INPLASY

Banxiashumi Decoction for the treatment of insomnia: a systematic review and meta-analysis

INPLASY202590059

doi: 10.37766/inplasy2025.9.0059

Received: 15 September 2025

Published: 15 September 2025

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ADMINISTRATIVE INFORMATION

Support - This study was funded by the Science and Technology Plan Project of the Jiangxi Provincial Administration of Traditional Chinese Medicine in the People's Republic of China (2021B174).

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202590059

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 September 2025 and was last updated on 15 September 2025.

INTRODUCTION

Review question / Objective The efficacy of Banxia Shumi decoction (BSD) and its combination with Chinese medicine (acupuncture, formula, etc.) and Western medicine in treating insomnia remains a controversial issue, with different research conclusions. This article describes a systematic review and meta-analysis investigating its impact on insomnia.

We conducted a comprehensive search of databases such as PubMed, Embase, Web of Science, and CNKI. Independently screened and extracted data from studies met the criteria for insomnia population, intervention, comparison, and outcome. Fixed- or random-effects models were used to calculate the standardized mean difference of the 95% confidence interval (CI). Publication bias and research quality were evaluated to ensurereliability.

Condition being studied Insomnia refers to one or more symptoms of difficulty falling asleep, early awakening, shallow sleep, and low-to-moderate sleep quality that occur repeatedly under sufficient sleep opportunities. It is a common sleep disorder that causes rhythm disorder and has been recognized as an independent disease in the 11th edition of the International Classification of Diseases (ICD-11). According to a research by the World Health Organization (WHO), approximately 20–35% of the global population suffers from sleep disorders. The 2024 World Sleep Report states that the number of people suffering from insomnia worldwide will exceed 2 billion. Long-term insomnia not only seriously affects personal health and reduces quality of life but can also lead to negative emotions such as anxiety and depression, exacerbating insomnia symptoms and forming a vicious cycle. Patients who do not receive effective intervention in a timely manner may experience long-term sleep disorders, daytime fatigue and weakness, decreased cardiovascular function, lack

of concentration, anxiety, irritability, and other functional disorders that seriously affect their physical and mental health and quality of life. It has gradually become a public issue related to national health, work efficiency, family happiness, and social harmony and has received social attention.
From the perspective of Western medicine, insomnia is mainly related to factors such as age differences, changes in the environment and physiological functions, personal behavior and social psychology, neurological and mental illnesses, medication, and food. The currently internationally recognized conventional treatments for insomnia include cognitive-behavioral therapy and Western medicine, but due to poor accessibility and side effects, these two therapies cannot meet the treatment needs of all patients. Currently, the most commonly used sedative hypnotic drugs for treating insomnia include barbiturates and benzodiazepines. New sedative hypnotic drugs mainly include non-benzodiazepines, melatonin receptor agonists, antihistamines, and appetite peptide receptor antagonists. These drugs have a fast onset, significant therapeutic effect, and few "sleeping effects"; however, they have significant adverse reactions, and long-term use can easily cause drug dependence.

METHODS

Participant or population The computer system searched the China National Knowledge Infrastructure, Wanfang Database, VIP Journal Network, PubMed, Embase, Web of Science, etc. The retrieval period was from the establishment of the database to June 2025. The Chinese search keywords include "Banxia Shumi Tang," "Integrated Traditional Chinese and Western Medicine," "Insomnia Disorders,"and "Insomnia." English search keywords included Banxia Shumi Decoction, insomnia, BSD, integrated Chinese and Western medicine, trial, and other related key terms. The search strategy applied to CNKI is presented in Table 1. The titles and contents of the included studies were checked manually to provide an objective summary evaluation and ensure that no relevant literature was omitted. Combining systematic and intensive strategies ensures comprehensiveness and broad literature coverage, thereby providing a robust base for evidence generation.

Intervention This article conducts a meta-analysis on the efficacy of modified BSD (Banxia Shumi decoction)and its combination with other Chinese medicine and Western medicine drugs in treating insomnia to provide a reference for clinical treatment.

Comparator Comparisons between BSD(Banxia Shumi decoction), BSD(Banxia Shumi decoction) +TCM(traditional Chinese medicine), and BSD(Banxia Shumi decoction)+WM(Western medicine). Multiple validated scales were analyzed (PSQI, ISI, AIS, CEF).

Study designs to be included The manuscript presents a systematic review and meta-analysis assessing the efficacy and safety of Banxia Shumi Decoction (BSD), alone or combined with traditional Chinese medicine (TCM) or Western medicine (WM), in the treatment of insomnia. Included 16 studies from multiple databases and reported improvements in clinical effectiveness rate (CEF), PSQI, ISI, and AIS scores, with subgroup analyses suggesting higher efficacy for BSD+WM.

Eligibility criteria Inclusion criteria. The analysis followed strict inclusion criteria that were applied only to randomized controlled trials (RCTs) in English or Chinese literature, regardless of the publication journal. RCTs that meet the criteria for inclusion in the literature must involve interventions using BSD alone or in combination with other drugs. If the study aims to test combination therapy, the control group can include traditional Chinese medicine, Western medicine, or placebo treatment. These studies must evaluate efficacy based on predetermined outcomes, such as symptom improvement rate or reduction in insomnia severity, where ineffectiveness is defined as <30% or one-third of the comprehensive feature score.
Exclusion criteria. Other studies were excluded. Articles with imprecise research methods that did not meet the required level for inclusion in the systematic evaluation were excluded. Non-RCTs, duplicate publications, and publications with insufficient methodological quality were not considered. Animal studies, case reports, and review articles were excluded to maintain attention to clinical trials. Comparative studies without control groups were also excluded. The inclusion of other treatment interventions besides BSD was the basis for excluding trials. Articles that do not define ineffectiveness as a reduction of at least 30% or 1/3 of the comprehensive characteristics score and do not provide extractable outcome indicators (including incidence rate or clinical efficacy) will also be excluded.

Information sources The computer system searched the China National Knowledge

Infrastructure, Wanfang Database, VIP Journal Network, PubMed, Embase, Web of Science, etc.

Main outcome(s) A retrieval approach was used to extract data from 517 references. There were 157 relevant studies in CNKI, 129 in the Wanfang Database, 116 in VIP, 53 in PubMed, 45 in Embase, and 17 in the Web of Science. After removing duplicate records, 219 references were screened by reading the title and abstract and were further included or excluded based on the criteria stated above, leaving 21 full-text articles to be assessed for eligibility, of which 5 were excluded, and 16 were finally included.

Quality assessment / Risk of bias analysis Two experienced researchers in this field conducted literature screening, data extraction, and quality assessment of the included studies and used bias risk assessment to conduct bias analysis on the included literature independently. When there were differences, a third reviewer was consulted to reach a consensus. The extracted data included the study design, patient population, inclusion/exclusion criteria, intervention protocol, control treatment, and measurement results, with a particular focus on insomnia resolution scale scores.

Strategy of data synthesis Revman 5.4 software was utilized for the statistical analysis. The relative risk of the binary variables was 95% confidence interval (CI), and the mean standard deviation (MD) of the continuous variables was 95%. Cochran Q and I statistical tests were used to evaluate statistical heterogeneity. I2 test was performed in each study to evaluate the heterogeneity between the included studies. When I20.05, it was considered that the heterogeneity between studies was small, and a fixed-effects model was used for analysis; I2>50% indicated significant heterogeneity between studies, and a random-effects model was used for heterogeneity analysis followed by meta-analysis.[13] If there is significant heterogeneity that makes meta-analysis impossible, descriptive analysis should be conducted. Subgroup analysis was conducted to determine if significant heterogeneity was detected and if there were statistically significant differences in the characteristics of the study population. If the source of heterogeneity could not be explained, descriptive analysis was performed.
A thorough assessment of publication bias was performed using funnel plot asymmetry analysis and Egger regression test, considering potential biases in research selection and reporting and providing corresponding explanations for the relevant reasons in the meta-analysis process.

Subgroup analysis Among the 16 articles that met the inclusion criteria, 7 studies used BSD as the intervention measure, 5 studies used BSD+TCM as the intervention measure, and 5 studies used BSD+WM. Subgroup analysis of clinical efficacy indicators for BSD treatment of insomnia showed no significant heterogeneity between studies ($p < 0.0001$, $I2 = 0\%$), and a fixed-effects model was used. The difference between the two groups was statistically significant (MDBSD+WM = 1.19, 95% CI [1.09, 1.30], $p < 0.0001$). The clinical efficacy of BSD+WM was more significant than that of BSD and BSD+TCM.

Sensitivity analysis After further analysis to determine the cause of heterogeneity, one study [14] was excluded, which mainly targeted patients with insomnia and depressive disorders. The research results had significant statistical significance, and the conclusions obtained were consistent with the original analysis results (MD = –2.13, 95% CI [–2.70, –1.55], $p < 0.0001$) .
If other accompanying insomnia conditions are excluded, only the primary insomnia will be studied. The research results have a more significant statistical significance, and the conclusions obtained are different from the original analysis. Compared with using BSD+WM, the effects of BSD and BSD+TCM have become more pronounced (MD= – 6.28, 95% CI – 6.46 to – 6.09, $p < 0.0001$) . This indicates that the combination of traditional Chinese and Western medicine has a good therapeutic effect on insomnia symptoms such as phlegm heat internal disturbance, depression with insomnia, etc. For primary insomnia, BSD and BSD+TCM have significant effects.

Country(ies) involved China.

Keywords Banxiashumi decoction, insomnia, curative effect, meta-analysis, systematicreview.

Contributions of each author
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