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STUDY PROTOCOL

A Systematic Review and Meta-Analysis Protocol to Establish How Common Clinical Acupoint Stimulation-Related Therapies Should Be Used for Managing Insomnia

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Background: Many studies have now investigated the effects of common clinical acupoint stimulation-related therapies (ASRTs) following the meridian theory of traditional Chinese medicine for the management of insomnia. However, ASRT choice is currently based on personal clinical experience or patient preference. This study will review the common ASRTs reported in clinical trials and analyze their efficacy and safety for managing insomnia with or without co-morbidities.

Methods: English and Chinese databases will be thoroughly searched, and other potentially eligible trials will be obtained by reviewing reference lists of identified studies and previous reviews. Only randomized controlled trials (RCTs) of common clinical ASRTs to manage insomnia published in peer-reviewed journals will be considered. Sleep quality questionnaires or indices will be considered as the main outcome, while the secondary outcomes will include sleep parameters, daytime dysfunction, quality of life, and adverse effects. Two reviewers will independently investigate eligible RCTs, extract information, analyze their methodological quality, and employ Grading of Recommendations, Assessment, Development and Evaluation (GRADE) criteria to evaluate the strength of the evidence. The treatment impact of various ASRTs will be calculated using meta-analysis techniques, and the degree of study heterogeneity will be assessed using Cochrane's Q and I-squared statistics. Subgroup and sensitivity analyses will be used to evaluate the reliability of the results.

Results: Our systematic review and meta-analysis will present up-to-date evidence on: 1) which common clinical ASRTs are beneficial for the management of insomnia; and 2) whether the effects of common clinical ASRTs on insomnia vary depending on clinical, participant, and treatment characteristics.

Conclusion: The results of our review should help decision-makers make educated choices regarding evidence-based non-pharmacological management options for insomnia.

Study Registration: The International Platform of Registered Systematic Review and Meta-analysis (INPLASY), record INPLASY2021120137.

Keywords: acupoint stimulation-related therapies, insomnia, systematic review and meta-analysis, randomized controlled trial, protocol

Introduction

Insomnia is a common clinical condition that occurs independent of or comorbid with other physical or psychological diseases.[1] An estimated 50% of adults suffer from insomnia symptoms each year, 15% experience chronic symptoms,[2] and lifetime prevalence estimates indicate that on average ~10% of the population meet the diagnostic criteria of

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insomnia disorder.[3–5] Prevalence estimates vary depending on age, assessment tools, and the criteria applied. Using stringent DSM-IV diagnostic criteria, point prevalence estimates in a large sample remained 6%,[6] whereas a recent cross-cultural and comparative epidemiological study reported that 10.8% fulfilled the newer DSM-5 criteria for insomnia disorder.[7] In a recent meta-analysis, the pooled prevalence of insomnia disorder in China was 15.0%.[8] Regardless of the population and instruments used, insomnia is common.

Insomnia can affect people of all ages, especially older adults (>65 years), women, smokers, and overweight individuals.[9] Patients with insomnia often complain of reduced sleep and/or quality of sleep that seriously affects their quality of life and social functioning during the daytime, especially through sleepiness, fatigue, malaise, mood lability, attention/concentration/memory impairment, productivity decline, work absenteeism, and even road traffic accidents.[1,10] Furthermore, persistent sleeplessness is associated with a higher risk of diabetes,[11] Alzheimer's disease,[12] psychological disorders,[13,14] and cardiovascular disease,[15,16] which might aggravate co-morbidities and suicidal thoughts.[17,18] Thus, patients should be aware of insomnia and be actively treated, while physicians should pay attention to the sleep quality of their patients who may have comorbid insomnia despite visiting for other reasons.

The management of insomnia currently relies on both pharmacological and non-pharmacological therapies.[19–21] Benzodiazepines and non-benzodiazepine hypnotics are frequently used to manage insomnia and promote sedation by enhancing gamma-aminobutyric acid (GABA) function in the brain.[22] In most guidelines, due to the potential risks of tolerance and reliance, hypnotic medications are only advised for short-term use (maximum 4 weeks).[19–21] Antidepressants have also widely been adopted to improve insomnia, especially in people with concomitant conditions such as chronic pain and depression, despite being off-label for insomnia and lacking sufficient evidence.[23] In addition, as a new kind of hypnotic, suvorexant has the potential to shorten sleep latency and lengthen total sleep time by antagonizing orexin receptors.[24] However, these hypnotic drugs and antidepressants give rise to some serious adverse reactions including hangover, parasomnias, sleep paralysis, memory problems, arrhythmia, falls, headache, nausea, fatigue, and rebound insomnia.[19–24] As a result, non-pharmacological interventions are the preferred treatment for insomnia. First-line treatment is cognitive behavioral therapy for insomnia (CBT-I), which has been proven to be highly effective and is recommended globally.[19–21,25] Nevertheless, CBT-I has some limitations. First, some CBT-I techniques place high demands on patients through sleep restriction, stimuli control, and cognitive restructuring, resulting in poor adherence.[26,27] Secondly, the high cost of treatment and the lack of behavioral sleep medicine specialists restrict access of CBT-I to many patients.[26,27] Third, CBT-I is ineffective in 20–30% of insomnia patients.[28] Therefore, other non-pharmacological alternatives are required to help more patients with insomnia.

Since ancient times, the Chinese healthcare system has made extensive use of acupoint stimulation-related therapies (ASRTs), which are based on the meridian theory of traditional Chinese medicine (TCM). ASRTs describe methods of preventing and treating diseases by stimulating particular places on the body (called acupoints) with various needles or other non-needle techniques and manipulations. Recently, an increasing number of randomized controlled trials (RCT) have demonstrated that manual acupuncture (MA),[29,30] electroacupuncture (EA),[31,32] laser acupuncture,[33] acupoint catgut embedding (ACE),[34] acupressure,[35] moxibustion,[36] and transcutaneous electrical acupoint stimulation (TEAS)[37] can improve the sleep quality of patients with primary insomnia without serious adverse effects, with EA even safe for use in pregnant women with insomnia.[38] In addition, individuals with comorbid insomnia are increasingly using these common clinical ASRTs, and several RCTs have reported positive outcomes for the management of insomnia with EA and MA in patients with stroke,[39,40] depression,[41,42] and in cancer survivors.[43,44] Numerous systematic reviews have also reported that the efficacies of these common clinical ASRTs for primary insomnia and comorbid insomnia were higher than that of routine care, placebo acupuncture, or waiting list controls.[45–53] However, the generalizability of these findings was constrained by the fact that the quality of the available literature is generally poor and these meta-analyses concentrated on a particular form of insomnia and/or a single therapy approach.

Each different ASRT has its own advantages and disadvantages. In clinical practice, the choice of ASRT is variable and flexible according to clinical experience or patient preference rather than a sound evidence base. Therefore, a thorough systematic review with strict inclusion criteria is required to shed light on the efficacy and safety of various common clinical ASRTs in patients with insomnia to inform clinical recommendations. Given the efficacy of ASRT depends on the choice of acupoints, the method of acupoint stimulation, and the pathophysiological condition of patients,

this meta-analysis will: 1) assess the effectiveness of the most frequently used common clinical ASRTs including MA, EA, laser acupuncture, ACE, acupressure, moxibustion, and TEAS as monotherapies or adjuncts to recommended treatments (hypnotic drugs or CBT-I) for primary insomnia and comorbid insomnia; and 2) undertake subgroup analyses to detect potential ASRT effect confounders such as treatment features (eg, acupoint selection, stimulation technique, and treatment duration) and patient characteristics (eg, age, comorbidities, severity, and course of insomnia).

Materials and Methods

Study Registration

The Preferred Reporting Items for Systematic review and Meta-Analysis-Protocols (PRISMA-P) guidelines[54] were followed in this protocol (Supplementary Table 1). Furthermore, the final review will be presented in accordance with PRISMA 2020 recommendations.[55] This protocol has been registered on the International Platform of Registered Systematic Review and Meta-analysis (INPLASY) platform with a registration DOI of 10.37766/inplasy2021.12.0137.

Eligibility Criteria for Study Selection

Eligibility requirements will be determined in accordance with the review objectives and the PICOS (participants, intervention, comparison, outcome, and study design) method to guarantee a high-quality review.[54]

Type of Study Design

In this review, only full-text publications of RCTs evaluating common clinical ASRTs for the management of insomnia written in English and Chinese will be accepted. In cases where several publications present data for the same population, the most thorough report—the one with the greatest sample size, the longest follow-up, an exhaustive methods section, and an exhaustive results report—will be chosen.

Type of Participants

Participants with explicit evidence of insomnia symptoms by objective measurements or through standardized assessments like the Pittsburgh Sleep Quality Index (PSQI)[56] or Athens Insomnia Scale (AIS);[57] insomnia diagnosed using at least one of the internationally recognized classifications or equivalent standardized diagnostic criteria, such as the Diagnostic and Statistical Manual of Mental Disorders (DSM),[58] International Classification of Sleep Disorders (ICSD),[59] International Classification of Diseases (ICD),[58] or Chinese Classification of Mental Disorders (CCMD);[60] or with a complaint of insomnia symptoms will be included regardless of the type, reason, intensity, and length of insomnia as well as age, gender, nationality, occupation, and level of education. We will also include participants with co-existent physical or neuropsychiatric disorders, because participants with insomnia symptoms or insomnia disorder observed in clinical practice are likely to have co-morbid problems.

Types of Interventions

Only common clinical ASRTs (acupoints applied in accordance with TCM meridian theory) to treat or manage insomnia including MA, EA, laser acupuncture, ACE, acupressure, moxibustion, and TEAS will be evaluated.

Types of Comparisons

No treatment or waiting lists, routine care, placebo or sham treatments, or mainstream clinical insomnia therapies (hypnotic drugs or CBT-I) will be considered as control interventions. Five comparisons will be considered: (1) ASRT with no treatment or waiting lists; (2) ASRT with placebo or sham intervention; (3) ASRT with hypnotic drugs or CBT-I; (4) ASRT plus hypnotic drugs or CBT-I with hypnotic drugs or CBT-I alone; and (5) ASRT plus hypnotic drugs or CBT-I with a placebo or sham intervention plus hypnotic drugs or CBT-I.

Type of Outcome Measures

The primary outcome will be changes in sleep quality questionnaires or indices determined by standardized sleep scales such as the PSQI, the Insomnia Severity Index (ISI),[61] the AIS,[57] or the Leeds Sleep Evaluation Questionnaire (LSEQ).[62] Additional outcomes will include: (1) objective sleep parameters, as determined by a sleep log or other sleep monitoring

devices and techniques like actigraphy, electroencephalography, or polysomnography; (2) daytime function, as evaluated through performance tasks and self-reporting using standardized tests such as the Stanford Sleepiness Scale[63] or Epworth Sleepiness Scale[64] or through performance task assessments; (3) health-related quality of life (HRQoL), as assessed as a continuous variable using any validated global tools for evaluating functioning, such as the Short Form-36 (SF-36)[65] or the WHO Quality of Life questionnaire;[66] and (4) adverse events (AEs), with incidence of AEs observed in studies or evaluated using validated scales like the Treatment Emergent Symptom Scale (TESS) or Side Effects Rating Scale (SERS).

The exclusion criteria will be: (1) studies not reported in Chinese or English peer-reviewed journals; (2) studies without specific diagnostic criteria or outcome indicators; (3) studies with inadequate or missing data and repeat publications; (4) treatment did not focus on stimulated acupoints, or acupoints and locations stimulated were not based on TCM meridian theory; (5) RCTs that only compared different ASRTs or the combination of two or more ASRTs; (6) trials in which the sample size is unknown or the total sample size is <20. (7) studies published as non-RCTs such as retrospective studies, cohort studies, case reports, animal mechanism studies, reviews, commentaries, expert experience, and practice guidelines.

Information Sources and Search Strategy

The PubMed, Cochrane Central Register of Controlled Trials, Embase, Web of Science Core Collection, Chinese National Knowledge Infrastructure (CNKI), and Wanfang databases will be searched through a comprehensive search from inception to the search date. Medical subject headings (MeSH) and free-text terms associated with ASRTs, insomnia, and RCTs will be combined in the electronic databases to retrieve all possibly pertinent studies.

Prior to the search, any necessary revisions will be made to the keywords and subject terms for each database. No time restrictions will be applied; however, only English and Chinese publications will be included. In the event of disagreements, a decision will be achieved through discussion. As the examples illustrated, Supplementary Tables 2 and 3 detail the search strategy for PubMed and Embase electronic databases.

To obtain any additional eligible studies missed through automatic searching, the reference lists of the relevant systematic reviews and included studies will also be manually searched. Due to the substantial possibility for bias without peer review, we will not include grey literature. If there are disagreements, they will be discussed and resolved by consensus.

Article Selection

To locate all eligible clinical studies, two reviewers (PG and MMX) will separately but concurrently use EndNote X20 citation management software (Thomson Reuters, New York, NY) to remove duplicates and sequentially assess the study titles and abstracts for eligibility. For studies that cannot clearly be included based on the title and abstract, the full text will be carefully read to check for suitability for inclusion. For persistent disagreements about trial selection between the two reviewers, a final decision will be made through group discussion. Summary of the study selection process is shown in Figure 1.

Data Extraction and Management

Two reviewers (PG and MMX) will independently extract the study details, study design, notes, participant characteristics, intervention and comparison characteristics, outcome data, and conclusions from the studies meeting the eligibility requirements. Data items are shown in Tables 1–4. In the event of a lack of consensus on data extraction and collection, a third reviewer (YG) will make the decision.

Risk of Bias Assessment

The Cochrane Collaboration's Risk of Bias (RoB) version 2.0 tool will be used by two independent reviewers (PG and MMX) to evaluate the RoB of each eligible RCT.[67] RoB is evaluated across five domains (randomization, deviations from interventions, missing data, outcome measurement, result selection). Each domain will be given a bias rating of low

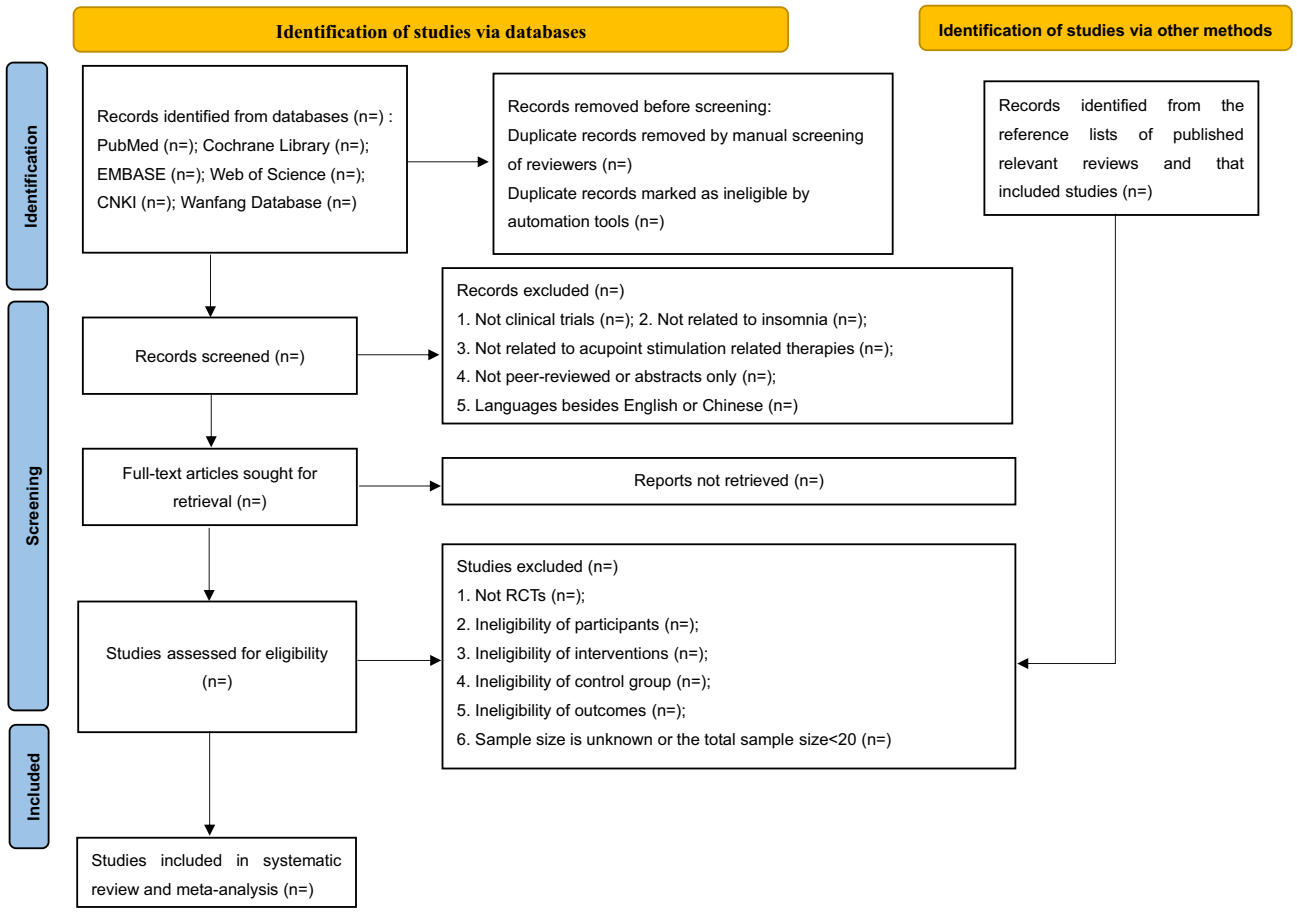

Figure 1 Study selection procedure flow diagram.

risk, high risk, or unclear risk.[67] Any questions or disagreement in the RoB assessment results between the reviewers will be resolved by consensus or adjudicated by a third reviewer (YG).

Dealing with Missing Data

We will contact appropriate authors or coauthors to ask about unclear data and/or request further details if the included data are insufficient or not supplied in the RCT reports. Studies will be disregarded if complete data cannot be obtained, and any potential impact of missing data on the findings will be evaluated in sensitivity analysis and discussed in the final review.

Data Analysis

Qualitative summaries of the included studies and results will be provided. A meta-analysis will be performed if more than three trials assess the same treatments and outcomes.[68,69] To calculate the treatment effect, RevMan v5.4 software (Cochrane, London, UK) will be used to meta-analyze RCTs with sufficient data. Because the included RCTs are likely to comprise a wide range of intervention components, we will employ Mantel-Haenszel random-effects models for all meta-analyses. For continuous data, 95% confidence intervals (CIs) with a weighted mean difference (WMD) and a standard mean difference (SMD) will be calculated, whereas the risk ratio (RR) with 95% CIs will be used when analyzing dichotomous data. Two-sided tests will be used for all analyses, and a P-value <0.05 will be regarded as statistically significant.[68] The evidence and results will be summarized in a written narrative if the data required for quantitative analysis are unavailable or insufficient.[69] Using Cochrane's Q statistic and its associated P-value, statistical heterogeneity across RCTs will be evaluated. The I-squared statistic (I^2 index), which ranges from 0–100%, will also be used as

Table 1 Basic Characteristics of the Included RCTs

First Author	Publication Year	Publication Source	Publication Language	Country	Setting	Eligibility Criteria	Recruitment Method	Randomization Method	Allocation Concealment Method	Blinding Method	Measuring Time Points	Follow-Up Period	Financial source	Competing interests

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Table 2 Summary of the Participant Characteristics

Participant Characteristics											
Number of Arms	Sample Size		Gender		Mean Age	Diagnosis Criteria	Baseline Insomnia Condition				
	I (O/A)	C (O/A)	I (M/F)	C (M/F)			Type	Cause	Severity	Duration	Co-morbidity

Abbreviations: I, Intervention group; C, comparison group; O/A, original data/analyzed data; M/F, male/female.

Table 3 Summary of the Intervention/Comparison Characteristics

Intervention Characteristics							Comparison Characteristics	
Type	Acupoint Selection	Provider	Frequency	Number of Sessions	Session Duration	Total Period	Type	Details of Comparison

Table 4 Summary of the Outcome Characteristics

Methods of Outcome Assessments	Sleep Quality Questionnaires or Indices	Objective Sleep Parameters	Daytime Function	Health-Related Quality of life	Adverse Events	Dates of Treatment Withdrawal	Reasons of Treatment Withdrawal	Conclusion

a measure to characterize heterogeneity between the included RCTs.[68] An RCT will be deemed to have significant heterogeneity when the *P*-value is ≤0.1 and I^2 index is ≥50%.[68]

Subgroup Analysis and Sensitivity Analysis

We will perform subgroup analyses for outcomes included in the RCTs when there are enough data to identify potential sources of heterogeneity in the following characteristics: publishing date, language, diagnostic criteria, characteristics of insomnia, presence or absence of co-morbidities, acupoint options, participant characteristics, intervention characteristics, comparison type, and level of RoB of included RCTs. After taking the impact of methodological quality, missing data, and sample size into account, sensitivity analyses will be performed on the results to explore the reliability and robustness of the review findings, when possible.

Reporting Bias Assessment

RevMan version 5.4 (Cochrane, London, UK) and STATA version 14.0 (Stata Corp., College Station, TX) statistical software will be applied to analyze reporting bias. Funnel plots[70] will be used to identify potential reporting bias if over ten RCTs are obtained. The publication bias depicted in the funnel plot will be quantified using Begg's and Egger's tests.[71]

Confidence Assessments

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines will be used to evaluate the quality of evidence for each result. Evidence quality will be rated as very low, low, moderate, or high depending on the methodological quality of the included RCTs, study limitations, (in)consistency of results, (in) directness of evidence, imprecision, and publication bias.[72]

Ethical Considerations

Ethical approval and consent were not unnecessary since no data are related to patient information and privacy in this protocol.

Discussion

Insomnia, a highly prevalent clinical problem across the world, is frequently reported by patients and may be a significant sign of a number of sleep and medical illnesses. Indeed, epidemiological research has shown that the prevalence of insomnia among people of all ages is rising year on year.[2,9] Insomnia places huge burdens on individuals, families, and society,[2] but, despite this, insomnia has not received sufficient recognition nor management in clinical practice. An increasing number of clinical trials have reported that ASRTs guided by TCM theory are helpful for improving insomnia disorder and daytime functioning as well as being relatively cheap, convenient, available, and safe.[29–37] ASRTs might represent a clinical treatment option that could be offered as a second-line treatment when first-line treatments are not viable or tolerated. In addition to acupuncture and acupressure, ASRTs have now evolved into numerous treatment techniques driven by clinical need, with acupoint selection varying from practitioner to practitioner. While several clinical common ASRTs for insomnia have been evaluated in previous systematic reviews,[45–53] in the face of such a wide range of ASRTs, there is no conclusion on how ASRT clinicians should manage insomnia in clinical practice. To develop guidelines and further drive future clinical practice and research, a more thorough and comprehensive evaluation of all the existing literature is required. The clinically recognized acupoint stimulation techniques for the management of insomnia with or without comorbid physical or neuropsychiatric illnesses will be reviewed and assessed for efficacy and safety in this review. By doing this, we hope to provide answers to the issues of whether efficacy differs depending on the part of sleep being addressed as well as whether the effects vary depending on the precise acupoints used, the form of acupoint stimulation, or the type of insomnia present.

We believe that the study's many strengths will make its contributions meaningful. First, we will include all current common clinical ASRTs for insomnia reported in the "gold standard" of clinical trials – RCTs. Second, a wide search strategy will be applied to the present date to identify the largest number of available studies across a comprehensive set of databases in both English and Chinese. Third, the public, researchers, and clinicians should be able to rapidly evaluate the existing information and judge its quality thanks to the adoption of the publication bias and GRADE frameworks to assess the strength of the evidence.

Despite our careful methodological considerations, there might be some limitations to our review. First, excluding papers published in languages other than English and Chinese may omit some relevant studies. Also, the inclusion of only peer-reviewed studies may exclude grey literature containing relevant data and information; however, this will also ensure a minimum quality of included studies. The diverse ASRTs, insomnia patients' characteristics, insomnia severity, and RCT quality may introduce inevitable heterogeneity, so we plan to analyze all relevant factors in the future to explore sources of heterogeneity.

Conclusion

This review will expand on previous reviews through its up-to-date search of English and Chinese databases and obtaining the fullest scope of evidence. Moreover, our meta-analyses of RCTs will provide more accurate and quantitative insight into the efficacy and safety of common, clinically prescribed ASRTs for the management of insomnia. It will also provide valuable information about how common clinical ASRTs should be used to improve insomnia. The findings of this review will benefit patients, physicians, and decision makers working in healthcare to make informed decisions on evidence-based non-pharmacological interventions for insomnia disorder.

Abbreviations

ASRTs, Acupoint Stimulation-Related Therapies; TCM, Traditional Chinese Medicine; RCTs, Randomized Controlled Trials; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; INPLASY, International Platform of Registered Systematic Review and Meta-analysis; GABA, Gamma-aminobutyric Acid; CBT-I, Cognitive Behavioral Therapy for Insomnia; MA, Manual Acupuncture; EA, Electro-acupuncture; PRISMA-P, Preferred Reporting

Items for Systematic Review and Meta-analysis Protocols; PRISMA, Preferred Reporting Items for Systematic Review and Meta-Analysis; PICOS, Participants, Intervention, Comparison, Outcome, and Study Design; PSQI, Pittsburgh Sleep Quality Index; AIS, Athens Insomnia Scale; DSM, Diagnostic and Statistical Manual of Mental Disorders; ICSD, International Classification of Sleep Disorders; ICD, International Classification of Diseases; CCMD, Chinese Classification of Mental Disorders; WASO, Wake After Sleep Onset; ISI, Insomnia Severity Index; LSEQ, Leeds Sleep Evaluation Questionnaire; HRQoL, Health-related quality of life; SF-36, Short Form-36; AEs, Adverse events; TESS, Treatment Emergent Symptom Scale; SERS, Side Effects Rating Scale; CNKI, Chinese National Knowledge Infrastructure; MeSH, Medical Subject Headings, RevMan, Review Manager; RoB, Risk of bias; WMD, Weighted Mean Difference; SMD, Standard Mean Difference; Cis, Confidence Intervals; RR, Risk Ratio.

Author Contributions

All authors made a significant contribution to this work, whether in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all of these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors have no conflicts of interest related to this work.

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