country(ies) involved: China.

Keywords: Complementary and Alternative Medicine; insomnia; Protocol; Systematic review.

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