INPLASY

Comparative Effectiveness of Traditional Chinese Medicine Treatment Strategies for Insomnia: A Systematic Review and Network Meta-analysis

INPLASY202680041
doi: 10.37766/inplasy2026.8.0041
Received: 10 August 2026
Published: 10 August 2026

Liu, W; Wang, X; Zhang, Y; Li, Y; Huang, Y.

Corresponding author:
Yini Huang

katrina_yinii@163.com

Author Affiliation:
Changsha Hospital of Traditional Chinese Medicine Hospital.

ADMINISTRATIVE INFORMATION

Support - No support.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202680041

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 August 2026 and was last updated on 10 August 2026.

INTRODUCTION

Review question / Objective This systematic review and network meta-analysis aimed to evaluate and compare the comparative effectiveness and safety of different Traditional Chinese Medicine (TCM)-based treatment strategies for insomnia.

Population (P):
Adults with insomnia symptoms or insomnia disorders diagnosed according to recognized diagnostic criteria, including DSM, ICSD, ICD, or validated Chinese diagnostic criteria. Studies involving primary insomnia, chronic insomnia, and secondary or comorbid insomnia populations were eligible when insomnia was the primary treatment target and standardized sleep-related outcomes were reported.

Intervention (I):
TCM-based interventions, including Chinese herbal medicines, decoctions, granules, capsules, or other clinically applied TCM formulations, used alone or combined with conventional therapies.

Comparator (C):
Comparators included Western medicine, placebo, cognitive behavioral therapy for insomnia (CBT-I), or other eligible treatment strategies.

Outcomes (O):
The primary outcomes were insomnia severity and sleep quality measured by validated instruments, including the Insomnia Severity Index (ISI) and Pittsburgh Sleep Quality Index (PSQI). Secondary outcomes included clinical efficacy response and adverse events (AEs). Treatment effects were assessed using comparative effect estimates with corresponding confidence intervals, and treatment rankings were summarized using SUCRA values.

Study design (S):
Randomized controlled trials (RCTs) evaluating TCM-based interventions for insomnia were included.

The objective of this review was to integrate direct and indirect evidence using network meta-analysis to compare the relative efficacy and safety of different TCM treatment strategies and provide evidence to support clinical decision-making for insomnia management.

Condition being studied Insomnia is a common sleep disorder characterized by persistent difficulties in initiating sleep, maintaining sleep, or experiencing restorative sleep, accompanied by significant daytime impairment, including fatigue, reduced cognitive performance, mood disturbances, and impaired quality of life. Insomnia may occur as an independent disorder or coexist with other medical, neurological, psychiatric, or psychological conditions.

Chronic insomnia represents a substantial public health burden due to its high prevalence and association with increased risks of depression, anxiety, cardiovascular disease, impaired functioning, and reduced overall well-being. Current evidence-based management strategies primarily include cognitive behavioral therapy for insomnia (CBT-I) and pharmacological treatments. Although effective, pharmacological therapies may be limited by adverse effects, tolerance, dependence, and suitability concerns, particularly for long-term use.

Traditional Chinese Medicine (TCM), including Chinese herbal medicines, decoctions, granules, and patent herbal formulations, has been widely used for the management of insomnia. TCM approaches are based on individualized treatment principles and have been investigated as potential complementary or alternative therapeutic options. Previous clinical studies and systematic reviews have suggested that TCM-based interventions may improve sleep quality and insomnia severity; however, the comparative effectiveness and safety of different TCM treatment strategies remain uncertain due to variations in interventions, comparators, and outcome assessments.

This systematic review and network meta-analysis focuses on insomnia as the health condition of interest and evaluates randomized controlled trials investigating TCM-based interventions for insomnia symptoms or insomnia disorders. Both primary insomnia and clinically relevant secondary or comorbid insomnia populations are considered when insomnia represents the primary treatment target and standardized sleep-related outcomes are reported.

METHODS

Participant or population Adults (≥18 years) with insomnia symptoms or insomnia disorders will be included in this review. Eligible participants will be diagnosed according to recognized diagnostic criteria, including the Diagnostic and Statistical Manual of Mental Disorders (DSM), International Classification of Sleep Disorders (ICSD), International Classification of Diseases (ICD), or validated Chinese diagnostic criteria (e.g., CCMD).

The review will include participants with primary insomnia, chronic insomnia, or clinically relevant secondary/comorbid insomnia (such as post-stroke insomnia, anxiety-associated insomnia, cancer-related insomnia, or sleep disturbance associated with other medical conditions), provided that insomnia is the primary treatment target and standardized sleep-related outcomes are evaluated.

Studies involving participants with insomnia symptoms of any duration, severity, or clinical subtype will be considered eligible. No restrictions will be applied regarding sex, ethnicity, or geographic location.

Studies involving pediatric populations, healthy participants without insomnia symptoms, or participants in whom insomnia is not the primary condition of interest will be excluded.

Intervention The interventions of interest are Traditional Chinese Medicine (TCM)-based treatment strategies for insomnia. These include Chinese herbal medicines, herbal decoctions, granules, capsules, patent medicines, and other clinically applied TCM formulations administered either alone or in combination with conventional treatments.

Eligible TCM interventions include:

TCM alone: Chinese herbal formulations used as monotherapy for insomnia.
TCM combined with Western medicine (WM): TCM interventions used as an adjunct to conventional pharmacological treatments.
Other TCM-based strategies will be considered eligible if they involve standardized herbal formulations and are evaluated in randomized controlled trials.

Because individual TCM formulas may differ substantially in composition, theoretical basis, and clinical indications, interventions will be categorized into broader treatment strategy nodes

(e.g., TCM alone and TCM plus WM) for network meta-analysis rather than assuming direct interchangeability among individual formulas.

Studies involving TCM combined with non-pharmacological interventions (such as exercise, nutritional interventions, or other complementary therapies) will be excluded unless the effect of the TCM component can be independently evaluated. The minimum intervention duration will be set at 4 weeks.

Comparator The comparative interventions of interest include any eligible treatments used as control conditions in randomized controlled trials evaluating TCM-based interventions for insomnia. Comparators will include:

Western medicine (WM): conventional pharmacological treatments for insomnia, including hypnotic agents or other medications commonly used in clinical practice.
Placebo: inert placebo preparations designed to mimic the appearance and administration of the active intervention.
Cognitive behavioral therapy for insomnia (CBT-I): structured psychological interventions targeting insomnia-related behaviors and cognition.
No treatment or usual care: standard clinical management without specific TCM intervention, when applicable.

Trials comparing different TCM-based strategies will also be considered eligible when an appropriate non-TCM comparator is available for network construction. Comparators will be categorized into predefined treatment nodes to facilitate direct and indirect comparisons using network meta-analysis. The classification will focus on broader treatment strategies rather than individual formulations because of the substantial heterogeneity among specific TCM prescriptions.

Study designs to be included This systematic review and network meta-analysis will include randomized controlled trials (RCTs) evaluating Traditional Chinese Medicine (TCM)-based interventions for insomnia. Eligible study designs include parallel-group RCTs and multi-arm RCTs in which participants are randomly allocated to different treatment strategies.Studies must provide sufficient data on at least one predefined outcome, including insomnia severity, sleep quality, clinical response, or adverse events. Non-randomized studies, observational studies, case reports, case series, animal studies, laboratory studies, review.

Eligibility criteria This systematic review and network meta-analysis will include randomized controlled trials (RCTs) evaluating Traditional Chinese Medicine (TCM)-based interventions for insomnia. Eligible RCTs may include parallel-group, multi-arm, or cluster randomized designs, provided that participants are randomly allocated to different treatment strategies and relevant sleep-related outcomes are reported.

Non-randomized studies, observational studies, case reports, case series, reviews, conference abstracts without sufficient data, and animal or laboratory studies will be excluded. Only studies with available full-text publications will be considered.

Information sources The following electronic databases will be searched to identify eligible studies: PubMed/MEDLINE, Embase, Web of Science, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL), EBSCOhost, China National Knowledge Infrastructure (CNKI), Wanfang Database, VIP Database, and SinoMed.

Additional studies will be identified through manual screening of reference lists of relevant systematic reviews and included studies. Clinical trial registries, including ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP), will be searched when appropriate to identify ongoing or unpublished trials. Grey literature sources, conference proceedings, and dissertations will also be considered if sufficient methodological and outcome data are available.

No restrictions will be applied based on publication status. Studies published in English or Chinese will be eligible. The final search will be updated before completion of the review to identify newly published evidence. Two independent reviewers will conduct the literature search and study selection, with disagreements resolved through discussion or consultation with a third reviewer.

Main outcome(s) The primary outcomes are insomnia severity and sleep quality after treatment, assessed using validated sleep-related instruments, including the Insomnia Severity Index (ISI) and Pittsburgh Sleep Quality Index (PSQI). The effect estimates will be expressed as mean differences (MDs) or standardized mean differences (SMDs) with 95% confidence intervals (CIs), depending on the measurement scales used across studies.

Secondary outcomes include clinical response/ efficacy rates and adverse events (AEs). Clinical

efficacy will be assessed according to the response criteria reported in the original studies and summarized using risk ratios (RRs) or odds ratios (ORs) with 95% CIs. Safety outcomes will include the incidence of adverse events, analyzed using comparative effect estimates with 95% CIs.

Outcomes reported at the end of the intervention period will be included. When multiple assessment time points are available, the post-treatment endpoint will be prioritized for the primary analysis. Treatment rankings will be summarized using SUCRA values, which will be interpreted together with comparative effect estimates and uncertainty intervals.

Quality assessment / Risk of bias analysis The methodological quality and risk of bias of the included randomized controlled trials will be independently assessed by two reviewers using the Cochrane Risk of Bias tool. The assessment will include the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other potential sources of bias.

Each domain will be categorized as low risk, high risk, or unclear risk of bias according to the information provided in the original publications. Any disagreements between reviewers will be resolved through discussion or consultation with a third reviewer.

The overall risk of bias assessment will be summarized using risk-of-bias graphs and tables. The impact of study quality on the robustness of the findings will be explored through sensitivity analyses where appropriate.

Strategy of data synthesis Data synthesis will be performed using both pairwise meta-analysis and network meta-analysis (NMA) methods. Continuous outcomes (e.g., PSQI and ISI scores) will be summarized as mean differences (MDs) or standardized mean differences (SMDs) with 95% confidence intervals (CIs), while dichotomous outcomes (e.g., clinical response rates and adverse events) will be analyzed using risk ratios (RRs) or odds ratios (ORs) with 95% CIs.

A random-effects model will be applied considering the expected clinical and methodological heterogeneity among studies. Network meta-analysis will be conducted to integrate direct and indirect evidence and compare the relative effectiveness and safety of different treatment strategies. Network geometry will be presented using network plots, and treatment rankings will be estimated using the surface under the cumulative ranking curve (SUCRA) values. SUCRA results will be interpreted together with comparative effect estimates and uncertainty intervals.

Statistical heterogeneity will be assessed using the I^2 statistic and τ^2. Network inconsistency will be evaluated using global inconsistency tests and local approaches, including node-splitting analyses. Sensitivity analyses will be performed by excluding studies with high risk of bias and by removing clinically heterogeneous populations where appropriate. Publication bias will be assessed using comparison-adjusted funnel plots and statistical tests when sufficient studies are available.

All analyses will be conducted using appropriate statistical software for meta-analysis and network meta-analysis.

Subgroup analysis Subgroup analyses will be performed to explore potential sources of clinical and methodological heterogeneity when sufficient studies are available. Planned subgroup analyses will include:

Type of insomnia: primary insomnia/chronic insomnia versus secondary or comorbid insomnia (e.g., post-stroke insomnia, cancer-related insomnia, anxiety-associated insomnia).
Type of intervention: TCM alone versus TCM combined with Western medicine.
Comparator type: Western medicine, placebo, CBT-I, or other control conditions.
Treatment duration: shorter-term interventions versus longer-term interventions based on the distribution of included studies.
Risk of bias: studies with low/unclear risk of bias versus studies with high risk of bias.

Sensitivity analyses will also be conducted by excluding studies with high risk of bias or clinically heterogeneous populations to evaluate the robustness of the findings. Subgroup results will be interpreted cautiously because the number of studies within each subgroup may limit statistical power.

Sensitivity analysis Sensitivity analyses will be conducted to assess the robustness and stability of the network meta-analysis findings. The primary sensitivity analysis will exclude studies involving secondary or comorbid insomnia populations, including post-stroke insomnia, cancer-related

insomnia, anxiety-associated insomnia, and sleep disturbance associated with methadone maintenance, thereby restricting the analysis to studies of primary or chronic insomnia.

Additional sensitivity analyses will be performed, where sufficient data are available, by excluding studies judged to have a high risk of bias, studies with small sample sizes, and studies with markedly different diagnostic criteria or treatment protocols.

We will also examine the influence of individual studies using a leave-one-out approach, in which each study is sequentially removed and the network estimates are recalculated. Changes in effect estimates, 95% confidence intervals, heterogeneity, inconsistency, and SUCRA rankings will be examined.

If the direction and magnitude of the treatment effects remain broadly consistent across these analyses, the findings will be considered robust. Any substantial changes following study exclusion will be reported and discussed as potential sources of uncertainty.

Country(ies) involved China.

Keywords Insomnia; Traditional Chinese Medicine; Chinese herbal medicine; Network meta-analysis; Systematic review; Sleep quality; Insomnia Severity Index; Pittsburgh Sleep Quality Index;.

Contributions of each author
Author 1 - Yan Liu.
Author 2 - Xiuying Wang.
Author 3 - Yaqin Zhang.
Author 4 - Yanfang Li.
Author 5 - Yini Huang.