

# Effectiveness of Acupuncture, Mind and Body Practices, and Natural Products for Insomnia: an overview of systematic reviews

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**Objectives:** This overview summarizes the evidence for the effectiveness and safety of complementary therapies for insomnia through systematic reviews (SRs) and meta-analyses (MAs).

**Methods:** A comprehensive literature search on SRs and MAs for complementary therapies for insomnia was conducted using six databases.

**Results:** This overview included 30 SRs/MAs. The Pittsburgh Sleep Quality Index (PSQI) analysis of insomnia included 383 randomized controlled trials and 31,748 participants. Twenty-four SRs/MAs (80%) out of 30 SRs/MAs reported a positive result, and six SRs/MAs reported a partially positive result. The most frequently used form of acupuncture reported a positive effect in 89.5% (17/19) of SRs/MAs and a superior effect to western medicine, sham/placebo, and no treatment. The lack of protocol registration and the excluded studies list resulted in generally poor methodological and reporting quality in SRs/MAs with AMSTAR 2.

**Conclusion:** This overview confirmed that complementary therapies positively affected the PSQI scores in patients with insomnia. However, better-designed primary studies are needed to strengthen the relevant evidence in the future. A more stringent assessment of multiple systematic reviews must be followed when performing SR and MA.

**Keywords:** complementary therapy, insomnia, overview, systematic review

## INTRODUCTION

Insomnia is a sleep-wake disorder in which one (or more) chief complaints of dissatisfaction with sleep quantity or quality, such as difficulty initiating sleep, difficulty maintaining sleep characterized by frequent waking or problems returning to sleep after waking, and early-morning waking with an inability to return to sleep [1]. Sleep takes up to 20%-40% of the day and is one of the most important biological requirements for maintaining human health and high quality of life [2]. Insufficient sleep leads to short-term effects, such as loss of concentration and attention, poor quality of life, decreased productivity, and accidents in everyday life. Long-term effects include increased

morbidity and mortality from hypertension, diabetes, stroke, and mental diseases [3].

Approximately one-third of adults report insomnia symptoms, and in primary care settings, approximately 10%-20% of individuals complain of significant insomnia disorders [1]. The prevalence of insomnia is steadily increasing among adults yearly [4-6]. Although conventional behavioral and pharmaceutical treatments for insomnia can be effective, many people seek alternative therapies to improve sleep [7]. According to a survey, 45% of adults with insomnia reported using at least one complementary and alternative medicine (CAM) [8].

The CAMs frequently used for insomnia symptoms include acupuncture, moxibustion, tai chi, yoga, Tui Na, and herbal

medicine. CAM for insomnia is increasingly popular among doctors and patients [9]. Many research reports on insomnia and CAM are available, but most have reported results focused on randomized controlled trials (RCTs) or one or two CAMs [10, 11].

Overview studies on CAM for insomnia based on meta-analyses (MAs) and systematic reviews (SRs) are rare. This overview reviewed the SR with or without MA of complementary therapies in patients with insomnia disorder to identify the current evidence level and suggest future research and practice.

## MATERIALS AND METHODS

### 1. Protocol and registration

The review protocol was registered on the Research Registry (Review Registry Unique Identifying Number: reviewregistry1059).

### 2. Research question

This study aimed to determine the status, effectiveness, safety, and methodological quality of SRs and MAs publications on complementary therapy for insomnia. The PICO can be described as follows:

#### 1) Type of participant

Participants diagnosed with insomnia clinically or according to national or international standards by health care providers or researchers were included. The gender, age, race, nationality, time of illness, comorbidities, etc., were not restricted.

#### 2) Types of interventions

All complementary therapies, including acupuncture, mind and body practices (MBP), and natural products.

#### 3) Types of outcome measurements

Primary outcome: The Pittsburgh Sleep Quality Index (PSQI) evaluated the sleep quality of people with insomnia [12].

Secondary outcomes: Seven outcomes, including the insomnia severity index (ISI) [13], the Athens insomnia scale (AIS) [14], the sleep onset latency (SOL), the total sleep time (TST), the wake time after sleep onset (WASO), the number of awakenings (NOA), and the sleep efficiency (SE).

#### 4) Type of study design

SR with or without MA on RCTs.

### 3. Search strategy

This overview searched the following databases with language restrictions for English and Korean: PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, KoreaMed ([www.koreamed.org](http://www.koreamed.org)), KMBase ([kmbase.medic.or.kr](http://kmbase.medic.or.kr)), and ScienceON (<https://scienceon.kisti.re.kr>) from their inception to November 2020. The search strategies were applied to each database using MeSH terms and natural language associated with the keywords “sleep disorders,” “insomnia,” and “complementary therapies” (Supplementary Table S1).

### 4. Data selection and extraction

Following the search, three reviewers (Yeo, Lee, and Kim) independently checked the titles and abstracts of the included articles to select potential eligible articles. The full texts of the chosen articles were screened according to the inclusion and exclusion criteria. Three independent reviewers performed data extraction. All discrepancies were resolved by consensus or consultation with a fourth reviewer. The data extraction form consisted of the authors' name, year of publication, country of authors' affiliation, participant characteristics, interventions, comparator, funding source, outcomes, results, and adverse events.

The main and subgroup results from each MA were extracted for the MA results. The SR results were classified and extracted according to whether the included RCT was statistically improved after extracting each SR/MA. If the results for each outcome measurement were all positive effects, the SR/MA was classified as P; a partially positive effect was classified as partially positive (pP); all negative effects were classified as N; a classification of U was given when positive and negative effects were mixed, or there was no difference.

### 5. Methodological quality assessment

The quality assessment was conducted by three reviewers independently based on the “assessment of multiple systematic reviews 2” (AMSTAR2), a 16-item validated measurement tool for assessing the methodological quality of SR [15]. The AM-

STAR2 items were evaluated as “Yes,” “Partial Yes,” and “No.” The overall confidence of the review results was rated as high, moderate, low, and critically low based on the number of critical or noncritical flaws [15].

strategy. Of the remaining 160 SR/MAs after deduplication and primary eligibility selection, 30 (25 in SR and MA and 5 in SR) were finally selected (Fig. 1). The following reasons led to the exclusion of the 130 SRs/MAs: patients without insomnia (n = 43), not complementary therapy (n = 28), no major outcomes to extract (n = 24), not SR (n = 23), not SR for RCT (n = 11), and not written in English or Korean (n = 1) (Supplementary Table S2).

## RESULTS

### 1. Search result

A total of 28,125 records were retrieved using the search

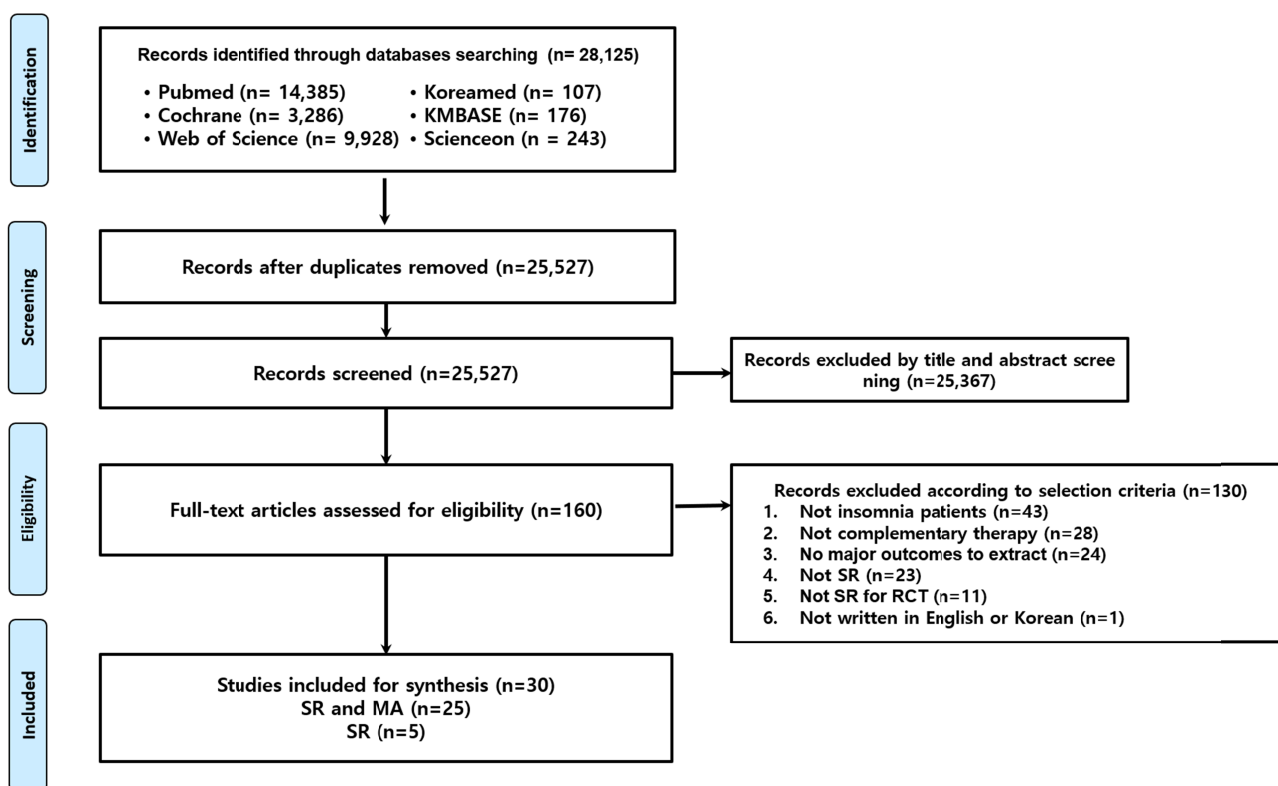


Figure 1. Study selection process.

Table 1. Outcomes of the included SRs/MAs according to the intervention

Interventions	SR and MA								SR							
	PSQI	ISI	AIS	SOL	TST	WASO	NOA	SE	PSQI	ISI	AIS	SOL	TST	WASO	NOA	SE
Acupuncture	16	4	5	4	5	3	1	5	3*	2*	2	NR	NR	NR	NR	2*
MBP	4	2	NR	1	2	1	NR	2	1	2	1	1	1	1	NR	1
Natural products	5	NR	2	4	5	1	NR	3	1	1*	NR	1*	1*	NR	1*	1*
Total	25	6	7	9	12	5	1	10	5	3	3	2	2	1	1	3

Note: \*One SR reported multiple outcomes (PSQI, ISI, SOL, TST, SE) using acupuncture, MBP, and natural product interventions.

Abbreviations: PSQI, Pittsburgh Sleep Quality Index; ISI, Insomnia Severity Index; AIS, Athens Insomnia Scale; SOL, sleep onset latency; TST, total sleep time; WASO, wake after sleep onset; NOA, number of awakenings; SE, sleep efficiency; NR, non-reported; MBP, mind and body practices; MA, meta-analysis; SR, systematic review.

**Table 2. Characteristics of the included SRs/MAs**

1st author (year)	No. of participants	No. of included RCT	Sample sizes per RCT	Mean age (range)	% of female	Comorbid disease		Funding source (Y/N/NR)
						Single	Multiple	
SR and MA								
Cao (2009) [25]	3811	10	22-181	NR (13-85)	NR		Poststroke (220), depression (179), schizophrenia (60), cervical spondylosis (166), drug addiction (100), end-stage renal disease (204)	Y
Cheuk (2012) [26]	2293	33	22-200	NR (15-98)	NR		Stroke, end-stage renal disease, perimenopause, pregnancy, psychiatric diseases	Y
Yeung (2012) [27]	4115	40	13-785	NR	NR			Y
Lan (2015) [28]	1429	15	21-300	NR (18-78)	64.30%			Y
Ni (2015) [29]	7886	76	42-366	28-74.1 (15-84)	56.70%			Y
Lee (2016) [30]	1111	13	30-300	NR	NR	Stroke		Y
Shergis (2016) [31]	2289	26	33-180	NR (17-75)	56.20%			Y
Choi (2017) [21]	475	6	45-120	NR (41-76)	NR	Cancer		Y
Dong (2017) [24]	1678	18	45-187	NR (18-75)	54.10%	Depression		Y
Huang (2017) [16]	4140	57	18-198	NR	NR			Y
Rubio-Arias (2017) [32]	660	5	30-249	48.6-55.8 (NR)	100%	Postmenopausal women		N
Cao (2019) [33]	5533	73	22-196	NR (18-60)	NR			Y
Feng (2019) [19]	1999	22	30-150	NR (NR)	55%			Y
Liu (2019) [20]	946	9	12-271	NR	NR	Chronic pain		Y
Wang (2019) [34]	4506	49	26-410	NA (21-78.1)	NR			Y
Zhang (2019) [35]	1500	15	33-227	29-44.85 (NR)	NR			Y
Zhao (2019) [18]	928	14	40-155	NR (18-95)	NR		Hypertension, diabetes, post-stroke, cerebral stroke, acute cerebral infarction, hepatocirrhosis, maintenance hemodialysis, chronic obstructive pulmonary disease, and hip fracture	Y

**Table 2. Continued**

1st author (year)	No. of participants	No. of included RCT	Sample sizes per RCT	Mean age (range)	% of female	Comorbid disease		Funding source (Y/N/NR)
						Single	Multiple	
Birling (2020) [36]	1780	19	60-150	34.7-68.1 (> 18)	54%	Single	Schizophrenia (1), hypertension (1), people with insomnia with a specific Chinese medicine pattern (1)	N
Kim (2019) [17]	1521	19	50-382	NR (> 18)	NR	Single		Y
Li (2020) [37]	1549	14	47-198	NR	63.40%	Single		Y
Liu (2020) [38]	1061	13	57-203	NR (17-67)	NR	Single	Perimenopausal women (1), depression (3), anxiety (1)	Y
Wang (2020) [39]	2029	22	57-268	35.38-66.8 (NR)	59.90%	Single		Y
Wang (2020) [40]	520	5	30-216	NR	66.50%	Single		Y
Zhang (2020) [41]	1108	15	27-192	36.6-58.55 (NR)	NR	Single		Y
Zhao (2020) [22]	1685	18	50-298	NR	NR	Single	Hypertension	Y
SR								
Yeung (2009) [42]	1956	20	30-190	NR (13-76)	NR	Single		NR
Sarris (2011) [43]	1806	20	30-405	NR	NR	Single		Y
Xie (2013) [23]	1376	12	60-330	30.6-62 (NR)	57.20%	Single		NR
Wang (2017) [44]	436	4	40-200	NR	NR	Single	Coronary heart disease; or need long-term care facilities (suffered from cerebral vascular accidents, dementia, chronic psychiatric conditions or psychosis, chronic obstructive pulmonary disease, or central nervous system injury); or anxiety	N
Lowe (2019) [45]	609	11	23-123	44-80 (30-90)	70.20%	Single		N

Abbreviations: MA, meta-analysis; SR, systematic review; Y, Yes; N, No; NR, non-reported; PTSD, posttraumatic stress disorder symptoms.

## 2. Publication trend

An analysis of the publishing trend for the included SRs/MAs based on the first author's information showed that the authors came from five countries, including China (73.3%), Australia (10%), the Republic of Korea (10%), Spain (3.3%), and the United Kingdom (3.3%). The annual publishing trend was 50% (15/30) in 2019 and 2020, with > 73.3% (22/30) being published since 2016 (Supplementary Table S3).

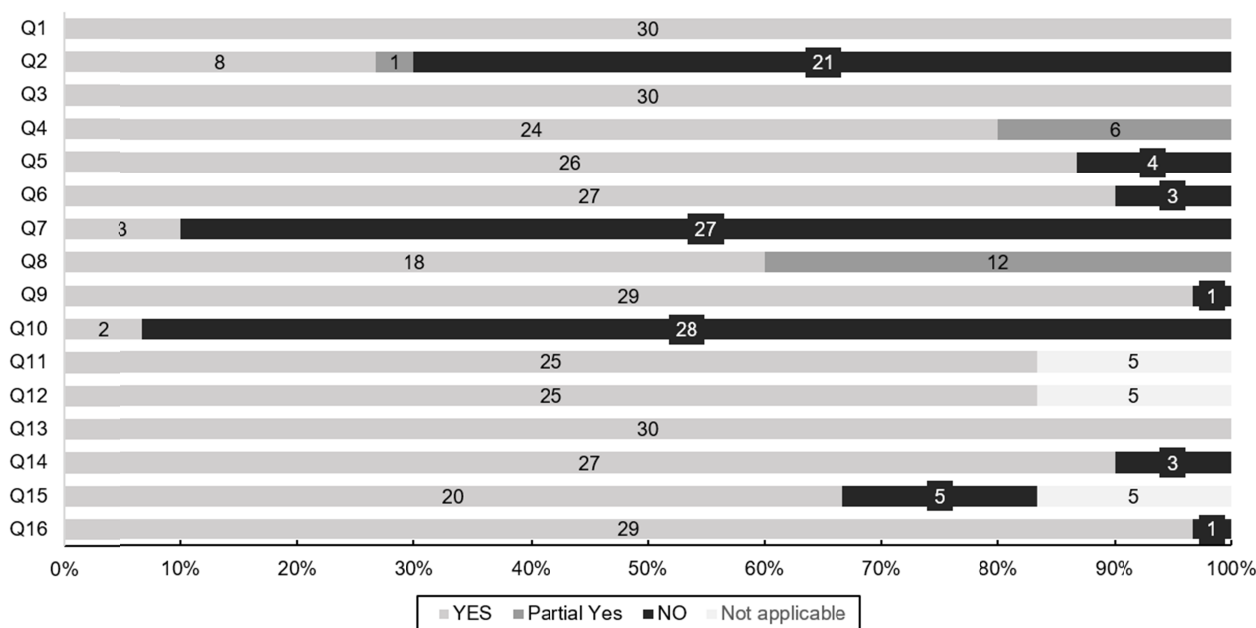
The most frequently reported interventions were acupuncture (63.3%, 19/30), followed by natural products (20%, 6/30)

(Supplementary Table S4).

Nine articles (8 MAs, 1 SR) [16-24] were reported with only PSQI (primary outcome), and the rest were reported with PSQI and secondary outcomes (ISI, AIS, SOL, TST, WASO, NOA, and SE) (Table 1).

## 3. Characteristics of included SRs/MAs

Table 2 [16-45] lists the main characteristics of the included MAs/SRs. Thirty SRs/MAs reported the PSQI outcomes for insomnia. Among them, MA included 25 studies, and SR in-



Critical flaw= Q2, 4, 7, 9, 11, 13, 15 (bold)

1. Did the research questions and inclusion criteria for the review include the components of PICO?
- 2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?**
3. Did the review authors explain their selection of the study designs for inclusion in the review?
- 4. Did the review authors use a comprehensive literature search strategy?**
5. Did the review authors perform study selection in duplicate?
6. Did the review authors perform data extraction in duplicate?
- 7. Did the review authors provide a list of excluded studies and justify the exclusions?**
8. Did the review authors describe the included studies in adequate detail?
- 9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?**
10. Did the review authors report on the sources of funding for the studies included in the review?
- 11. If meta-analysis was performed, did the review authors use appropriate methods for statistical combination of results?**
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?
- 13. Did the review authors account for RoB in primary studies when interpreting/discussing the results of the review?**
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?
- 15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?**
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

Figure 2. Methodological and reporting quality: Evaluation results of each AMSTAR2 question of included SRs/MAs.

cluded five [23, 42-45].

The total number of participants was 62,735 [436-7, 886], the number of included RCTs was 673, and the sample size of each RCT ranged from 12-785.

Age was reported in 21 SRs/MAs (70%), and five SRs/MAs included adolescents.

The age range of the participants was 13-98 years.

Gender was reported in 12 SRs/MAs (40%), and in all SRs/MAs where gender was mentioned, > 50% were female, and in one case were only female.

Eighteen SRs/MAs did not report the comorbidity of insomnia; six SRs/MAs reported single comorbidity, and six SRs/MAs reported multiple comorbidities. The comorbidities reported were cancer, depression, postmenopausal women, stroke, and posttraumatic stress disorder (Table 2). Twenty-eight SRs/MAs (93.3%) reported the presence or absence of funding (Table 2).

#### 4. Methodological and reporting quality of the included SRs/MAs

AMSTAR-2 was used to evaluate the methodological quality of the included SRs/MAs. Although the SR/MA quality was generally low, half of the SRs/MAs were published before the development of AMSTAR-2 in September 2017 and were evaluated retrospectively. Twenty SRs/MAs [17-20, 23, 24, 27-32, 34-37, 40-42, 45] were evaluated as critically low methodological quality; the main reasons were an omission in the protocol registration and the excluded studies list. Nine SRs/MAs (30%, 9/30) provided a review method in advance of the protocol, and three SRs/MAs (10%, 3/30) provided a list of the excluded studies. Additionally, two SRs/MAs (6.7%, 2/30) reported the funding sources for the research in the review analysis. Among the AMSTAR2 items, however, > 90% of SRs/MAs were reported well in Q1, Q3, Q6, Q9, Q13, Q14, and Q16 (Fig. 2, Supplementary Table S5).

#### 5. Effects of included SRs/MAs

##### 1) Primary outcome: Global score on PSQI

PSQI is a self-assessment questionnaire that assesses sleep quality and disturbances over one month [12].

In 30 MAs/SRs, 383 RCTs (31,748 participants) were included in the PSQI analysis of insomnia. Of the 30 SRs/MAs, 24 SRs/MAs (80%, 21 MAs and 3 SRs) reported a positive effect (P), and six SRs/MAs reported a pP (Table 3 [16-45], Supplementary Tables S6, 7).

tary Tables S6, 7).

##### (1) Acupuncture

The acupuncture reported in the SRs/MAs was manual acupressure, auricular, electroacupuncture, needle-rolling, and warm acupuncture. Among 30 SRs/MAs, 19 SRs/MAs reported the effects of acupuncture on the PSQI based on insomnia. Of these, 17 SRs/MAs (89.5%, 17/19) reported positive results. The remaining two SRs/MAs reported partially positive results [24, 43]. As a result, acupuncture was reported to be effective for insomnia except for some SRs/MAs using electroacupuncture and needle-rolling acupuncture.

##### ① Acupuncture vs. western medicines

In 13 out of 19 SRs/MAs [16-18, 20-22, 24, 25, 30, 31, 33, 42, 43], PSQI was reported by comparing the effects of acupuncture to western medicines for insomnia. Twelve out of 13 SRs/MAs reported that acupuncture was more effective than western medicine, and one SR/MA [43] reported that acupuncture (needle-rolling acupuncture) and clonazepam had the same effect.

##### ② Acupuncture vs. sham/placebo acupuncture

In 13 out of 19 SRs/MAs [16, 20, 24-28, 31, 33, 38, 41, 43, 44], PSQI was reported by comparing the effect of acupuncture to sham/placebo acupuncture for insomnia. Among 13 SRs/MAs, 11 SRs/MAs reported that acupuncture was more effective than sham/placebo acupuncture, and two SRs/MAs [24, 43] reported similar effects between electroacupuncture and sham/placebo acupuncture.

##### ③ Acupuncture vs. no treatment

Three out of 19 SRs/MAs [25, 26, 33] compared acupuncture with no treatment for insomnia, and all reported that acupuncture was effective.

##### (2) MBP

Five out of 30 SRs/MAs [19, 32, 34, 40, 45] reported the effect of MBP on PSQI for insomnia. Three SRs/MAs [32, 34, 40] reported positive effects, and two SRs/MAs [19, 45] reported partially positive results.

##### ① Tui na

One SR/MA reported the PSQI results of Tui Na therapy in insomnia [19]. Tui Na therapy was superior to estazolam therapy in the treatment areas (head and abdomen). Still, there was no significant difference between Tui Na therapy and estazolam therapy in the treatment areas (head and trunk, head, trunk, and extremities).

##### ② Exercise

PSQI results of the exercise in insomnia were reported in

**Table 3. PICO and effects of the included SRs/MAS**

1st author (year)	Intervention	Control	PSQI	Secondary outcomes							
				ISI	AIS	SOL	TST	WASO	NOA	SE	
SR and MA											
Cao (2009) [25]	Acupuncture Acupressure	Western medication	P								
Cheuk (2012) [26]	G1: Acupuncture alone G2: Acupuncture alone G3: Acupuncture adjunctive to other treatment G4: Acupuncture adjunctive to other treatment	G1: NT G2: Placebo or sham treatment G3: Other treatment alone G4: Placebo or sham treatment adjunctive to other treatment	P	P	P	P	P	P	P	P	P
Yeung (2012) [27]	Acupressure	Sham acupressure	P								
Lan (2015) [28]	G1: Auricular acupuncture G2: Auricular acupuncture	G1: Sham or placebo G2: Medications comparison	P								
Lee (2016) [30]	Acupressure	Drugs, Sham AT	P	P	P						
Shergis (2016) [31]	Acupuncture	Sham/placebo, standard pharmacotherapy	P								N
Choi (2017) [21]	G1: Acupuncture G2: Acupuncture G3: Acupuncture	G1: Sham Acupuncture G2: Conventional drug G3: Hormone therapy	P								
Dong (2017) [24]	G1: Acupuncture G2: Acupuncture combined with western medicine G3: Electroacupuncture	G1: Western medicine G2: Single medicine G3: Sham or placebo acupuncture	pP								
Huang (2017) [16]	G1: Acupuncture and/or moxibustion G2: Acupuncture and/or moxibustion combined with western medication or oral Chinese medicine	G1: Common therapies (western drugs, sham acupuncture, oral Chinese medicine) G2: Same western medication or oral Chinese medicine	P								
Cao (2019) [33]	Acupuncture	NT, sham acupuncture, conventional therapy, western medication	P								P
Liu (2019) [20]	Acupuncture	Sham acupuncture or conventional drugs	P								
Zhao (2019) [18]	G1: APT G2: APT	G1: Western medications G2: Sham APT and NT	P								
Kim (2019) [17]	Acupressure	Medications	P								
Liu (2020) [38]	Acupuncture	Sham acupuncture	P	P						N	N
Zhang (2020) [41]	Acupuncture	Sham/placebo acupuncture or WL	P	P						N	P
Zhao (2020) [22]	Auricular acupuncture	Any type of control group (including conventional western medicine, routine nursing, or blank control)	P								



**Table 3. Continued**

1st author (year)	Intervention	Control	PSQI	Secondary outcomes														
				ISI	AIS	SOL	TST	WASO	NOA	SE								
	Mind and body practices																	
Rubio-Arias (2017) [32]	Exercise	Non-exercising controls	P	P														
Feng (2019) [19]	Tui Na	Estazolam	pP															
Wang (2019) [34]	Meditation, tai chi, qigong, and yoga, alone or in combination	Inactive (TAU or WL) and active (pharmacotherapy and CBT) control	P	P	U	P	N											
Wang (2020) [40]	Mindfulness-based interventions	NT, WL, pharmacotherapy, SHE	P															
	Natural products																	
Ni (2015) [29]	CHM, CHM combined with conventional therapies	Placebo, BZDs, non-BZDs, psychotherapy such as CBT and SHE	P	U	P	P												
Zhang (2019) [35]	Chinese herbal medicine (CHM)	Placebo	P	P	P	P												
Birling (2020) [36]	Zao Ren An Shen (ZRAS)	Conventional treatments, a placebo or no-treatment	pP		U	P												
Li (2020) [37]	TCM Yangxin Anshen Therapy (TYAT)	Placebo, BDZs	pP		P	P	N											
Wang (2020) [39]	Chaihu Longgu Muli decoction (CLMD) monotherapy or CLMD plus conventional treatment	Placebo, NT, or conventional medicine	P															
	SR																	
	Acupuncture																	
Yeung (2009) [42]	Traditional needle acupuncture (TNA)	Placebo, western medication, non-treated controls	P	P	P													
Sarris (2011) [43]	Acupuncture, acupressure	Sham, western medicine	pP	U														
Wang (2017) [44]	HT7 stimulation	No HT7 stimulation, sham	P															
	Mind and body practices																	
Lowe (2019) [45]	Tai chi, exercise	A suitable, non-physically active control condition (i.e., non-/other intervention, WL)	pP	P	U	U	U											
	Natural products																	
Sarris (2011) [43]	Tryptophan, Valerian, Kava	Placebo, diphenhydramine (active control)			U													
Xie (2013) [23]	Suanzaoren decoction (SZRD) as a monotherapy or as an adjunct therapy to conventional medicine	Conventional medicine (BDZ), placebo, or NT	P															

Abbreviations: MA, meta-analysis; SR, systematic review; P, positive result; pP, partially positive result; N, negative result; U, uncertain result; PSQI, Pittsburgh Sleep Quality Index; ISI, Insomnia Severity Index; AIS, Athens Insomnia Scale; APT, auricular plaster therapy; SOL, sleep onset latency; TST, total sleep time; WASO, wake after sleep onset; NOA, number of awakenings; SE, sleep efficiency; CBT, cognitive behavioral therapy; CHM, Chinese herbal medicine; EC, education control; C, control group; NR, non-reported; NT, no treatment; RCT, randomized controlled trial; SHE, sleep hygiene education; TAU, treatment as usual; WL, wait list control.

## DISCUSSION

two SRs/MAs [32, 45]. One SR/MA [32] reported that exercise (aerobic activity and yoga) was more effective than the non-exercising control conditions, and one SR/MA [45] reported improvement but no significance.

### ③ Tai chi

The PSQI results of tai chi in insomnia were reported in two SRs/MAs [34, 45]. One SR/MA [45] reported that tai chi improved sleep compared to health education, weekly health talk, and sleep seminar. Another SR/MA [34] reported that MBTs, such as meditation, tai chi, qigong, and yoga, can improve sleep quality.

### ④ Mindfulness-based interventions (MBI)

MBI for insomnia was reported to be more effective in improving sleep than regular health education, pharmacotherapy, and waitlist [40].

### (3) Natural products

Six out of 30 SRs/MAs [23, 29, 35-37, 39] reported the results of natural products on PSQI for insomnia. Chinese herbal medicine (CHM) was compared with placebo or medication in all six cases. Four SRs/MAs [23, 29, 35, 39] reported that CHM was more effective in treating insomnia, and two SRs/MAs [36, 37] reported that CHM was more effective than a placebo. Still, there was no significant difference with western medicine, but they had fewer side effects.

## 2) Secondary outcomes

### (1) ISI

Nine SRs/MAs (6MAs and 3SRs) [26, 30, 32, 34, 38, 41-43, 45] reported ISI results for insomnia, and eight SRs/MAs (88.9%) reported positive results, and one SR/MA reported an uncertain result [43]. The results of the other secondary outcomes can be found in Table 3.

## 6. Safety of the included SRs/MAs

Twenty out of 30 SRs/MAs (66.7%) [16-21, 23-29, 31, 33, 36, 37, 39, 41, 42] reported whether they had adverse events. According to the intervention, 14 SRs/MAs (68%, 14/19) reported the side effects of acupuncture, one (20%, 1/5) for MBP, and five for natural products (83.3%, 5/6) (Supplementary Table S8). The side effects included pain, headache, and dizziness, but no SRs/MAs reported serious side effects (Supplementary Table S8).

This overview reviewed SRs with or without MA of RCTs for complementary therapies in patients with insomnia published until November 2020. Recently, the overview of complementary and alternative therapies for insomnia was mostly reported based on the RCT, SR, or MA for some CAM interventions [9-11, 46]. On the contrary, there are few overview studies based on MA and SR on the overall CAM for insomnia. Hence, this overview may provide insight into complementary therapies' MA and SR trends for insomnia.

The publication trend of the SRs/MAs included has appeared since 2009, with more than 50% (51.6%) published in 2019 and 2020. This suggests that SRs/MAs on complementary therapies for improving insomnia have rapidly increased in recent years.

This overview showed that complementary therapies, such as acupuncture, MBP, and natural product intervention, could improve sleep quality. The primary outcome, the PSQI, reported positive and positive results in all interventions. The PSQI is a commonly used tool for assessing the validity of other sleep quality measurement tools [47].

The most frequently reported interventions were acupuncture, followed by natural products. Acupuncture showed a superior result than conventional medications, sham/placebo, and no treatment. This is similar to the results of previous studies [48]. Acupuncture has been studied because it is a representative CAM intervention consistent with studies on other diseases [49-51]. MBPs such as exercise, tai chi, and MBI improved insomnia symptoms and sleep quality for patients with insomnia [32, 34, 40]. Tui Na therapy appeared to be superior to estazolam therapy in treating specific areas (head or abdomen); however, there was no significance in treating combined areas (head and trunk; head, trunk, and extremities) [19]. CHM for insomnia was more effective than a placebo or conventional medications (66.7%, 4/6).

Sleep problems might have a bidirectional relationship with various diseases, such as cancer and mental disorders. Twelve of the 30 SRs/MAs analyzed in this overview reported single or multiple comorbidities, including cancer, depression, and chronic pain [18, 20-22, 24-26, 30, 32, 36, 38, 44]. Therefore, the publication trends reflect the actual clinical situation.

The many studies on insomnia are the most common sleep disorder that can cause interpersonal, social, and occupational problems, increasing steadily every year [1, 4-6].

Decreased concentration and attention in insomnia may be

associated with higher accident rates. Persistent insomnia is also associated with hypertension, major depressive disorders, myocardial infarction, reduced productivity, increased absenteeism at work, and increased economic burden [1]. The results of this overview confirmed the positive effects of acupuncture, MBP, and natural products as measured by PSQI on insomnia. CAM for insomnia is considered a therapy that can be applied safely to insomnia because it has excellent effects, and no severe side effects have been reported.

When interpreting the finding, it is necessary to consider that AMSTAR-2 released in 2017, is more stringent than previous versions. Half of the included SRs/MAs were conducted before the development of AMSTAR-2, with rigorous retrospective assessments applied, resulting in low or critically low ratings. Therefore, to meet the stricter reporting standards in the future, it is necessary to register the protocol before the SR/MA and report the list of excluded studies and funding sources.

This overview had some limitations. First, this overview analyzed only SR with or without MA for RCT to compare the outcomes. The value of observational studies reflecting real-world clinical data has been re-evaluated recently, so analyses including various study designs are necessary for further research [52]. Second, the methodological quality of the included SRs with or without MA for RCT was low, so future reports based on SR/MA with better reporting quality are required. Third, this overview has a limitation in restricting the publishing languages to English and Korean. On the contrary, recent scholarly publications are written mainly in English. Moreover, a significant bias due to language restrictions is not expected as half of the SRs/MAs included in this overview were published by Chinese-affiliated researchers.

## CONCLUSION

This overview provides evidence that complementary therapy can improve insomnia symptoms and sleep quality and provide relevant healthcare professionals and patients with a basis for decision-making on the efficacy and safety of complementary therapies for insomnia. PSQI was used to confirm the positive effects of acupuncture, MBP, and natural products on insomnia. More well-designed primary and secondary research will be needed to improve and reinforce the level of evidence for complementary therapies for insomnia disorders under rigorous reporting tools, such as AMSTAR 2.

## SUPPLEMENTARY MATERIALS

Supplementary data is available at <https://doi.org/10.3831/KPI.2022.25.3.186>.

Supplementary Table S1. Search strategies (November 2020).  
Supplementary Table S2. List of excluded studies and reasons for exclusion.  
Supplementary Table S3. Number of SRs/MAs according to the year and country.  
Supplementary Table S4. Interventions of the included SRs/MAs according to the year.  
Supplementary Table S5. Methodological and reporting quality of the included SRs/MAs.  
Supplementary Table S6. PSQI in MA.  
Supplementary Table S7. PSQI in SR.  
Supplementary Table S8. Adverse events of the included SRs/MAs.

## CONFLICTS OF INTEREST

The authors declare no conflict of interest.

## AUTHORS' CONTRIBUTIONS

Conceptualization, Hyun, Yeo, and Lee.; performed the analysis, Yeo, Lee, and Kim; writing—original draft preparation, Yeo, and Hyun; writing—review and editing, Yeo, and Hyun; supervision, Hyun; project administration, Hyun; funding acquisition, Hyun. All authors have read and agreed to the published version of the manuscript.

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