META-ANALYSIS

The Efficacy of Tiaoshen Acupuncture in Traditional Chinese Medicine for Insomnia Treatment: A Systematic Review and Meta-analysis

Weijun Luo, MM; Zhulin Wu, MD; Siyi Li, MD; Weiqing Zhang, MM; Mingbo Lai, MM; Zihao Lin, MD; Shuying Chen, MM; Zhuoxin Yang, PhD

ABSTRACT

Background • In recent years, Tiaoshen acupuncture in Traditional Chinese Medicine (TCM) has been employed for treating patients with insomnia, but the clinical efficacy remains to be substantiated.

Objective • To assess the efficacy and safety of acupuncture in treating insomnia using the Tiaoshen method in TCM.

Design • A systematic review and meta-analysis was conducted.

Setting • The research was conducted in Shenzhen.

Methods • Electronic databases, including Chinese National Knowledge Infrastructure (CNKI), Wanfang, SinoMed, Weipu, PubMed, Web of Science, EMBASE, and Cochrane databases, were retrieved up to September 15, 2023. Randomized controlled trials (RCTs) meeting inclusion criteria were screened. Quality assessment of included articles was performed using the Cochrane Risk of Bias tool. Valid data were then extracted and analyzed via meta-analysis using Review Manager 5.3. The study was registered in the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY), 2023100051.

Results • A total of 13 articles were included, comprising 849 patients with insomnia (diagnosed as chronic insomnia or primary insomnia). Meta-analysis results indicated that acupuncture with the Tiaoshen method could decrease the Pittsburgh Sleep Quality Index (PSQI) score [RR=-3.03, 95% CI (-3.73, -2.33), $P < .00001$], hyperarousal (HAS) scale score [RR=-7.75, 95% CI (-12.29, -3.22), $P < .0008$], and fatigue scale-14 (FS-14) score [RR=-2.11, 95% CI (-2.83, -1.38), $P < .00001$] compared with superficial acupuncture on non-effective acupoints or conventional acupuncture manipulation. Additionally, acupuncture with the Tiaoshen method demonstrated safety. However, the funnel plot suggested the presence of publication bias.

Conclusions • Acupuncture with the Tiaoshen method could enhance sleep quality and efficiency. Due to the low quality of some literature, further high-quality RCTs are needed to improve the level of evidence. (*Altern Ther Health Med.* 2024;30(12):132-138).

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INTRODUCTION

Insomnia is a prevalent condition, with approximately one-third of the general population exhibiting symptoms of insomnia,[1] indicating a chronic progression. The prevalence of chronic insomnia is estimated to be between 10% and 15%, while transient insomnia ranges from 25% to 35% in adults.[2,3] This high occurrence is attributed to the numerous stressors faced by adults in modern society, such as job-related stress, financial pressures, and relationship issues.[4] Prolonged insomnia can result in impaired daytime functioning, significantly impacting their quality of life.[5]

Sleep medication stands as the most commonly prescribed therapeutic agent in contemporary medicine. Owing to the chronic nature of insomnia, there is a growing reliance on sleeping pills for its treatment.[6] Prolonged use of these medications may lead to side effects such as dizziness, daytime drowsiness, gastrointestinal disturbances, difficulty maintaining balance, and a tendency to develop drug dependence.[7] Consequently, the timely, safe, and effective management of insomnia in patients and enhancing their quality of life hold significant importance in clinical practice.

Acupuncture involves needle puncture, a prominent therapeutic method in traditional Chinese medicine (TCM) for over 2500 years.[8] It holds notable advantages in treating insomnia, demonstrating significant efficacy, safety, and simplicity. Studies indicate that the overall effectiveness rate

of acupuncture, based on TCM pattern identification, surpasses that of medication.[9] However, the efficacy of acupuncture is significantly influenced by clinicians' styles, with the stimulation of different acupoints using specific manipulations resulting in distinct curative effects.

Acupuncture for regulating the "Shen" has a history spanning 2000 years, dating back to its first mention in the ancient Chinese book "Lingshu." This historical reference underscores the significance of the "Shen" in acupuncture treatment for insomnia. According to TCM theory, sleep is intricately connected to the "Shen," which is controlled by the "heart" and resides within the five Zang Viscera. Sleep ensues when the "Shen" is calm, whereas restlessness in the "Shen" disrupts sleep. The term "Tiaoshen" signifies regulating the Shen and conveys the idea of spiritual cultivation.

The theory of Tiaoshen is rooted in the control and coordination of the functions of the five Zang Viscera by Shen in TCM, along with the balance and regulation of emotional activities. Acupoints proposed by Tiaoshen acupuncture include Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), and Shenmen (HT7), among others. These acupoints, according to TCM theory, possess tranquilizing and heart-nourishing effects. In recent years, Tiaoshen acupuncture has been utilized in the treatment of insomnia, although its clinical efficacy still needs to be fully demonstrated.

Previous studies have presented conflicting findings regarding the use of Tiaoshen acupuncture in treating insomnia. Ma et al.[10] reported no noteworthy change in the Pittsburgh Sleep Quality Index (PSQI) score when comparing insomnia patients to controls after undergoing Tiaoshen acupuncture therapy. In contrast, a separate study[11] observed a substantial difference in the PSQI scores of insomnia patients who received Tiaoshen acupuncture compared to those in the control group.

Therefore, it is imperative to combine previous findings to establish a more reliable reference. Our study aims to explore further the impact of Tiaoshen acupuncture in treating insomnia by selecting relevant randomized controlled trials (RCTs). The focus was placed on utilizing meta-analysis to thoroughly assess the existing literature, specifically on the application of Tiaoshen acupuncture for patients experiencing insomnia.

DATA AND METHODS

Study Design

This study employed a precise research design, utilizing a systematic approach to investigate the efficacy of Tiaoshen acupuncture in treating insomnia. Only RCTs were selectively chosen; the emphasis was on examining the outcomes of Tiaoshen acupuncture interventions specifically tailored for patients with insomnia. The selected studies underwent thorough quality assessment using the Cochrane Risk of Bias tool. Valid data from these studies were then extracted and subjected to meta-analysis using Review Manager 5.3.

Inclusion Criteria

Type of Articles. The analysis exclusively considered RCTs. This study is duly registered in the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY) under registration number 2023100051. No ethical statement was considered necessary for this meta-analysis.

Participant Inclusion Criteria for Insomnia Studies. This meta-analysis included studies that focused on adult participants meeting diagnostic criteria for primary or chronic insomnia. The diagnostic methods covered various authoritative sources, including the Diagnostic and Statistical Manual of Mental Disorders,[12] the International Classification of Diseases,[13] the Chinese Classification and Diagnostic Criteria of Mental Disorders,[14] the Chinese Guideline for the Diagnosis and Treatment of Insomnia in Adults.[15]

Study Criteria and Treatment Protocols. The included studies centered on specific criteria. The treatment group underwent TCM Tiaoshen acupuncture, and studies were required to mention the utilization of Tiaoshen explicitly. In this investigation, the specified acupoints Encompassed Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), or Shenmen (HT7). Conversely, the control group received treatment involving superficial acupuncturing on non-effective acupoints or conventional acupuncture manipulation.

Study Focus and Observation Indicators. The included studies centered on specific criteria for observation. The designated indicators were as follows: (1) Main observation indicator: included articles were required to report the PSQI score as the primary outcome measure; (2) Other observation indicators: additional metrics considered were the hyperarousal (HAS) scale score, fatigue scale-14 (FS-14) score, and corticosterone (CORT) index; (3) Safety, including adverse events, was evaluated descriptively.

Exclusion Criteria

The following criteria guided the exclusion of participants from the study: (1) Secondary insomnia: patients with insomnia attributed to organic diseases were excluded; (2) Severe mental disorders: individuals with severe mental disorders, such as schizophrenia, depressive disorders, and anxiety disorders, were omitted; (3) Intervention measures: cases where other treatments were employed as intervention measures were excluded; (4) Sleeping pills: participants undergoing interventions involving sleeping pills were not considered; (5) Repetitive or plagiarized literature: duplicate or plagiarized articles, as well as those with incomplete data, were excluded; (6) Language limitations: articles not in Chinese or English were excluded; (7) Review and animal experimental articles: studies falling under the categories of reviews or animal experiments were excluded from consideration.

Search Strategy

A comprehensive computer search was conducted across English and Chinese databases to gather relevant literature. English databases included PubMed, Cochrane Library, Embase,

and Web of Science. Chinese databases encompassed the China Journal Full-text Database (CNKI), Wanfang Data, VIP Chinese Journal Full-text (VIP) Database, and China Biomedical Literature (CBM) Database. The search covered articles from the inception of the databases until September 15, 2023. The search terms employed were: "Sleep disorder OR insomnia," "Tiaoshen," and "randomized." This precise search strategy aimed to retrieve a robust selection of relevant articles for analysis.

Literature Screening and Quality Evaluation

Two authors independently carried out the selection of retrieved literature identified in the database search to minimize bias. The exclusion of irrelevant articles was determined through a thorough examination of titles and abstracts. Subsequently, the quality of the selected articles was carefully assessed, and the extracted study data was cross-compared. The methodological quality of RCTs was evaluated using the Cochrane Risk of Bias tool, comprising seven key items: random sequence generation, allocation concealment, participant and subject blinding, outcome assessment blinding, completeness of outcomes, outcome reporting bias, and other biases.[16]

The recorded quality of each study was categorized as "high risk," "unclear risk," or "low risk." Articles meeting all criteria were considered to have a low risk of bias, whereas those not meeting any criteria were considered to have a high risk of bias. Otherwise, articles were classified as having an unclear risk of bias. This process ensures a thorough evaluation of study quality, minimizing potential biases in the subsequent analysis.

Data Extraction

The authors devised a data extraction table to gather essential information from the literature, encompassing authors, publication year, case numbers, baseline characteristics, intervention methods, treatment duration, observation indicators, and adverse reactions to the interventions. The data were carefully organized using Excel 2010 software for systematic analysis.

Statistical Analysis

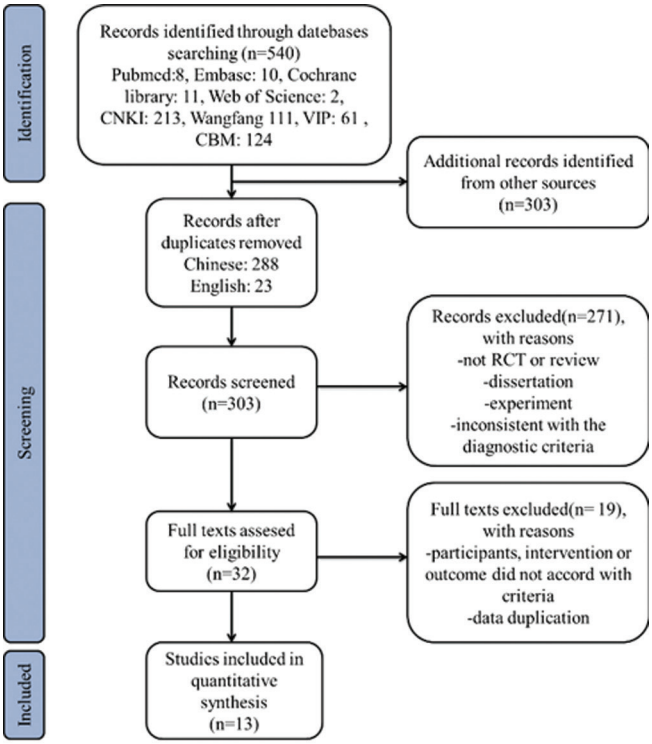
A meta-analysis was conducted to integrate the findings of the included articles using Review Manager 5.3. The Risk Ratio served as the effect size measure for dichotomous variables, while continuous variables utilized the mean difference (MD). This study exclusively dealt with continuous variables data, and the outcomes were computed with 95% confidence intervals (95% CIs). Additionally, the heterogeneity among articles was assessed through the I^2 test. If the I^2 value was below 50%, the fixed-effects model was employed for the analysis; for values exceeding 50%, either the random-effects model or descriptive analysis was conducted. The results of the meta-analysis were visually presented using a forest plot. $P < .05$ were considered significant, and a funnel plot was generated to analyze publication bias.

RESULTS

Literature Retrieval and Selection Process

A comprehensive search of the Chinese database yielded a total of 509 relevant articles, distributed as 213 from CNKI, 111 from Wanfang, 61 from VIP, and 124 from CBM. In the English databases, 8, 2, 10, and 11 articles were identified in PubMed, Web of Science, EMBASE, and the Cochrane Library, respectively. Adhering to the predetermined inclusion and exclusion criteria, 13 Chinese randomized controlled trials[10,11,17-27] were carefully chosen for further analysis.

Figure 1. Flow Chart Illustrating the Study Selection Process



Note: The flow chart depicts the systematic process of selecting studies for inclusion in the meta-analysis, highlighting the steps involved in screening and selecting relevant articles based on predetermined criteria.

Quality Assessment of Included Trials

Every trial incorporated in this study explicitly mentioned randomization. Among them, nine articles[10,11,17,19,21,22,24,26,27] described the specific method for random sequence generation, and all employed random number table methods. Additionally, five articles[11,19,21,26,27] provided details about specific allocation concealment methods utilizing the envelope method.

Three articles[10,19,23] explained the blinding procedures for participants, personnel, and outcome assessment. Moreover, nine articles[11,17-19,21-23,26,27] outlined their strategies for handling incomplete outcome data. The risk of selective reporting bias in ten articles[10,11,17-19,21-23,26,27] was considered very low. However, in cases where other articles did not explicitly describe relevant aspects, they were categorized as "unclear." The risk of bias is visually represented in the risk of bias graph and summary in Figure 2 and Figure 3.

Baseline Characteristics and Treatment Protocols

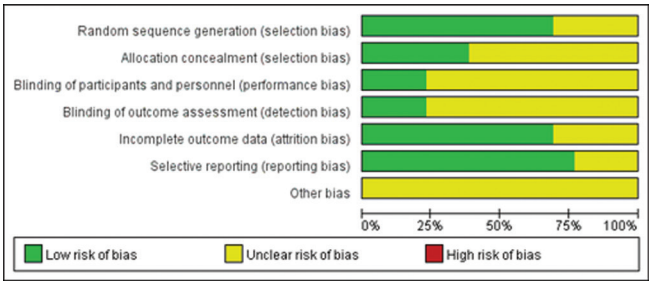
Except for one study[20] that did not provide information on baseline characteristics, the other included articles consistently reported no significant differences in baseline characteristics, including gender, age, and observation indicators, between the

Table 1. The Basic Characteristics of the Included Studies

Study (Year)	Sample (T/C)	Intervention (T/C)	Course	Indicators	Adverse Reactions
Huo et al. (2023)[26]	30/30	Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), Shenmen (HT7), Neiguan (PC6), Sanyinjiao (SP6) /Superficial Acupuncturing	4W	①③	NA
Gai et al. (2023)[25]	30/30	Shenting (GV24), Baihui (GV20), Sishenchong (EX-HN1), Shenmen (HT7), Shangwan (CV13), Zhongwan (CV12), Xiawan (CV10), Zusanli (ST36), Tianshu (ST25), Shenmai (BL62), Zhaohai (K16)/ Conventional Acupuncture	4W	①	NA
Ma et al. (2022)[10]	11/16	Sishencong (EX-HN1), Shenting (GV24), Baihui (GV20)/ Superficial Acupuncturing	6W	①	√
Chen et al. (2022)[17]	50/49	Baihui (GV20), Shenting (GV24), Shuigou (GV26), Waiguan (TE5), Hegu (L14), Yangfu (GB38), Taichong (LR3)/ Conventional Acupuncture	4W	①	NA
Xi et al. (2021)[11]	29/29	Baihui (GV20), Shenting (GV24), Yintang (GV29), Shenmen (HT7), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①②	√
Li et al. (2021)[21]	30/30	Baihui (GV20), Shenting (GV24), Yintang (GV29), Shenmen (HT7), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①④	√
Zhao et al. (2021)[23]	29/27	Baihui (GV20), Yintang (GV29), Shenmen (HT7), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①②④	NA
Xi et al. (2020)[27]	29/30	Baihui (GV20), Shenting (GV24), Yintang (GV29), Shenmen (HT7), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①④	√
Zhang et al. (2020)[24]	30/30	Sishencong (EX-HN1), Neiguan (PC6), Shenmen (HT7), Zhongwan (CV12), Xiawan (CV10)/ Conventional Acupuncture	20d	①	NA
Guo et al. (2019)[18]	56/56	Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), Shenmen (HT7), Neiguan (PC6), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①③	√
Yuan et al. (2019)[22]	42/40	Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), Shenmen (HT7), Neiguan (PC6), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①②	√
Li et al. (2017)[20]	30/27	Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), Shenmen (HT7), Neiguan (PC6), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①③	NA
Guo et al. (2017)[19]	30/30	Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), Neiguan (PC6), Sanyinjiao (SP6)/ Superficial Acupuncturing	4W	①②	NA

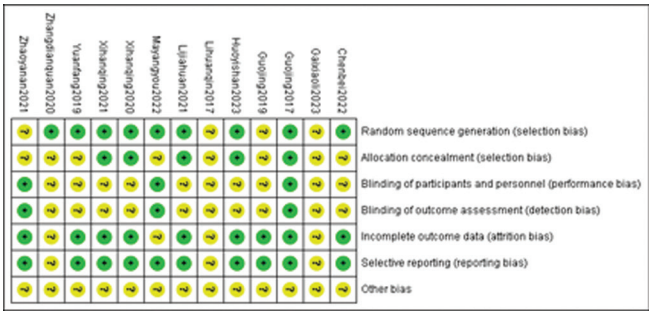
Abbreviations: T, Treatment; C, Control; Observation Indicators: ① PSQI (Pittsburgh Sleep Quality Index), ② HAS (Hyperarousal Scale), ③ FS-14 (Fatigue Scale-14), ④ CORT (Cortisol) Level. NA represents unavailable.

Figure 2. Graphical Representation of Risk of Bias in Included Studies



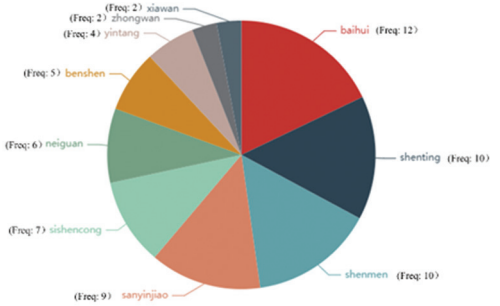
Note: The risk of bias graph visually presents the assessment of methodological quality across various criteria in the included studies, providing an overview of potential biases and their distribution.

Figure 3. Summary of Risk of Bias in Included Studies



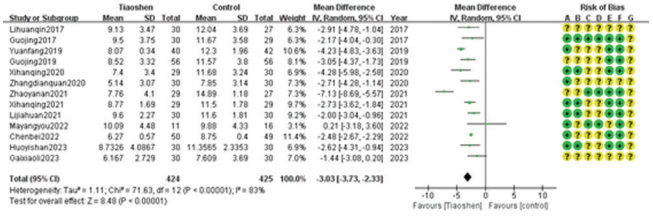
Note: The risk of bias summary provides a comprehensive overview of the methodological quality of the included studies, detailing specific criteria assessed. Types of bias considered include random sequence generation, allocation concealment, participant and subject blinding, outcome assessment blinding, completeness of outcomes, outcome reporting bias, and other potential sources of bias.

Figure 4. Distribution of Acupoints in the Included Studies



Note: The pie diagram illustrates the frequency and distribution of acupoints used in the selected studies, providing an overview of the commonly targeted acupuncture points in the treatment of insomnia using the Tiaoshen method.

Figure 5. Meta-analysis of PSQI Scale Scores



Note: The forest plot displays the results of the meta-analysis on PSQI scale scores. Each study's effect size is represented by a square, and the horizontal line through the square indicates the confidence interval. The diamond at the bottom signifies the overall effect size. The letters (A-G) correspond to specific components of the Cochrane risk of bias tool: A - Random Sequence Generation, B - Allocation Concealment, C - Participant and Subject Blinding, D - Outcome Assessment Blinding, E - Completeness of Outcomes, F - Outcome Reporting Bias, and G - Other Biases.

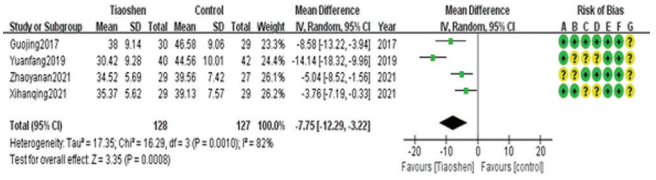
experimental group (receiving Tiaoshen acupuncture) and the control group. All patients in the experimental group underwent treatment with TCM Tiaoshen acupuncture. Conversely, the control group received conventional acupuncture manipulation or superficial acupuncturing on non-effective acupoints, including Shousanli (LI10), Binao (LI14), Jianyu (LI15), Futu (ST32), Feiyang (BL58), Yangchi (TE4), Fengshi (GB31), Waiguan (TE5), Liangqiu (ST34).

This study encompassed a total of 13 selected studies involving 849 patients with insomnia. The assessment included four observation indexes: PSQI score, HAS score, FS-14 score, CORT, and safety, refer to Table 1. The frequency distribution of acupoints is visually represented in the pie diagram presented in Figure 4.

Meta-analysis Results of Tiaoshen Acupuncture in Treating Insomnia

Tiaoshen Acupuncture's Impact on PSQI Scale Scores. The main indicator assessed in this meta-analysis was the PSQI scale score, with 13 articles[10,11,17-27] included. The heterogeneity test demonstrated an I^2 of 83% ($P < .00001$), indicating high heterogeneity. Consequently, the random-

Figure 6. Meta-analysis of HAS Scale Scores



Note: The forest plot illustrates the meta-analysis results concerning HAS scale scores. A square represents each study's effect size, and the horizontal line through the square indicates the confidence interval. The diamond at the bottom reflects the overall effect size. The letters (A-G) correspond to specific components of the Cochrane risk of bias tool: A - Random Sequence Generation, B - Allocation Concealment, C - Participant and Subject Blinding, D - Outcome Assessment Blinding, E - Completeness of Outcomes, F - Outcome Reporting Bias, and G - Other Biases.

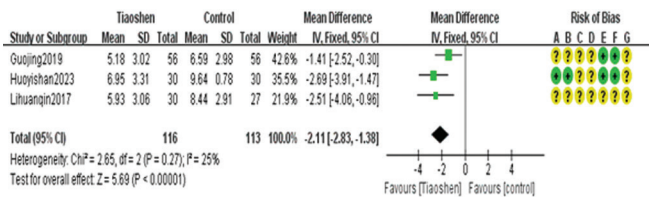
effect model was employed for the meta-analysis. The results, presented in the forest plot in Figure 5, illustrate that acupuncture utilizing the Tiaoshen method from TCM effectively reduces PSQI scale scores, signifying an enhancement in sleep quality (MD = -3.03; 95% CI = -4.31, -0.94; *P* for effect <.00001).

Reduced HAS Scale Scores with Tiaoshen Acupuncture. In this meta-analysis, we explored the reduction of the HAS score as an indicator of Tiaoshen Acupuncture efficacy. Four selected studies[11,19,22,23] were considered for evaluation. The heterogeneity test yielded an I^2 of 82% (*P* = .0010), indicating substantial heterogeneity. Consequently, the random-effect model was applied for the meta-analysis. The outcome of the meta-analysis revealed that the application of acupuncture with the Tiaoshen method exhibited a notable reduction in the HAS score (MD = -7.75; 95% CI = -12.29, -3.22; *P* for effect <.0008). This effect was notably superior to that observed in the control group, as illustrated in Figure 6.

Enhanced FS-14 Scale Score with Tiaoshen Acupuncture. We investigated the meta-analysis and concentrated on diminishing the score of the FS-14. Three relevant studies[18,20,26] provided insights into the FS-14 scale. The heterogeneity test indicated an I^2 of 25% (*P* = .27), signifying low heterogeneity. Consequently, the fixed-effect model was employed for the meta-analysis. The results revealed that the implementation of acupuncture with the Tiaoshen method exhibited a significant reduction in the FS-14 scale score (MD = -2.11; 95% CI = -2.83, -1.38; *P* for effect <.0001), as depicted in Figure 7.

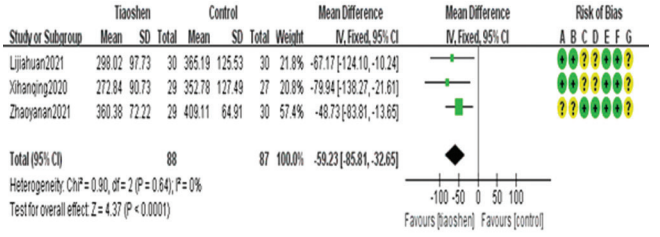
CORT Index Improvement with Tiaoshen Acupuncture. We also conducted a meta-analysis assessing the enhancement of the CORT Index. Three included studies[21,23,27] contributed information on the CORT index. The heterogeneity test revealed an I^2 of 0% (*P* = .64), indicating minimal heterogeneity. Consequently, the fixed-effect model was applied for the meta-analysis. The outcomes of the meta-analysis indicate that the application of acupuncture with the Tiaoshen method significantly decreased the score of the CORT index (MD = -59.23; 95% CI = -85.81, -32.65; *P* for effect < .0001), as illustrated in Figure 8.

Figure 7. Meta-analysis of FS-14 Scale Scores



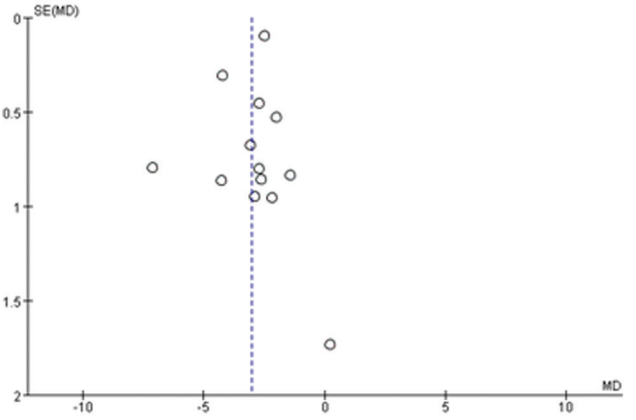
Note: The forest plot depicts the meta-analysis outcomes related to FS-14 scale scores. Each study's effect size is represented by a square, with the horizontal line through the square indicating the confidence interval. The diamond at the bottom reflects the overall effect size. The letters (A-G) correspond to specific components of the Cochrane risk of bias tool: A - Random Sequence Generation, B - Allocation Concealment, C - Participant and Subject Blinding, D - Outcome Assessment Blinding, E - Completeness of Outcomes, F - Outcome Reporting Bias, and G - Other Biases.

Figure 8. Meta-analysis of the CORT Index



Note: The forest plot presents the meta-analysis findings concerning the CORT index. Each study's effect size is denoted by a square, and the horizontal line through the square indicates the confidence interval. The diamond at the bottom illustrates the overall effect size. The letters (A-G) correspond to specific components of the Cochrane risk of bias tool: A - Random Sequence Generation, B - Allocation Concealment, C - Participant and Subject Blinding, D - Outcome Assessment Blinding, E - Completeness of Outcomes, F - Outcome Reporting Bias, and G - Other Biases.

Figure 9. Funnel Plot Analysis for PSQI Scale Score



Note: The funnel plot provides an assessment of publication bias regarding the PSQI scale score. Each point represents a study, and the distribution of points is examined for symmetry. Asymmetry may indicate the presence of small-study effects or publication bias.

Publication Bias Analysis and Safety Evaluation

We utilized a funnel plot for analysis to evaluate the PSQI scale score indicator across the 13 included studies.[10,11,17-27] Figure 9 illustrates a slightly asymmetrical distribution in the funnel plot, suggesting a potential publication bias or variability in study outcomes among the

analyzed studies. Furthermore, six studies[10,11,18,21,22,27] documented the adverse reactions associated with the interventions. No adverse reactions were observed in any of the patients, and mild reactions such as skin allergy, dizziness, and hematoma were reported in individual cases. One study reported the incidence of subcutaneous ecchymosis in both groups, showing no significant difference.

DISCUSSION

Insomnia refers to a subjective experience characterized by dissatisfaction with sleep duration or quality, impacting functioning despite suitable sleep opportunities and conditions [28]. Globally, the prevalence of insomnia is estimated to be around 30% to 35%, and a survey conducted in 2005 indicated that 45.4% of respondents in China reported suffering from insomnia to varying degrees.[29,30] While insomnia may spontaneously improve or disappear in the short term, it frequently evolves into chronic insomnia, highlighting its persistent nature.[31]

Insomnia is associated with an elevated risk of mental and medical disorders, including depression, hypertension, and cardiovascular diseases[32] Furthermore, it impacts the quality of life for affected individuals and contributes to an increased economic burden on society. While modern medicine offers various targets for treating insomnia, including the use of multiple drugs, prolonged or unregulated usage of sleeping pills can lead to adverse effects such as hangovers, drug resistance, or dependence.[33] It underscores the importance and necessity of further research in the treatment of insomnia.

Previous studies have highlighted the advantages of non-drug therapies for insomnia, including safety, significant therapeutic effects, and minimal adverse reactions, making non-drug therapy a prominent area of research.[34] Recent studies have demonstrated the efficacy and safety of TCM Tiaoshen acupuncture in alleviating insomnia symptoms.[11,22] This study comprehensively evaluated the clinical effectiveness and safety of TCM Tiaoshen acupuncture in treating insomnia, building upon its known advantages.

Our findings indicated that the methodological quality of the 13 studies included in this study was generally mediocre. Additionally, most studies lacked complete information, preventing further analysis of potential biases. This systematic review aimed to eliminate the interference of other intervention measures, ensuring the homogeneity of intervention methods for reliable results. The meta-analysis results demonstrated that acupuncture with the TCM Tiaoshen method could significantly reduce the scores of insomnia-related scales, such as PSQI, compared to conventional acupuncture manipulation or superficial acupuncturing non-effective acupoints. This finding suggests that TCM Tiaoshen acupuncture may contribute to the improvement of insomnia.

Among commonly used scales, the PSQI was developed to measure general sleep quality and is recommended for studying global insomnia. Additionally, some articles suggest that acupuncture with the Tiaoshen method is safe, but further research is required to explore its safety in the future. Concerning the primary observation indicator, the PSQI score, the funnel plot indicates a potential presence of small-study or publication bias. Furthermore, there was little change in the combined result and heterogeneity after systematically removing included studies one by one, indicating relatively strong stability in the meta-analysis results.

The high heterogeneity in certain outcome measures may stem from various factors. Inconsistencies in baseline data among the included studies and variations in the confounders adjusted for in each research contribute to this heterogeneity. Differences in the severity of insomnia among patients across studies also play a role. Additionally, variations in the acupoints used for Tiaoshen acupuncture contribute to heterogeneity. Currently, there is no standardized consensus on the sub-category of Tiaoshen acupuncture, preventing the implementation of subgroup analysis.

The meta-analysis results also indicated that TCM Tiaoshen acupuncture could decrease serum CORT index. This mechanism could be one of the ways by which TCM Tiaoshen acupuncture exerts its therapeutic effects on insomnia. As a significant stress hormone, CORT plays a crucial role in neuroendocrine regulation. Excessive CORT levels contribute to abnormal structural and functional connections in brain regions associated with mood regulation, potentially influencing insomnia symptoms.[35]

Additionally, our frequency analysis revealed that Sanyinjiao may play a significant role as an associated acupoint in Tiaoshen acupuncture. Studies suggest that stimulating Baihui (DU20), Shenmen (HT7), and Sanyinjiao (SP6) can impact the cAMP/CREB/BDNF and PI3K/Akt pathways, reducing apoptosis in the central nervous system of insomnia rats.[36] However, there remains a gap in understanding the mechanisms of stimulating other acupoints, including Shenting (GV24), Sishencong (EX-HN1), and Benshen (GB13), in the treatment of insomnia. It presents an avenue for future research in the field of insomnia.

Study Limitations

A few limitations should be acknowledged in this meta-analysis. Firstly, the methodological quality of the included studies was generally deemed mediocre, with incomplete information and challenges in analyzing potential biases. It could impact the reliability of the results. Additionally, heterogeneity in outcome measures was noted, attributed to inconsistencies in baseline data, variations in adjusted confounders, and varying severity of insomnia among the studies. The lack of consensus on the sub-category of Tiaoshen acupuncture hindered subgroup analysis.

Moreover, the absence of a unified definition for Tiaoshen acupuncture acupoints, with Sanyinjiao emerging as a potential associated acupoint through frequency analysis, underscores the need for more comprehensive research. Finally, the funnel plot indicated potential small-study or publication bias, urging caution in interpreting the findings.

These limitations highlight areas for improvement in future studies in this domain.

CONCLUSION

In conclusion, despite acknowledging potential biases indicated by high heterogeneity and asymmetrical funnel plots, the meta-analysis results consistently point towards the effectiveness of TCM Tiaoshen acupuncture in reducing PSQI score, HAS score, FS-14 score, and serum CORT index. These findings suggest a potential alleviation of insomnia symptoms through the application of Tiaoshen acupuncture. However, the limitations in sample size, literature quality, and the presence of publication bias underscore the need for further validation through high-quality, large-sample RCTs. Addressing these limitations will strengthen the evidence base and enhance the credibility of the observed therapeutic effects of Tiaoshen acupuncture in treating insomnia.

AUTHORS' DISCLOSURE STATEMENT

The authors declare there is no conflict of interest.

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AUTHORS' CONTRIBUTIONS

Zhulin Wu and Zhuoxin Yang are regarded as co-corresponding authors.

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