



Original Article

Efficacy of intradermal acupuncture for insomnia: a meta-analysis

Ruizhi Jing ^{a,*}, Kangle Feng ^b^a Shaoxing Keqiao District Traditional Chinese Medicine Hospital Medical Community General Hospital, China^b Shaoxing Central Hospital, Zhejiang, China

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ABSTRACT

Objectives: To provide updated evidence from randomized controlled trials (RCTs) on the efficacy of intradermal acupuncture for insomnia.

Methods: A search of relevant literatures was performed on major medical databases, including the Cochrane Library, PubMed, EMBASE, CBM, CNKI, VIP, Wanfang Data and so on. Risk of bias evaluation, meta-analysis, sensitivity analysis and evidence rating of all extracted information were also conducted.

Results: A total of 508 studies were initially identified. However, only 45 studies were deemed eligible for the present review. Meta-analyses were conducted in three comparisons separately: intradermal versus acupuncture, Effective rate (RR = 0.08, 95% CI -0.02 to 0.19), Global scales score (points) (SMD = -0.52, 95% CI: -0.81, -0.24, P = 0.02); intradermal acupuncture versus non acupuncture, Effective rate (RR = 1.22, 95% CI 1.04 to 1.42), Global scales score (points) (SMD = -0.81, 95% CI: -1.23, -0.38, P < 0.00001); control group versus control add intradermal acupuncture. Effective rate (RR = 1.27, 95% CI 1.13 to 1.42), Global scales score (points) (SMD = -1.15, 95% CI: -1.46, -0.84, P < 0.00001). Although these results suggested benefits of intradermal acupuncture, the overall quality of evidence rated was low.

Conclusions: The summary estimates indicate that it improved the clinical effective rate and lowered PSQI or other scales score, when compared to sham acupuncture or placebo/conventional medications/herbs. Also, it significantly improved the clinical effective rate and lowered PSQI or other scales score, when the control groups add intradermal acupuncture. However, the quality of the evidence is varied from very low to low due to the potential risk of bias and inconsistency among included trials. The more larger sample size and much more rigorous designed RCTs are still further studied.

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1. Introduction

Sleep disorders, especially insomnia, affect many people in their daily life. It is found that >25% of adults experience insomnia [1]. In China, more than 300 million Chinese have sleep disorders, it is much higher than the international level, which reported by the World Health Organization (WHO) [2]. Growing empirical evidence, including meta-analytic, suggests that insomnia is a significant risk factor for diseases as follows: cardiovascular diseases [3–5], eg arterial hypertension, myocardial infarction and chronic heart failure etc. [5–10], cardiometabolic outcomes [11,12], eg obesity, diabetes, etc. [13–18], neurodegenerative disease,

especially dementia [19], inflammatory processes [20], depression [21,22], suicide [23,24], also increases mortality [25]. At present, The treatment of insomnia including Cognitive behavioural therapy, Benzodiazepines, benzodiazepine receptor agonists and some antidepressants, Complementary and alternative treatments (eg acupuncture) need to be further evaluated, intradermal acupuncture as one type of acupuncture is currently undergoing clinical trials in different medical centers. However, there is a lack of systematic evaluation and analysis. Our study will provide efficacy assessments for clinical applications.

1.1. Study registration

The protocol of this systematic review was registered at PROSPERO (CRD42021228140): Efficacy of intradermal acupuncture for Insomnia: Meta-Analysis. The following was a brief introduction of methods.

* Corresponding author. Shaoxing Keqiao District traditional Chinese Medicine hospital medical community general hospital, 868 Diyang Road, Keqiao District, Shaoxing City, Zhejiang Province, 312030, China.

E-mail addresses: jingruizhi5@163.com (R. Jing), kangle163@163.com (K. Feng).

2. Methods

2.1. Inclusion criteria

2.1.1. Studies

Collected only randomised controlled trials (RCTs), blind or not, with Chinese and English, were included in this systematic review. Articles of the following research types will be excluded: case series, observational studies (including cohort and case–control studies) and animal experiments, review articles, non-RCTs.

2.1.2. Participants

This review included patients of any age who had been diagnosed with insomnia without limitations related to gender, race, study area and education status. The diagnosis of insomnia needs to be consistent with the international classification of diseases, diagnostic and statistical manual of mental disorders the Chinese classification and diagnostic criteria of mental disorders, or other guidelines for the diagnosis and treatment of insomnia in China.

2.1.3. Intervention

The experimental group received intradermal acupuncture with/without additional treatment against the control group; The control group received placebos, medications, sham acupoint catgut embedding, no treatment, or acupuncture/electro-acupuncture, etc.

2.1.4. Outcomes

2.1.4.1. Main outcome(s). Pittsburgh sleep quality index (PSQI), clinical effective rate.

Measures of effect.

We will not restrict timing of measurement.

2.1.4.2. Additional outcome(s). Insomnia Severity Index (ISI), Athens Insomnia Scale (ASI), Health Survey Questionnaire, Hamilton Depression Scale (HAMD) et al.;

Measures of effect.

We will not restrict timing of measurement.

2.1.5. Exclusion criteria

Non-RCTs, repeated publication, unable to get full-text and outcomes, outcomes inconsistent were excluded.

2.2. Search strategy

In attempt to identify all eligible studies, we searched the following seven databases from their inception to 22 Dec 2020, with Chinese and English: the Cochrane Library, PubMed, EMBASE, the Chinese Biomedical Literature Database (CBM), the Chinese Scientific Journal Database (VIP database), the Wan-Fang Database and the China National Knowledge Infrastructure (CNKI). Besides, we also searched the clinicaltrials.gov and screened the references of included studies to identify other potential clinical trials.

The search terms included intervention methods, diseases and research types: (Sleep [Mesh] OR Sleep disorders [Mesh] OR sleep* OR insomnia* OR wakeful* OR sleepless* OR dyssomn* OR insomn*) AND (intradermal acupuncture OR intradermal needl*). The equivalent search words were used in the Chinese databases. A search strategy created according to the Cochrane handbook guidelines was conducted in all the electronic databases.

2.3. Literature selection and data collection

Two review authors independently extracted data and assessed risk of bias. Risk ratio (RR) and standardized mean difference for binary and continuous outcomes respectively.

2.4. Assessment of risk bias

Two review authors independently carried out assessment of risk of bias according to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We resolved all disagreements by consensus.

2.5. Summary statistics

Effect sizes with their 95% confidence intervals (CI) will be extracted. We will analyze the data using STATA16.0 and RevMan software (Version 5.3) provided by The Cochrane Collaboration. A meta-analysis using random effects models will be conducted to summarize the data. Continuous data will be pooled and presented as standardized mean difference with their 95% CI. Dichotomous data will be pooled and expressed as risk ratio with their 95% CI. Statistical heterogeneity will be investigated using the I^2 values.

Subgroup analysis will be conducted to evaluate the specific influence of intervention type. If the data is insufficient, qualitative synthesis will be conducted instead of quantitative synthesis. In addition, sensitivity analysis will be performed to examine the robustness of the results by eliminating low quality trials.

3. Results

3.1. Searching results

A total of 508 studies were initially identified. After a series of procedures (removal of duplicate publications, screening of titles and abstracts, and assessment of full text), 45 [26–40] [40–70] RCTs were finally included for analysis (4 published in English, the rest in Chinese). The flow chart of study searching and screening is shown in Fig. 1.

3.2. Study characteristics

A total of 45 studies, including 3058 patients were enrolled, among which 1540 patients were in the intervention group and 1518 patients in the control group, and 71 pairs of comparisons were provided. Among them, nine RCTs [26,27,30–32,35,37,39,43] compared the efficacy of intradermal vs. acupuncture, 12 RCTs [28,29,33–36,38,40–42,44,45] compared the efficacy of intradermal vs. non-acupuncture, and 26 RCTs [37,46–70] compared the efficacy of control group vs. control add intradermal acupuncture. The mean age of the patients varied from 37.12 months to 71.99 years in studies. The mean course of disease varied from 3.54 days to 15 years. Sessions of intradermal acupuncture varied from 4 weeks to 21 weeks. The period of follow-up varied from after the treatment immediately to 1 month later. In addition, the main descriptive and clinical characteristics of these 45 studies were summarized in Supplementary file 1.

3.3. Quality assessment

Parameters of quality assessment included the following. (a) Random sequence generation: 30 RCTs [26,29–34,38–43,46–50], [52,55,56,58–60,62,64–66,68,70] clearly described the methods of randomization. The other 15 RCTs did not specify the methods of randomization. (b) Allocation concealment: only seven RCTs

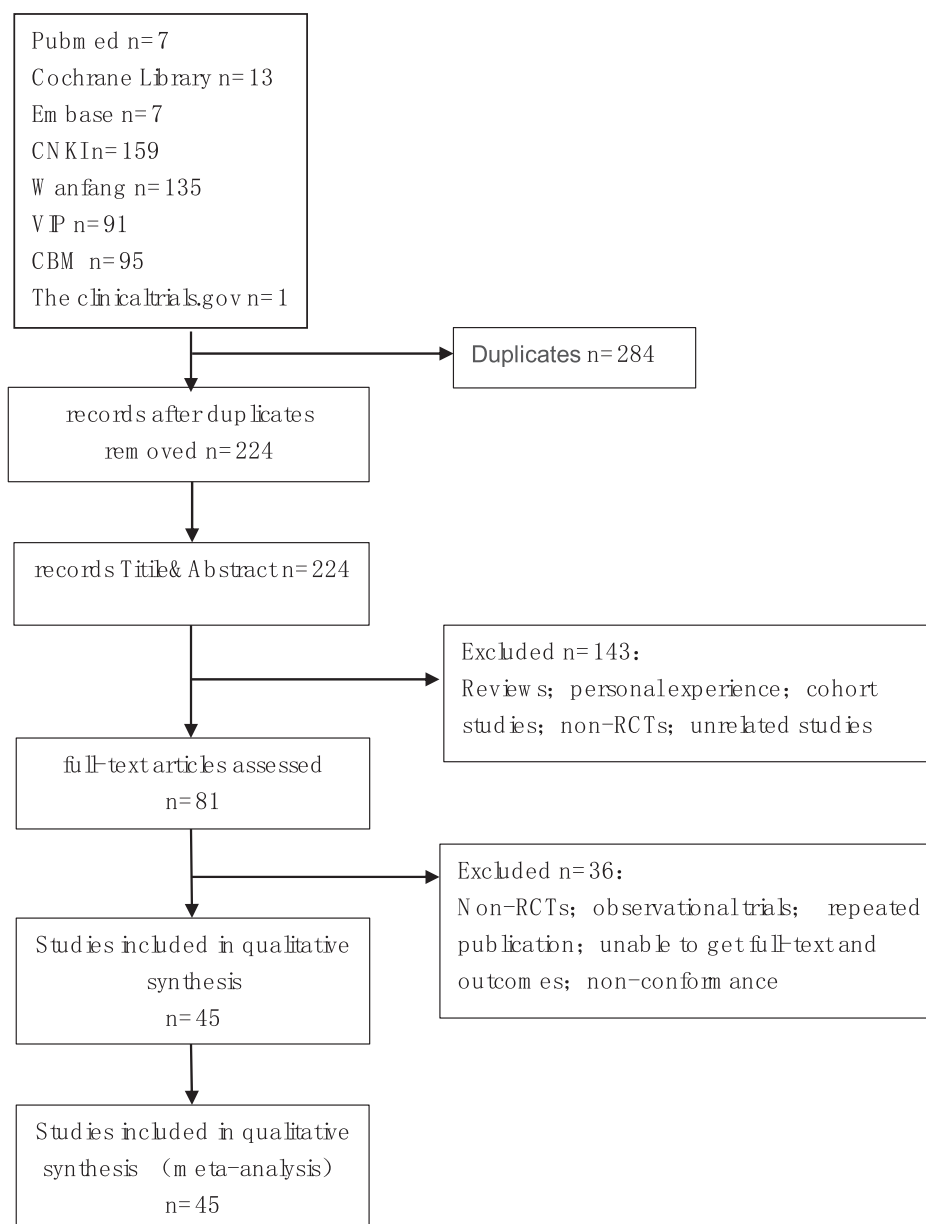


Fig. 1. Flow chart of the study searching and selecting process.

[29,32,34,40,48,68,70] used envelopes. The other 38 RCTs were unable to be determined. (c) Blinding of participants and personnel: Only one study [45] clearly contained the allocation concealment. (d) Blinding of outcome assessment: six RCTs [34,40,44,45,62,70] mentioned blinding of outcome assessment. The other 39 RCTs were unable to be determined. (e) Incomplete outcome data: the results of 45 RCTs were complete. (f) Selective reporting and other bias: none of these 45 RCTs mentioned selective reporting and other sources of bias. The results of the quality assessment were shown in Fig. 2 and Supplementary file 1 (see Figs. 3–9).

3.4. Meta-analysis

According to various control methods tested in the trials, we conducted meta-analyses in three comparisons respectively:

intradermal versus acupuncture, intradermal acupuncture versus non acupuncture, control group versus control add intradermal acupuncture.

3.4.1. Effective rate

This is a dichotomous outcome and a subjective assessment of overall effectiveness, defined as the proportion of participants who had improved obviously in sleep quality.

3.4.1.1. Intradermal versus acupuncture. Eight studies [26,27,31,32,35,37,39,43] reported the effective rate after intervention. The pooled results showed that the intradermal acupuncture group was similar effective rate when compared to the acupuncture group (RR = 0.08, 95% CI -0.02 to 0.19) (Fig. 3). With a high heterogeneity ($\chi^2 = 23.23$, $P = 0.002$, $I^2 = 70\%$).

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Baona Wang, 2019	?	?	?	?	?	?	?
Bo Liu, 2019	?	?	?	?	?	?	?
Chao Jiang, 2019	?	?	?	?	?	?	?
Chenghan Wu, 2017	?	?	?	?	?	?	?
Chulan Yu, 2019	?	?	?	?	?	?	?
Chunxiang Li, 2018	?	?	?	?	?	?	?
Haiying Cui, 2020	?	?	?	?	?	?	?
Jinchai Xu, 2020	?	?	?	?	?	?	?
Jing GAO, 2020	?	?	?	?	?	?	?
Jingju Han, 2019	?	?	?	?	?	?	?
Jixia Wu, 2019	?	?	?	?	?	?	?
Juan Lin, 2019	?	?	?	?	?	?	?
Juan Shan, 2020	?	?	?	?	?	?	?
Kim, Y.S., 2004	?	?	?	?	?	?	?
Lanzhen Zheng, 2020	?	?	?	?	?	?	?
Lee, S., 2009	?	?	?	?	?	?	?
Li Jiang, 2020	?	?	?	?	?	?	?
Lina Guo, 2019	?	?	?	?	?	?	?
Liubo Fan, 2006	?	?	?	?	?	?	?
Liyuan Jiao, 2017	?	?	?	?	?	?	?
Lu Chen, 2018	?	?	?	?	?	?	?
Ning Wang, 2020	?	?	?	?	?	?	?
Qingling Li, 2017	?	?	?	?	?	?	?
Qingxuan Kong, 2013	?	?	?	?	?	?	?
Qiong Liu, 2019	?	?	?	?	?	?	?
Shuai Dai, 2020	?	?	?	?	?	?	?
Shufang Gao, 2016	?	?	?	?	?	?	?
Tianjun Wang, 2008	?	?	?	?	?	?	?
wanyan Yu, 2020	?	?	?	?	?	?	?
Wen, X., 2018	?	?	?	?	?	?	?
Xiangru Cai, 2020	?	?	?	?	?	?	?
Xiaodong Zhao, 2019	?	?	?	?	?	?	?
Xiaomei Liang, 2017	?	?	?	?	?	?	?
Xiaoqing Xia, 2020	?	?	?	?	?	?	?
Xi Chen, 2018	?	?	?	?	?	?	?
Xujie Yao, 2019	?	?	?	?	?	?	?
Yan Zhang, 2020	?	?	?	?	?	?	?
Yan Zheng, 2019	?	?	?	?	?	?	?
Yingqi Lu, 2020	?	?	?	?	?	?	?
Yuru Hou, 2012	?	?	?	?	?	?	?
Yu Tan, 2018	?	?	?	?	?	?	?
Zehong Liu, 2009	?	?	?	?	?	?	?
Zhiying Lv, 2018	?	?	?	?	?	?	?
Zumao Ma, 2019	?	?	?	?	?	?	?
Zuoshan Wang, 2019	?	?	?	?	?	?	?

Fig. 2. Results of quality assessment of included randomized controlled trials.

3.4.1.2. *Intradermal acupuncture versus non acupuncture.* Eight studies [28,29,33–36,40,42] reported the effective rate after intervention. The pooled results showed that the intradermal

acupuncture group had a better effective rate when compared to the non-acupuncture group (RR = 1.22, 95% CI 1.04 to 1.42) (Fig. 4). With a high heterogeneity ($\chi^2 = 23.66$, $P = 0.001$, $I^2 = 70\%$).

3.4.1.3. *Control group versus control add intradermal acupuncture.* Twenty studies [37,46–50,52–58,60,62–67,69] reported the effective rate after intervention. The pooled results showed that the control group add intradermal acupuncture had a better effective rate when compared to the control group (RR = 1.27, 95% CI 1.13 to 1.42) (Fig. 5). With a high heterogeneity ($\chi^2 = 107.95$, $P < 0.00001$, $I^2 = 82\%$).

3.4.2. *Global scales score (points)*

3.4.2.1. *Intradermal versus acupuncture.* 7 studies [26,30–32,35,39,43] were included for analysis. The meta-analysis showed that intradermal acupuncture had a better effect on reducing the scales score than acupuncture (SMD = -0.52, 95% CI: -0.81, -0.24, $P = 0.02$) with a moderate heterogeneity ($P = 0.02$, $I^2 = 60\%$). Fig. 6.

3.4.2.2. *Intradermal acupuncture versus non acupuncture.* 10 studies [33–36,38,40–42,44,45] were included for analysis. The meta-analysis showed that intradermal acupuncture had a better effect on reducing the scales score than non-acupuncture (SMD = -0.81, 95% CI: -1.23, -0.38, $P < 0.00001$) with a high heterogeneity ($P < 0.00001$, $I^2 = 84\%$). Fig. 7.

3.4.2.3. *Control group versus control add intradermal acupuncture.* 20 studies [46–53,56–61,65–70] were included for analysis. The meta-analysis showed that intradermal acupuncture had a better effect on reducing the scales score than non-acupuncture (SMD = -1.15, 95% CI: -1.46, -0.84, $P < 0.00001$) with a high heterogeneity ($P < 0.00001$, $I^2 = 86\%$). Fig. 8.

3.4.3. *Sensitivity analysis*

Sensitivity analysis was used to identify the potential sources of heterogeneity and to examine the stability of the quantitative synthesis results. In the leave-one-out analysis by omitting one study each time, the overall combined results of scales score did not change substantially. These indicated that the synthetic results were robust and no single study had a significant impact on the overall results (Supplementary file 2).

3.4.4. *Publication bias on PSQI (points)*

PSQI is a numeric rating scale range from 0 to 21. Its seven components yield one global score [71]. Higher score indicates worse sleep quality. Clinically important effects were defined as a decrease by at least 1.93 for a beneficial effect and an increase of at least 2.9 for a negative effect [72]. Fig. 9.

4. Discussion

4.1. *Summary of main outcomes*

Although there was no difference in the clinical effective rate between intradermal and traditional acupuncture, but with significant difference lowered PSQI score. We found intradermal acupuncture showed benefit in all meta-analyses with significant differences between treatment groups and control groups. It improved the clinical effective rate and lowered PSQI or other scales score, when compared to sham acupuncture or placebo/ conventional medications/herbs. Also, it significantly improved the clinical effective rate and lowered PSQI or other scales score, when the control groups add intradermal acupuncture.

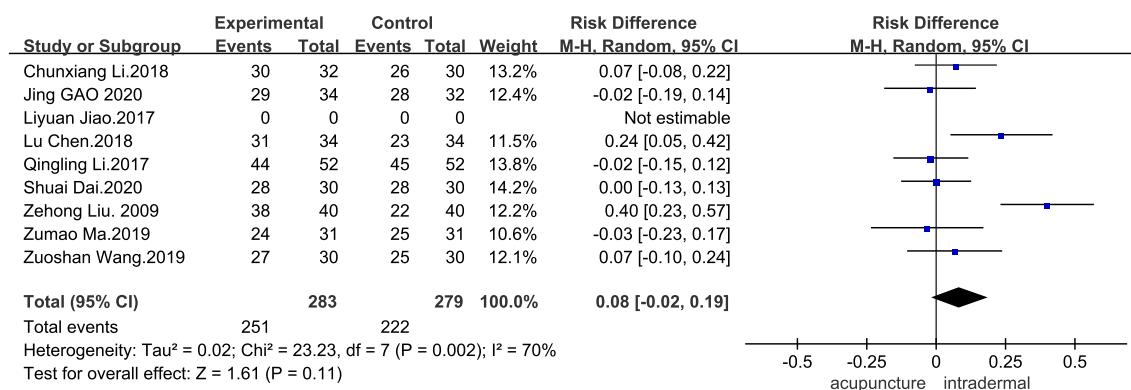


Fig. 3. The pooled outcomes of effective rate revealed no significant difference effect of intradermal acupuncture, statistically. Forest plot of effective rate; Proportion of patients had positive response to the intervention.

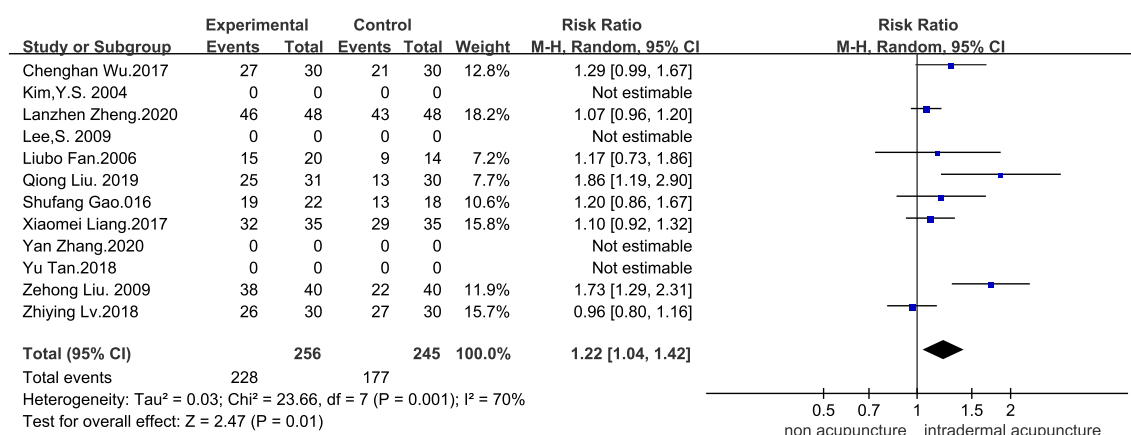


Fig. 4. The pooled outcomes of effective rate revealed significant difference effect of intradermal acupuncture, statistically. Forest plot of effective rate; Proportion of patients had positive response to the intervention.

4.2. Comparison with other reviews

Our work narrowed the inclusion criteria to studies in which intradermal acupuncture was the sole intervention, and conducted a comprehensive search had no limitations for age, duration, and types of insomnia. Although we draw a consistent conclusion with previous trials in terms of PSQI total score for comparisons between acupuncture and no treatment/sham acupuncture, we found a better effect of acupuncture-combined drug therapy for insomnia compared with single drug.

4.3. Implications for clinical practice

In this review, we included all kinds of insomnia without restricted disease courses. The baseline total scores of PSQI More than 5, associated with poor sleep quality. It can be seen from the results that intradermal acupuncture showed better improvement than no treatment or sham acupuncture or single drug on PSQI total score (by reducing 5–8 scores). So, for the insomniacs with no effect or inefficiency treated by the single drug therapy, the treatment of acupuncture-combined drug therapy may be a better choice. Furthermore, this study suggests that intradermal acupuncture may get a better effect when the treatment course is more than 14 days. However, due to the inadequate follow-up, the conclusion needed further researches to be confirmed.

4.4. Implications for future research

Future researches are urged to use more rigorous methodology, including appropriate sample sizes and adequate follow-up with long-term duration. In the outcome assessment, the objective outcome may be better than personal satisfaction of improvement, such as recognized sleep scale (PSQI, AIS, etc.) or other monitoring facility, to confirm the conclusion less affected by subjective factors. Acupoint selection (the number or different position) might have an influence on the curative effect of acupuncture treatment for insomnia. The relationship between treatment duration and the dose of western medicine and the follow-up effect of acupuncture needs further investigation.

4.5. Limitation

Several limitations in this review should be noted. Firstly, The acupoints and treatment duration in the included studies were heterogeneous, which may have affected the outcomes. Secondly, The random methods were not clear enough and there were some errors in the random methods in some studies. Thirdly, the study designs were not robust. There is no specific description of the blind method in some articles selected in this report, but we think that these articles are rigorous, so the method of evaluating these articles are judged to be “unclear”. Besides, six included studies all

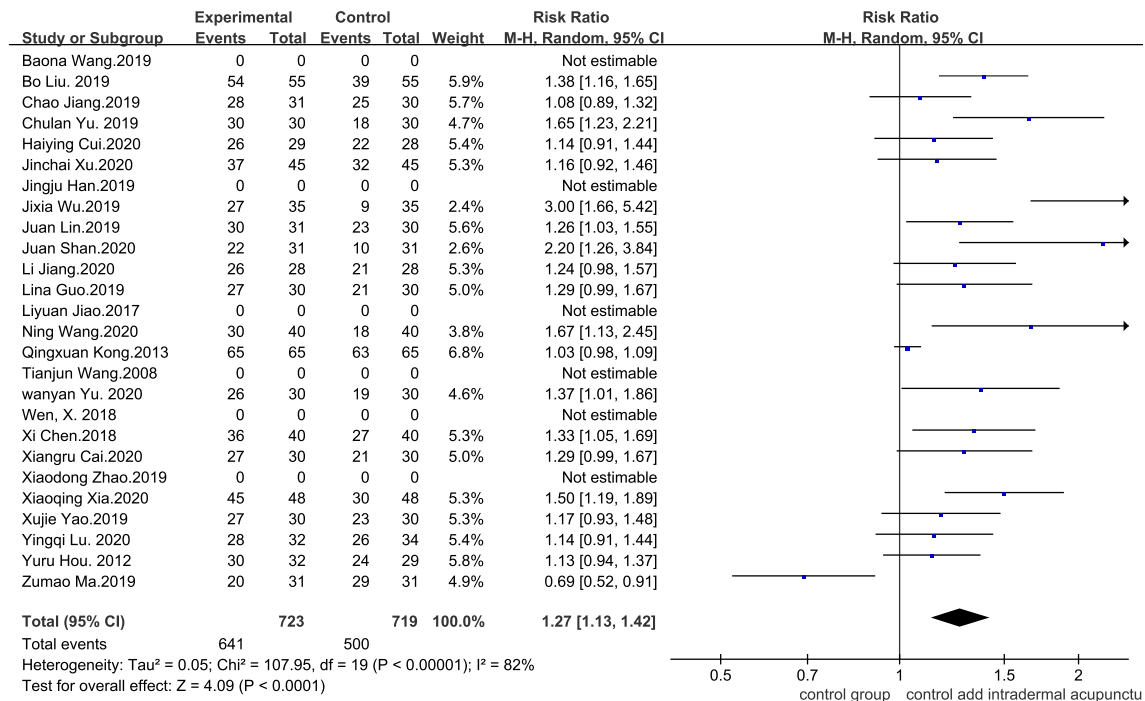


Fig. 5. The pooled outcomes of effective rate revealed significant difference effect of the control group add intradermal acupuncture, statistically. Forest plot of effective rate; Proportion of patients had positive response to the intervention.

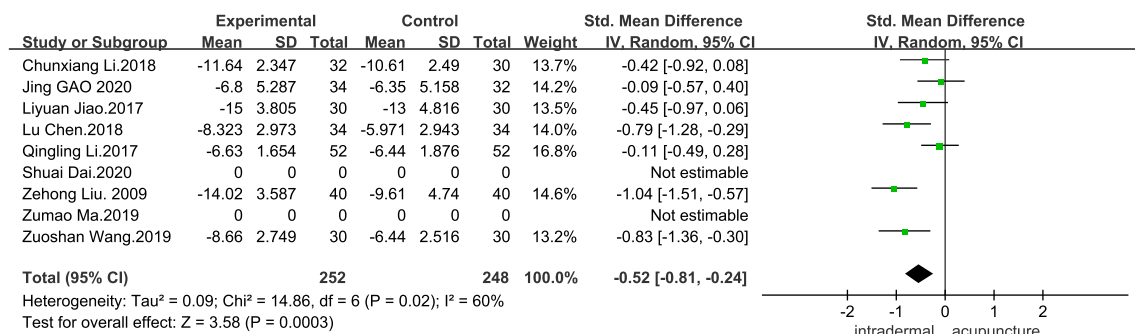


Fig. 6. The pooled outcomes of scales score revealed significant difference effect of intradermal acupuncture, statistically.

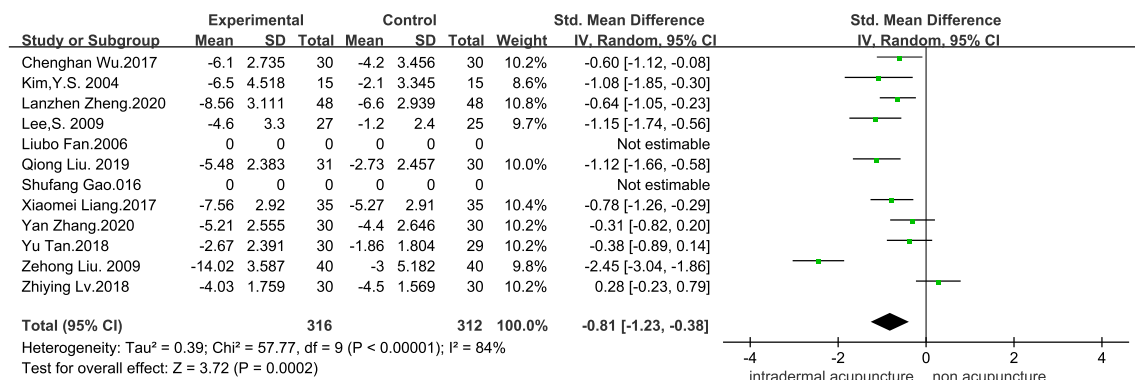


Fig. 7. The pooled outcomes of scales score revealed significant difference effect of intradermal acupuncture, statistically.

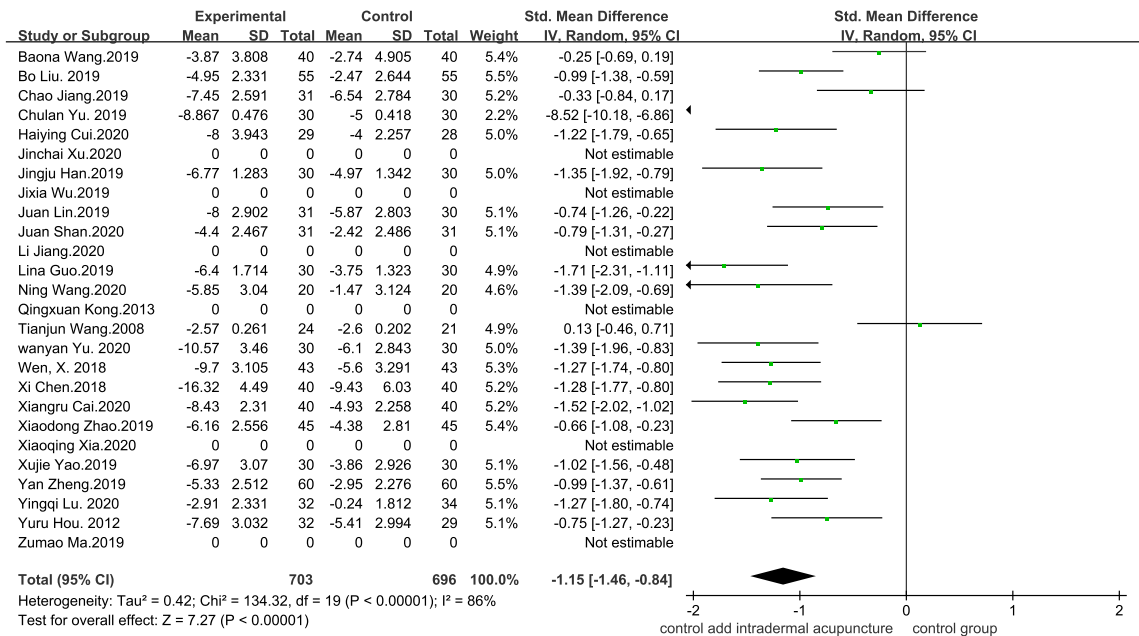


Fig. 8. The pooled outcomes of scales score revealed significant difference effect of control group add intradermal acupuncture, statistically.

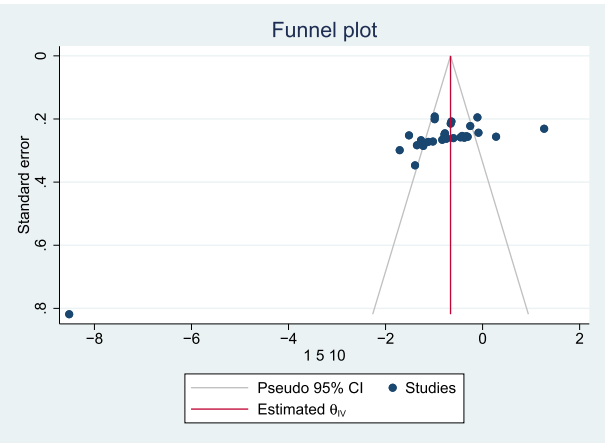


Fig. 9. Publication bias for PSQI score of the treatment of intradermal acupuncture.

claimed double-blind use but three of the studies didn't mention the technical details except Lee S et al. (2009) [45],Wen X et al. (2018) [70] and Qiong Liu(2019) [34] mentioned that they used double-blind in participants and assessors. Finally, Only four in this review were published in English. Other studies were published in Chinese. Additionally, we only conducted a search for Chinese and English articles so that inclusion bias was unavoidable. Thus, if we want to draw a reasonable conclusion for a meta-analysis,we need larger sample sizes and more rigorously randomized controlled trials.

5. Conclusion

Complementary and alternative therapies have been accepted by an increasing number of persons suffered from sleep disorders for certain advantages like convenient, cheap, and less side effects. As one of the complementary and alternative therapies, intradermal acupuncture has been widely applied in clinic especially in

Asian countries.Research evidence supported the use of intradermal acupuncture as an effective treatment to improve symptoms of insomnia. Compared with conventional Western medicine, intra-dermal acupuncture may be more effective in decreasing PSQI score. Intradermal Acupuncture combined with medicine showed to be significantly effective in decreasing score of PSQI compared to sole medication.Current existing evidence allows limited conclusions to be reached through comparing acupuncture and medicine, and additional trials are needed to improve the reliability of these findings. Since several recent clinical researches have focused on this promising treatment for insomnia, it is necessary to perform a high-quality systematic review and meta-analysis. Therefore, this review is expected to provide rigorous and objective evidence of the efficacy of intradermal acupuncture therapy for insomnia.

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Abbreviations

- WHO World Health Organization
- RCTs randomised controlled trials
- PSQI Pittsburgh sleep quality index
- ISI Insomnia Severity Index
- ASI Athens Insomnia Scale
- HAMD Hamilton Depression Scale
- CBM Chinese Biomedical Literature Database
- CNKI China National Knowledge Infrastructure
- RR Risk ratio
- CI confidence intervals

Conflict of interest

None declared.

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: <https://doi.org/10.1016/j.sleep.2021.06.034>.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sleep.2021.06.034>.

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