Quality in Primary Care
ISSN: 1479-1064

Open access Mini Review

Efficacy of Body Acupuncture for Primary Insomnia: Protocol for a Systematic Review and Meta-analysis

Sheng Lee*

Department of Medicine, Southwest Medical University, China

ABSTRACT

Background: Primary insomnia is a common sleep disorder that can have negative effects on patients' health and quality of life. While clinical randomized controlled trials have suggested that acupuncture is effective in treating primary insomnia, further validation is needed to compare the efficacy of body acupuncture with medication. Therefore, this protocol outlines a program to evaluate the efficacy and adverse effects of body acupuncture and medication for the treatment of primary insomnia.

Methods: A systematic search will be conducted across 8 bibliographic databases from their inception to March 1, 2024. The databases include Cochrane Library, MEDLINE (*via* PubMed), Embase, Web of Science, Chinese National Knowledge Infrastructure (CNKI), Wanfang Database, VIP Database, and Chinese Biomedical Literature Database (CBM). Randomized controlled trials published in English or Chinese, comparing body acupuncture with pharmacological approaches for primary insomnia, will be included. The primary outcomes of the study will be sleep quality measured by the Pittsburgh Sleep Quality Index (PSQI) and clinical treatment effectiveness rate. Two reviewers will independently screen studies, extract data, and assess risk of bias. The quality of included literature will be evaluated according to the Cochrane Handbook of Risk of Bias. Meta-analysis will be conducted using review manager 5.4 software.

Discussion: The findings of this study will provide credible evidence to evaluate the efficacy and safety of body acupuncture and medication in treating patients with primary insomnia.

Keywords: Acupuncture; Primary insomnia; Insomnia

INTRODUCTION

Primary Insomnia (PI) refers to a specific type of sleep disorder that is not caused by other psychiatric disorders, physical illnesses, substance abuse, or other specific sleep disorders. It is characterized by difficulties in falling asleep, maintaining sleep, or regaining energy after sleep. Epidemiological studies reveal that the prevalence of insomnia in the adult population is approximately 23.2% in the United States [1], 11.7% to 37% in certain European countries [2-4], and 9.2% to 11.9% in Asia [5-7]. In the general population, PI accounts for about 2% to 4% of cases, making up 25% of all chronic insomnia cases [8]. Chronic insomnia is frequently accompanied by substantial distress and impairment of daytime functioning. Impairment of daytime functioning is commonly linked to symptoms such as fatigue, lethargy, decreased concentration, and mood disorders [9-11]. Furthermore, chronic insomnia has been identified as an independent risk factor for cardiovascular disease and diabetes mellitus [12], and it elevates the risk of depression and mortality in men. Benzodiazepine agonists are supported by the highest level of evidence in pharmacotherapy for insomnia. However, it is important to note that this class of drugs is also associated with undesirable side effects, including residual daytime sedation, cognitive impairment, and the potential for dependence. Acupuncture is widely accepted as an alternative therapy by insomnia patients, mainly due to

Received:	01-April-2024	**Manuscript No:**	ipqpc-24-19087
Editor assigned:	03-April-2024	**PreQC No:**	ipqpc-24-19087 (PQ)
Reviewed:	17-April-2024	**QC No:**	ipqpc-24-19087
Revised:	22-April-2024	**Manuscript No:**	ipqpc-24-19087 (R)
Published:	29-April-2024	**DOI:**	10.36648/1479-1064.32.2.10

Corresponding author Sheng Lee, Department of Medicine, Southwest Medical University, China, E-mail: leesheng0923@163.com

Citation Lee S (2024) Efficacy of Body Acupuncture for Primary Insomnia: Protocol for a Systematic Review and Meta-analysis. Qual Prim Care. 32:10.

its reliable efficacy, safe administration, and minimal adverse effects. Numerous randomized controlled studies, both domestic and international, have compared acupuncture to medication for the treatment of primary insomnia. These studies indicate that acupuncture can effectively improve sleep quality in individuals with primary insomnia. However, it is important to note that existing meta-analyses comparing acupuncture and medications for primary insomnia primarily focus on Western drugs, with limited discussion on the efficacy of body acupuncture as a standalone treatment. Therefore, the purpose of this review is to conduct a comprehensive and objective Meta-analysis to evaluate the differences in the Pittsburgh Sleepiness Quotient Index (PSQI), effectiveness rate, and adverse effects between body acupuncture and both Western medicine and traditional Chinese medicine for the treatment of primary insomnia. By doing so, we aim to provide a more comprehensive and reliable basis for the use of body acupuncture in the treatment of primary insomnia.

METHODS

The protocol was performed in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement. Meanwhile, it has been registered with Prepero with registration number.

Types of Studies

Randomized controlled trials in English and Chinese will be included; reviews, systematic evaluations, case reports, expert experience, conference proceedings, animal experiments, duplicate publications, or similar literature will be excluded.

Types of Patients

Patients diagnosed with primary insomnia according to internationally recognized criteria such as the International Classification of Diseases (10th edition) (ICD-10), International Classification of Sleep Disorders, 3rd edition (ICSD-3), Chinese Classification and Diagnostic Criteria for Mental Disorders, 3rd edition (CCMD-3), Diagnostic and Statistical Manual of Mental Disorders, 4th and 5th editions (DSM-IV, DSM-V), or accepted diagnostic standards will be included in this study. The inclusion criteria are not restricted by gender, race, economic status, ethnicity, or the severity of primary insomnia. However, patients with insomnia caused by other mental disorders, physical illnesses, substance abuse, or other specific sleep disorders, as well as those with primary insomnia coexisting with other disorders, will be excluded from the study.

Types of Interventions

In the experimental group, the treatment will solely consist of body acupuncture without any combined pharmacologic or non-pharmacologic therapies. There will be no limitations placed on the selection of specific acupoints, the number of acupoints used, the frequency or duration of treatments, or the overall course of treatment. However, specialized acupuncture interventions such as auricular acupuncture, eye acupuncture, electroacupuncture, acupoint injections, acupressure, intradermal needling, and moxibustion will be excluded from the study.

Types of Control Groups

Treatments in the control groups will include oral Western or Chinese medicine, with no restriction on specific drugs.

Types of Outcome Measures

Studies that report one or more of the below-mentioned outcomes will be included. Otherwise, the trial will be excluded.

Primary outcomes: This study focuses on the effectiveness of body acupuncture over medication in the treatment of primary insomnia. Therefore, the change in the Pittsburgh Sleep Index（PSQI） and the Clinical effectiveness rate will be used to measure treatment efficacy.

Secondary outcomes: The secondary outcomes will include adverse events measured by Treatment Symptom Scale（TESS）or the incidence of adverse events.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

Electronics Searches

The following eight electronic databases including Cochrane Library, MEDLINE (*via* PubMed), Embase, Web of Science, Chinese National Knowledge Infrastructure (CNKI), Wanfang Database, VIP Database, and Chinese Biomedical Literature Database (CBM) will be searched from their inception to 1 March 2024. Gray literature should also be searched. All randomized controlled trials reported in English or Chinese will be included. In addition, qualified research conference abstracts, reference lists of manuscripts and trial registry database WHO International Clinical Trials Registry Platform and Clinical Trials. gov will be retrieved to identify additional studies. The search strategy consists of Medical Subject Headings (MeSH) and free-text terms. The proposed detailed search strategy for PubMed is presented in **Table 1**.

Table 1: Search strategy in PubMed database

No	Search Items
#1	Sleep initiation and maintenance disorders.
#2	Disorders of initiating and maintaining sleep.
#3	Early awakening
#4	Nonorganic insomnia
#5	Primary insomnia
#6	Rebound insomnia
#7	Sleep initiation dysfunction
#8	Sleeplessness
#9	Insomnia disorder
#10	Insomnia disorders
#11	Insomnia
#12	Insomnias
#13	Chronic insomnia
#14	Awakening
#15	Insomnia nonorganic
#16	Insomnia primary
#17	Insomnia rebound.

#18	Dysfunction, sleep initiation
#19	Dysfunctions, sleep initiation
#20	Sleep initiation dysfunctions
#21	Insomnia, chronic
#22	1 or 2-21
#23	Acupuncture
#24	Acupuncture therapy
#25	Body acupuncture
#26	Acupuncture point
#27	23 or 24-26
#28	Randomized Controlled Trial.Publication Type
#29	Randomized
#30	placebo

Selection of Studies

Studies obtained through database searches will be imported into the Endnote21 software and duplicates will be removed. The remaining studies will be screened by 2 researchers (DL and SW) based on inclusion and exclusion criteria by reading the titles, abstracts, and full text of relevant studies to finalize the literature for inclusion. For unspecified studies, the authors will be contacted for detailed information to determine if the study will be included. Any analysis of the article will be resolved through discussion or reviewed by a third researcher (SL) until consensus is reached. An outline of the study selection process will be presented in the Preferred Reporting Items for Systematic Evaluation and Meta-Analysis flowchart (**Figure 1**).

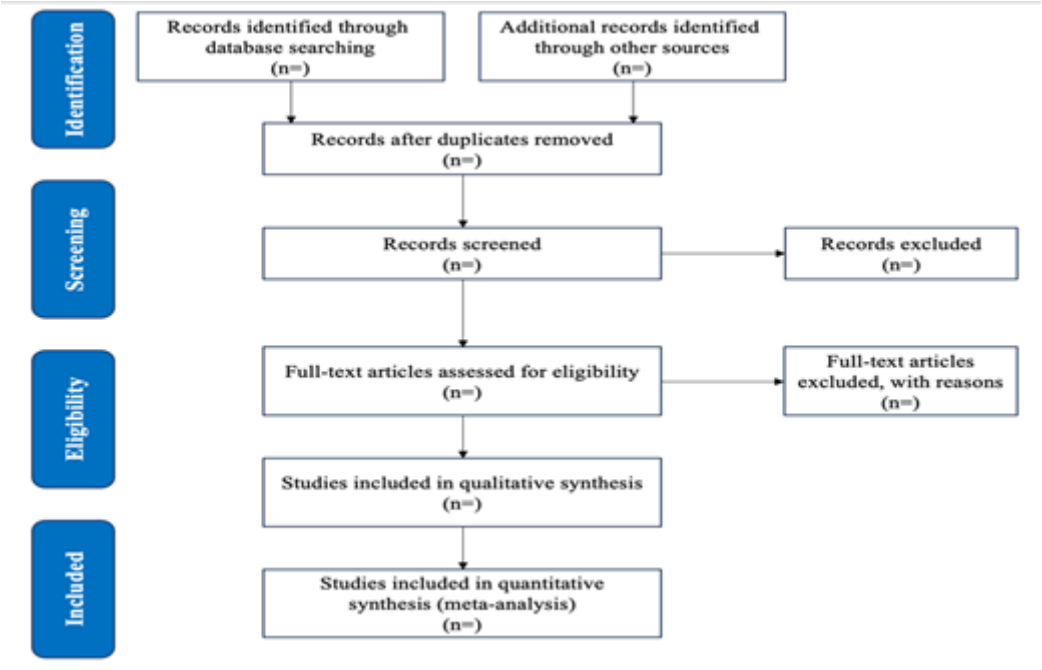

Figure 1: The PRISMA flow diagram of the study selection process

DATA EXTRA-ACTION AND MANAGEMENT

Based on self-designed data acquisition forms, 2 researchers (YC and SP) will independently extract the following information from eligible studies:

- General information (country, first author, year of publication, sample size, and study design);
- Patient information (age, sex, race);
- interventions and comparisons (treatment duration, treatment frequency, total number of treatments, and medications);
- Outcome indicators (type of outcome indicator, data and time of each measurement);
- Adverse events; for unclear or incomplete data, the corresponding author will be contacted by phone or e-mail to obtain complete information.

Disagreements, if any, will be resolved by discussion or involvement of a third researcher SW. Finally, the data will be imported into RevMan 5.4 software.

QUALITY ASSESSMENT

Two researchers (DZ and XW) will independently conduct a quality evaluation of the included studies according to the Cochrane Risk of Bias Evaluation Tool. The evaluation includes the following aspects:

- Selection bias (method of generating randomized sequences and concealment of allocation);
- Implementation bias (blinding of investigators and subjects);
- Measurement bias (blinding of outcome evaluators);
- Follow-up bias (completeness of the outcome metrics);
- Reporting bias (selective reporting of study results); and
- Other bias (other sources of bias).

The results of the risk of bias evaluation of the two investigators

will be checked, and in case of disagreement, the decision will be made by a third investigator (DL). A risk of bias map will be made of the evaluation results of the included studies using RevMan 5.4 software.

Statistical Analysis

Meta-analysis of the included studies will be performed using RevMan 5.4 with publication bias, heterogeneity test and sensitivity analysis. Relative risk (RR) will be used as the efficacy analysis statistic for count data, and Mean Difference (MD) will be used as the efficacy analysis statistic for count data, and each effect size will be expressed as 95% confidence interval (95% CI).

1. Heterogeneity test: If $P<0.1$ and $I2>50\%$, it suggests that there is a large heterogeneity among studies, and a random effect model will be used; if $P \geq 0.1$ and $I2 \leq 50\%$, it suggests that there is no significant heterogeneity among studies, and a fixed effect model will be used.

2. Publication bias test: The funnel plot will be used to evaluate the publication bias of the included studies.

3. Sensitivity analysis: The studies to be included will be excluded one by one for Meta-analysis to analyze the impact of the excluded studies on the combined effect size. If there will be no substantial change in the results, the results will be considered credible; if the conclusions will be changed, it will suggest that there will be some potential factors for the effect of the intervention.

Ethics and Consents

No ethics approval is required since this systematic review and meta-analysis do not collect confidential personal data and do not perform interventions in treating patients. Besides, the findings will be disseminated through a peer-reviewed journal.

CONCLUSION

Acupuncture offers various treatment options, some of which have shown effectiveness in addressing primary insomnia. Among these, body acupuncture is widely used in clinical practice. This meta-analysis aims to comprehensively compare the efficacy of body acupuncture with Western and Chinese medicines in treating primary insomnia. The findings from this study have the potential to provide valuable insights for doctors and patients in their clinical treatment decisions. It is important to acknowledge that there may be certain limitations in this review. Firstly, our focus will primarily be on body acupuncture therapy, with less emphasis on factors such as the specific acupuncture point selection, timing, and frequency of acupuncture sessions. Secondly, the study population will specifically include individuals with primary insomnia, thereby potentially overlooking the severity of the condition within this population.

AUTHORS' CONTRIBUTIONS

L-DY and W-ST will identify eligible studies after reading the title, abstract, and full text, and studies with differing views will be identified by LS.CY and P-SQ will extract data from the original report, and studies with differing views will be identified by W-ST.Z-DC and WX will perform the assessment of risk of bias, and any disagreements will be resolved through discussion with the third-party L-DYs. The L-DY conceptualizes the the review protocol and drafts the manuscript.LS will oversee every step of the review process. All authors have read and approved the protocol for publication.

FUNDING

Sichuan Provincial Department of Science and Technology, the clinical study of "Kaixuan Jieyu" acupuncture method based on "Yingwei Nishun" in the treatment of insomnia after stroke (2022YFS0613-B13).

AVALIABILITY OF DATA AND MATERIALS

Not applicable.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

COMPETING INTERESTS

The authors declare that they have no competing interests.

REFERENCES

1. Kessler RC, Berglund P, Coulouvrat C (2011) Insomnia and the performance of US workers: Results from the America insomnia survey. Sleep 34(9): 1161-1171.
2. Chee CC, Bayon V, Bloch J (2011) Epidemiology of insomnia in France. Rev Epidemiol Sante Publique59(6): 409-422.
3. Morphy H, Dunn F, Lewis M (2007) Epidemiology of insomnia: A longitudinal study in a UK population. Sleep 30(3): 274-280.
4. Pallesen S, Nordhus F, Nielsen GH (2001) Prevalence of insomnia in the adult Norwegian population. Sleep 24(7): 771-779.
5. Li RH, Wing Yk, Fong SY (2002) Gender differences in insomnia: A study in the Hong Kong Chinese population. J Psychosom Res 53(1): 601-609.
6. Kim K, Uchiyama M, Ogihara R (2000) An epidemiological study of insomnia among the Japanese general population. Comparat Study 23(1): 41-47.
7. Xiang YT, Ma X (2008) The prevalence of insomnia, its sociodemographic and clinical correlates, and treatment in rural and urban regions of Beijing, China: A general population based survey. Sleep 31(12): 1655-1662.
8. Ohayon MM (2002) Epidemiology of insomnia: What we know and what we still need to learn. Sleep Med Rev 6(2): 97-111.
9. Buysse D, Thompson W, Scott J, Franzen P, Germain A, et al. (2007) Daytime symptoms in primary insomnia:

A prospective analysis using ecological momentary assessment. Sleep Med 8(3): 198-208.

10. Hauri PJ (1997) Cognitive deficits in insomnia patients. Acta Neurol Belg 97(2):113-117.
11. Moul DE, Pilkonis PA, Houck PR, Miewald JM (2002) Symptom reports in severe chronic insomnia. 25(5): 553-563.
12. Winkelman JW: Clinical practice: Insomnia Disorder. N Engl J Med 373(15): 1437-1444.