



Effectiveness and Safety of Acupuncture and Moxibustion in the Treatment of Insomnia: A Meta-Analysis Based on Randomized Controlled Trials

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Abstract

Background: We aimed to conduct a systematic evaluation of the efficacy and safety of acupuncture and moxibustion in treating insomnia, and to provide evidence-based guidance for clinical practice.

Methods: A comprehensive literature search was performed using PubMed, CNKI, and other databases to identify randomized controlled trials (RCTs) and clinical controlled trials of acupuncture or moxibustion for the treatment of insomnia. The search was conducted up to May 2025. The articles were screened based on the inclusion and exclusion criteria and the quality of the literature was assessed using the Cochrane 5.1.0 bias risk assessment tool. Meta-analysis was conducted using Review Manager 5.4 software.

Results: A total of 1215 subjects were included in 25 relevant articles. Meta-analysis demonstrated that acupuncture or moxibustion significantly increased treatment effectiveness (odds ratio [OR] = 4.94, 95% CI: 3.52-6.92, $P < 0.00001$) while substantially reducing symptom scores: Pittsburgh Sleep Quality Index (weighted mean difference [WMD] = 3.81, 95% CI: 2.95-4.66, $P < 0.00001$), Self-rating Depression Scale (WMD = 10.77, 95% CI: 5.43-16.11, $P < 0.00001$), and Self-rating Anxiety Scale (WMD = 8.25, 95% CI: 4.21-12.28, $P < 0.00001$). The incidence of adverse reactions was relatively low.

Conclusion: Acupuncture or moxibustion therapy demonstrates potential advantages in the treatment of insomnia and warrants further investigation in a clinical setting.

Keywords: Acupuncture; Moxibustion; Meta-analysis; Effectiveness; Security

Introduction

Insomnia is a sleep disorder characterized by difficulties in falling asleep, difficulties in initiating and maintaining sleep, waking up early, leading to daytime consequences such as fatigue, decreased attention and emotional instability. Insomnia can be a manifestation of various neurological, psychiatric, or other medical conditions, leading to substantial healthcare and occupational costs.

Additionally, it poses significant risks for cardiovascular and mental diseases, including cognitive decline (1).

It is estimated that from 30% to 50% of the world's population experiences insomnia symptoms, with half of those cases being chronic (2). In traditional Chinese medicine, insomnia is referred to by terms such as "sleeplessness" (3).



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Chronic insomnia is challenging to treat and often requires non-pharmacologic approaches (4). Acupuncture, as a traditional Chinese medicine treatment modality, offers several advantages such as ease of use, broad applicability, good therapeutic effect and minimal adverse reactions, making it a popular option for the treatment of insomnia. However, the existing research on the treatment of insomnia with acupuncture and moxibustion has limitations such as small sample sizes and flawed experimental designs.

Thus, we aimed to provide evidence-based support for the use of acupuncture and moxibustion in the treatment of insomnia by conducting a systematic literature search of clinical randomized controlled trials and conducting a comprehensive Meta-analysis to evaluate the efficacy and safety of this treatment.

Methods

Data Retrieval Strategy

Studies were retrieved from multiple databases including PubMed, Web of Science, CNKI, and China Academic Journal Database (CSPD). The search was limited to Chinese and English languages, with the retrieval time frame from the inception of the databases to May 2025. The subject words were "acupuncture," "moxibustion," "insomnia," and "sleeplessness."

Inclusion and exclusion criteria

Inclusion criteria: ① Randomized controlled trials (RCTs) on acupuncture for insomnia; ② Subjects diagnosed with insomnia (any gender/race); ③ Intervention: Observation group—acupuncture/moxibustion (including silver acupuncture, scalp acupuncture, electric acupuncture, moxibustion, ginger moxibustion and other treatment methods); control group—sham acupuncture/drugs/psychological therapy; ④ The outcome indicators included Pittsburgh Sleep Index (PSQI), Insomnia Severity Index (ISI), Self-Rating Depression Scale (SAS), and Self-Rating Anxiety Scale (SAS). Exclusion criteria: ① Repetitive literature; ② Graduation papers, conference abstracts and other non-journal doc-

uments; ③ Unable to get full text. ④ Missing or unable to calculate and extract relevant data; ⑤ Non-Chinese and English literature.

Data collection and analysis

Two evaluators independently screened the obtained literature, extracted data, and assessed the quality of the literature. In the event of inconsistent data, it was resolved through mutual discussion and negotiation, or by consulting a third evaluator. The initial screening of the literature involved reviewing the title and abstract, eliminating any obviously non-compliant literature, and then conducting a thorough review of the full text of documents that meet the preliminary screening criteria to determine their compliance with the inclusion criteria. If necessary, the primary authors or corresponding authors of the literature was contacted through email or telephone to obtain additional important information and data relevant to this study. The extracted literature data were recorded in a table that includes the following information: the title of the article, year of publication, author information, name of the journal published, sample size of study participants, main intervention measures and control conditions, risk assessment of potential bias in the study, and the primary outcome indicators and their results.

Quality Assessment of Documents

Two independent evaluators utilized the "Randomized Controlled Trial Bias Risk Assessment Tool" recommended by Cochrane 5.1.0 to assess the potential for bias in the studies included. The evaluation focused on factors such as the randomization process, allocation concealment, potential for implementation bias, data integrity, and report integrity. The results of the evaluation were cross-verified by the two evaluators.

Statistical Analysis

This study utilized Review Manager 5.4 software for statistical analysis of the collected literature data. Heterogeneity among studies was evaluated by calculating the I^2 value. If I^2 is less than or equal to 50%, indicating minimal heterogeneity, a

fixed effect model was used for Meta-analysis. However, if I^2 is greater than 50%, indicating substantial heterogeneity, the source of heterogeneity was first analyzed before conducting meta-analysis with a random effect model. All statistical tests were two-tailed and a significance level of $\alpha = 0.05$ was employed. Results were considered statistically significant if $P < 0.05$.

Results

Literature retrieval and screening

A total of 2323 documents related to acupuncture, moxibustion and insomnia were retrieved

from PubMed, Web of Science, CNKI and other domestic and foreign databases. 178 duplicate documents were removed with the help of the document management software Endnote, and the title and abstract of the document were read through, and 1963 documents that did not meet the standard were excluded. According to the requirements of literature inclusion, 168 non-randomized controlled experimental articles were excluded from the full text, and 25 articles were finally included (5-29), as shown in Fig. 1.

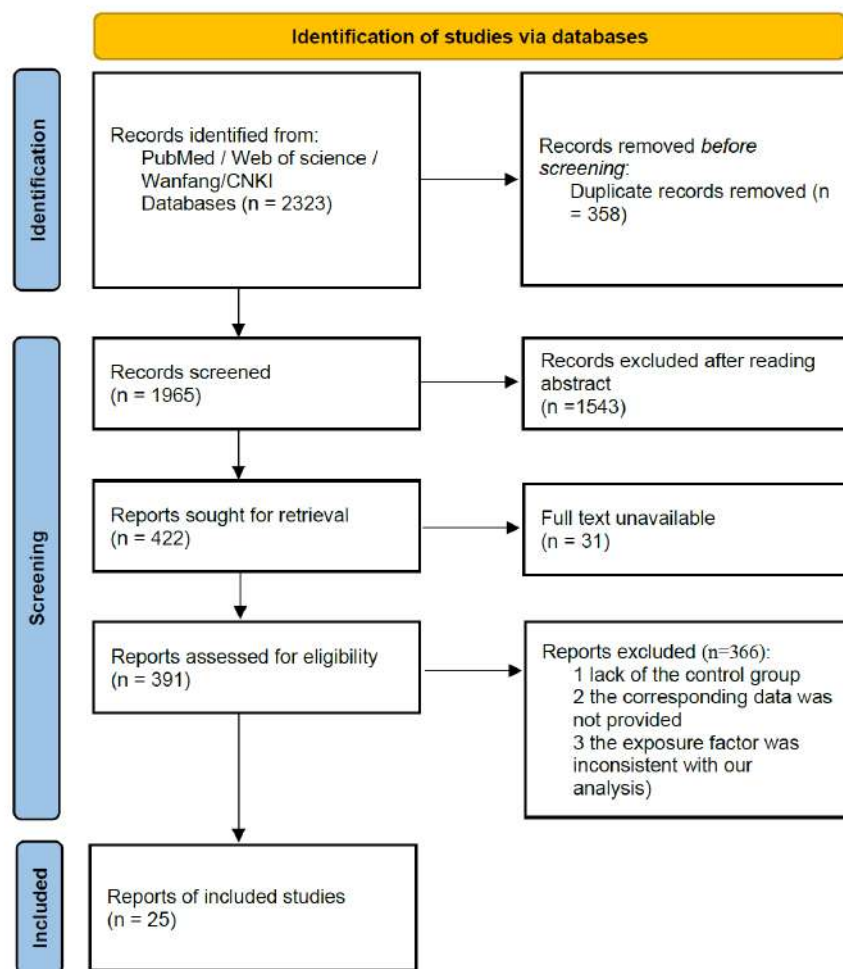


Fig. 1: Flow chart of literature retrieval and screening

Basic characteristics and quality evaluation of included documents

Twenty-five articles (2211 participants: 1103 control, 1108 intervention) were included. Basic characteristics are shown in Table 1. Quality was assessed using Cochrane's bias risk criteria across seven domains: randomization, allocation con-

cealment, blinding, outcome completeness, outcome accuracy, selective reporting, and other biases. Results were categorized as low, high, or unclear risk. 19 articles were 'excellent' (≥ 4 low-risk) and 4 were 'good' (≥ 2 but < 4 low-risk). Overall quality was acceptable (Fig. 2).

Table 1: Basic information of inclusion study

Authors	Groups	Age (yr)	Sex	Interventions	Country
Cong Fu, et al (5)	2	Control group 52.5 \pm 5.9, Intervention group 52.0 \pm 5.3	Male/female	Control group: comfort needle; Intervention group: acupuncture	China
Yuan Chen, et al (6)	2	Control group 42.1 \pm 11.6, intervention group 45.3 \pm 11.2	Male/female	Control group: moxibustion; Intervention group: acupuncture+moxibustion	China
Guoming Feng, et al (7)	2	Control group 41.95 \pm 4.53, Intervention group 41.43 \pm 4.68	Male/female	Control group: alprazolam; Intervention group: acupuncture	China
Peiguo Gao (8)	2	Control group 5.15 \pm 4.93, Intervention group 40.92 \pm 3.61	Male/female	Control group: alprazolam; Intervention group: acupuncture	China
Xiyan Gao, et al (9)	2	Control group 51.03 \pm 3.94, Intervention group 50.91 \pm 4.45	Male/female	Control group: acupuncture at Shenmen, Neiguan and Sanyinjiao points; Intervention group: acupuncture at Baihui, Shenmai, Sishenchong and Zhaohai	China
Huan Feng, et al (10)	2	Control group 51.03 \pm 3.94, Intervention group 50.91 \pm 4.45	-	Control group: acupuncture at Shenmen, Neiguan and Sanyinjiao points; Intervention group: acupuncture at Baihui, Shenmai, Sishenchong and Zhaohai	China
Zhonghe Li, et al (11)	2	49.38 \pm 8.76	Male/female	Control group: methaqualone; Intervention: acupuncture	China
Qiaoling Ma, et al (12)	2	Control group 42.5 \pm 5.2, Intervention group 42.3 \pm 5.4	Male/female	Control group: estazolam; Intervention group: estazolam+acupuncture	China
Jianting Qin, et al (13)	2	Control group 66.51 \pm 4.44, Intervention group 66.58 \pm 4.47	Male/female	Control group: dopamine hydrochloride; Intervention group: acupuncture	China

Table 1: Continued...

Xinping Sun, et al (14)	2	Control group 41.21±6.47, Intervention group 40.04±6.12	Male/female	Control group: estazolam; Intervention group: moxibustion+acupuncture	China
Yingzhe Sun, et al (15)	2	Control group 39±11, Intervention group 36±12	Male/female	Control group: conventional acupuncture; Intervention group: abdominal acupuncture	China
Yanlong Tan, et al (16)	2	Control group 47.23±6.45, Intervention group 46.94±6.47	Male/female	Control group: Guipi pill; Intervention group: acupuncture	China
Tang Dong, et al (17)	2	43.41±6.53	Male/female	Control group: massage; Intervention group: massage+acupuncture	China
Rensheng Wang, et al (18)	2	Control group 41.7±1.5, Intervention group 41.8±1.4	Male/female	Control group: estazolam; Intervention group: acupuncture	China
Yu-Kai Wang, et al (19)	3	Control group 51.10±11.60 , Single acupuncture group 55.42±9.23, Multiple acupuncture group 51.45±12.10	Male/female	Control group: non-acupoints; Intervention group: single or multiple acupoints	China
Chang Xu (20)	2	Control group 46.93±4.84, Intervention group 48.38±4.72	Male/female	Control group: alprazolam; Intervention group: acupuncture	China
Hongbing Xu (21)	2	Control group 51.1±4.1, Intervention group 51.1±4.2	Male/female	Control group: alprazolam; Intervention group: acupuncture	China
Xuan Yin, et al 2017 (22)	-	Control group 37.3±15.1, Intervention group 39.7±12.9	Male/female	Control group: comfort needle; Intervention group: acupuncture	China
Xuan Yin, et al 2022 (23)	3	Control group 49.6±14.9, Sham acupuncture group 50.5±14.0, Intervention group 50.9±14.0	Male/female	Control group, sham acupuncture group, acupuncture group	China
Dongmei Yang, et al (24)	2	Control group 63.49±6.47, Intervention	Male/female	Control group: estazolam; Intervention group: moxibustion+acupuncture	China

Table 1: Continued...

		group 64.48±6.49			
Dechou Zhang, et al (25)	2	Control group 29±21, Intervention group 36±19	Male/female	Control group: estazolam; In- tervention group: acupuncture	China
Leixiao Zhang, et al (26)	2	Control group 39.2±13.8, Intervention group 36.6±14.4	Male/female	Control group: comfort needle; Intervention group: acupunc- ture	China
Yanyan Zhang, et al (27)	2	Control group 45.47±6.53, Intervention group 45.82±6.94	Male/female	Control group: alprazolam; Intervention group: alprazo- lam+acupuncture	China
Qi Zhang, et al (28)	2	Control group 36, Intervention group 31	Male/female	Control Group: Acupuncture at non-effective points Experimental Group: Acupunc- ture at the following acupoints: Baihui (GV20), Shenting (GV24), Sishencong (EX-HN1), Benshen (GB13), Shenmen (HT7), Neiguan (PC6), and Sanyinjiao (SP6) Superficial needling was applied along the Governor Vessel (Du Meridian) and the Bladder Me- ridian of Foot-Taiyang regions.	China
Yan Wang (29)	2	Control group 40.94±5.73, Intervention group 41.35±5.86	Male/female	Control Group: Western medi- cation treatment Experimental Group: Com- bined treatment with acupunc- ture in addition to the control group's regimen	China

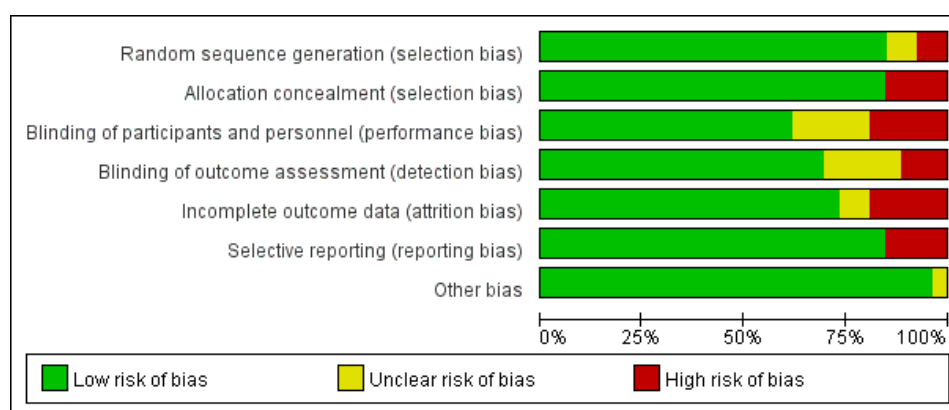


Fig. 2: Evaluation results of literature bias included in the study

A meta-analysis of the therapeutic effect of acupuncture or moxibustion on insomnia

Effect of acupuncture or moxibustion on PSQI score

Meta-analysis of 21 RCTs (n=1871; control=935, acupuncture/moxibustion=936) demonstrated significantly lower PSQI scores (indicating great-

er improvement) with acupuncture/moxibustion vs. control (Fig. 3). Substantial heterogeneity ($I^2=94\%$, $P<0.00001$) warranted a random-effects model. The pooled weighted mean difference (WMD) was 3.81 (95% CI: 2.95 to 4.66; $P<0.00001$). Funnel plot analysis revealed no significant publication bias.

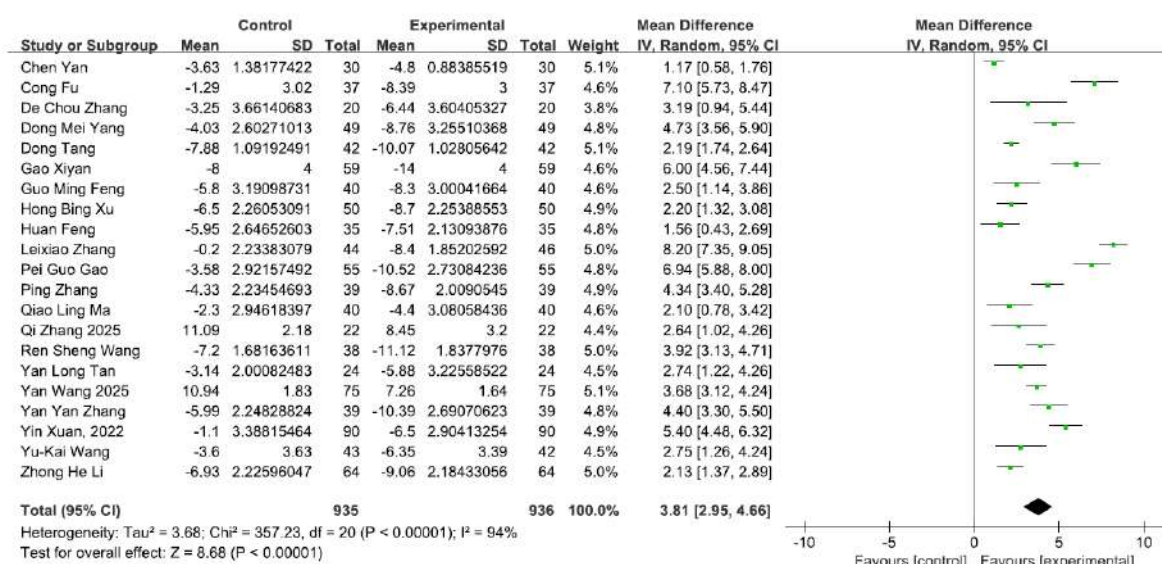


Fig. 3: Meta-analysis forest plot of the effect of acupuncture or moxibustion on PSQI

Effect of acupuncture or moxibustion on the score of the Self-rating Depression Scale

Long-term insomnia often co-occurs with emotional disorders like anxiety and depression, worsening patients' psychological strain. The Self-Rating Depression Scale (SDS) effectively assesses depression severity, where higher scores indicate worse symptoms. This study analyzed 5 articles reporting SDS scores from 250 controls and 252 acupuncture/moxibustion patients. Fig.

4A shows acupuncture/moxibustion's effect on insomnia patients' SDS scores. Heterogeneity was high ($I^2=96\%$, $P<0.00001$), requiring a random-effects model. Meta-analysis showed significant SDS reduction (WMD=10.77, 95% CI:5.43-16.11, $P<0.00001$), indicating depression relief. The funnel plot appeared symmetrical with even study distribution.

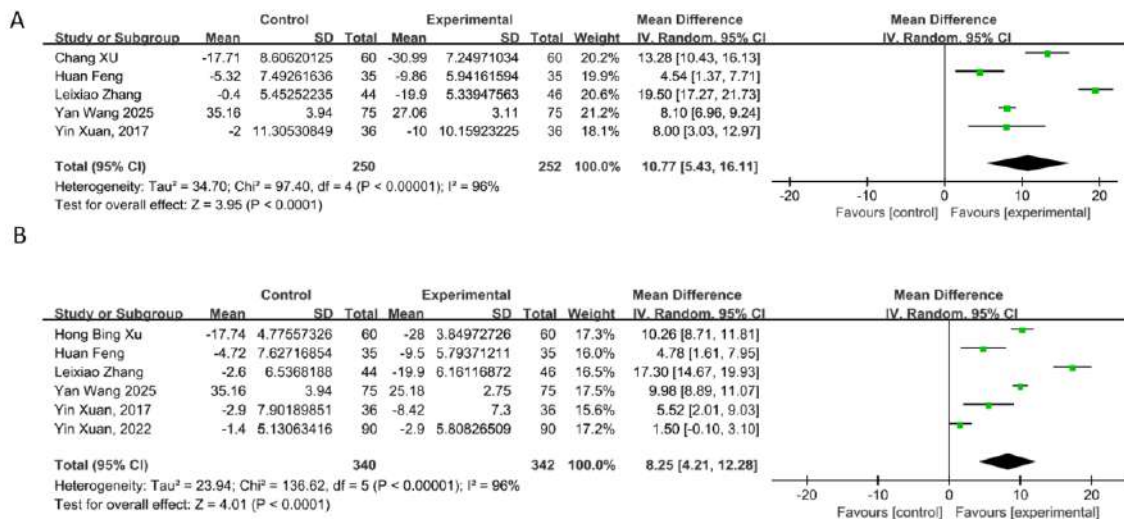


Fig. 4: Meta-analysis forest plot of the effect of acupuncture or moxibustion on SDS and SAS.
 A. SDS; B. SAS

Effect of acupuncture or moxibustion on the score of the Self-rating Anxiety Scale

Self-rating Anxiety Scale (SAS) score effectively evaluates patient anxiety, with higher scores indicating greater severity. This study analyzed 6 papers (control: 340; acupuncture/moxibustion: 342). Figure 4B shows the treatment's impact on insomnia patients' SAS. Heterogeneity testing revealed significant statistical heterogeneity ($I^2=96\%$, $P<0.00001$), prompting use of a random-effects model. Meta-analysis demonstrated that acupuncture/moxibustion significantly reduced SAS scores in insomnia patients (WMD=8.25, 95% CI: 4.21–12.28, $P<0.00001$), indicating improved anxiety. The funnel plot

showed no obvious asymmetry, with studies evenly distributed.

Effect of acupuncture or moxibustion on insomnia severity index scale score

Meta-analysis of four RCTs ($n=386$; control=193, acupuncture/moxibustion=193) demonstrated significantly lower ISI scores (indicating greater improvement) with acupuncture/moxibustion vs. control (Fig. 5). Substantial heterogeneity ($I^2=64\%$, $P<0.05$) warranted a random-effects model. The pooled WMD was 5.24 (95% CI: 1.94 to 8.54; $P<0.05$). Publication bias analysis showed no significant asymmetry.

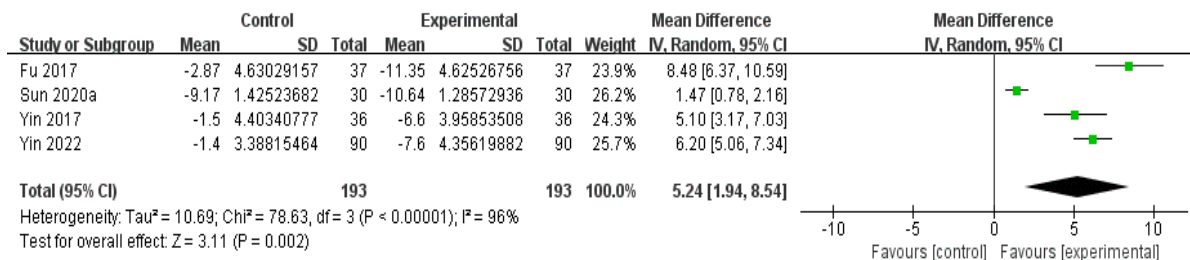


Fig. 5: Meta-analysis forest plot of the impact of acupuncture or moxibustion on ISI

Effect of acupuncture or moxibustion on the effective rate of insomnia treatment

This meta-analysis included 14 trials ($n=1,276$; control=630, acupuncture/moxibustion=646). Despite moderate heterogeneity ($I^2=49\%$, $P=0.02$), a fixed-effect model was applied due to

clinical homogeneity across studies. The pooled odds ratio (OR) was 4.94 (95% CI: 3.52 to 6.92; $P<0.00001$), indicating acupuncture/moxibustion significantly increased treatment effectiveness versus control (Fig. 6). Funnel plot symmetry suggested no substantial publication bias.

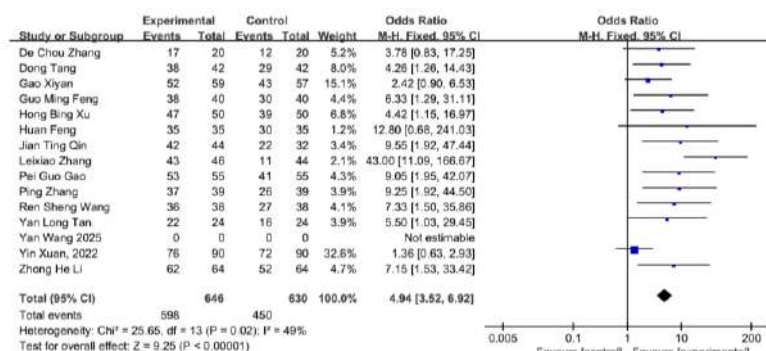


Fig. 6: Meta-analysis forest plot of the effect of acupuncture or moxibustion on the effective rate of insomnia treatment

Safety analysis of acupuncture or moxibustion

Acupuncture's effectiveness and safety limit its promotion. This study reviewed two articles assessing its safety for insomnia treatment, involving 81 controls and 83 acupuncture/moxibustion patients. Lei Xiao Zhang's results (26) showed higher adverse reaction rates in the treatment group (4.2% hematoma, 2.1% dizziness) compared to sham acupuncture. Unlike estazolam (which caused dry mouth and fatigue), acupuncture showed no adverse reactions in Sun Xinping et al.'s study (14), highlighting its promise as a low-risk insomnia treatment.

Discussion

Insomnia, characterized by difficulty initiating or maintaining sleep, affects approximately 14.5% of adults, with higher prevalence in women and individuals over 65 (30). While Western treatments face limitations due to side effects and dependency risks (31), Traditional Chinese Medicine (TCM) effectively addresses insomnia through pattern differentiation—targeting deficiency (e.g., organ dysfunction, yin-yang imbalance) or excess

(e.g., phlegm-fire, qi stagnation) syndromes—and therapies like acupuncture, which regulates organ-meridian harmony. Common acupuncture points for insomnia include Sanyinjiao, Baihui, and Shenmen. Human sleep consists of wakefulness, NREM (divided into N1-N3 stages), and REM sleep (32). Luo et al. (33) found acupuncture improves sleep in insomnia patients by increasing total sleep time, efficiency, N2 spindle density, and reducing latency and awakenings.

This study confirms that acupuncture significantly reduces PSQI scores and improves sleep quality in insomnia patients, although substantial heterogeneity was observed across trials—primarily attributable to variations in control groups (e.g., sham acupuncture vs. pharmacotherapy), intervention protocols (acupoint selection/technique differences), patient characteristics (age, gender, insomnia subtype/severity), and trial design (randomization/blinding inconsistencies). Future research should adopt stricter methodologies and standardized protocols to enhance comparability; nevertheless, acupuncture consistently demonstrated therapeutic benefits for insomnia symptoms despite these heterogeneous conditions.

Acupuncture's multi-target mechanisms for sleep disorders involve: modulating neurotransmitters

(5-HT, NE, DA, GABA) to stabilize sleep cycles (34); activating the vagus nerve to balance the autonomic nervous system and reduce stress (35); regulating circadian genes (Per1, Per2, Clock, Bmal1) to restore rhythms (34); suppressing ERK/NF- κ B signaling to decrease inflammatory cytokines (36); and potentially influencing neurotransmitter synthesis via gut microbiota modulation (34). Functional magnetic resonance imaging (fMRI) evidence elucidates acupuncture's central mechanisms for insomnia via multi-level modulation: At the brain-network level, it enhances DMN activity (e.g., anterior cingulate cortex) to improve environmental awareness and reduce negative memories, while increasing prefrontal fALFF (e.g., dorsolateral superior frontal gyrus) to alleviate sleep-onset anxiety (37-38). Limbic regulation involves normalizing amygdala-thalamus-hippocampus connectivity to suppress hyperarousal (39). Molecular actions include bidirectional neurotransmitter modulation (upregulating 5-HT/GABA to inhibit hyperarousal; down-regulating DA/NE to reduce awakenings), suppressing HPA-axis overactivation (lowering cortisol), and inhibiting ERK/NF- κ B signaling to reduce pro-inflammatory cytokines (e.g., 40%-50% decrease in TNF- α) (36). Recent findings demonstrate enhanced DMN-SMN connectivity counteracting hyperarousal (37). Collectively, acupuncture's therapeutic effects involve synergistic modulation of brain networks, limbic circuits, neurotransmitters, and inflammatory pathways (35,40).

Differences in adverse event rates between acupuncture and control groups were observed: acupuncture typically causes mild reactions (e.g., local hematoma, transient dizziness) (41), while pharmacotherapy controls (e.g., estazolam) induce more side effects like dry mouth and drowsiness (42). Ye et al. (43) demonstrated that combining acupuncture with estazolam significantly reduces adverse reactions, suggesting acupuncture may mitigate drug side effects. Variations across studies (e.g., acupoint selection, patient heterogeneity) may contribute to rate discrepancies, but overall evidence supports acupuncture's superior safety profile versus drug controls.

Conclusion

Acupuncture and moxibustion are evidence-supported interventions for improving sleep quality and alleviating comorbid anxiety/depression in insomnia patients. Further clinical research—particularly on protocol standardization and long-term safety—is warranted to consolidate their therapeutic potential.

Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

Acknowledgements

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Conflicts of Interest

The authors have no conflicts of interest to declare.

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