

Acupuncture for Treatment of Insomnia: A Systematic Review of Randomized Controlled Trials

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Abstract

Background: Acupuncture is commonly used in treating insomnia in China, and clinical studies have shown that acupuncture may have a beneficial effect on insomnia compared with Western medication.

Methods: We included randomized controlled trials on acupuncture for insomnia. We searched PubMed, the Cochrane Library (2008 Issue 3), China Network Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), and Wan Fang Database. All searches ended in December 2008. Two authors extracted data and assessed the trials' quality independently. RevMan 5.0.17 software was used for data analysis with effect estimate presented as relative risk (RR) and mean difference (MD) with a 95% confidence interval (CI).

Results: Forty-six (46) randomized trials involving 3811 patients were included, and the methodological quality of trials was generally fair in terms of randomization, blinding, and intention-to-treat analysis. Meta-analyses showed a beneficial effect of acupuncture compared with no treatment (MD -3.28 , 95% CI -6.10 to -0.46 , $p = 0.02$; 4 trials) and real acupressure compared with sham acupressure (MD -2.94 , 95% CI -5.77 to -0.11 , $p = 0.04$; 2 trials) on total scores of Pittsburgh Sleep Quality Index. Acupuncture was superior to medications regarding the number of patients with total sleep duration increased for >3 hours (RR 1.53, 95% CI 1.24–1.88, $p < 0.0001$). However, there was no difference between acupuncture and medications in average sleep duration (MD -0.06 , 95% CI -0.30 – 0.18 , $p = 0.63$). Acupuncture plus medications showed better effect than medications alone on total sleep duration (MD 1.09, 95% CI 0.56–1.61, $p < 0.0001$). Similarly, acupuncture plus herbs was significantly better than herbs alone on increase of sleep rates (RR 1.67, 95% CI 1.12–2.50, $p = 0.01$). There were no serious adverse effects with related to acupuncture treatment in the included trials.

Conclusions: Acupuncture appears to be effective in treatment of insomnia. However, further large, rigorous designed trials are warranted.

Introduction

INSOMNIA IS ONE OF THE MOST COMMON SLEEP DISORDERS, with a prevalence of 40% in adults. It is generally believed that 10%–15% of the adult population suffers from chronic insomnia, and an additional 25%–35% have transient or occasional insomnia.¹ The symptoms of insomnia may be difficult falling asleep, sleep latency more than 30 minutes, or sleep efficiency less than 85%, which usually happened more than 4 nights a week and occurred at least 3 weeks.² Patients with insomnia may feel tired, tense, lazy, or have delayed reactions, distraction, or headache. The serious consequence of insomnia can be mental illness, and the worst mental illness is schizophrenia.

Insomnia can be treated with medications, herbal therapy, and psychologic or physical therapy. The commonly used medications include hypnotic sedative agents, such as zaleplon and benzodiazepines, but they may cause adverse

effects such as damage of memory, drug resistance, dependency, and addiction.³ Nondrug therapy including acupuncture is commonly used by patients with insomnia. The mechanism of acupuncture treatment may be regulating *yin* and *yang* to reinforce health and eliminate the pathogenic, thus improving sleep.⁴ In modern medicine, acupuncture can increase the content of γ -amino butyric acid, and then enhance sleep quality.⁵ We performed this systematic review to evaluate the beneficial and harmful effects of acupuncture for treatment of insomnia in randomized trials.

Methods

Inclusion criteria

Parallel randomized controlled trials (RCTs) of acupuncture compared with no treatment, placebo, or basic medical therapy in patients with insomnia were included. Combined

therapy of acupuncture and other interventions compared with other interventions in RCTs was also included. Outcome measures include duration and quality of sleep, such as total sleep duration and increased sleep duration, Pittsburgh Sleep Quality Index (PSQI) scores, Index of Severity of Insomnia, Sleep Quality, and other validated scores, as well as adverse effects. Multiple publications reporting the same groups of participants were excluded. There was no limitation on language and publication type.

Identification and selection of studies

We searched China Network Knowledge Infrastructure (1979–2008), Chinese Scientific Journal Database VIP (1989–2008), Wan Fang Database (1985–2008), PubMed (1966–2008), and the Cochrane Library (Issue 3, 2008). All of the searches ended at December 2008. The search terms included “acupuncture,” “acupressure,” “acupoint,” “electroacupuncture,” or “meridian” combined with “insomnia,” “sleepless,” or “dysomnia.” Two authors (H.J. Cao and H. Li) selected studies for eligibility and checked against the inclusion criteria independently.

Data extraction and quality assessment

Two authors (H.J. Cao and H. Li) extracted the data from the included trials independently. Quality of the included trials was evaluated according to the following categories⁶: Category A (good): studies have the least biases and their results are considered valid. These studies are likely to consist of (1) clear description of the population, setting, interventions, and comparison groups; (2) appropriate measurement of outcomes; (3) appropriate statistical and analytical methods; (4) no reporting errors; (5) less than 20% dropouts; (6) clear reporting of dropouts; and (7) appropriate consideration and adjustment for potential confounders. Category B (fair): studies are susceptible to some degrees of biases that are not sufficient to invalidate the results. These studies may have suboptimal adjustments for potential confounders and may also lack certain information that is needed to assess limitations and potential problems. Category C (poor): studies have significant biases that may invalidate the results. These studies either do not consider potential confounders or do not make adjustments for them appropriately. These studies may have critical flaw in design, analysis, and/or reporting, missing information, and/or discrepancies in reporting.

Data analysis

Data were summarized using relative risk (RR) with 95% confidence intervals (CI) for binary outcomes or mean difference (MD) with 95% CI for continuous outcomes. Revman5.0.17 software was used for data analyses. Meta-analysis was used if the trials had a good homogeneity on study design, participants, interventions, control, and outcome measures. Publication bias was explored by funnel plot analysis.

Results

Description of studies

After primary searches from seven databases, 1956 citations were identified, and the majority were excluded due to

obvious ineligibility, and full text papers of 67 studies were retrieved. Forty-six (46) RCTs were included in this review (Fig. 1),^{7–47} and among them, five trials were unpublished and were from graduate student dissertations.* There were 21 studies including 16 RCTs excluded from this review due to multiple publications, non-RCT design, data unavailable, or not meeting one of the inclusion criteria.^{48–68} The characteristics of included trials are listed in Table 1, and the reasons for excluded studies are listed in Table 2.

The 46 trials involved a total of 3811 patients with insomnia, of whom 2882 were patients with primary insomnia, 220 were insomnia patients with poststroke, 179 with depression, 60 in remittent stage with schizophrenia, 166 with cervical spondylosis, 100 with drug addiction, and 204 with end-stage renal disease. There was a wide variation in the age of subjects (13–85 years) and disease duration (10 days–40 years). Thirty-three (33) trials specified six diagnostic criteria, including four national criteria in China, one criterion from the United States, and one international classification of disease (ICD). The interventions included acupuncture (body, auricular acupuncture, electroacupuncture, acupressure, and acupoint injection), acupuncture plus conventional medication, or herbal medicine. The controls included no treatment, sham acupuncture, medication, or herbal medicine. The acupoints used were not fixed, the number of acupoints selected ranged from 2 to 20, and the total treatment duration ranged from 2 days to 10 weeks. The top 10 commonly used body acupoints and top 5 auricular acupoints are presented in Figures 2 and 3. Ten (10) of the 46 trials used the scores (PSQI) as the outcome measure and 12 kinds of scores were used for sleep measurement. Thirty-three (33) trials used four classes to evaluate treatment effects including cure, markedly effective, effective, and ineffective according to the degree of overall symptom improvement.

Methodological quality

The majority of the included trials were assessed to be of generally fair methodological quality. According to our predefined quality assessment criteria, seven trials (15.22%) were evaluated as good (A), and the remaining as fair (B). The sample size varied from 22 to 182 participants, with an average of 35 patients in each group. Only 1 of the 46 trials⁴⁰ reported sample size calculation that used Sample Power

*Huang XQ, Dong GR. Clinical study of acupuncture with combining Yin-Yang or Qi-Blood points on treatment of insomnia [in Chinese]. Dissertation for the master degree from Heilongjiang University of Traditional Chinese Medicine. 2000;

Kou JY, Sun YZ. Clinical observation of effect of acupuncture with Tiaozang Anshen method on Treatment of Insomnia [in Chinese]. Dissertation for the master degree from Heilongjiang University of Traditional Chinese Medicine. 2003;

Luo L, Yu SG. Effect of rolling acupuncture on treatment of insomnia [in Chinese]. Dissertation for the master degree from Chengdu University of Traditional Chinese Medicine. 2005;

Luo WZ, Lai XS. Clinical study of therapeutic effect of acupuncture with Jieyutiao shen method on treatment of insomnia with depressive disorder [in Chinese]. Dissertation for the master degree from Guangzhou University of Traditional Chinese Medicine. 2006;

Zhang Q, Dong GR. Study of therapeutic effect of acupuncture with combining Yin-Yang or Qi-Blood points method on treatment of insomnia and its effect on polysomnography [in Chinese]. Dissertation for the master degree from Heilongjiang University of Traditional Chinese Medicine. 2006;

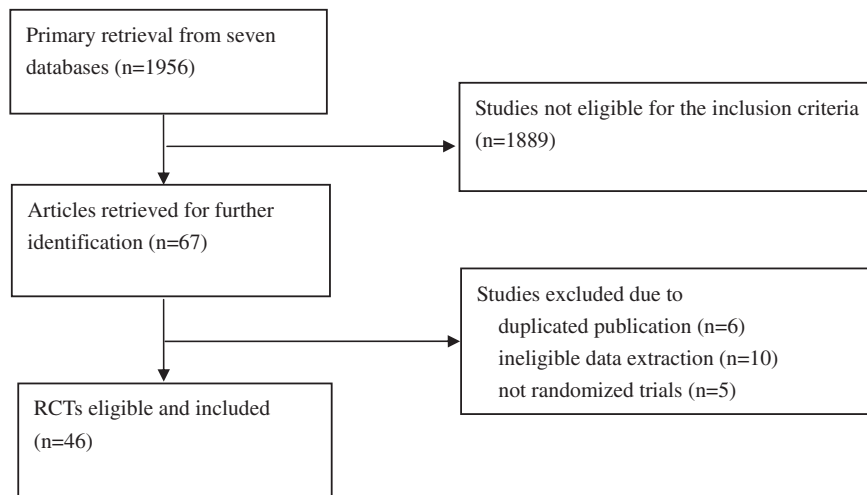


FIG. 1. The process of study selection. RCTs, randomized controlled trials.

software, essential for ensuring adequate statistical power of 82%. Fourteen (14) trials described the randomization procedure, using random number table, drawing, or coin tossing. Three trials^{37,41} (Luo L 2005, unpublished data) used envelope as the method for allocation concealment. Eight trials^{7,27,35,39,42} (Huang X 2000; Kou J 2003; Zhang Q 2006, unpublished data) employed a blinding procedure: four of them used patient blinding, three used assessor blinding, and one trial provide no information on blinding. There was high potential to have bias caused by belief of the subjects and the measurers in the remaining 38 trials. Nine (9) of the 46 trials reported the number of dropouts^{7,15,17,27,35,36,41} (Kou J 2003; Luo L 2005, unpublished data), six trials^{7,8,16,35,36,40} (Huang X 2000, unpublished data) mentioned follow-up, and none of them used intention to treat method. The reporting quality of 46 trials according to Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRIC-TA) varied among different trials (Table 3).

Effect estimates (Table 4)

Acupuncture versus no treatment. Five (5) trials^{7,33,35,36,46} compared acupuncture with no treatment. Data from the no-treatment group was divided in half when compared with the other two interventional groups to avoid duplicated use in a three-arm trial⁴⁰ in the meta-analysis. The result showed that acupressure was significantly better than no treatment on improving the total scores of PSQI (MD -3.28 , 95% CI -6.10 to -0.46 , $p = 0.02$).

Real acupuncture versus sham acupuncture. Three trials^{7,19,35} compared real versus sham acupuncture or acupressure, respectively. The result of meta-analysis showed that real acupuncture was more effective than sham acupuncture on improving total scores of PSQI (MD -2.94 , 95% CI -5.77 to -0.11 , $p = 0.04$).

Acupuncture versus Western medication. Twenty-six (26) trials compared acupuncture with Western medications. Most meta-analyses showed positive effect of acupuncture in treatment of insomnia, but one meta-analysis^{16,41} reported no

difference between acupuncture and drugs on improving sleep duration evaluated by patients (MD -0.06 , 95% CI -0.30 to 0.18 , $p = 0.63$), one pooled results¹⁵ (Luo W 2006, unpublished data) showed no difference between acupuncture and trazodone on improving total scores of the Self-rating depression scale (SDS; MD -0.02 , 95% CI -0.34 to 0.30 , $p = 0.90$), and also another one trial³⁰ reported no significant difference (MD -1.55 , 95% CI -4.25 to 1.15 , $p = 0.26$) between electroacupuncture and clonazepam on improving the scores of Hamilton Anxiety Scale.

Acupuncture plus other interventions versus other interventions. Seven trials compared acupuncture plus Western medications versus medications. Meta-analysis of two trials^{8,20} showed significant difference between acupuncture plus medications compared with the same medications on increasing the total sleep duration by hour (MD 1.09 , 95% CI 0.56 – 1.61 , $p < 0.0001$). Other results of meta-analysis were consistent that acupuncture plus medications had a much more therapeutic effect than medications alone.

Four trials^{13,27,28,34} compared acupuncture plus herbal medicine with herbal medicine. Only one trial²⁸ showed there was no significant difference between the combination therapy and herbal group on increasing the numbers of patients whose total sleeping time increased for more than 3 hours (RR 1.30 , 95% CI 0.93 – 1.82 , $p = 0.13$). However, the meta-analyses showed a positive effect of acupuncture plus herbal medicine compared with herbal medicine on increasing the numbers of patients with sleep rates that increased by more than 60% (RR 1.67 , 95% CI 1.12 – 2.50 , $p = 0.01$).

Meta-analysis of 10 trials showed a better effect of acupuncture than medications for the outcome of the number of patients whose total sleep duration increased for more than 3 hours (RR 1.53 ; 95% CI 1.24 – 1.88 ; $p < 0.0001$; 10 trials).

A funnel plot analysis of the 10 trials was generated, and it showed a significant asymmetry (Fig. 4).

Adverse effect. Outcome of adverse effect with relation to acupuncture was described in 12 trials; only 3 of them reported minor adverse effect in the acupuncture group.

TABLE 1. CHARACTERISTICS OF INCLUDED STUDIES

Study	Number of patients		Age (mean or range)	Diagnostic criteria	Acupuncture (no. of points used)	Control group	Duration of treatment (day)	Outcome measure
	Treatment M/F	Control M/F						
Chen M 1999 ⁷	28	28	79	Pittsburgh Sleep Quality Index (PSQI)	Real acupuncture (5) 15 min per session, 5 sessions per week for 3 weeks	1) Sham acupuncture at nonacupuncture points 15 min per session, 5 sessions per week for 3 weeks 2) Conversation only	21	PSQI
Chen X 2003 ⁸	28	28	50	Government guideline in China	Real acupuncture (5) 15 min per session, 5 sessions per week for 3 weeks	Estazolam 2 mg once per night	36	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Chen F 2007 ⁹	18/22	17/23	18-64	Unavailable	Electroacupuncture (3 + x) ^a plus auricular acupuncture (8), 25 min, once daily; estazolam 2 mg once per night	Diazepam 2.5 mg plus oryzanol 20 mg and VB1 20 mg 3 times a day	14	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Cui R 2001 ¹⁰	34/26	28/32	27-67	Government criteria in China	Body acupuncture (8) once daily plus estazolam 1-2 mg once per night	Estazolam 1-2 mg once per night	30	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Ding D 2008 ¹¹	13/19	11/13	20-71	CCMD-2	Body acupuncture (7 + x) ^a 30 min/3 hours once daily	Estazolam 1 mg once per night	28	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Ding W 2006 ¹²	44/40	16/16	13-75	Unavailable	Body acupuncture (2 + x) ^a	Diazepam 5 mg 3 times a day	7-14	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Du M 2007 ¹³	12/22	7/13	20-82	Unavailable	Body acupuncture (5 + x) ^a 30-60 min every 2 days plus herbal medicine twice a day	Herbal medicine 200 mL twice a day	20	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Fan D 2006 ¹⁴	17/23	12/16	19-65	CCMD-2	Body acupuncture (5) 30 min once daily	Diazepam 5 mg once per night plus oryzanol 10 mg 3 times a day	22	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Hong Y 2005 ¹⁵	30	30	22-76	ICD-10/CCMD-3	Electroacupuncture (2 + x) ^a 45 min once daily	Trazodone 50 mg-100 mg once per night	28	Self-rating Depression Scale (SDS) and Self-rating Anxiety Scale (SAS) Asberg Rating Scale (ARS)

Huang X 2000	40	36	18-65	Government criteria in China	Body acupuncture (17 + x) ^a 30 min once daily	Estazolam 2 mg once per night	21	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy; PSQI
Huang L 2007 ¹⁶	38/52	34/56	Unavailable	ICD-10	Rolling acupuncture 15-20 min once daily	Clonazepam 4-6 mg once per night	28	PSQI
Jian J 2005 ¹⁷	50	30	29-76	Hollister	Body acupuncture (9) ^a 40 min once daily plus <i>Ciwiujia</i> injection 60 mL once daily	<i>Ciwiujia</i> injection 60 mL once daily	25	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Kang F 2006 ¹⁸	36/42	14/16	18-61	CCMD-3	Body acupuncture (3 + x) ^a 30 min once daily plus auricular therapy (7)	Diazepam 5 mg once per night plus oryzanol 20 mg 3 times a day	12	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Kim 2004 ¹⁹	15	15	67	Insomnia Severity Index (ISI)	Acupuncture (4) 2 days	Placebo (sham) acupuncture 2 days	2	MQ (morning questionnaire), ISI
Kou J 2003	14/16	15/15	18-70	CCMD-2	Body acupuncture (17) 30 min once daily	Stilnox 10 mg once per night	28	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Li Q 2005 ²⁰	10/16	9/15	31-80	Unavailable	Electroacupuncture (3) 45 min every 2 days plus Prozac 20 mg once daily	Prozac 20 mg once daily	28	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Li X 2007 ²¹	53/80	21/27	17-65	Government guideline in China	Body acupuncture (6 + x) ^a 30 min every 2 days plus auricular therapy (4 + x)	Estazolam 2 mg once per night	20	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Li T 2007 ²²	18/14	17/15	68	Unavailable	Body acupuncture (7) 20-30 min once daily plus auricular therapy (1)	Diazepam 2.5 mg once per night or estazolam 1 mg once per night	28	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Liu Y 2001 ²³	56	30	56-82	Unavailable	Body acupuncture (4 + x) ^a 40 min once daily plus <i>Ciwiujia</i> injection 60 mL once daily	<i>Ciwiujia</i> injection 60 mL once daily	25	Significant as "cured," "improved," "ineffective" according to improvement of symptom
Liu Q 2000 ²⁴	36	36	18-70	Unavailable	Body acupuncture (4 + x) ^a once daily plus auricular therapy (4)	Estazolam 2 mg once per night	32-51	Significant as "markedly effective," "improved," "ineffective" according to improvement of symptom

(continued)

TABLE 1. (CONTINUED)

Study	Number of patients		Age (mean or range)	Diagnostic criteria	Acupuncture (no. of points used)	Control group	Duration of treatment (day)	Outcome measure
	Treatment M/F	Control M/F						
Liu J 2006 ²⁵	15/17	15/15	68	Unavailable	Body acupuncture (8) 30 min once daily plus auricular therapy (1)	Diazepam 2.5 mg once per night or estazolam 1 mg once per night	28	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Liu Z 2007 ²⁶	34/36	35/45	49	CCMD-3	Scalp acupuncture 6 hours once daily	Clonazepam 4 mg once per night	28	Significant as "cured," "improved," "ineffective" according to improvement of symptom
Lu W 1998 ²⁷	14/21	10/13	16-60	Government criteria in China	Body acupuncture (2) 30 min once daily plus <i>Qiyi Anshien</i> tablet 100 mg 3 times a day	<i>Qiyi Anshien</i> tablet 100 mg 3 times a day	30	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficiency
Luo L 2005	13/19	15/17	41	CCMD-3	Rolling acupuncture 10-15 min once daily/every 2 days plus clonazepam 2 mg once per night	Clonazepam 2 mg once per night	28	Significant as "cured," "improved," "ineffective" according to improvement of symptom; PSQI; Visual Analogue Scale (VAS)
Luo W 2006	33	32	21-64	CCMD-3	Body acupuncture (8) 30 min once daily	Trazodone 50-150 mg once per night	28	PSQI; SDS; Asberg Rating Scale (ARS); Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Lv Y 2007 ²⁸	13/21	11/23	18-70	ICD-10	Electroacupuncture (10 + x) ^a 20 min once daily and auricular therapy (5) plus <i>Suanzaoren</i> decoction once daily	<i>Suanzaoren</i> decoction 300 mL once daily	30	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Ma X 2006 ²⁹	4/26	5/25	17-75	Unavailable	Body acupuncture (6 + x) ^a 30 min once daily plus alprazolam 0.4-0.8 mg once per night and antipsychotic drug	Alprazolam 0.4-0.8 mg plus antipsychotic drug	21-32	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Ma Z 2006 ³⁰	11/20	16/15	17-72	CCMD-3	Electroacupuncture (5 + x) ^a 60 min once daily	Clonazepam 2 mg once per night plus oryzanol 20 mg 3 times a day	30	Sleep Dysfunction Rating Scale (SDRS); Self-rating Sleep Dysfunction Scale (SSDS); Hamilton Anxiety Scale (HAMA)
Pan Q 2005 ³¹	22/34	20/36	15-70	CCMD-2	Body acupuncture (more than 5) 30 min once daily	Estazolam 1 mg once per night	36	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom

Qiu R 1999 ³²	53	36	Unavailable	Unavailable	Acupressure once per night plus herbal medicine once daily	Estazolam 2 mg once per night plus herbal medicine once daily	23	Significant as "markedly effective," "improved," "ineffective" according to improvement of symptom
Tang W 2007 ³³	16/24	18/22	47-84	Unavailable	Auricular therapy (7) plus Tuina and acupressure	No treatment	21	Significant as "excellent," "good," "fair," "ineffective" according to improvement of symptom
Tian H 2006 ³⁴	39	39	35-70	Government criteria in China	Body acupuncture (6) ^a 30 min once daily plus herbal medicine once daily	Herbal medicine once daily	25	Significant as "cured," "improved," "ineffective" according to improvement of symptom
Tsay S 2003 ³⁵	35	31		PSQI	Real acupressure (3) 14 min 3 days per week	Usual care	28	Medical Outcome Study-Short Form 36 (SF-36)
Tsay S 2004 ³⁶	35	32	55.52		Real acupressure (3) 14 min 3 days per week	Sham acupressure (3) 14 min 3 days per week	30	Piper Fatigue Scale (PFS); PSQI; Beck Depression Inventory (BDI)
Wang M 2003 ³⁷	22/38	19/36	16-70	CCMD-2	Acupressure (4) 15 min 3 times a week Transcutaneous electrical acupoint stimulation Body acupuncture (7) 30 min once daily	Usual care Diazepam 5 mg once per night	22	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Wang Q 2003 ³⁸	17/23	17/23	19-65	Unavailable	Electroacupuncture (4) 30 min once daily plus acupoint injection with <i>Citriifolia</i> injection (2) 4 mL once daily	Diazepam 2.5 mg 3 times a day plus oryzanol 20 mg 3 times a day and VB ₁ 20 mg 3 times a day	14	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Wang X 2008 ³⁹	21	23	22-56	CCMD-3	Abdominal acupuncture (12) once daily for the first 3 days and once every 3 days for the remaining 11 days plus placebo pill once daily	Estazolam once daily plus sham acupuncture once daily for the first three days and once every three days for the remaining 11 days	14	Leeds Sleep Evaluation Questionnaire (LSEQ)
Wang Y 2004 ⁴⁰	22/12	17/13	41-70.5	Unavailable	Scalp acupuncture with electrical stimulation plus auricular therapy (1) and body acupuncture (5) 20-30 min 5 times a week	Diazepam 2.5 mg once per night plus clozapine 25 mg once per night	28	PSQI; Hamilton Rating Scale for Depression (HRSD)
Xuan Y 2007 ⁴¹	11/13	10/12	49	ICD-10	Body acupuncture (5) 30 min once daily	Estazolam 1 mg every two night	30	PSQI
Ye T 2008 ⁴²	10	12	29-67	Diagnostic and Statistical Manual of Mental Disorders 4th ed. (DSM-IV)	Abdominal acupuncture (12) 30 min once daily 5 times a week plus estazolam 2 mg once per night	Estazolam 2 mg once per night	14	PSQI

(continued)

TABLE 1. (CONTINUED)

Study	Number of patients		Age (mean or range)	Diagnostic criteria	Acupuncture (no. of points used)	Control group	Duration of treatment (day)	Outcome measure
	Treatment M/F	Control M/F						
Zhang H 2003 ⁴³	55/82	25/20	16-62	CCMD-3/SRSS	Body acupuncture (8 + x) ^a 30-60 min once daily	Clonazepam 2 mg once per night	28	Self-Rating Sleep Scale (SRSS)
Zhang X 2005 ⁴⁴	10/35	14/31	23-70	Unavailable	Body acupuncture (3 + x) ^a 45 min once daily	Estazolam 2 mg once per night plus oryzanol 20 mg 3 times a day	25	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Zhang Q 2006	18/20	20/17	18-64	ICD-10/CCMD-3	Body acupuncture (10 + x) ^a 1 hour once daily	Estazolam 2 mg once per night	20	Significant as "cured," "markedly effective," "improved," "ineffective" according to sleeping efficacy
Zhong Z 2008 ⁴⁵	15/17	12/14	40	CCMD-3	Body acupuncture (7 + x) ^a 30 min once per night and massage of sole once daily plus alprazolam 0.4-0.8 mg once per night	Alprazolam 0.4-0.8 mg once per night	40	PSQI, SDS, SAS, significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom
Zhu Z 2004 ⁴⁶	50/0	50/0	18-47	ICD-10	Electroacupuncture (6) 20 min 3 times a week	No treatment	40	Scores evaluated by patients
Zou Y 2008 ⁴⁷	28/32	30/28	18-68	Government criteria in China	Electroacupuncture (8 + x) ^a 30 min once daily	Alprazolam 0.4 mg once per night	20	Significant as "cured," "markedly effective," "improved," "ineffective" according to improvement of symptom

CCMD, Chinese Classification of Mental Disease; CCMD-2, second version of CCMD; CCMD-3, third version of CCMD; ICD-10, 10th version of International Classification of Disease.

^aThe selection of the acupoints according to syndrome differentiation.

TABLE 2. EXCLUDED STUDIES WITH REASONS

Study	Reason for exclusion
Chen Z 2002 ⁴⁸	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Chen Z 2002 ⁴⁹	Randomized controlled trial that was a replicated publication of Chen Z 2002 ⁵³
Chen X 2003 ⁵⁰	Randomized controlled trial that was a replicated publication of Chen X 2003 ⁸
Chen H 2004 ⁵¹	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Cui G 2000 ⁵²	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Cui R 2003 ⁵³	Randomized controlled trial that was a replicated publication of Cui R 2003 ¹⁰
Dai M 2002 ⁵⁴	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Gao H 2001 ⁵⁵	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Hou C 2005 ⁵⁶	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Li Z 2006 ⁵⁷	Quasi-randomized trial that did not meet the include criteria of this review
Luo L 2006 ⁵⁸	Randomized controlled trial that was a replicated publication of Luo L 2005 ³⁰
Sjoling M 2008 ⁵⁹	Quasi-randomized trial that did not match the included criteria of this review
Su X 2005 ⁶⁰	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Tsay S 2003 ⁶¹	Randomized controlled trial that was a replicated publication of Tsay 2003 ³⁹
Wang J 2004 ⁶²	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Wang J 2006 ⁶³	Quasi-randomized trial that did not match the include criteria of this review
Wang C 1992 ⁶⁴	Retrospective study that did not match the include criteria of this review
Huang L 2007 ¹⁶	Randomized controlled trial that was a replicated publication of Huang L 2007 ¹⁶
Weng M 2007 ⁶⁶	Randomized controlled trial but data were not available for analysis due to inadequate reporting
Yang Z 2008 ⁶⁷	Prospective cohort study that did not match the included criteria of this review
Zhu H 2002 ⁶⁸	Randomized controlled trial but data were not available for analysis due to inadequate reporting

Two (2) trials¹⁶ (Kou J, 2003, unpublished data) reported no adverse effect observed in the acupuncture group. Another trial¹⁵ reported mild headache (1 case), and lassitude (1 case) in the acupuncture group ($n = 28$), whereas there was dizziness (3 cases), constipation (3 cases), dry mouth (2 cases), palpitation (1 case), and oscitation (1 case) in the trazodone group ($n = 27$).

Two (2) trials^{15,28} evaluated the scores of the adverse effect rating scale. The result showed that acupuncture was safer than trazodone (MD -3.12 , 95% CI -4.92 to -1.32 , $p = 0.0007$).

Discussion

Based on the results of meta-analyses, the majority showed that compared with no treatment, sham acupuncture, or medications, acupuncture was significantly better on improving parameters in sleep quality and duration, and the combination of acupuncture and other interventions appears more effective than those interventions alone, though it was

possible that the beneficial effect from acupuncture is overvalued because of the small sample size, flawed methodology of the included trials and the short follow-up duration.

There are several limitations in this review. First, the quality of the included studies is generally fair, which means the existence of moderate risk of bias. Because of inadequate reporting of randomization and blinding in the majority of trials, it was possible that there was performance bias and detection bias due to patients and researchers being aware of the therapeutic interventions for the subjective outcome measures. Intention-to-treat analysis was not applied in data analyses in the trials. The funnel plot asymmetry suggests the possibility of publication bias and small, low-quality trials. In addition, there is probably language bias because 43 of 46 included trials were published in Chinese, and 3 were published in English, but conducted in Taiwan and Korea. Vickers⁶⁹ found that some Asian countries including China publish unusually high proportions of positive results, for which publication bias is a possible explanation. Second, 22

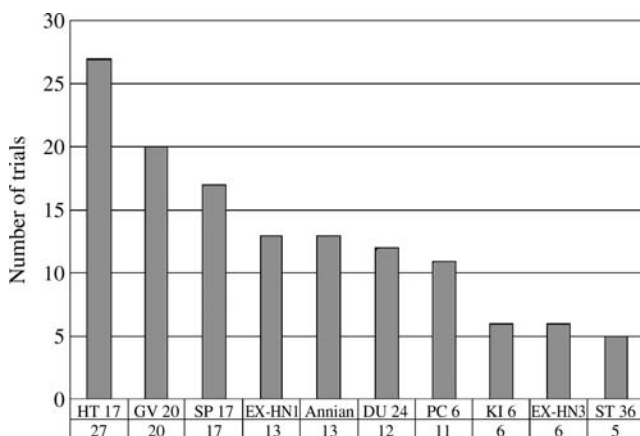


FIG. 2. Top 10 points used for meridian acupuncture treatment.

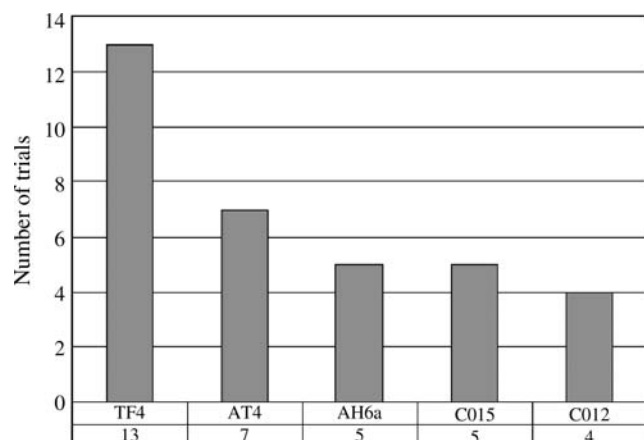


FIG. 3. Top five points for auricular acupuncture treatment.

TABLE 3. REPORTING QUALITY OF 46 RANDOMIZED CONTROLLED TRIALS ACCORDING TO STANDARDS FOR REPORTING INTERVENTIONS IN CONTROLLED TRIALS OF ACUPUNCTURE (STRICTA)

<i>Intervention</i>		<i>Description of item</i>	<i>No. trials eligible to the principle</i>	<i>Percentage</i>
(1) Acupuncture rationale	1	1a) Style of acupuncture	46	100.00%
		1b) Rationale for treatment (e.g., syndrome patterns, segmental levels, trigger points) and individualization if used	46	100.00%
		1c) Literature sources to justify rationale	33	71.74%
(2) Needling details	2	2a) Points used (uni/bilateral)	46	100.00%
		2b) Numbers of needles inserted	24	52.17%
		2c) Depths of insertion (e.g., <i>cun</i> or tissue level)	21	45.65%
		2d) Responses elicited (e.g., <i>de qi</i> or twitch response)	21	45.65%
		2e) Needle stimulation (e.g., manual or electrical)	27	58.70%
		2f) Needle retention time	46	100.00%
		2g) Needle type (gauge, length, and manufacturer or material)	25	54.35%
(3) Treatment regimen	3	3a) Number of treatment sessions	46	100.00%
		3b) Frequency of treatment	46	100.00%
(4) Co-interventions	4	4a) Other interventions (e.g., moxibustion, cupping, herbs, exercises, lifestyle advice)	46	100.00%
(5) Practitioner background	5	5a) Duration of relevant training	2	4.35%
		5b) Length of clinical experience	2	4.35%
		5c) Expertise in specific condition	3	6.52%
(6) Control intervention(s)	6	6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g., active comparison, minimally active penetrating or nonpenetrating sham, inert)	11	23.91%
		6b) Explanations given to patients of treatment and control interventions	7	15.22%
		6c) Details of control intervention (precise description, as for item 2 above, and other items if different)	12	26.09%
		6d) Sources that justify choice of control	7	15.22%

trials used Chinese diagnostic criteria of insomnia, 1 trial used U.S. criterion, and 6 trials used an ICD, but there were no specified diagnostic criteria for insomnia in the remaining trials. The participants are quite heterogeneous in terms of type of insomnia, such as in elderly with an average age of 81 years, or in heroin addicts with dyssomnia after detoxification. Third, there were different acuapunctures used in the trials, which included acupuncture as a unique treatment in 18 trials, and acupuncture combined with other treatments in 28 trials. Twenty (20) trials selected the acupoints according to syndrome differentiation based on Chinese medicine theory, and 26 trials used fixed acupoints throughout the treatment. According to STRICTA, all of the 46 trials reported the style of acupuncture, rationale for treatment, points used, number of treatment sessions, frequency of treatment, and other interventions, but only about 50% of trials reported needling techniques such as the depth of insertion, responses elicited, needle stimulation and needle type, and less than 30% of trials mentioned the details of control intervention and practitioner's background. Controls were also heterogeneous in these trials, including Western medications, no treatment, sham acupuncture, acupressure,

or herbal medicine. The treatment duration varied from 2 days to 10 weeks. Fourth, the use of composite outcome measures in 34 trials to evaluate overall improvement of symptoms limits the generalization of the findings. The classification of cure—markedly effective, effective, or ineffective—is not internationally recognized, and it is hard to interpret the effect. We suggest future trials to comply with international standards in the evaluation of treatment effect. Although there is no major statistical heterogeneity among the data analyses, we realized that the clinical heterogeneity would be very significant due to the variations in study quality, participants, intervention, control, and outcome measures. The interpretation of the positive findings from the meta-analyses needs to be incorporated with the clinical characteristics of the included trials and evidence strength. Therefore, the conclusion of the beneficial effect of acupuncture for insomnia needs to be confirmed in large and rigorously designed RCTs.

Our latest searches identified three systematic reviews of acupuncture for insomnia. One (1) Cochrane review published in 2007 included only 7 randomized trials published in English, and it concluded that current evidence was

TABLE 4. EFFECT ESTIMATES OF ACUPUNCTURE TREATMENT IN 46 INCLUDED TRIALS

Study	Comparisons	Effect estimate (95% CI)	p value
Acupuncture/auricular/acupressure/TEAS versus no treatment			
1 No. patients with total sleeping time increased >3 hours			
Tang W 2007 ³³	Auricular therapy plus <i>Tuiina</i> and acupressure versus no treatment	RR 1.81 (1.19, 2.77)	0.006
2 Quality scores of sleeping evaluated by patients			
Zhu Z 2004 ⁴⁶	Electroacupuncture versus no treatment	MD -2.16 (-2.80, -1.52)	<0.0001
3 Total scores of PSQI			
Chen M 1999 ⁷	Acupressure versus conversation	-6.32 (-7.47, -5.17)	
Tsay 2003 ³⁵	Acupressure versus usual care	-3.78 (-5.98, -1.58)	
Tsay 2004 ³⁶	Acupressure versus usual care	-1.20 (-3.91, 1.51)	
Tsay 2004 ³⁶	Transcutaneous electrical acupoint stimulation versus usual care	-1.45 (-4.06, 1.16)	
Meta-analysis			0.02
Real acupuncture/acupressure versus sham acupuncture/acupressure			
1 Total scores of PSQI			
Chen M 1999 ⁷	Real acupressure versus sham acupressure	-4.25 (-5.49, -3.01)	
Tsay 2003 ³⁵	Real acupressure versus sham acupressure	-1.35 (-3.49, 0.79)	
Meta-analysis			0.04
2 Total sleeping duration (hours)			
Kim 2004 ¹⁹	Real acupuncture versus sham acupuncture	MD 74.00 (15.61, 132.39)	0.01
Kim 2004 ¹⁹	Real acupuncture versus sham acupuncture	MD 34.00 (19.30, 48.70)	<0.0001
Acupuncture/auricular/acupressure versus Western medicine			
1 No. patients with total sleeping time increased >3 hours			
Ding D 2008 ¹¹	Body acupuncture versus estazolam	1.01 (0.73, 1.42)	
Huang X 2000	Body acupuncture versus estazolam	1.50 (1.03, 2.18)	
Kang F 2005 ¹⁸	Body acupuncture plus auricular therapy versus diazepam and oryzanol	3.91 (1.89, 8.08)	
Kou J 2003	Body acupuncture versus stilnox	1.80 (1.23, 2.62)	
Liu J 2006 ²⁵	Body plus auricular acupuncture versus diazepam or estazolam	2.25 (1.31, 3.88)	
Liu Z 2007 ²⁶	Scalp acupuncture versus clonazepam	0.97 (0.68, 1.39)	
Luo W 2006	Body acupuncture versus trazodone	1.55 (1.02, 2.37)	
Wang M 2003 ³⁷	Body acupuncture versus diazepam	1.64 (1.26, 2.15)	
Wang Y 2004 ⁴⁰	Scalp with electrical stimulation plus body acupuncture and auricular therapy versus diazepam and clonazepam	2.03 (1.16, 3.54)	
Zhang X 2005 ⁴⁴	Body acupuncture versus estazolam plus oryzanol	1.20 (0.94, 1.54)	
Meta-analysis			<0.0001
2 No. patients with total sleeping time increased >2 hours			
Liu Q 2000 ²⁴	Body plus auricular acupuncture versus estazolam	0.78 (0.46, 1.31)	
Qiu R 1999 ³²	Acupressure plus herbal medicine versus estazolam plus herbal medicine	0.79 (0.50, 1.26)	
Zou Y 2008 ⁴⁷	Electroacupuncture versus alprazolam	1.25 (1.08, 1.44)	
Meta-analysis			0.84
3 No. patients with total sleeping time >4 hours			
Ding W 2006 ¹²	Body acupuncture versus diazepam	1.58 (1.18, 2.12)	
Pan Q 2005 ³¹	Body acupuncture versus estazolam	1.48 (1.17, 1.89)	

(continued)

TABLE 4. (CONTINUED)

Study	Comparisons	Effect estimate (95% CI)	p value
Meta-analysis			
4 Total scores of PSQI		RR 1.53 (1.27, 1.84)	<0.00001
Huang X 2000	Body acupuncture versus estazolam	1.50 (1.03, 2.18)	
Kou J 2003	Body acupuncture versus stilnox	1.80 (1.23, 2.62)	
Li T 2007 ²²	Body plus auricular acupuncture versus diazepam or estazolam	-2.66 (-4.91, -0.41)	
Liu J 2006 ²⁵	Body plus auricular acupuncture versus diazepam or estazolam	2.25 (1.31, 3.88)	
Liu Z 2007 ²⁶	Scalp acupuncture versus clonazepam	0.97 (0.68, 1.39)	
Luo W 2006	Body acupuncture versus trazodone	1.55 (1.02, 2.37)	
Wang Y 2004 ⁴⁰	Scalp with electrical stimulation plus body acupuncture and auricular therapy versus diazepam and clonazepam	-5.48 (-8.16, -2.80)	
Meta-analysis			
5 Scores of sleep time evaluated by patients		MD -2.83 (-4.47, -1.19)	0.0007
Huang L 2007 ¹⁶	Rolling acupuncture versus clonazepam	-0.15 (-0.42, 0.12)	
Xuan Y 2007 ⁴¹	Body acupuncture versus estazolam	0.32 (-0.24, 0.88)	
Meta-analysis			
6 No. patients with sleep rates >65%		MD -0.06 (-0.30, 0.18)	0.63
Chen F 2007 ⁹	Electroacupuncture versus diazepam plus oryzanol and VitB1	1.36 (1.04, 1.79)	
Fan D 2006 ¹⁴	Body acupuncture versus diazepam plus oryzanol	1.28 (0.91, 1.80)	
Li X 2007 ²¹	Body plus auricular acupuncture versus diazepam or estazolam	1.33 (0.99, 1.78)	
Wang Q 2003 ³⁸	Electroacupuncture plus acupoint injection versus diazepam plus oryzanol and VitB1	1.46 (1.10, 1.93)	
Zhang Q 2006	Body acupuncture versus estazolam	0.79 (0.45, 1.41)	
Meta-analysis			
7 Total scores of SDS		RR 1.28 (1.11, 1.48)	0.001
Hong Y 2005 ¹⁵	Electroacupuncture versus trazodone	-0.06 (-5.91, 5.79)	
Luo W 2006	Body acupuncture versus trazodone	-0.02 (-0.34, 0.30)	
Meta-analysis			
8 Total scores of SQ		MD -0.02 (-0.34, 0.30)	0.9
Hong Y 2005 ¹⁵	Electroacupuncture versus trazodone	MD -19.01 (-21.65, -16.37)	<0.00001
Hong Y 2005 ¹⁵	Electroacupuncture versus trazodone	-4.00 (-5.19, -2.81)	
Luo W 2006	Body acupuncture versus trazodone	-2.16 (-3.58, -0.74)	
Meta-analysis			
10 Total scores of LSEQ		MD -3.12 (-4.92, -1.32)	0.0007
Wang X 2008 ³⁹	Abdominal acupuncture plus placebo pill versus estazolam plus sham acupuncture	MD -18.78 (-29.81, -7.76)	<0.01
Meta-analysis			
11 Total scores of SRSS		MD -3.00 (-4.41, -1.59)	<0.0001
Zhang H 2003 ⁴³	Body acupuncture versus clonazepam	MD -1.55 (-4.25, 1.15)	0.26
Ma ZX 2006 ³⁰	Electroacupuncture versus clonazepam		
Meta-analysis			
12 Total scores of HAMA			
Acupuncture/auricular plus Chinese medicine versus Chinese medicine			
1 No. patients with total sleeping time increased >3 hours		RR 1.30 (0.93, 1.82)	0.13
Lv Y 2007 ²⁸	Electroacupuncture plus auricular acupuncture and <i>Suanzaoren</i> decoction versus <i>Suanzaoren</i> decoction		

2	No. patients with total sleeping time >4 hours	Body acupuncture plus herbal medicine versus herbal medicine	RR 1.71 (1.26, 2.32)	0.0005
	Tian H 2006 ³⁴			
3	Total sleeping duration (hour)	Electroacupuncture plus auricular therapy and <i>Suanzaoren</i> decoction versus <i>Suanzaoren</i> decoction	MD 1.25 (1.13, 1.37)	<0.00001
	Lv Y 2007 ²⁸			
4	No. patients with sleep rates >60%	Body acupuncture plus herbal medicine versus herbal medicine	1.41 (0.87, 2.30)	
	Du M 2007 ¹³		2.07 (1.06, 4.03)	
	Lu W 1998 ²⁷	Body acupuncture plus <i>Qiyanshen</i> tablet versus <i>Qiyanshen</i> tablet	RR 1.67 (1.12, 2.50)	0.01
	Meta-analysis			
	<i>Acupuncture/auricular plus Western medicine versus Western medicine</i>			
1	Total sleeping duration (hour)	Body plus auricular acupuncture and estazolam versus estazolam	1.01 (0.31, 1.71)	
	Chen X 2003 ⁸		1.18 (0.40, 1.96)	
	Li Q 2005 ²⁰	Electroacupuncture plus Prozac versus Prozac	MD 1.09 (0.56, 1.61)	<0.0001
	Meta-analysis			
2	Total scores of PSQI	Rolling acupuncture plus clonazepam versus clonazepam	-1.00 (-4.00, 2.00)	
	Luo L 2005	Abdominal acupuncture plus estazolam versus estazolam	-2.08 (-3.77, -0.39)	
	Ye T 2008 ⁴²	Body acupuncture and massage of sole plus alprazolam versus alprazolam	-2.10 (-3.03, -1.17)	
	Zhong Z 2008 ⁴⁵		-2.02 (-2.81, -1.24)	<0.00001
	Meta-analysis			
3	No. patients with total sleeping time increased >3 hours	Body plus auricular acupuncture and estazolam versus estazolam	1.01 (0.31, 1.71)	
	Chen X 2005 ⁸		1.28 (0.82, 2.00)	
	Li Q 2005 ²⁰	Electroacupuncture plus Prozac versus Prozac	1.18 (0.40, 1.96)	
	Luo L 2005	Rolling acupuncture plus clonazepam versus clonazepam	1.73 (1.18, 2.55)	
	Ma X 2006 ²⁹	Body acupuncture plus alprazolam and antipsychotic drug versus alprazolam plus antipsychotic drug		
	Meta-analysis			
4	No. patients with total sleeping time increased >2 hours	Body acupuncture plus <i>Citwujia</i> injection versus <i>Citwujia</i> injection	RR 1.33 (1.03, 1.71)	0.03
	Liu Y 2001 ²³		RR 1.48 (1.06, 2.07)	0.02
5	No. patients with sleep rates >55%	Body acupuncture plus <i>Citwujia</i> injection versus <i>Citwujia</i> injection	RR 2.00 (1.47, 2.73)	<0.0001
	Jian J 2005 ¹⁷			
6	No. patients with sleep rates increased >10%	Body acupuncture plus estazolam versus estazolam	RR 1.79 (1.33, 2.39)	0.0001
	Cui R 2001 ¹⁰			

TEAS, transcutaneous electrical acupoint stimulation; CI, confidence interval; PSQI, Pittsburgh Sleep Quality Index; MD, mean difference; RR, relative risk; SDS, Self-rating Depression Scale; SQ, sleep quality; ARS, Asberg Rating Scale; LSEQ, Leeds Sleep Evaluation Questionnaire; SRSS, Self-Rating Sleep Scale; HAMA, Hamilton Anxiety Scale.

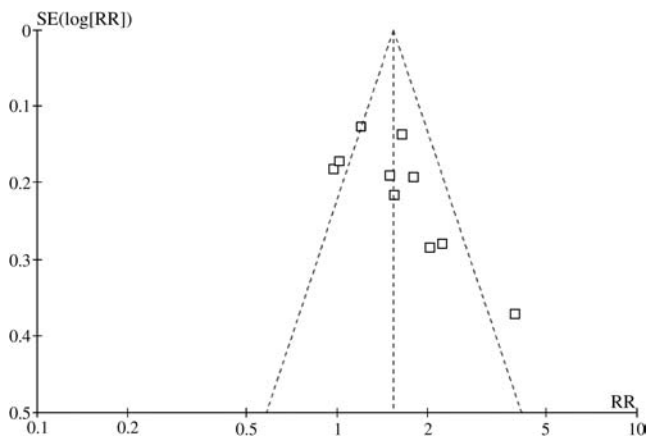


FIG. 4. Funnel plot of 10 randomized controlled trials for the outcome of number of patients with sleeping time increased over 3 hours. SE, standard error; RR, relative risk.

not sufficient to support the use of any form of acupuncture for the treatment of insomnia.⁷⁰ Another systematic review published in Chinese in 2005 included only 6 Chinese trials with low quality, and had a similar conclusion.⁷¹ The most recent review published in 2009⁷² included 12 clinical trials (including 3 randomized trials) and 18 case series. However, the authors were not able to access Chinese databases and quite a lot of studies published in Chinese were missed. This review by Huang and colleagues described the TCM diagnosis for insomnia and acupuncture treatment, which is considered relevant to clinical practice. We conducted comprehensive searches in both English and Chinese databases, and included 46 randomized trials. Our review suggests that acupuncture improves sleep quality and increases sleep duration. However, the beneficial findings of this systematic review still are not conclusive due to the limitations of the methodological quality of the included trials. Further rigorous trials are warranted.

Most of the existing trials are small and there is a moderate risk of bias. Further high-quality studies with larger sample size are needed to confirm the effectiveness of acupuncture in treating insomnia. Randomization methods need to be clearly described and fully reported. Although blinding of the acupuncturists might be very difficult, blinding of patients and outcome assessors should be attempted as far as possible to minimize performance and assessment biases. Analysis of outcomes based on intention-to-treat principle is important. Since insomnia is a highly heterogeneous disease with different etiology and severity, acupuncture is likely to have different effects on different subgroups of patients. Therefore, future clinical trials should be focused on particular subgroups or include a very large sample size to delineate the effect of acupuncture on different types of patients or different treatment techniques. In addition, well-defined diagnostic or classified criteria such as ICD-10 or the third version of Chinese Classification of Mental Disease should be employed to make a precise clinical diagnosis of insomnia, and hence increase the comparability between trials. Reporting of trials should follow the Consolidated Standards of Reporting Trials⁷³ to explicitly explain the process of the treatment, so that the clinicians or other researchers can possibly use this process. Because the acupuncturist's tech-

nical competence may influence the therapeutic effect, we suggest that researchers describe the detailed treatment and that trials be conducted by qualified, well-trained acupuncturist in future studies according to STRICTA.⁷⁴ Since insomnia may wax and wane with or without treatment, a longer follow-up period with serial measurement of outcomes is important to determine the effectiveness and long-term effect of acupuncture.

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Disclosure Statement

No competing financial interests exist.

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