

Acupuncture Combined with Chinese Herbal Medicine for Insomnia: A Systematic Review and Meta-Analysis

Yinghui Qi¹, Xiujuan Xue¹ & Huaian Li¹

¹ Qinhuangdao Hospital of Traditional Chinese Medicine, Qinhuangdao 066000, China

Correspondence: Xiujuan Xue, Qinhuangdao Hospital of Traditional Chinese Medicine, Qinhuangdao 066000, China.

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Abstract

Background: Insomnia affects more than a tenth of the world's population. Acupuncture combined with Chinese herbal medicine (CHM), which is used for the treatment of insomnia, has been clinically demonstrated to be effective. However, Evidence-based medicine is still lacking. A systematic review of the treatment of insomnia was conducted to obtain a consistent evaluation of clinical efficacy between acupuncture & CHM and West Medicine (WM). **Methods:** Articles about insomnia published before Oct 1, 2022, were searched in English databases Pubmed, EMBase, Web of Science, Cochrane Library, CNKI, CQVIP, and Wanfang. Two researchers assessed the quality of the studies that were included in the review. Review manager 5.3 was used to conduct a meta-analysis on the efficacy of the included studies. **Results:** Data on 734 (372/362) patients from 7 studies were included in the meta-analysis. It was shown that treatment of insomnia with acupuncture & CHM had higher effective rate [RR=1.22, 95%CI (1.07, 1.38), P=0.0003], comparing with WM. **Conclusion:** This study extended complementary alternative therapies for insomnia by providing evidence of the efficacy of acupuncture & CHM in the treatment of insomnia.

Keywords: acupuncture, herbal medicine, insomnia, systematic review, meta-analysis

1. Introduction

Insomnia is a psychiatric disorder with symptoms such as difficulty falling asleep, waking up frequently during the night, or early awakening. (Morales-Munoz I, Broome MR & Marwaha S., 2020) It affects tens of millions of people around the world, has become a major human health concern. (Palesh OG, Roscoe JA & Mustian KM, 2010) Insomnia is mainly divided into short-term insomnia, chronic insomnia and other insomnia, of which, chronic insomnia is the main type of insomnia. (Gauld C, Lopez R & Geoffroy PA, 2021) Insomnia is accompanied by mental fatigue. It can also induce palpitations, chest paralysis, vertigo, headache, stroke disease and many other diseases. (Zhao ZH, Zhou Y & Li WH, 2020)

Traditional Chinese medicine (TCM) treatment for insomnia focuses on regulating the body's internal environment. It includes Chinese herbal medicine (CHM), acupuncture, qigong (e.g., Ba Duan Jin) and massage. (Yeung WF, Chung KF & Poon MK, 2012; Guo J, Wang LP & Liu CZ, 2013; Ren G, Zhong Y & Ke G., 2019; Chan J, Ho R & Ka-Fai C., 2014). Among them, acupuncture & CHM is the most effective way in the clinical treatment of insomnia. Many studies have shown the advantages of acupuncture & CHM in insomnia patients, in terms of the clinical outcomes.

According to current medical theory, clinical investigations for insomnia using acupuncture & CHM as a treatment are substantial. However, there has yet to be a systematic review of the efficacy and safety of

acupuncture & CHM for insomnia. There is a scarcity of evidence-based medical evidence. As a result, a meta-analysis was used to perform a systematic review of studies utilizing acupuncture & CHM for insomnia in order to give solid evidence for its insomnia efficacy assessment.

2. Methods

2.1 Search Methods for the Identification of Studies

The databases such as Pubmed, EMbase, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP) and Wanfang Database were used to find studies of insomnia published before October 1, 2022. The detailed search strategy contains “disorders of sleep”, “insomnia”, “Chinese herbal medicine”, “acupuncture” and “random”.

2.2 Inclusion Criteria for Study Selection

2.2.1 Types of Studies

For this systematic review, following studies were excluded: (1) Non-clinical research. (2) Studies with missing data. (3) Republished studies.

2.2.2 Types of Participants

The RCT participants must fulfill one of the commonly accepted WM and TCM diagnostic criteria for insomnia. These standards contain the International Classification of Sleep Disorders criteria and the Chinese Classification of Mental Disorders Third Edition.

2.2.3 Types of Interventions

In control groups, WM was often used to alleviate insomnia. Benzodiazepines such as Estazolam, Diazepam or Alprazolam were included. Acupuncture & CHM was used as the treatment of insomnia in the trial group.

2.2.4 Types of Outcome Measures

The efficacy was the primary outcome measure.

2.3 Data Collection and Analysis

Two researchers reviewed the titles, keywords, abstracts, and full texts of the publications to filter out non-compliant papers based on the stated inclusion and exclusion criteria. As shown in Figure 1, the filtering and including process were described in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flowchart. As shown in Table 1, the data included in the articles were summarized in the table of characteristics of the included studies.

2.4 Risk of Bias Assessment

The two researchers used the Cochrane Handbook for Systematic Reviews of interventions to evaluate the risk of bias in each of the included RCTs. Random sequence generation, allocation concealment, blinding of participants and personnel, integrity of outcome, reporting bias, and other biases are contained by the indicators for assessing the quality of RCTs. Each indicator correlates to three risk levels: low risk, unclear risk, and high risk.

2.5 Quantitative Data Synthesis and Statistical Methods

The data was statistically analyzed using Review Manager 5.3 and Stata 16.0. The effect measure for the binary variables was relative risk (RR). Effect measures were provided estimates with 95 percent confidence intervals (95% CI). The chi-square test (test level $\alpha=0.05$) was used to assess heterogeneity between the outcome of the included RCTs. The heterogeneity of included RCTs was minor if $I^2 < 50\%$, hence fixed effects models were utilized for this meta-analysis. If $I^2 > 50\%$, random effects models were utilized for this meta-analysis. The funnel plot's distribution symmetry was used to analyze the reporting bias of the included RCTs.

3. Results

3.1 Search Results

As shown in Figure 1, 374 studies were obtained from seven databases. 98 duplicate articles were removed with the help of Endnote. The remaining 276 papers' titles, keywords, and abstracts were examined. A total of 194 of them were filtered out. A total of 7 articles with 734 patients were finally included in the systematic review. (Ye XW & Dai WJ, 2006; Qiu S., 2011; Deng ZR., 2012; Ma L & Zhang EX, 2012; Zhang M, 2017; Jia JJ, Li AY, Liu LH & Yang CX, 2019; Wang LX, Zhou J & Li CZ, 2020)

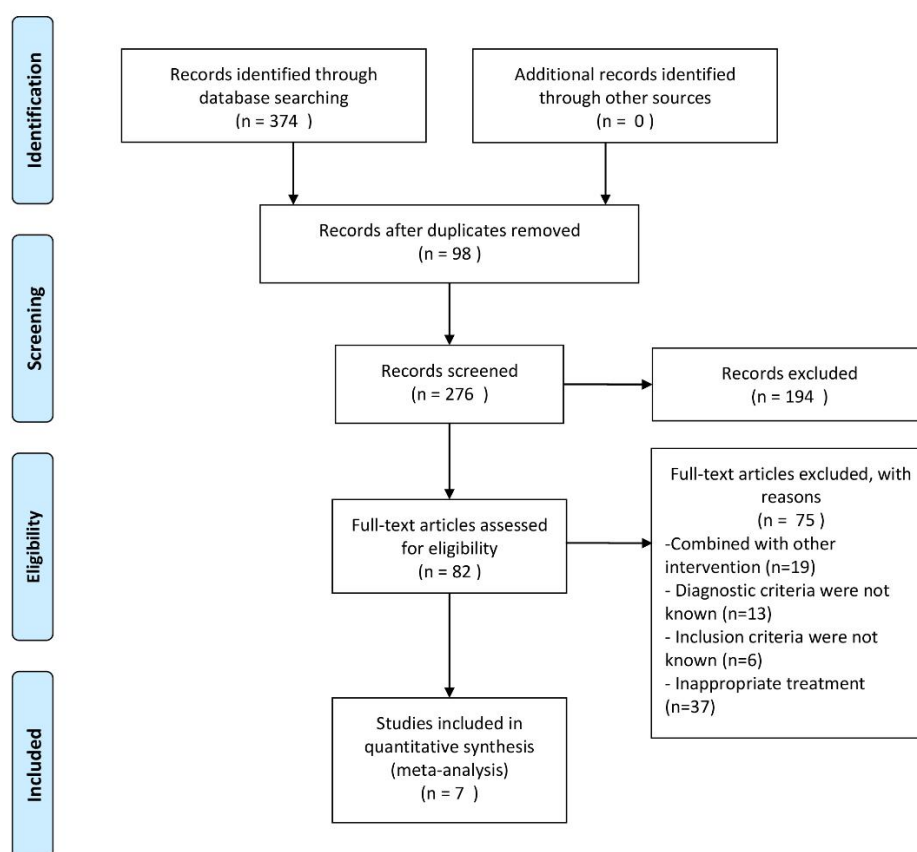


Figure 1. Flow chart of study inclusion

3.2 General Characteristics of Included Studies

Table 1 shows the detailed data from the 7 RCTs. All of the studies were conducted in China. It contained 734 patients (372 patients in the trial group and 362 patients in the control group). The age of the patients ranged from 37 to 52.4. The intervention period ranged from 14 to 42 days.

Table 1. Summary of the feature in included studies

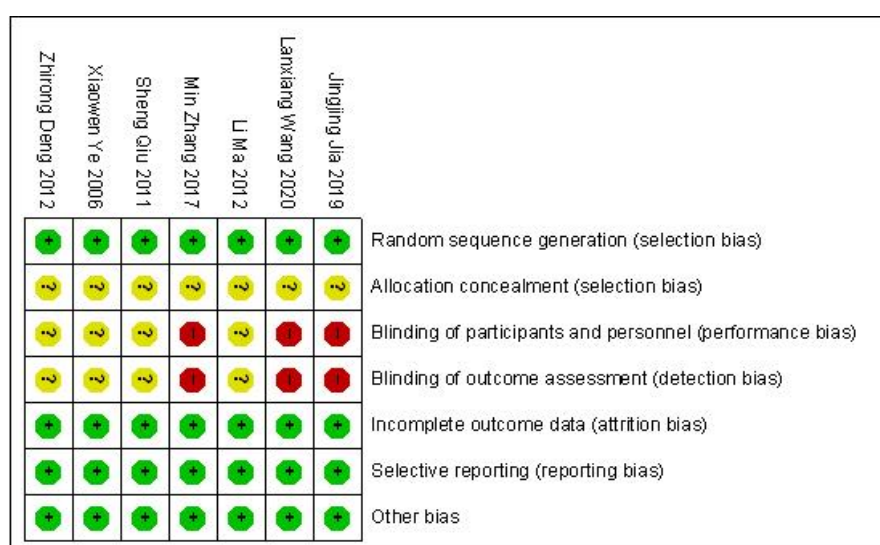
Trial/Year	Sample size (Men (T)/Women(C))	Mean Age or Age Range (T/ C)	Number (T/C)	Trial Group	Control Group	Duration	Outcomes
Xiaowen Ye 2006 ²²	(20/22)/ (17/20)	37±5.4/ 35.1±7.4	42/37	acupunctu re & CHM	Estazolam	21d	Efficacy
Sheng Qiu 2011 ²³	(23/17)/ (25/15)	42.5±6.5/43. 3±5	40/40	acupunctu re & CHM	Estazolam	30d	Efficacy
Zhirong Deng 2012 ²⁴	(16/22)/ (18/20)	40.1/ 38.8	38/38	acupunctu re & CHM	Estazolam	15d	Efficacy
Li Ma 2012 ²⁵	(13/17)/ (16/14)	40.5±8/ 45.1±5	30/30	acupunctu re &	Estazolam	42d	Efficacy

Trial/Year	Sample size (Men (T)/Women(C))	Mean Age or Age Range (T/C)	Number (T/C)	Trial Group	Control Group	Duration	Outcomes
Min Zhang 2017 ²⁶	(45/45)/ (48/37)	52±5.9/ 52.4±6.2	90/85	CHM acupuncture & CHM	Hypnotone	10d	Efficacy
Jingjing Jia 2019 ²⁷	(27/18)/ (29/16)	37±0.3/38± 0.5	45/45	acupuncture & CHM	Diazepam	14d	Efficacy/PS QI/Adverse rate
Lanxiang Wang 2020 ²⁸	(36/52)/ (37/50)	45±2.7/ 43.5±2.4	55/55	acupuncture & CHM	Estazolam	30d	Efficacy

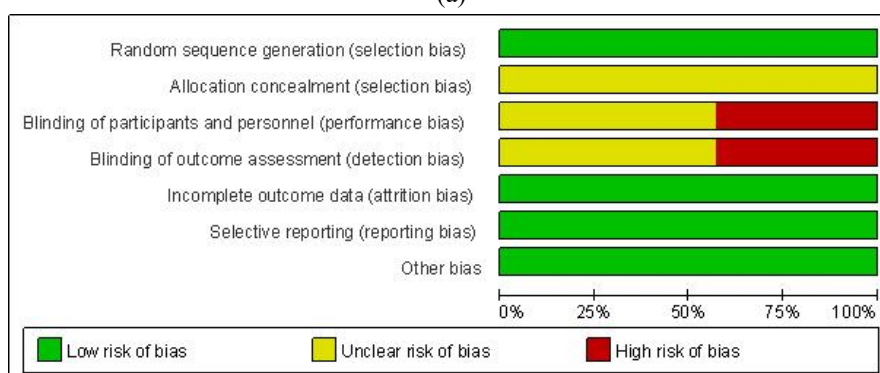
Note: Abbreviations: days

3.3 Quality Evaluation

The quality assessment results of the included 7 studies are shown in Fig 2a and Fig 2b. All of studies employed the randomized grouping approach. In all trials, the blinding method was not used in 3 studies, and there is no mention of the blinding method in the remaining studies. In all studies, there was no evidence of case shedding. The baseline levels for both trial and control groups were consistent, indicating that there was no danger of bias.



(a)



(b)

Figure 2. (a) Risk of bias summary (b) Risk of bias graph

4. Meta-Analysis Results

4.1 Clinical Efficacy

As shown in Figure 3, the included 7 studies, tested for heterogeneity, were found to have $I^2=73\%$ and $P=0.001$ for the Q statistics. There was a significant heterogeneity between the included studies in terms of statistical significance. Therefore, they were meta-analyzed by the random effects model. The difference in efficacy between the trial group and the control group was statistically significant [RR=1.22, 95% CI (1.07, 1.38), $P=0.0003$]. The acupuncture & CHM can improve efficacy in the treatment of insomnia compared with the WM.

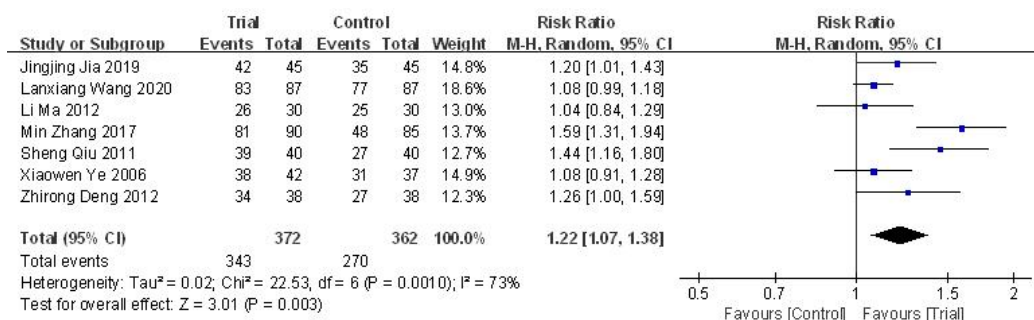


Figure 3. Forest plots of the clinical efficacy of acupuncture & CHM compared with WM

4.2 Publication Bias

The publication bias of the 7 studies included was tested by the funnel plot. As shown in Figure 4, substantial asymmetry could not be observed in funnel plot and this indicated that our results are accurate and reliable against publication bias.

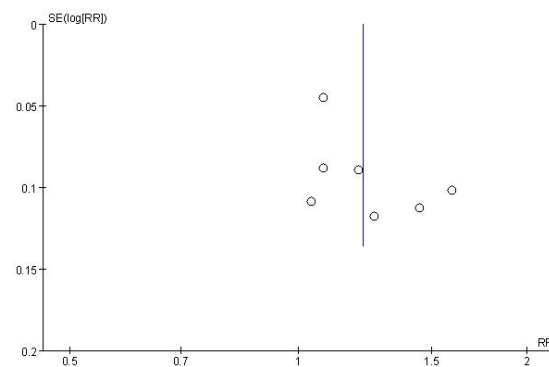


Figure 4. Funnel plot analysis of the efficacy

5. Discussion

Insomnia is a disease that makes people have difficulty falling asleep naturally or maintaining deep sleep for long periods of time. It is one of the common neurological disorders, and worldwide, over 10% of the population has suffered from insomnia. Insomnia has long been a public health concern, evolving into a global disease that impedes human progress.

Medication for insomnia mainly uses western medicine, among which the most effective drugs are benzodiazepines and antidepressants. However, their side effects are large. Dependence and resistance to drugs may also occur, endangering the physical and mental health of patients. (Gerlach LB, Maust DT & Leong SH, 2018)

Compared with WM, TCM has also gradually become an effective complementary alternative therapy for

insomnia. (He Y, Guo X & May BH, 2020; Yeung WF, Chung KF & Poon MM, 2012; Garland SN, Xie SX & DuHamel K, 2019; Liang X, Li H & Shao L, 2014; Juneidi S, Gao Z, Yin H & et al, 2020). Among them, the clinical efficacy of acupuncture & CHM in insomnia is particularly remarkable, which is a classic TCM therapy used in the clinical treatment of insomnia.

7 clinical studies, for a total of 734 participants, were included in this meta-analysis. The noteworthy clinical efficacy of acupuncture & CHM in the treatment of insomnia was demonstrated by the results.

6. Summary and Conclusion

In conclusion, acupuncture & CHM shows evident efficacy in the treatment of insomnia.

Author Contributions

Conceptualization: Yinghui Qi.

Data curation: Yinghui Qi, Xuejuan Xue.

Formal analysis: Yinghui Qi, Xuejuan Xue.

Methodology: Yinghui Qi.

Project administration: Yinghui Qi, Xuejuan Xue, Huaian Li.

Supervision: Xuejuan Xue, Huaian Li.

Validation: Yinghui Qi.

Writing – original draft: Yinghui Qi.

Conflict of Interest Statement

QYH is the first author and XXJ is the corresponding author. The authors have no conflicts of interest to disclose.

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