

Acupuncture for insomnia (Review)

Cheuk DKL, Yeung J, Chung KF, Wong V



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Acupuncture for insomnia (Review)

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[Intervention Review]

Acupuncture for insomnia

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ABSTRACT

Background

Although conventional non-pharmacological and pharmacological treatments for insomnia are effective in many people, alternative therapies such as acupuncture are still widely practiced. However, it remains unclear whether the existing evidence is rigorous enough to support its use.

Objectives

To determine the efficacy and safety of acupuncture in people with insomnia.

Search strategy

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, PsycINFO, Dissertation Abstracts International, CINAHL, AMED (the Allied and Complementary Medicine Database), TCMLARS (Traditional Chinese Medical Literature Analysis and Retrieval System), National Center for Complementary and Alternative Medicine, the National Institute of Health Clinical Trials Database, the Chinese Acupuncture Trials Register, the Trials Register of the Cochrane Complementary Medicine Field, from inception to 2006, and the sleep bibliography, which is available at www.websciences.org/bibliosleep. We searched reference lists of retrieved articles, and contacted trial authors and experts in the field for information on ongoing/completed trials.

Selection criteria

Randomised controlled trials evaluating any form of acupuncture involving participants of any age with any type of insomnia were included. Included trials compared acupuncture with placebo or sham or no treatment, or acupuncture plus other treatments compared with the same other treatments. Trials that compared only acupuncture methods or compared acupuncture alone against other treatments alone were excluded, since they did not yield the net effect of acupuncture.

Data collection and analysis

Two review authors independently extracted data and assessed quality according to a set of criteria for risk of selection bias, performance bias, attrition bias and detection bias. Relative risk (RR) and standardised mean difference (SMD) with 95% confidence intervals were used for binary and continuous outcomes respectively. Data were combined in meta-analyses (on an intention-to-treat basis), where more than one trial without significant clinical heterogeneity presented the same outcome.

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Main results

Seven trials met the inclusion criteria. The studies included 590 participants with insomnia, of whom 56 dropped out. Participant age ranged from 15 to 98 years, and the duration of insomnia varied from 6 months to 19 years. Co-existing medical conditions contributing to insomnia included stroke, end-stage renal disease and pregnancy. Apart from conventional needle acupuncture, different variants of acupuncture such as acupressure, auricular magnetic and seed therapy, and transcutaneous electrical acupoint stimulation (TEAS) were evaluated. Meta-analysis was limited because of considerable heterogeneity between comparison groups and between outcome measures.

Based on the findings from individual trials, the review suggested that acupuncture and acupressure may help to improve sleep quality scores when compared to placebo (SMD = -1.08, 95% CI = -1.86 to -0.31, $p=0.006$) or no treatment (SMD -0.55, 95% CI = -0.89 to -0.21, $p=0.002$). TEAS also resulted in better sleep quality score in one trial (SMD = -0.74, 95% CI = -1.22 to -0.26, $p=0.003$). However, the efficacy of acupuncture or its variants was inconsistent between studies for many sleep parameters, such as sleep onset latency, total sleep duration and wake after sleep onset. The combined result from three studies reporting subjective insomnia improvement showed that acupuncture or its variants was not more significantly effective than control (RR = 1.66, 95% CI = 0.68 to -4.03) and significant statistical heterogeneity was observed. Only one study reported an adverse event, with one out of 16 patients (6.3%) withdrawing from acupuncture because of pain.

Authors' conclusions

The small number of randomised controlled trials, together with the poor methodological quality and significant clinical heterogeneity, means that the current evidence is not sufficiently extensive or rigorous to support the use of any form of acupuncture for the treatment of insomnia. Larger high quality clinical trials employing appropriate randomisation concealment and blinding with longer follow-up are needed to further investigate the efficacy and safety of acupuncture for the treatment of insomnia.

PLAIN LANGUAGE SUMMARY

Acupuncture for insomnia

Although conventional non-pharmacological and pharmacological treatments for insomnia are effective in many people, alternative therapies such as acupuncture are still widely practiced. Acupuncture is mainly evaluated in observational and uncontrolled studies, and randomised controlled trials are scarce and of poor methodological quality. This review was conducted to examine the effectiveness of acupuncture in treating insomnia. Seven studies were eligible for inclusion in the review, involving 590 participants. The studies were of low methodological quality and were diverse in the types of participant, acupuncture treatments and sleep outcome measures used, which limited the ability to pool the findings and draw conclusions. Currently there is a lack of high quality clinical evidence supporting the treatment of people with insomnia using acupuncture. More rigorous studies are needed to assess the efficacy and safety of various forms of acupuncture for treating people with insomnia.

BACKGROUND

Description of the condition

Insomnia may be defined as a complaint of disturbed sleep in the presence of adequate opportunity and circumstance for sleep (NIH 2005). The revised edition of the International Classification of Sleep Disorders lists more than 100 differential diagnoses of insomnia (AASM 2005). The 4th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), defines primary insomnia as the subjective difficulty in initiating or maintaining sleep or non-restorative sleep that lasts for at least 1 month. The sleep disturbance causes clinically significant distress or impair-

ment in social, occupational or other important areas of functioning and is not associated with another mental disorder, substance related disorder, general medical disorder or other specific sleep disorder (APA 1994).

A review on the epidemiology of insomnia found that the prevalence of insomnia symptoms that occurred at least 3 nights/week or often or always occurred was between 16 and 21% (Ohayon 2002). The prevalence of insomnia symptoms with daytime consequences ranged from 9 to 15%, while 8 to 18% of the population had dissatisfaction with sleep quality and quantity. The prevalence of insomnia diagnoses according to the DSM-IV classifica-

tion was 6%. Primary insomnia was the most frequent diagnosis, with prevalence ranging between 2% and 4%, followed by insomnia related to another mental disorder, with prevalence ranging from 1% to 3% (Ohayon 2002). Insomnia may result in fatigue, irritability and impaired concentration and is associated with reduced quality of life, increased risk of traffic accidents, impaired job performance and absenteeism (Leger 2001; Walsh 2004). The economic impact of insomnia is high, with an estimated total cost ranging from US\$30-35 billion annually in 1994 (Chilcott 1996). A recent review found that the 6-month predicted direct and indirect costs for adults with insomnia were US\$1,253 greater than that for matched control without insomnia. For the elderly with insomnia, it was US\$1,143 greater than that for matched non-insomniacs (Ozminkowski 2007). In addition, there is a strong relationship between insomnia and depression, anxiety disorders, other psychological disorders, alcohol and drug abuse or dependence, suicide, decreased immune functioning, possibly cardiovascular disease and mortality (Taylor 2007). It is important to evaluate and treat insomnia early, since acute untreated insomnia can progress into chronic insomnia that might be more difficult to treat (Ancoli-Israel 2000).

Description of interventions

The general approach in the management of insomnia is to evaluate the cause of the symptom before an appropriate treatment is proposed. The underlying medical, psychiatric or behavioral causes of insomnia should be treated in the first place (Hajak 2000). However, it is not always possible to abolish or alleviate the primary disease process. In such situation, the approach is to focus on interventions that will positively promote sleep. Regardless of the cause of insomnia, physicians treating sleep disorders almost always counsel patients about sleep hygiene. Some key sleep hygiene instructions include regular bedtime and wake up time, avoiding daytime napping, using the bedroom only for sleep, keeping the bedroom dark, quiet, well ventilated, and at a comfortable temperature throughout the night, practicing a bedtime ritual, getting regular exercise each day, avoiding alcohol and nicotine 4 to 6 hours before bedtime, avoiding caffeine entirely or limiting caffeine use to no more than three cups no later than 10 a.m., and avoiding heavy meals and strenuous exercise in the evening (Zarcone 2000).

A recent review found types of psychological and behavioural treatment including cognitive-behavioural therapy, stimulus control therapy, sleep restriction therapy, relaxation training and paradoxical intention to have empirical evidence for the treatment of insomnia (Morin 2006). However, such non-pharmacological therapies have remained largely underutilized in primary care, perhaps because they are time consuming and require significant training for effective implementation (Krystal 2004).

Many prescription and over-the-counter medications are available

for treating insomnia. Benzodiazepine receptor agonists are the only agents currently approved by the FDA for the treatment of insomnia. There are two broad groups of benzodiazepine receptor agonists: benzodiazepines and the non-benzodiazepine hypnotics (e.g., zaleplon, zolpidem, zopiclone, eszopiclone). Although insomnia is often a chronic condition, the FDA has only approved eszopiclone for use without a specified time limit. The other medications have approved use limited to 35 days or less. The major concerns limiting the use of benzodiazepine receptor agonists are its potential for abuse, dependence and adverse effects, such as residual daytime sedation, cognitive impairment and poor motor coordination (NIH 2005). Faced with the limitations of pharmacological and psychological treatments of insomnia, many alternative therapies have been used to treat insomnia.

How the intervention might work

Acupuncture is a therapeutic procedure in which specific body areas (meridian points), are pierced with fine needles. It is one of the major modalities of treatment in Traditional Chinese Medicine. It's theory of diagnosis and treatment is based on the systems of medicine and philosophy of ancient China and use in China can be traced back more than 2000 years (Wu 1996). Acupuncture involves complex theories of regulation of Yin and Yang forces, Qi (air), blood and body fluids. According to Traditional Chinese Medicine an imbalance in the Yin and Yang forces of the body, or an excess or a deficiency of Qi, blood or body fluids are the main causes of pain or diseases. Acupuncture treats illness by recreating the balance between the Yin and Yang forces and restoration of normal Qi, blood and body fluids through stimulation of different meridian points which govern different parts of the body and their interaction (Maciocia 1989).

Apart from traditional needle acupuncture, various forms of acupuncture have been developed, including electroacupuncture, laser acupuncture, acupressure, auricular therapy and transcutaneous electrical acupoint stimulation (TEAS). Electroacupuncture is a form of acupuncture in which acupuncture needles are attached to a device that generates continuous electric pulses, generating a small electric current that flows between pairs of needles. Laser acupuncture employs laser beam to stimulate the acupoints instead of stimulation using fine needles. Acupressure is a technique that involves firm manual pressure on the acupoints. Auricular therapy employs acupuncture needles, seeds or magnetic peals to stimulate the acupoints located on the auricles. TEAS combines the technique of both acupuncture and transcutaneous electrical nerve stimulation by using electrode pads placed on the skin to stimulate the acupoints.

Acupuncture is well accepted by many people and is widely used in treating various illnesses including back pain, arthritis, headache, asthma, digestive disorders, alcohol and substance dependence and other psychiatric disorders (Johansson 1993, Vickers 1999). Acupuncture is one of the most commonly used complementary

therapies in many Western countries (Thomas 2003 , Zollman 1999).

Many studies in animals and humans have demonstrated that acupuncture can cause multiple biological responses (Ulett 1998). A review article summarised that the nervous system, neurotransmitters and endogenous substances could respond to needling stimulation and electro-acupuncture, that mediate pain relief, autonomic regulation and other therapeutics (Ma 2004). A recent study showed that acupuncture increased melatonin secretion and was associated with improvement in sleep (Spence 2004).

Why it is important to do this review

Anecdotal reports suggest acupuncture may improve sleep and relieve insomnia. Recently, a number of clinical trials have been performed to study the efficacy of acupuncture for insomnia. It remains uncertain whether the existing evidence is rigorous enough to reach a definitive conclusion. For this reason, we decided to undertake a systematic review of randomised controlled trials of acupuncture therapy for insomnia.

OBJECTIVES

The objectives of this systematic review were to determine the efficacy and safety of acupuncture therapy in people with insomnia. We intended to test the following hypotheses:

1. Whether acupuncture is efficacious in reducing symptoms of insomnia and improving sleep;
2. Whether acupuncture for insomnia can improve the quality of life and overall functioning;
3. Whether acupuncture is associated with any adverse effects.

METHODS

Criteria for considering studies for this review

Types of studies

1. Randomised controlled studies were included in the review.
2. Studies comparing acupuncture or its variants with at least one control group that used no treatment, placebo treatment or sham treatment were included.
3. Studies were single, double blind or unblinded.
4. Parallel group or crossover designs were included.

Types of participants

People of any age and gender with insomnia explicitly documented by standardised measures (e.g. the Pittsburgh Sleep Quality Index (Buysse 1989)), objective measures in sleep laboratory (e.g. polysomnography, actigraphy) or by reports/diaries kept by patients, partners, other informants or nursing staff; or patients with insomnia diagnosed by standard diagnostic criteria such as Diagnostic and Statistical Manual of Mental Disorders (APA 1994), International Classification of Sleep Disorders (AASM 2005) or International Classification of Diseases (WHO 1992), or with a complaint of sleep difficulties.

Types of interventions

Trials evaluating all forms of acupuncture therapy including acupressure, laser acupuncture or electroacupuncture were included in the review, regardless of the number of times of treatment or the length of treatment period. Either traditional acupuncture in classical meridian points or contemporary acupuncture in non-meridian or trigger points were included, regardless of the source or methods of stimulation (e.g. hand, needle, laser, seed, magnetic or electrical stimulation).

The control interventions could be no treatment, placebo acupuncture or sham acupuncture. Placebo acupuncture refers to a needle attached to the skin surface (not penetrating the skin but at the same acupoints) (Van Tulder 2000). Sham acupuncture refers to a needle placed in an area close to but not in acupuncture points (Van Tulder 2000) or subliminal skin electrostimulation via electrodes attached to the skin (SCSSS 1999).

Comparisons investigated were:

1. acupuncture alone versus no treatment
2. acupuncture alone versus placebo or sham treatment
3. acupuncture in addition to baseline medication or treatment versus baseline medication or treatment alone
4. acupuncture in addition to baseline medication or treatment versus placebo or sham treatment in addition to baseline medication or treatment.

Trials comparing only different forms of acupuncture or acupuncture with other forms of treatment were excluded, since these studies could not yield the net effect of acupuncture and could not reach the conclusion as to whether acupuncture per se is efficacious or not.

Types of outcome measures

Primary outcome

Subjective report of sleep quality (likelihood of subjects satisfied with insomnia improvement)

Secondary outcomes

1. Sleep parameters
 - a. Sleep onset latency

- b. Total wake-time
 - c. Total sleep duration
 - d. Wake after sleep onset (WASO)
 - e. Nocturnal and early morning waking (defined by the trialist)
 - f. Sleep efficiency (ratio of time asleep to time in bed)
2. Standardised scales related to sleep, e.g. the Pittsburgh Sleep Quality Index (Buysse 1989)
 3. Daytime functioning (as measured by attentional tasks tests, self-report using a standardised measure, e.g. the Stanford Sleepiness Scale (Hoddes 1973), the Epworth Sleepiness Scale (Johns 1991)
 4. Quality of life, as measured by validated scales
 5. Frequency of adverse effects
- Outcomes were divided, where possible, into immediate post-treatment, medium term (3-12 months), and long term (more than 12 months).

Search methods for identification of studies

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (latest issue), MEDLINE (1966-2006), EMBASE (1980-2006), PsycINFO (1887-2006), Dissertation Abstracts International (1861-2006), CINAHL (1982-2006), AMED (the Allied and Complementary Medicine Database, 1985-2006) and TCMLARS (Traditional Chinese Medical Literature Analysis and Retrieval System, 1984-2006) which is a database of Chinese biomedical research literature. We also searched relevant clinical trials and research databases including the National Center for Complementary and Alternative Medicine, the National Institute of Health Clinical Trials Database, the Chinese Acupuncture Trials Register, the Trials Register of the Cochrane Complementary Medicine Field, and the sleep bibliography available at www.websciences.org/bibliosleep/ (1991 - 2006).

The following search strategy, using a combination of controlled vocabulary and text word terms, was used for MEDLINE, and was modified to suit other databases:

1. exp acupuncture
2. acupunc\$.mp
3. acupress\$.mp
4. electroacupunc\$.mp
5. meridian\$.mp
6. acupoint\$.mp
7. or/1-6
8. exp sleep
9. sleep\$.mp
10. insomnia\$.mp
11. wakeful\$.mp
12. sleepless\$.mp
13. somnambul\$.mp
14. or/8-13
15. 7 and 14

The reference lists of all relevant papers were searched for further studies. If unpublished studies were encountered, we had planned to obtain copies of such unpublished material; but none was identified in the process. In addition, we contacted colleagues and experts in the field to ascertain any unpublished or ongoing studies. Multiple publications reporting the same group of participants or their subsets were excluded.

Data collection and analysis

Two review authors independently examined titles and abstracts retrieved from the search and selected all potentially relevant studies. Copies of these articles were obtained, and reviewed independently by the same review authors against the inclusion criteria used in each study. Review authors were not blinded to the names of the authors, institutions or journal of publication. The review authors then extracted data from included trials and assessed trial quality independently. All disagreements were resolved by consensus.

Extraction of data

The following data were extracted:

1. Study methods
 - a. Design (e.g. parallel or crossover design).
 - b. Randomisation method (including list generation)
 - c. Method of allocation concealment
 - d. Blinding method
 - e. Stratification factors used if stratified randomisation was employed
2. Participants
 - a. Inclusion/exclusion criteria
 - b. Number (total/per group)
 - c. Age and sex distribution
 - d. Specific diagnosis/diagnostic subtypes
 - e. Associated physical or neuropsychiatric diseases
 - f. Duration of disorder
 - g. Previous treatments
3. Intervention and control
 - a. Type of acupuncture
 - b. Details of treatment regime including duration of treatment
 - c. Type of control
 - d. Details of control treatment including drug dosage
 - e. Details of co-interventions
 - f. Washout period in cross-over design
4. Follow-up data
 - a. Duration of follow-up
 - b. Dates of treatment withdrawal and reasons for treatment withdrawal
 - c. Withdrawal rates
5. Outcome data as described above in the Types of Outcome Measures section
6. Analysis data
 - a. Methods of analysis (intention-to-treat/per-protocol analysis)

- b. Comparability of groups at baseline (yes/no)
- c. Statistical techniques

Data were entered on to Review Manager software by one review author and then checked by the second review author.

Quality assessment

We evaluated the validity of the trials using the following criteria:

1. Selection bias:
 - a. Was allocation of patients to treatment and control groups randomised?
 - b. Was randomisation concealed?
2. Performance bias:
 - a. Were the recipients of treatment blinded to the assigned intervention?
 - b. Were those providing treatment and care blinded to the assigned intervention?
3. Attrition bias:
 - a. Were there systematic differences between the comparison groups in the loss of participants from the study?
4. Detection bias:
 - a. Were those assessing outcomes of the intervention blinded to the assigned intervention?

We summarised the quality of a trial into one of the three following categories:

- A. Low risk of bias: all the validity criteria met.
- B. Moderate risk of bias: one or more validity criteria partly met
- C. High risk of bias: one or more validity criteria not met

Data analysis

Missing data

Authors of included studies were contacted to supply missing information on study methods, participants, intervention and control, follow-up data, outcome data, and statistical summary indices such as means and standard deviations. Missing data and drop-outs/attrition were assessed for each included study, and the extent to which the results/conclusions of the review could be altered by the missing data was assessed and discussed.

Summarising data

Data were summarised using relative risk (RR) with 95% confidence intervals (CI) was used for binary outcomes. Standardised mean difference (SMD) with 95% CI was used for continuous outcomes, if different measures (scales) of the same outcome were used in different trials. All analyses included all participants in the treatment groups to which they were allocated, provided that data were available.

Heterogeneity

Clinical heterogeneity was assessed by noting the difference in the distribution of important participant factors between trials (age, gender, specific diagnosis/diagnostic subtypes, duration of disorder, associated diseases), and methodological heterogeneity was assessed by noting different trial design factors (randomisation concealment, blinding, losses to follow-up, treatment type, co-interventions). Statistical heterogeneity was assessed by examining I^2 (

Higgins 2002), a quantity that describes approximately the proportion of variation in point estimates due to heterogeneity rather than sampling error. In addition, chi-squared test of homogeneity was employed to determine the strength of evidence that the heterogeneity is genuine.

Meta-analysis

Where the interventions were the same or similar enough, we synthesized results in a meta-analysis, if there was no important clinical heterogeneity. The random-effects model was used in the meta-analysis if there was significant statistical heterogeneity, otherwise the fixed-effect model was used.

Sub-group analysis

Analysis of a number of sub-groups can lead to misleading conclusions (Alderson 2003 section 8.7), and are best kept to a minimum. If data permitted, we planned to conduct sub-group analyses for different age groups, diagnostic subtypes or severity of disease to assess whether the treatment effects were different in different subgroups. However insufficient data reported in studies meant sub-group analysis was not performed in this review.

Sensitivity analyses

Sensitivity analyses were planned to be conducted to assess the impact of study quality, provided that sufficient studies were available. These included:

1. all studies
2. only those using adequate methods of allocation concealment such as sealed opaque envelopes or telephone randomisation
3. only those with more than 70% follow-up rate

However, no included studies had adequate allocation concealment and all studies had more than 70% follow-up. Therefore sensitivity analyses in these respects were not performed.

To assess the effect of drop-outs on the outcome, another sensitivity analysis was performed on binary outcomes including

1. best case scenario: all the drop outs from the treatment group were assumed they had a positive outcome and all the drop outs from the control group had a negative outcome
2. worst case scenario: all the drop outs from the treatment group were assumed they had a negative outcome and all the drop outs from the control group had a positive outcome

Assessment of bias

Funnel plots (effect size against standard error) were to be generated if sufficient studies were found. Asymmetry could be due to publication bias, but could also be due to a relationship between trial size and effect size. In the event that a relationship was found, clinical diversity of the studies would have been examined (Egger 1997). However, since fewer than five studies were included in any meta-analyses, funnel plots were not generated.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Selection of studies

Twenty-six studies were identified by the search strategy. Nineteen studies were excluded due to reasons listed in 'Characteristics of excluded studies'.

Included studies

Seven studies fulfilled the inclusion criteria ([Chen 1999](#); [Cui 2003](#); [Da Silva 2005](#); [Kim 2004](#); [Suen 2002](#); [Tsay 2003](#); [Tsay 2004](#)). Details of the seven included studies are described in 'Characteristics of included studies'.

Populations

The included trials were performed in China (n=1) ([Cui 2003](#)), Taiwan (n=3) ([Chen 1999](#); [Tsay 2003](#); [Tsay 2004](#)), Hong Kong (n=1) ([Suen 2002](#)), Korea (n=1) ([Kim 2004](#)) and Brazil (n=1) ([Da Silva 2005](#)). All trials were published in English. The seven trials included a total of 590 participants, of whom 56 dropped out. [Kim 2004](#) included post-stroke participants who had insomnia, [Tsay 2003](#); [Tsay 2004](#) included participants with end-stage renal disease and [Da Silva 2005](#) examined women between 15-30 weeks' pregnancy. There was a wide variation in the age of subjects and duration of insomnia between studies. The subjects' age ranged from 15 to 98 years and the duration of insomnia varied from 6 months to 19 years.

Participants were recruited from living-assisted residences ([Chen 1999](#)), elderly care home ([Suen 2002](#)), inpatients ([Kim 2004](#)), outpatient clinic ([Cui 2003](#); [Da Silva 2005](#)) and dialysis centres ([Tsay 2003](#); [Tsay 2004](#)). None of the studies diagnosed insomnia based on DSM-IV or ICSD or ICD criteria. Participants recruited in the included studies had a complaint of insomnia. Four studies used a questionnaire as a diagnostic instrument. [Chen 1999](#), [Tsay 2003](#), [Tsay 2004](#) used a score of five or greater in the Pittsburgh Sleep Quality Index (PSQI), and [Kim 2004](#) used a score of 15 or greater in the Insomnia Severity Index (ISI) as a diagnostic criterion. Two studies ([Cui 2003](#); [Suen 2002](#)) used sleep efficiency to define insomnia. [Cui 2003](#) defined insomnia as a self-reported sleep efficiency of lower than 60%. [Suen 2002](#) defined insomnia as a sleep efficiency of lower than 85% as measured by actigraphy. [Suen 2002](#) was the only study that employed an objective measure as a diagnostic instrument and outcome measure.

Three studies ([Chen 1999](#); [Cui 2003](#); [Kim 2004](#)) did not report whether their protocol had been reviewed by an institutional review board or whether adequate informed consent was obtained from participants. [Suen 2002](#) obtained informed consent from the participants but approval by institutional review board was not mentioned. The three other studies ([Da Silva 2005](#); [Tsay 2003](#); [Tsay 2004](#)) reported their protocols had been approved by an institutional review board and adequate informed consent obtained.

Interventions

Interventions tested in the trials included acupuncture alone ([Kim 2004](#)), acupuncture plus medication (estazolam) ([Cui 2003](#)),

acupuncture plus sleep hygiene ([Da Silva 2005](#)), acupressure ([Chen 1999](#); [Tsay 2003](#); [Tsay 2004](#)), auricular therapy ([Suen 2002](#)) and transcutaneous electrical acupoint stimulation (TEAS) ([Tsay 2004](#)). Acupoints chosen were fixed and universally applied to all subjects in six trials ([Chen 1999](#); [Cui 2003](#); [Kim 2004](#); [Suen 2002](#); [Tsay 2003](#); [Tsay 2004](#)). The remaining study ([Da Silva 2005](#)) allowed some flexibility in the use of additional acupoints on top of the protocol acupoints set for the participants. All seven trials used a parallel group design.

The number of acupoints selected ranged from 4 ([Kim 2004](#)) to 15 ([Cui 2003](#)). The number of acupuncture sessions ranged from 2 ([Kim 2004](#)) to 30 ([Cui 2003](#)) and the total treatment duration ranged from 2 days ([Kim 2004](#)) to 8 weeks ([Da Silva 2005](#)). Except for one study on pregnant women ([Da Silva 2005](#)) that employed individualised acupoints selected by the acupuncturists, all the other six studies used a standardised set of acupoints. The most frequently used acupoints were: Shenmen on hands (HT7) (used in 5 studies), Shenmen on ears (used in 3 studies), Baihui (GV20) (used in 3 studies) and Neiguan (PC6) (used in 3 studies).

Three trials ([Suen 2002](#); [Tsay 2003](#); [Tsay 2004](#)) had a 3-group design while the others used a single control group. The control group was sham treatment ([Tsay 2003](#)), placebo treatment ([Suen 2002](#); [Kim 2004](#)), no treatment ([Tsay 2003](#); [Tsay 2004](#)), medication (estazolam) ([Cui 2003](#)) and sleep hygiene ([Da Silva 2005](#)). The duration of follow-up ranged from 3 to 12 weeks in six trials ([Chen 1999](#); [Suen 2002](#); [Cui 2003](#); [Tsay 2003](#); [Tsay 2004](#); [Da Silva 2005](#)) and was not mentioned in the remaining one trial ([Kim 2004](#)).

Outcomes

Three studies reported patients' subjective evaluation of overall sleep satisfaction as an outcome ([Chen 1999](#); [Cui 2003](#); [Da Silva 2005](#)). [Chen 1999](#) reported the proportions of subjects with any improvement in sleep quality. [Cui 2003](#) categorised insomnia improvement into four grades: "basically cured" (sleep efficiency improved by $\geq 75\%$), "markedly effective" (sleep efficiency improved by 10-20%), "improved" (sleep efficiency improved by $< 10\%$) or "ineffective" (no improvement in sleep efficiency). [Da Silva 2005](#) reported the proportion of subjects with improvement in insomnia score of 50% or more. One study employed an actigraph as an objective measure of treatment outcome ([Suen 2002](#)). The remaining six studies assessed sleep parameters based on patients' self-report. Four studies ([Chen 1999](#); [Kim 2004](#); [Tsay 2003](#); [Tsay 2004](#)) employed validated questionnaires to assess outcome and one study ([Da Silva 2005](#)) used a self-administered numerical rating scale. One study included a quality of life questionnaire as an outcome measure ([Tsay 2003](#)).

Risk of bias in included studies

The majority of the included trials were assessed to be of poor methodological quality. The sample size varied from 30 to 108

participants (15 to 60 participants in treatment groups and 13 to 72 participants in control groups). None of the studies reported sample size calculation, essential for ensuring adequate statistical power. Only three studies described the randomisation procedure (Chen 1999; Kim 2004; Da Silva 2005). None of the studies described the method of allocation concealment. One study (Da Silva 2005) allocated participants into treatment and control groups based on the date of attendance, which failed to conceal allocation properly.

The designs of the control group varied in different studies. Only four studies employed a blinding procedure. Two of these were described as single-blind (Chen 1999; Kim 2004); and another two studies were double-blind (Suen 2002; Tsay 2003). Chen 1999 blinded participants to treatment allocation while the therapists and outcome assessors were not blinded (single blind design). Kim 2004 blinded assessors to the treatment allocation in all the outcome measures. Although Kim 2004 used a sham acupuncture design, the trialists did not mention whether the participants were blinded to the treatment, and hence this study was regarded as a single-blind design. For the two double-blind studies (Suen 2002; Tsay 2003), both the participants and outcome assessors were blinded to treatment allocation. In both of these studies, assessors were blinded in the questionnaire assessments, but Suen 2002 did not blind the assessors in the analysis of actigraphy data.

The placebo treatments in the trials were problematic. In one study participants in the control group were touched with acupuncture needles, but without penetrating the skin (Kim 2004). However, the study did not mention whether the patients were aware that no needles had been inserted. In another study, a soft material that did not cause pressure was used as a placebo to acupressure (Suen 2002), but again, the authors did not mention whether the patients felt the pressure or not. Significant bias was likely to occur in the subjective report of insomnia outcomes where participants were not blinded to treatments. Assessment bias was also possible if the outcome assessors were not blinded to the treatment groups. Six of the seven included trials reported the number of dropouts (Chen 1999; Da Silva 2005; Kim 2004; Suen 2002; Tsay 2003; Tsay 2004), but Chen 1999 failed to mention the reason(s) for the dropouts. These six studies did not include the data of the dropouts in the outcome analysis, and hence did not fulfil the intention-to-treat principle. According to our pre-defined quality assessment criteria, all seven included studies had a high risk of bias (one or more validity criteria not met).

Effects of interventions

Comparison 1: Acupuncture alone versus no treatment or sham or placebo treatment

Acupressure versus no treatment

Three studies compared acupressure with no treatment (Chen 1999; Tsay 2003; Tsay 2004).

Sleep quality (primary outcome)

Two studies reported an outcome of post-treatment sleep quality (Tsay 2003; Tsay 2004) that was better in the treatment group, and the combined result reached statistical significance (SMD = -0.55, 95% CI = -0.89 to -0.21, $p=0.002$) (Figure 01.03). Since there were only two trials in this meta-analysis, tests of heterogeneity were unreliable and the random-effects model was equivalent to the fixed-effect model. A change in sleep quality score was reported by Chen 1999 that was significantly better in the treatment group (SMD = -2.49, 95% CI = -3.20 to -1.78, $p<0.00001$) (Figure 01.04).

Sleep latency

Tsay 2003 reported a significantly better post-treatment sleep onset latency score for acupressure (SMD = -0.54, 95% CI = -1.03 to -0.05, $p=0.03$), but there was no significant difference between the treatment and the control groups in total sleep duration score (Figures 01.06, 01.10). Because of baseline differences in the patients' education levels between the treatment and the control groups, the result was potentially biased. Chen 1999 reported change in the sleep onset latency score (SMD = -1.07, 95% CI = -1.63 to -0.51, $p=0.0002$) that was significantly better in the treatment group (Figure 01.07).

Sleep duration

Chen 1999 reported change in total sleep duration score (SMD = -1.59, 95% CI = -2.20 to -0.99, $p<0.00001$) that was significantly better in the treatment group (Figure 01.11).

Quality of life

In one study which reported change in quality of life scores (Mental and Physical components) before and after treatment (Tsay 2003), there was no statistically significant difference between the treatment and the control groups (Figures 01.15, 01.16).

Acupuncture versus placebo

Only one study compared acupuncture with placebo control (Kim 2004).

Sleep quality (primary outcome)

The sleep quality score was significantly better in the treatment group than in the placebo control group (SMD = -1.08, 95% CI = -1.86 to -0.31, $p=0.006$) (Figure 01.03).

Sleep latency

There was no significant difference in sleep onset latency between the treatment group and the placebo group (Figure 01.05).

Sleep duration

Total sleep duration was significantly longer in the treatment group than in the placebo group (210 versus 124 minutes, $p=0.01$) (Figure 01.09).

Acupressure versus sham

Two studies (Chen 1999; Tsay 2003) compared acupressure with sham control. They used different outcome measures.

Sleep quality (primary outcome)

In Chen 1999, self-rated sleep quality and body comfort did not differ significantly between the treatment and the control groups (Figures 01.01, 01.02) However, the change in sleep quality score

before and after treatment was reported to be significantly better in the acupressure group compared to the sham control group (SMD = -1.76, 95% CI = -2.39 to -1.14, $p < 0.00001$) (Figures 01.03, 01.04). In Tsay 2003 the post-treatment sleep quality score and the total sleep duration score were not significantly different between the treatment and the control groups (Figure 01.03, 01.10).

Sleep latency

Chen 1999 reported that the change in sleep onset latency score was significantly better in the treatment group than in the sham treatment group (SMD = -0.68, 95% CI = -1.22 to -0.14, $p = 0.01$) (Figures 01.06, 01.07). In Tsay 2003 the post-treatment sleep onset latency score was also significantly better in the treatment group (SMD = -0.75, 95% CI = -1.25, -0.26, $p = 0.003$) (Figure 01.06).

Sleep duration

The change in total sleep duration score in Chen 1999, (SMD = -1.25, 95% CI = -1.82 to -0.67, $p < 0.0001$) was significantly better in the treatment group than in the sham treatment group (Figure 01.11).

Quality of life

In Tsay 2003, the change in quality of life scores were worse in the treatment group than in the sham treatment group (physical component score SMD = 0.76, 95% CI = 0.26, 1.26, $p = 0.003$) (Figure 01.15, 01.16). However, the education level and the working status of the patients in the treatment and the control groups were significantly different in this trial, which could be a potential source of bias.

TEAS versus no treatment

Only one study compared TEAS with no treatment (Tsay 2004).

Sleep quality (primary outcome)

The post-treatment sleep quality score was significantly better in the treatment group than in the no treatment group (SMD = -0.74, 95% CI = -1.22 to -0.26, $p = 0.003$) (Figure 01.03).

Auricular therapy versus placebo

One study compared auricular therapy (two forms: magnetic and seed therapies) with placebo (Suen 2002).

Sleep latency

Sleep onset latency was found to be significantly better in the group treated with auricular magnetic therapy compared to the placebo group (19.42 versus 26.83 minutes, $p = 0.03$), but there was no significant difference between the seed therapy group and the placebo group (Figure 01.05).

Sleep efficiency

The sleep efficiency as measured by actigraphy was significantly higher in the auricular magnetic therapy group compared to the placebo group (79.28% versus 67.73%, $p < 0.0001$) but was not significantly different between the auricular seed therapy group and the placebo group (Figure 01.12, 01.14).

Sleep duration

The total sleep duration, the wake after sleep onset, the total wake time and the number of mid-sleep awakenings were also significantly better in the auricular magnetic therapy group compared to

the placebo group (434.5 versus 381.8 minutes, $p = 0.003$; 89.62 versus 144.6 minutes, $p = 0.0002$; 116.18 versus 184.83 minutes, $p = 0.0001$ and 16.55 versus 21.8, $p < 0.0001$ respectively), but there was no significant difference between the auricular seed therapy group and the placebo group (Figure 01.09).

Comparison 2: Acupuncture in addition to baseline medication or treatment versus the same other medication or treatment alone

Acupuncture plus estazolam versus estazolam alone

One study compared acupuncture plus estazolam with estazolam alone (Cui 2003).

Sleep efficiency

The study found no significant difference between the treatment and the control groups in any improvement of insomnia or improvement of sleep efficacy by greater than 50% (Figures 02.01, 02.02).

Acupuncture plus sleep hygiene versus sleep hygiene alone

Only one study compared acupuncture plus sleep hygiene with sleep hygiene alone (Da Silva 2005).

Sleep quality (primary outcome)

The sleep quality score was significantly better in the treatment group (SMD = -1.22, 95% CI = -2.14 to -0.29, $p = 0.01$). However, there was no significant difference between the two groups in self-rated insomnia improvement by greater than 50% (Figure 02.02).

Acupuncture plus estazolam or sleep hygiene versus estazolam or sleep hygiene alone

Sleep quality (primary outcome)

When the results of the two studies (Cui 2003; Da Silva 2005) were combined in a meta-analysis, acupuncture combined with estazolam or sleep hygiene was significantly more likely to result in insomnia improvement greater than 50% compared with control treatment (RR = 1.87, 95% CI = 1.15 to 3.04, $p = 0.01$) (Figure 02.03).

Effect size of acupuncture

The relative likelihood of acupuncture to produce any subjective improvement in insomnia was examined through pooling data from three trials (acupuncture/acupressure versus sham acupressure, acupuncture plus estazolam versus estazolam alone, and acupuncture plus sleep hygiene versus sleep hygiene alone) (Chen 1999; Cui 2003; Da Silva 2005). There was significant statistical heterogeneity, $I^2 = 68.6\%$, chi-squared test of homogeneity: $p = 0.04$. The results showed that acupuncture was not significantly more likely to result in self-rated improvement in insomnia compared to control treatment (Figure 03.01). Since only three trials were included in this meta-analysis, publication bias could not be reliably assessed. As all three trials were considered to have a high risk of bias, sensitivity analysis excluding poor quality trials was not performed.

Sensitivity analysis on best and worst case scenarios for drop-outs

All missing data were due to drop-outs for various reasons, most of which were unrelated to trial interventions, and the numbers were roughly equal in the treatment and the control groups, and did not exceed 30%. One drop-out (Kim 2004) was due to an adverse effect (pain) of the acupuncture treatment. Reasons for 17.6% drop-out was not mentioned in one study (Chen 1999). To investigate the influence of drop-outs, we performed a sensitivity analysis on best and worst case scenarios for studies reporting binary outcomes. For the best case scenario, improvement in sleep quality (RR = 11.00, 95% CI = 1.51 to 80.28, $p=0.02$) and body comfort (RR = 2.35, 95% CI = 1.13 to 4.90, $p=0.02$) in the acupuncture group became significantly better than the sham control group in Chen 1999. In Da Silva 2005, the likelihood of self-rated improvement of insomnia in the acupuncture group became significantly higher than the control group (RR = 3.57, 95% CI = 1.29 to 9.86, $p=0.01$). For the worst case scenario, results from both Chen 1999 and Da Silva 2005 were insignificant; and the combined analysis of Cui 2003; Da Silva 2005 on acupuncture combined with other treatment compared with control treatment became insignificant in the outcome of insomnia improvement by greater than 50% (RR = 1.48, 95% CI = 0.95 to 2.31, $p=0.08$). The results on best and worst case scenarios suggested that the drop-outs may have influenced the conclusions of these studies.

Adverse effects

Only one study mentioned adverse effect of treatment (Kim 2004), in which 1 out of 16 patients (6.3%) in the acupuncture group withdrew treatment because of pain induced by the acupuncture needle. All other studies did not report any adverse effects of the acupuncture treatments.

DISCUSSION

Based on these results, no firm conclusions can be drawn on the efficacy of acupuncture for insomnia. The number of randomised controlled trials was scarce, with small numbers of participants. The trials satisfying the inclusion criteria were heterogeneous with respect to the age of patients, underlying cause for insomnia, type of acupuncture variants, control groups used, and outcomes examined. The definition of insomnia was different between studies. There was no precise clinical diagnosis of insomnia. Some studies recruited participants who had a complaint of insomnia, while others used validated questionnaires as screening tools. The variation in the diagnosis of insomnia further increased the baseline difference between the studies and made the results difficult to interpret. The comparison groups and outcome measures were so heterogeneous that meaningful meta-analysis was almost impossible. Only three studies (Chen 1999; Cui 2003; Da Silva 2005) reported our pre-defined primary outcome of participant's sleep quality. However, their precise definition of insomnia improvement, comparison groups and patients' clinical characteristics were

all different and the treatment effects were statistically heterogeneous. The combined result showed that acupuncture or its variants was not significantly better than control.

Although results of individual studies suggested that acupuncture, acupressure and TEAS might improve sleep quality score, their efficacy in most sleep parameters such as total sleep duration, sleep onset latency, total wake-time, wake after sleep onset, sleep efficiency and awakenings were inconsistent or not measured. The only study which reported quality of life even showed that the physical component score was worse in the acupressure group compared to sham control (Tsay 2003). Auricular magnetic therapy, which was evaluated in one trial (Suen 2002), appeared more promising as it more consistently resulted in better outcomes, including total sleep duration, sleep onset latency, total wake time, wake after sleep onset, sleep efficiency and number of mid-sleep awakenings as measured by both subjective (sleep questionnaire and sleep diaries) and objective (actigraphy) measures. However, the study was also considered to have a high risk of bias; and the sample size was small and the duration of follow-up was short and no firm and reliable conclusions are warranted.

In general, the included studies were not of sufficient methodological quality to support any firm conclusion. There is a high probability of bias, since no study had adequate concealment of randomisation and only two studies were double-blind. Significant baseline differences between the treatment and the control groups in one study (Tsay 2003) cast doubt on the success of randomisation to ensure comparability of the treatment groups. As a result, the post-treatment comparisons of outcomes between the treatment groups might be invalid. As improvement in insomnia is largely subjective, proper randomisation concealment, double-blinding and standardised assessment of outcomes are extremely important. Since all studies used per-protocol instead of intention-to-treat analysis, the results might have been biased to the advantage of acupuncture. Our sensitivity analysis showed that the drop-outs may affect the results and conclusions in the studies and hence the results should be viewed with caution. In addition, the follow-up period used in the included trials were either very short or not clearly stated. Whether acupuncture is efficacious in the long run certainly needs further investigations.

In the studies we reviewed herein, "sham acupuncture" was defined as needle placed in an area close to but not in acupuncture points (non-acupoints). Although the non-acupoints selected may not produce the specific effects that the real acupoints do, the non-acupoints may still be physiologically active and may produce non-specific effects in addition to the placebo effects (Birch 2003). In other words, sham acupuncture might not be an entirely physiologically inert treatment and hence researchers need a larger sample size to detect a significant difference when sham acupuncture control group is used. Similarly, "placebo acupuncture", with needles attached to but not penetrating skin surface on acupoints, can also have non-specific effects. Therefore, interpreting randomised

controlled trials of complex physical therapies such as acupuncture have inherent difficulties, as placebo and Hawthorn effects can mask the results (Mason 2002). Incidental factors are not clear in this type of study as they are with pharmacological treatments (Paterson 2005). In these non-pharmaceutical therapies the characteristic and incidental factors are intertwined and elements categorised as incidental in the context of drug trials are integral to complex non-pharmaceutical interventions such as acupuncture. Therefore, the choice of a randomised design with pragmatic characteristics is important too (Vickers 2004), as placebo or sham controlled trial designs could lead to false negative results.

Adverse effect of acupuncture was mentioned in only one trial (pain in one patient necessitating treatment withdrawal) (Kim 2004). No other adverse effects were mentioned in other included trials. Although existing literature on acupuncture in patients with insomnia and patients with a variety of other conditions have supported that it is a relatively safe treatment modality which obviates the side-effects of sleeping pills, acupuncture is not without risks. Apart from pain, infections and inappropriate needle placement causing inadvertent damage do occur occasionally. Acupressure or electrical or magnetic stimulation of acupoints might cause less pain and might be safer as no breach of skin occurs. However, excessive pressure applied to skin for a long period might result in tissue ischemia or necrosis and electrical or magnetic stimulation might have other untoward effects. Therefore, all forms of acupuncture should only be performed by a well-trained therapist who is experienced, understands the theories behind, and takes the necessary precautions.

AUTHORS' CONCLUSIONS

Implications for practice

This review suggests that there is insufficient high-quality evidence to support the use of acupuncture or its variants to improve people's self-rated sleep quality. Although some forms of acupuncture, e.g. auricular magnetic therapy, might improve sleep parameters in the short-term, the current evidence is still not rigorous enough to

allow recommendation to be made about wide application of any form of acupuncture for the treatment of insomnia of any etiology in people of any age group. The long-term effect of acupuncture or its variants is not known and its potential adverse effects are not entirely clear.

Implications for research

The number of randomised controlled trials on treatment of insomnia using acupuncture are scarce. Existing trials are of small size and low methodological quality. Further high quality studies of larger sample size are needed to assess the effectiveness of acupuncture in treating insomnia. Randomisation methods need to be more rigorous and concealed. Although blinding of the therapist who applied acupuncture might be very difficult, blinding of the patients, the other care providers and outcome assessors should be attempted as far as possible to minimise 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 sub-groups of patients. Therefore, future clinical trials should be focused on a particular sub-group or include a very large sample size to delineate the effect of acupuncture on different types of patients. In addition, well-defined diagnostic criteria such as DSM-IV or ICSD, should be employed to make a precise clinical diagnosis of insomnia, and hence increase the comparability between studies. Since insomnia may wax and wane with or without treatment, a longer follow-up period with serial measurements of outcomes is important to determine the genuine effectiveness of acupuncture and its long-term effect. It might also be worthwhile to examine the effectiveness of combination therapy for insomnia using acupuncture with other non-pharmacological or pharmacological treatments.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Chen 1999

Methods	RCT Block randomisation Single blinding (patients)
Participants	Treatment group: 28 Control 1 (Sham acupressure): 28 Control 2 (No treatment): 28 Overall (males): 84 (52) Age (years): range 61-98, mean 79.04 (SD 7.77). Inclusion: PSQI score >5, with clear mental status, without dementia, able to communicate in Mandarin or Taiwanese, not out of town during weekdays, age >60 years, able to sit > 15 min, absence of any amputations of the upper extremities and no infection, injury, bleeding, thrombophlebitis, or tumors nearby the chosen acupressure points in the head, neck and hands Exclusion: Nil Specific diagnoses/ diagnostic subtypes: No Associated disease: No Duration of disorder: Not mentioned Previous treatments: Not mentioned
Interventions	Acupressure Treatment: acupressure, at Baihui, Fengchi, Anmian in the head, and Shenmen in the ears and hands for 15 min, which consisted of 5 min of finger massage and 10 min of acupoints massage (2 min per each acupoint). The correctness of acupressure was confirmed if the subjects felt sore, numb, heavy, distended, and/or warm. Administration time of interventions was between 1 pm and prior to sleep (before 10 pm). Control 1: sham acupressure, at nonacupressure points Control 2: Conversation only Duration of treatment: 15 min per session, 5 sessions per week for 3 weeks
Outcomes	Table 01.01, 01.02 Self-reported improvement in sleep quality: Treatment group: 19.2%; Control 1: 3.8% Self-reported improvement in body comfort: Treatment group: 41%; Control 1: 26.8% Table 01.04 Mean PSQI score differences in pre- and post-intervention in sleep satisfaction: Treatment group: 5.93 +/- 2.36; Control 1: 1.68 +/- 2.39; Control 2: 0.39 +/- 2.02 Table 01.07 Mean PSQI score differences in pre- and post-intervention in sleep onset latency: Treatment group: -0.82 +/- 0.90; Control 1: -0.29 +/- 0.60; Control 2: 0.07 +/- 0.38 Table 01.11 Mean PSQI score differences in pre- and post-intervention in total sleep duration: Treatment group: -1.36 +/- 0.87; Control 1: -0.32 +/- 0.77; Control 2: 0.07 +/- 0.72 Mean PSQI score differences in pre- and post-intervention in habitual sleep efficiency: Treatment group: -1.57 +/- 0.88; Control 1: -0.18 +/- 0.98; Control 2: -0.04 +/- 1.00 Mean PSQI score differences in pre- and post-intervention in subjective sleep quality: Treatment group: -1.32 +/- 0.61; Control 1: -0.36 +/- 0.56; Control 2: 0.14 +/- 0.59

Chen 1999 (Continued)

	<p>Mean PSQI score differences in pre- and post-intervention in sleep disturbances: Treatment group: -0.36 +/- 0.49; Control 1: -0.07 +/- 0.47; Control 2: 0.11 +/- 0.42</p> <p>Mean PSQI score differences in pre- and post-intervention in sleep sufficiency: Treatment group: -0.39 +/- 0.63; Control 1: -0.32 +/- 0.67; Control 2: 0.07 +/- 0.72</p> <p>Mean PSQI score differences in pre- and post-intervention in use of sleep medication: Treatment group: -0.11 +/- 0.57; Control 1: -0.14 +/- 0.36; Control 2: -0.04 +/- 0.43</p> <p>Mean reduction in nocturnal awakenings: Treatment group: 0.91; Control 1: 0.53; Control 2: 0.13 (SDs not available)</p>
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Notes	<p>Risk of bias: High</p> <p>Dropouts due to various reasons (not described), Treatment group: 6; Control 1: 6; Control 2: 6.</p> <p>Duration of follow-up: 5 weeks;@;@;@;@</p>
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Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Cui 2003

Methods	<p>RCT</p> <p>Randomisation method not mentioned</p> <p>No blinding</p>
Participants	<p>Treatment group (males): 60(34)</p> <p>Control (males): 60 (28)</p> <p>Age: range 28 to 67 years, average 43.2 years in the treatment group; average 38.5 years in the control group</p> <p>Inclusion: Outpatients suffering from insomnia due to "interior-stirring by phlegm-heat"</p> <p>Exclusion: Nil</p> <p>Specific diagnoses/ diagnostic subtypes: "interior-stirring by phlegm-heat" based on the TCM theory</p> <p>Associated disease: Not mentioned</p> <p>Duration of disorder: Not mentioned</p> <p>Previous treatments: Not mentioned</p>
Interventions	<p>Treatment: Acupuncture plus estazolam 1-2mg, at Baihui (GV 20), Shenting (GV 24), Sishencong (EX-HN1), Shenmen (HT 7), Neiguan (PC 6), Zhongwan (CV12), Fenglong (ST 40) and Gongsun (SP 4). The filiform needles 1-1.5 cun in length were used, and acupuncture with the uniform reinforcing-reducing maneuvers was give once daily.</p> <p>Control: Estazolam 1-2mg</p> <p>Duration of treatment: 30 days (once a day, 10 days of treatment as a course, 3 courses in total)</p>
Outcomes	<p>Table 02.01, 02.02</p> <p>Effective rate: Treatment group: cured (sleep efficiency increased by >75%) 24(40%), markedly effective (sleep efficiency increased by 10-20%) 26 (43.3%), improved 8 (sleep efficiency increased by <10%) (13.3%), ineffective 2 (3.3%), total effective rate 94.7%; Control group: cured 14(23.3%), markedly effective 14 (23.3%), improved 24 (40%), ineffective 8 (13.3%), total effective rate 86.7%</p>

Cui 2003 (Continued)

Notes	Risk of bias: High Dropouts: Not mentioned Duration of follow up: 30 days;@;@;@
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Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Da Silva 2005

Methods	RCT Simple randomisation (based on the date of attendance) No blinding
Participants	Treatment group (males): 17 (0) Control (males): 13 (0) Age (years): Treatment group: 26.5 (SD 7.7); Control group: 26.5 (SD 5.6) Inclusion: informed consent, aged from 15 to 39 years, between 15 and 30 weeks of pregnancy, complaint of insomnia. Exclusion: women in the first trimester, had suffered from insomnia before pregnancy, belonged to a high-risk obstetric group, treated by acupuncture within the preceding year, taking hypnotic drugs. Specific diagnoses/ diagnostic subtypes: No Associated disease: No Duration of disorder: Not mentioned Previous treatments: sleep hygiene
Interventions	Treatment: Acupuncture plus sleep hygiene, acupuncture at pre-defined acupoints, with an option of up to 4 points permitted in addition. The most used points were HT7, PC6, GB21 and Anmian bilaterally, Yintang, GV 20 and CV17(middle point). Traditional acupuncture was applied, respecting the classic acupuncture points including depth of needle insertion. Sterilised stainless steel needles of 40mm in length and 0.2mm in diameter were used. An attempt was made to elicit de qi at each point. Needles were left in place for about 25 min. Control: sleep hygiene was given by a nurse to groups from 4 to 8 pregnant women, and consisted of instructions to avoid stimulants, heavy meals and liquid excess before bed time, and to establish a set bed time ritual including : fixed routine, bath before bed, no working late, use of relaxation techniques, and routine posture for sleep. Duration of treatment: once a week but occasionally twice when it was deemed necessary for severe symptoms, minimum of 8 and a maximum of 12 sessions over an 8-week period.
Outcomes	Table 02.02 Significant improvement of self-rated insomnia score (by 50% or more): Treatment group: 75%; Control group: 30%. Table 02.03 Sleep disturbance on numerical rating scale: Treatment group: baseline: 6.7 +/- 3.5; at the second interview: 3.2 +/- 2.4; at the 3rd interview: 3.0 +/- 2.7; at the 4th interview: 3.4 +/- 3.7; at the 5th interview: 1.6 +/- 1.7; Control group: baseline: 4.6 +/- 3.0; at the 2nd interview: 4.7 +/- 3.3; at the 3rd interview: 3.4

Da Silva 2005 (Continued)

	+/- 3.1; at the 4th interview: 4.0 +/- 2.5; at the 5th interview: 4.6 +/- 3.0.	
Notes	Risk of bias: High Dropouts : 5 in treatment group because of missing at least two consecutive interviews, 3 in control group, 2 were because of missing interviews and 1 moved away from the region Duration of follow-up: 8 weeks	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Kim 2004

Methods	RCT Simple randomisation (random digit) Single blinding (assessors)	
Participants	Treatment group (males):15 (8) Control (males): 15 (9) Age (years): Acupuncture group: mean 65.1 (SD 9.0); Control group: mean 68.3 (SD 10.4). Inclusion: persistent insomnia >3 days in a row (Insomnia Severity Index > 15), hospitalized at the Department of Cardiovascular and Neurologic Disease (Stroke Center), Hospital of Oriental Medicine, Kyung Hee Medical Center, Seoul, Korea, from 1 Nov 2002 to 31 Jul 2003 Exclusion: treated with sedative, antidepressant, tranquilizer, narcotic analgesics, antihistamine, or amphetamine-containing drug; or with disorientation, dysphasia, or nocturnal voiding frequency. Specific diagnoses/ diagnostic subtypes: No Associated disease: Stroke; some were with hypertension, diabetes mellitus, ischemic heart disease Duration of disorder: Not mentioned Previous treatments: No	
Interventions	Treatment: Four needles were inserted on Shen-Men(He-7) and Nei-Kuan (EH-6) in both arms. A piece of skin tape was put on each needle to fix it persistently for 2 days. Control: Placebo acupuncture, the needles were laid down on the same points as in acupuncture treatment group, not letting the needles penetrate the skin. Duration of treatment: 2 days;@;@;@;@;@	
Outcomes	Table 01.03 Sleep satisfaction measured by Insomnia Severity Index (ISI): Treatment Group: baseline: 21.9 +/- 2.0; at 1 day later: 14.2 +/- 5.8; at 2 days later: 14.9 +/- 5.5; Control Group: baseline: 22.3 +/- 2.1; at 1 day later: 21.9 +/- 3.4; at 2 days later: 20.9 +/- 3.1 Sleep satisfaction measured by Athens Insomnia Scale (AIS): Treatment group: baseline: 17.1 +/- 1.6; at 1 day later: 9.4 +/- 5.7; at 2 days later: 10.6 +/- 5.1; Control group: baseline: 17.7 +/- 2.5; at 1 day later: 16.2 +/- 4.2; at 2 days later: 15.6 +/- 3.8 Table 01.05 Sleep onset latency measured by Morning Questionnaire: Treatment group: baseline: 189.3 +/- 138.7 min; at 1 day later: 126.0 +/- 125.2 min; at 2 days later: 126.7 +/- 128.7 min; Control group: baseline:	

Kim 2004 (Continued)

	<p>196.0 +/- 161.1 min; at 1 day later: 202.0 +/- 156.1 min; at 2 days later: 186.0 +/- 141.3 min. Table 01.09 Total sleep duration measured by Morning Questionnaire: Treatment group: baseline: 116.0 +/- 65.0 min; at 1 day later: 222.0 +/- 112.7 min; at 2 days later: 210.0 +/- 105.0 min; Control group: baseline: 104.0 +/- 53.0 min; at 1 day later: 120.0 +/- 62.1 min; at 2 days later: 124.0 +/- 55.3 min. Sleep quality index measured by Morning Questionnaire: Treatment group: baseline: 17.3 +/- 14.8; at 1 day later: 46.7 +/- 28.9; at 2 days later: 57.3 +/- 24.6; Control group: baseline: 16.7 +/- 1.9; at 1 day later: 22.0 +/- 21.4; at 2 days later: 22.7 +/- 18.3 Condition upon awakening measured by Morning Questionnaire: Treatment group: baseline: 22.0 +/- 12.1; at 1 day later: 57.3 +/- 24.9; at 2 days later: 56.7 +/- 26.6; Control group: baseline: 21.3 +/- 14.1; at 1 day later: 22.0 +/- 21.4; at 2 days later: 25.3 +/- 16.8 Ability to concentrate measured by Morning Questionnaire: Treatment group: baseline: 23.3 +/- 18.3; at 1 day later: 57.3 +/- 32.4; at 2 days later: 53.3 +/- 30.7; Control group: baseline: 19.3 +/- 15.3; at 1 day later: 29.3 +/- 19.8; at 2 days later: 30.7 +/- 16.2 Ease of falling asleep measured by Morning Questionnaire: Treatment group: baseline: 34.7 +/- 28.7; at 1 day later: 68.0 +/- 27.8; at 2 days later: 62.0 +/- 27.7; Control group: baseline: 33.3 +/- 31.7; at 1 day later: 39.3 +/- 25.7; at 2 days later: 42.7 +/- 24.9 Morning sleepiness measured by Morning Questionnaire: Treatment group: baseline: 31.3 +/- 20.3; at 1 day later: 60.0 +/- 22.0; at 2 days later: 59.3 +/- 24.3; Control group: baseline: 26.0 +/- 10.5; at 1 day later: 30.7 +/- 21.5; at 2 days later: 31.3 +/- 16.4</p>
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Notes	<p>Risk of bias: High Dropouts: 2 (1 in treatment group, 1 not clear about group assignment), one could not stand the pain induced by needle insertion, the other was administered psychoactive drug during the study. Duration of follow-up: Not mentioned</p>
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Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Suen 2002

Methods	<p>RCT Randomisation method not mentioned Double-blind (patients and assessors)</p>
Participants	<p>Treatment group: 60 Control 1 (Semen Vaccariae): 30 Control 2 (Junci Medulla (placebo)) : 30 Overall (males): 120 (10) Age (years): mean 81.66 (SD 5.80) Inclusion: Age >= 60, suffering from sleep disturbances, sleeping poorly on at least 3 night per week, insomnia lasted for a minimum 6 month, actigraph monitoring of sleep efficiency of 85% Exclusion: Serious physical and psychological illness; such as stroke, mental illness, dementia, major depression and impairment such as being bedridden, sleep apnea, regular use of a hypnotic medication or other psychotropic medication with an inability or unwillingness to discontinue medication, wearing</p>

	<p>pacemaker, or implanted electrical device, having a sleep partner, infection or abscess of external ear.</p> <p>Specific diagnoses/ diagnostic subtypes: "Excessive" syndrome and "Deficiency" syndrome based on traditional Chinese Medicine theory</p> <p>Associated disease: 96% reported having good or acceptable health condition. Diabetes mellitus and hypertension, which were under control by regular treatment, were most commonly reported among the subjects</p> <p>Duration of disorder: Range from 6 month to more than 20 yrs.</p> <p>Previous treatments: Not mentioned</p>
Interventions	<p>Treatment: Auricular therapy using magnetic pearl, magnetic pearls with a magnetic flux densities ranging from 0.01mT to 2 T were stick to seven sterilized auricular points: Shenmen, Heart, Kidney, Liver, Spleen, Occiput, Subcortex. The pearls were applied to the most sensitive area of each selected auricular point. The sensitive point was detected by means of an electrical detector (Potentiometer). The pearls were replaced every 3 days.</p> <p>Control 1: Auricular seed therapy using Semen Vaccariae, the procedure and acupoints used were the same with the treatment group.</p> <p>Control 2: Auricular therapy using Junci Medulla (placebo), the procedure and acupoints used were the same with the treatment group. Junci Medulla is a soft material that does not induce any pressure on the acupoints.</p> <p>Duration of treatment: 3 weeks</p>
Outcomes	<p>Table 01.05</p> <p>Sleep onset latency post-therapy measured by actigraph: Treatment: 19.42 +/- 14.54 min; Control 1: 21.47 +/- 8.71 min; Control 2: 26.83 +/- 14.99min;</p> <p>Table 01.08</p> <p>Total wake-time post-therapy measured by actigraph: Treatment: 116.18 +/- 68.68 min; Control 1: 159.13 +/- 83.13 min; Control 2: 184.93 +/- 90.74min</p> <p>Table 01.12</p> <p>Wake after sleep onset post-therapy measured by actigraph: Treatment: 89.62 +/- 54.79 min; Control 1: 127.30 +/- 78.50 min; Control 2: 144.60 +/- 76.07 min</p> <p>Table 01.13</p> <p>Number of mid-sleep awakenings post-therapy measured by actigraph: Treatment: 16.55 +/- 4.74; Control 1: 19.27 +/- 6.64; Control 2: 21.8 +/- 7.29</p> <p>Total sleep time before therapy measured by actigraph: Treatment: 399.58 +/- 78.08 min; Control 1: 404.20 +/- 75.92 min; Control 2: 404.73 +/- 95.36 min</p> <p>Total sleep time during therapy measured by actigraph: Treatment: 421.53 +/- 71.70 min; Control 1: 391.07 +/- 76.68 min; Control 2: 395.03 +/- 94.75 min</p> <p>Table 01.09</p> <p>Total sleep time after therapy measured by actigraph: Treatment: 434.50 +/- 70.99 min; Control 1: 387.20 +/- 70.66 min; Control 2: 381.80 +/- 86.56 min</p> <p>Sleep efficiency before therapy measured by actigraph: Treatment: 74.33 +/- 11.97%; Control 1: 74.40 +/- 12.49%; Control 2: 71.23 +/- 14.50%</p> <p>Sleep efficiency during therapy measured by actigraph: Treatment: 76.85 +/- 10.52%; Control 1: 70.87 +/- 13.36%; Control 2: 70.23 +/- 13.36%</p> <p>Table 01.14</p> <p>Sleep efficiency after therapy measured by actigraph: Treatment: 79.28 +/- 10.77%; Control 1: 71.63 +/- 12.97%; Control 2: 67.73 +/- 15.04%</p>

Suen 2002 (Continued)

Notes	<p>Risk of bias: High</p> <p>Dropouts: 8 in treatment group, 11 in 2 control groups due to home leave (n=8), refusal to wear an actigraph as a monitoring device (n=3), admission to hospital (n=2), being treated for influenza (n=3), unreported reasons (n=3).</p> <p>Duration of follow-up: 3 weeks;@;@</p>	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Tsay 2003

Methods	<p>RCT</p> <p>Randomisation method not mentioned</p> <p>Double blinding (patients and assessor)</p>	
Participants	<p>Treatment group (males): 35 (17)</p> <p>Control 1 (males): 32 (10)</p> <p>Control 2 (males): 31 (15)</p> <p>Age (years): average 55.52 (SD 12.98)</p> <p>Inclusion: PSQI scores of > or =5, age 18-65 years, good mental health status without dementia, able to communicate in Chinese, end-stage renal disease (ESRD) subjects routinely receiving afternoon haemodialysis three times a week, agreement to participate in the status</p> <p>Exclusion: psychiatric diagnoses, major chronic illness such as insulin dependent diabetes, cancer, or lupus erythematosus</p> <p>Specific diagnoses/ diagnostic subtypes: No</p> <p>Associated disease: End-stage renal disease</p> <p>Duration of disorder: Not mentioned</p> <p>Previous treatments: Haemodialysis</p>	
Interventions	<p>Treatment: Acupressure plus usual care, finger pressure of 3-4 kg was exerting on the Shenmen (HT 7) in ears and hand, Yungchuan (K 11); patients were requested to refrain from massaging any acupoints during the study. Precision of acupressure was confirmed if subjects felt sore, numb, heavy, distended and/or warm. The time of interventions consisted of 5 min of massage to relax the person and 9 min of acupoint massage (3 min per acupoint)</p> <p>Control 1: Sham acupressure plus usual care</p> <p>Control 2: Usual care</p> <p>Duration of treatment: 3 times a week for 4 weeks</p>	
Outcomes	<p>Global PSQI sleep satisfaction score: Treatment group: pre-treatment: 9.94 +/- 3.95; post-treatment: 7.29 +/- 4.36; Control 1: pre-treatment: 10.53 +/- 3.56; post-treatment: 9.23 +/- 4.36; Control 2: pre-treatment: 8.43 +/- 4.50; post-treatment: 9.56 +/- 4.00</p> <p>Table 1.06</p> <p>PSQI sleep onset latency score: Treatment group: pre-treatment: 2.12 +/- 1.04; post-treatment: 1.41 +/- 1.08; Control 1: pre-treatment: 2.47 +/- 0.73; post-treatment: 2.23 +/- 1.07; Control 2: pre-treatment: 2.27 +/- 1.00; post-treatment: 2.00 +/- 1.08</p>	

Tsay 2003 (Continued)

	<p>Table 1.10 PSQI total sleep duration score: Treatment group: pre-treatment: 1.76 +/- 1.10; post-treatment: 1.44 +/- 0.99; Control 1: pre-treatment: 1.90 +/- 1.18; post-treatment: 1.90 +/- 1.18; Control 2: pre-treatment: 1.36 +/- 1.18; post-treatment: 1.83 +/- 1.17</p> <p>Table 1.03 PSQI sleep quality score: Treatment group: pre-treatment: 1.56 +/- 0.82; post-treatment: 1.03 +/- 0.83; Control 1: pre-treatment: 1.90 +/- 0.82; post-treatment: 1.27 +/- 0.83; Control 2: pre-treatment: 1.47 +/- 0.73; post-treatment: 1.60 +/- 0.86</p> <p>PSQI habitual sleep score: Treatment group: pre-treatment: 1.58 +/- 1.30; post-treatment: 1.00 +/- 1.10; Control 1: pre-treatment: 1.43 +/- 1.16; post-treatment: 1.23 +/- 1.25; Control 2: pre-treatment: 1.06 +/- 1.17; post-treatment: 1.66 +/- 1.21</p> <p>PSQI sleep disturbance score: Treatment group: pre-treatment: 0.85 +/- 0.50; post-treatment: 0.97 +/- 0.45; Control 1: pre-treatment: 1.10 +/- 0.54; post-treatment: 1.06 +/- 0.69; Control 2: pre-treatment: 0.90 +/- 0.40; post-treatment: 1.00 +/- 0.45</p> <p>PSQI sleep sufficiency score: Treatment group: pre-treatment: 0.52 +/- 0.66; post-treatment: 0.35 +/- 0.69; Control 1: pre-treatment: 0.76 +/- 0.66; post-treatment: 0.63 +/- 0.61; Control 2: pre-treatment: 0.56 +/- 0.67; post-treatment: 0.96 +/- 0.61</p> <p>PSQI sleep medication score: Treatment group: pre-treatment: 1.41 +/- 1.51; post-treatment: 1.20 +/- 1.47; Control 1: pre-treatment: 1.00 +/- 1.38; post-treatment: 0.86 +/- 1.30; Control 2: pre-treatment: 0.73 +/- 1.20; post-treatment: 0.60 +/- 1.16</p> <p>Table 1.15, 1.16 SF-36 physical component score change: Treatment group: -2.04 +/- 8.69; Control 1: -8.49 +/- 8.02; Control 2: 1.53 +/- 6.64</p> <p>SF-36 mental component score change: Treatment group: -1.15 +/- 11.65; Control 1: -1.85 +/- 7.92; Control 2: 2.54 +/- 8.21</p>
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Notes	<p>Risk of bias: High</p> <p>Dropouts: 3 in sham acupressure plus usual care group, 4 in usual care group, due to hospitalization or being transferred to other dialysis center</p> <p>Duration of follow-up: 4 weeks;@;@</p> <p>Note: The education level and working status was significantly different between the Treatment group and the Control 1 group; and the education level was significantly different between the Treatment group and the Control 2 group</p>
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Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Tsay 2004

Methods	<p>RCT</p> <p>Randomisation method not mentioned</p> <p>No blinding</p>
Participants	<p>Treatment 1 (acupressure) group: 36</p> <p>Treatment 2 (TEAS) group: 36</p>

	<p>Control: 36 Overall (males): 108 (66% female, no mention of exact number) Age (years): average 58.16 (SD 12.19) Inclusion: ages > or = 18 or, diagnosis with end-stage renal disease (ESRD) and treatment with haemodialysis for at least 3 months, complaints of fatigue symptoms, PSQI scores > or = 5, Beck Depression Inventory (BDI) > or = 10 Exclusion: Patients with lower-extremity amputations, co-morbid diagnoses of psychiatric disorders, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, neuromuscular disease, SLE, rheumatoid arthritis, cancer, regular steroid therapy, or use of anti-hypertension medications Specific diagnoses/ diagnostic subtypes: No Associated disease: End-stage renal disease Duration of disorder: Not mentioned Previous treatments: Haemodialysis</p>	
Interventions	<p>Treatment 1: Acupressure, at Yungchuan (K-1) in both feet, Zusanli (St-36), Yanglingchuan (GB-34) and Sanyingjiao (Sp-6) in both legs, finger force between 3 to 4 kg was provided by a trained investigators and research assistants. The treatment was limited to 15 min, consisting of 3 min of massage to relax the person and 12 min of acupressure. Treatments were given 3 times per weeks. Treatment 2: Transcutaneous Electrical Acupoint Stimulation (TEAS), at Yungchuan (K-1) in both feet, Zusanli (St-36), Yanglingchuan (GB-34) and Sanyingjiao (Sp-6) in both legs, the TEAS was standardized before each treatment and was set at 2/100 (2 Hz alternating with 100 Hz, each lasting for 3 seconds). Paired skin electrodes were placed on the acupoints. Subjects were instructed not to massage any acupoints during the study period. Each treatment takes 15 min, and 12 min of TEAS (3 min per acupoint). Treatments were given 3 times per weeks Control: Routine unit care Duration of treatment: 4 weeks</p>	
Outcomes	<p>Table 01.03 Sleep quality index: Acupressure group: baseline: 8.85 +/- 4.50; at follow-up: 7.80 +/- 4.00; TEAS group: baseline: 7.12 +/- 4.51; at follow-up: 6.32 +/- 4.55; Control group: baseline: 9.35 +/- 3.48, at follow-up: 9.75 +/- 4.65 Piper fatigue scale: Acupressure group: baseline: 5.92 +/- 1.39; at follow-up: 4.61 +/- 1.72; TEAS group: baseline: 5.60 +/- 1.30; at follow-up: 4.70 +/- 1.50; Control group: baseline: 6.01 +/- 1.60, at follow-up: 5.70 +/- 1.80 Depression score: Acupressure group: baseline: 20.37 +/- 10.65; at follow-up: 13.52 +/- 8.82; TEAS group: baseline: 18.20 +/- 11.11; at follow-up: 12.62 +/- 7.55; Control group: baseline: 21.61 +/- 11.69, at follow-up: 18.88 +/- 9.55</p>	
Notes	<p>Risk of bias: High Dropouts: 1 in treatment group and 1 in control group. One was lost for medical reasons, while the other patients relocated. Duration of follow-up: 12 weeks</p>	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Characteristics of excluded studies *[ordered by study ID]*

Becker-Carus 1985	Allocation of participant is not randomized
Cohen 2003	The primary complaint is not insomnia
Cummings 2003	Commentary, not RCT
Gao 1997	Case-series, not RCT
Lian 1990	RCT comparing acupuncture with estazolam, no placebo or sham control group
Lu 2002	No mention of using randomization
Phillips 2001	single arm trial, not RCT
Ruan 2001	No mention of using randomization
Shang 2000	Case-series, not RCT
Shen 2004	Case-series, not RCT
Shi 2003	Case-series, not RCT
Suen 2003	A study using repeated measures without control group.
Tsay 2003b	Multiple publication of Tsay 2003
Wang 2000	Commentary on methodology
Xu 1997	Case-series, not RCT
Yao 1999	Case-series, not RCT
Yu 1997	Case-series, not RCT
Zhang 2002	Case-series, not RCT
Zhang 2003	Case-series, not RCT

DATA AND ANALYSES

Comparison 1. Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Self-rated improvement in sleep quality	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Acupressure vs. Sham	1	52	Risk Ratio (M-H, Random, 95% CI)	5.0 [0.63, 39.91]
2 Self-rated improvement in body comfort	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Acupressure vs. Sham	1	53	Risk Ratio (M-H, Random, 95% CI)	1.51 [0.69, 3.30]
3 Post-treatment Sleep Quality Score	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 Acupuncture vs. Placebo	1	30	Std. Mean Difference (IV, Random, 95% CI)	-1.08 [-1.86, -0.31]
3.2 Acupressure vs. Sham	1	67	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-0.77, 0.20]
3.3 Acupressure vs. No Treatment	2	138	Std. Mean Difference (IV, Random, 95% CI)	-0.55 [-0.89, -0.21]
3.4 TEAS vs. No Treatment	1	72	Std. Mean Difference (IV, Random, 95% CI)	-0.74 [-1.22, -0.26]
4 Change in Sleep Quality Score	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
4.1 Acupressure vs. Sham	1	56	Std. Mean Difference (IV, Random, 95% CI)	-1.76 [-2.39, -1.14]
4.2 Acupressure vs. No Treatment	1	56	Std. Mean Difference (IV, Random, 95% CI)	-2.49 [-3.20, -1.78]
5 Post-treatment Sleep Onset Latency (in min)	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.1 Auricular (Magnetic)Therapy vs. Auricular (Seed) Therapy	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.60, 0.28]
5.2 Auricular (Magnetic)Therapy vs. Placebo	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.50 [-0.94, -0.06]
5.3 Auricular (Seed) Therapy vs. Placebo	1	60	Std. Mean Difference (IV, Random, 95% CI)	-0.43 [-0.94, 0.08]
5.4 Acupuncture vs. Placebo	1	30	Std. Mean Difference (IV, Random, 95% CI)	-0.43 [-1.15, 0.30]
6 Post-treatment Sleep Onset Latency Score	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
6.1 Acupressure vs. Sham	1	67	Std. Mean Difference (IV, Random, 95% CI)	-0.75 [-1.25, -0.26]
6.2 Acupressure vs. No Treatment	1	66	Std. Mean Difference (IV, Random, 95% CI)	-0.54 [-1.03, -0.05]
7 Change in Sleep Onset Latency Score	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
7.1 Acupressure vs. Sham	1	56	Std. Mean Difference (IV, Random, 95% CI)	-0.68 [-1.22, -0.14]
7.2 Acupuncture vs. No Treatment	1	56	Std. Mean Difference (IV, Random, 95% CI)	-1.07 [-1.63, -0.51]
8 Post-treatment Total Wake-time (in min) as measured by Actigraphy	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only

8.1 Auricular (Magnetic)Therapy vs. Auricular (Seed) Therapy	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.58 [-1.02, -0.13]
8.2 Auricular (Magnetic)Therapy vs. Placebo	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.89 [-1.35, -0.43]
8.3 Auricular (Seed) Therapy vs. Placebo	1	60	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-0.80, 0.22]
9 Post-treatment Total Sleep Duration (in min)	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
9.1 Auricular (Magnetic)Therapy vs. Auricular (Seed) Therapy	1	90	Std. Mean Difference (IV, Random, 95% CI)	0.66 [0.21, 1.11]
9.2 Auricular (Magnetic)Therapy vs. Placebo	1	90	Std. Mean Difference (IV, Random, 95% CI)	0.68 [0.23, 1.13]
9.3 Auricular (Seed) Therapy vs. Placebo	1	60	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.44, 0.57]
9.4 Acupuncture vs. Placebo	1	30	Std. Mean Difference (IV, Random, 95% CI)	1.00 [0.23, 1.76]
10 Post-treatment Total Sleep Duration Score	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
10.1 Acupressure vs. Sham	1	67	Std. Mean Difference (IV, Random, 95% CI)	-0.42 [-0.90, 0.07]
10.2 Acupressure vs. No Treatment	1	66	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.84, 0.13]
11 Change in Total Sleep Duration Score	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
11.1 Acupressure vs. Sham	1	56	Std. Mean Difference (IV, Random, 95% CI)	-1.25 [-1.82, -0.67]
11.2 Acupressure vs. No Treatment	1	56	Std. Mean Difference (IV, Random, 95% CI)	-1.59 [-2.20, -0.99]
12 Post-treatment Wake After Sleep Onset (in min) as measured by Actigraphy	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
12.1 Auricular (Magnetic) Therapy vs. Auricular (Seed) Therapy	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.59 [-1.03, -0.14]
12.2 Auricular (Magnetic) Therapy vs. Placebo	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.87 [-1.33, -0.41]
12.3 Auricular (Seed) Therapy vs. Placebo	1	60	Std. Mean Difference (IV, Random, 95% CI)	-0.22 [-0.73, 0.29]
13 Post-treatment number of mid-sleep awakenings as measured by actigraphy	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
13.1 Auricular (Magnetic) Therapy vs. Auricular (Seed) Therapy	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.50 [-0.94, -0.05]
13.2 Auricular (Magnetic) Therapy vs. Placebo	1	90	Std. Mean Difference (IV, Random, 95% CI)	-0.91 [-1.37, -0.45]
13.3 Auricular (Seed) Therapy vs. Placebo	1	60	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.87, 0.15]
14 Post-treatment Sleep Efficiency as measured by Actigraphy	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only

14.1 Auricular (Magnetic) Therapy vs. Auricular (Seed) Therapy	1	90	Std. Mean Difference (IV, Random, 95% CI)	0.66 [0.21, 1.11]
14.2 Auricular (Magnetic) Therapy vs. Placebo	1	90	Std. Mean Difference (IV, Random, 95% CI)	0.93 [0.47, 1.39]
14.3 Auricular (Seed) Therapy vs. Placebo	1	60	Std. Mean Difference (IV, Random, 95% CI)	0.27 [-0.23, 0.78]
15 Change in QoL Score (Physical component)	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
15.1 Acupressure vs. Sham	1	67	Std. Mean Difference (IV, Random, 95% CI)	0.76 [0.26, 1.26]
15.2 Acupressure vs. No Treatment	1	66	Std. Mean Difference (IV, Random, 95% CI)	-0.45 [-0.94, 0.04]
16 Change in QoL Score (Mental component)	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
16.1 Acupressure vs. Sham	1	67	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.41, 0.55]
16.2 Acupressure vs. No Treatment	1	66	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.85, 0.13]

Comparison 2. Acupuncture or its variants plus another treatment versus the same other treatment alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Self-rated improvement of insomnia	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Acupuncture + estazolam vs. estazolam alone	1	120	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.98, 1.23]
2 Self-rated improvement of insomnia by >=50%	2	142	Risk Ratio (M-H, Random, 95% CI)	1.87 [1.15, 3.04]
2.1 Acupuncture + sleep hygiene vs. sleep hygiene alone	1	22	Risk Ratio (M-H, Random, 95% CI)	2.5 [0.92, 6.81]
2.2 Acupuncture + estazolam vs. estazolam alone	1	120	Risk Ratio (M-H, Random, 95% CI)	1.71 [0.99, 2.98]
3 Post-treatment Sleep Quality Score	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 Acupuncture + sleep hygiene vs. sleep hygiene alone	1	22	Std. Mean Difference (IV, Random, 95% CI)	-1.22 [-2.14, -0.29]

Comparison 3. Effect size of acupuncture or its variants

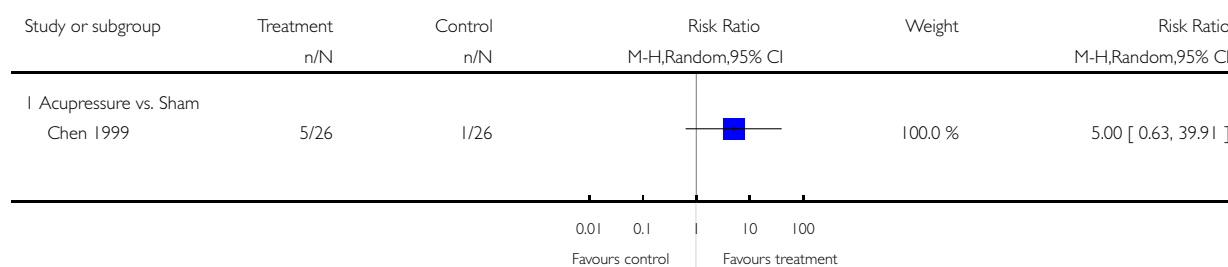
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Relative likelihood of acupuncture or its variants in self-rated improvement of insomnia	3	194	Risk Ratio (M-H, Random, 95% CI)	1.66 [0.68, 4.03]

Analysis 1.1. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 1 Self-rated improvement in sleep quality.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 1 Self-rated improvement in sleep quality

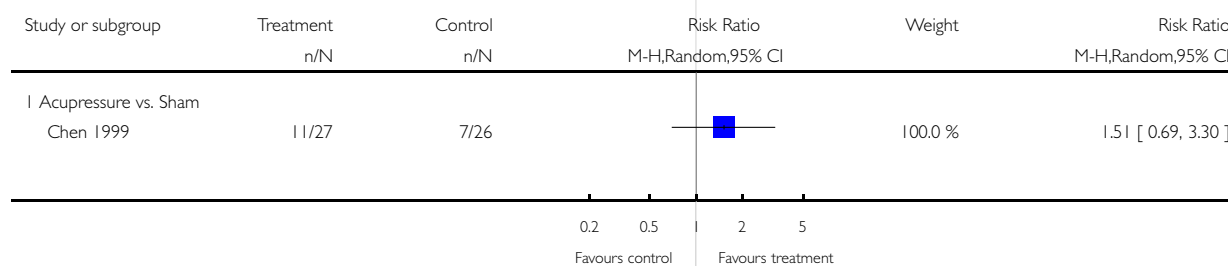


Analysis 1.2. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 2 Self-rated improvement in body comfort.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 2 Self-rated improvement in body comfort

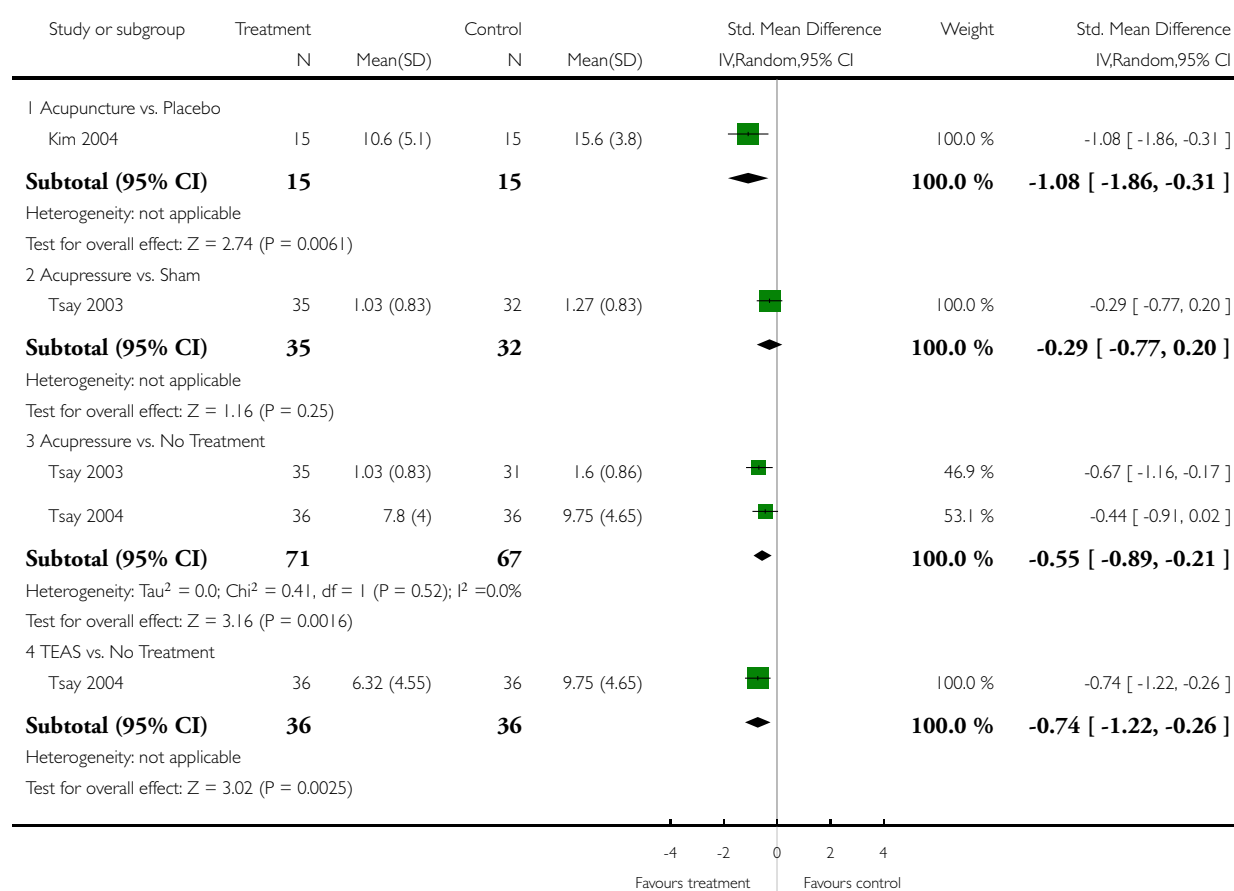


Analysis I.3. Comparison I Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 3 Post-treatment Sleep Quality Score.

Review: Acupuncture for insomnia

Comparison: I Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 3 Post-treatment Sleep Quality Score

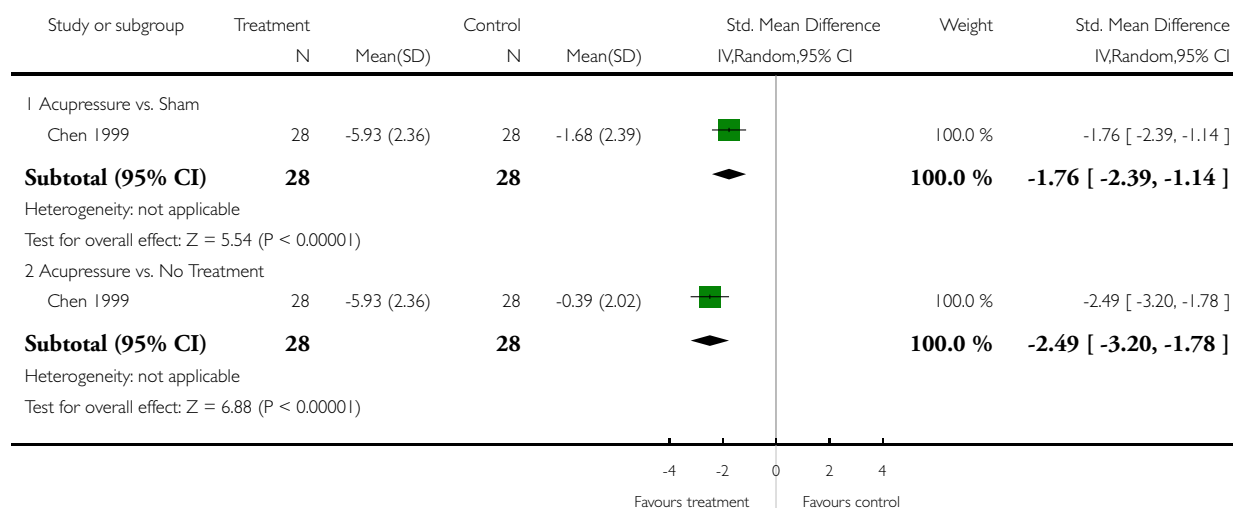


Analysis 1.4. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 4 Change in Sleep Quality Score.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 4 Change in Sleep Quality Score

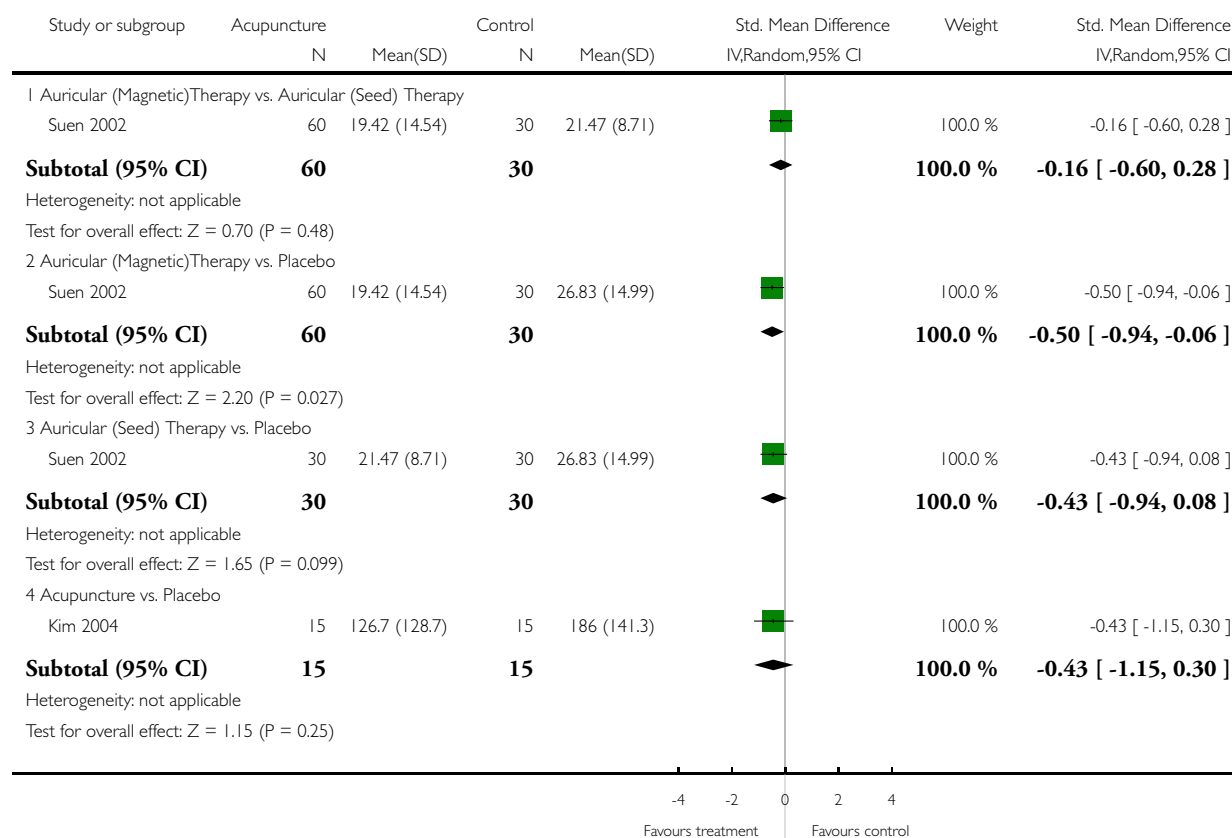


Analysis 1.5. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 5 Post-treatment Sleep Onset Latency (in min).

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 5 Post-treatment Sleep Onset Latency (in min)

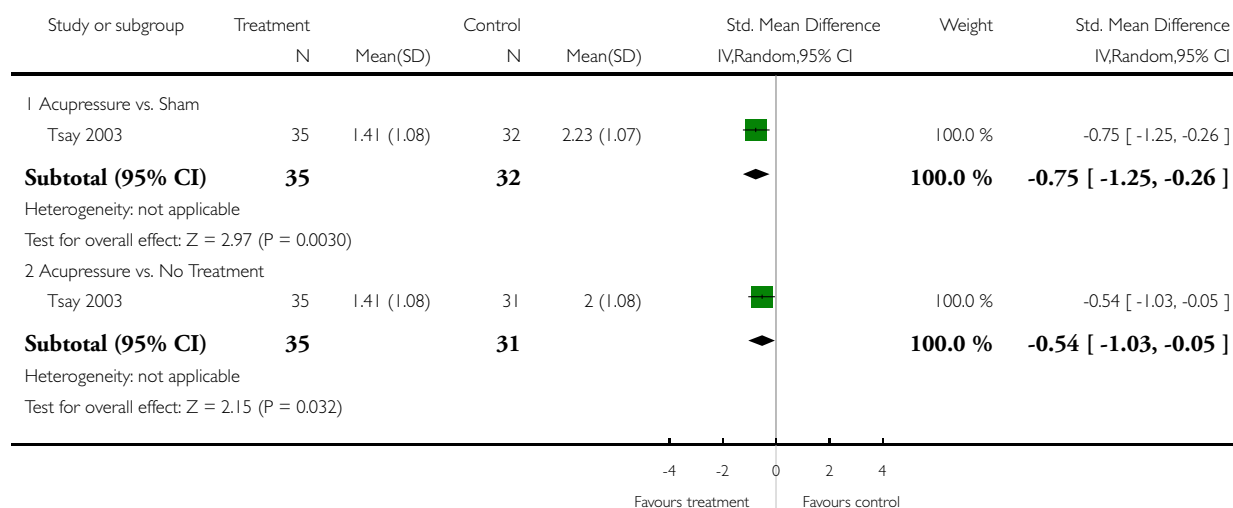


Analysis 1.6. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 6 Post-treatment Sleep Onset Latency Score.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 6 Post-treatment Sleep Onset Latency Score

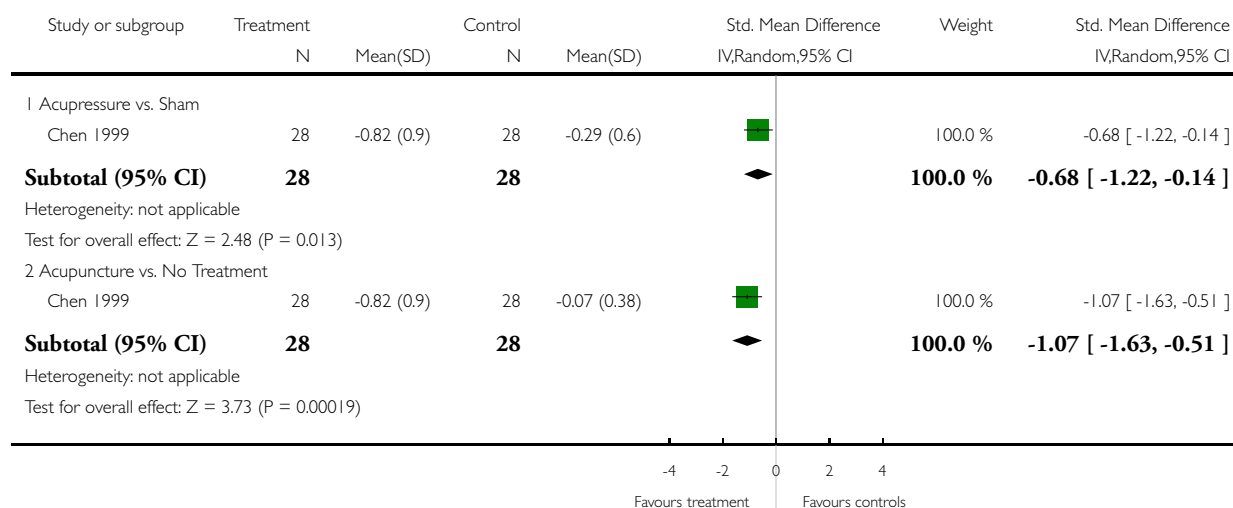


Analysis 1.7. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 7 Change in Sleep Onset Latency Score.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 7 Change in Sleep Onset Latency Score

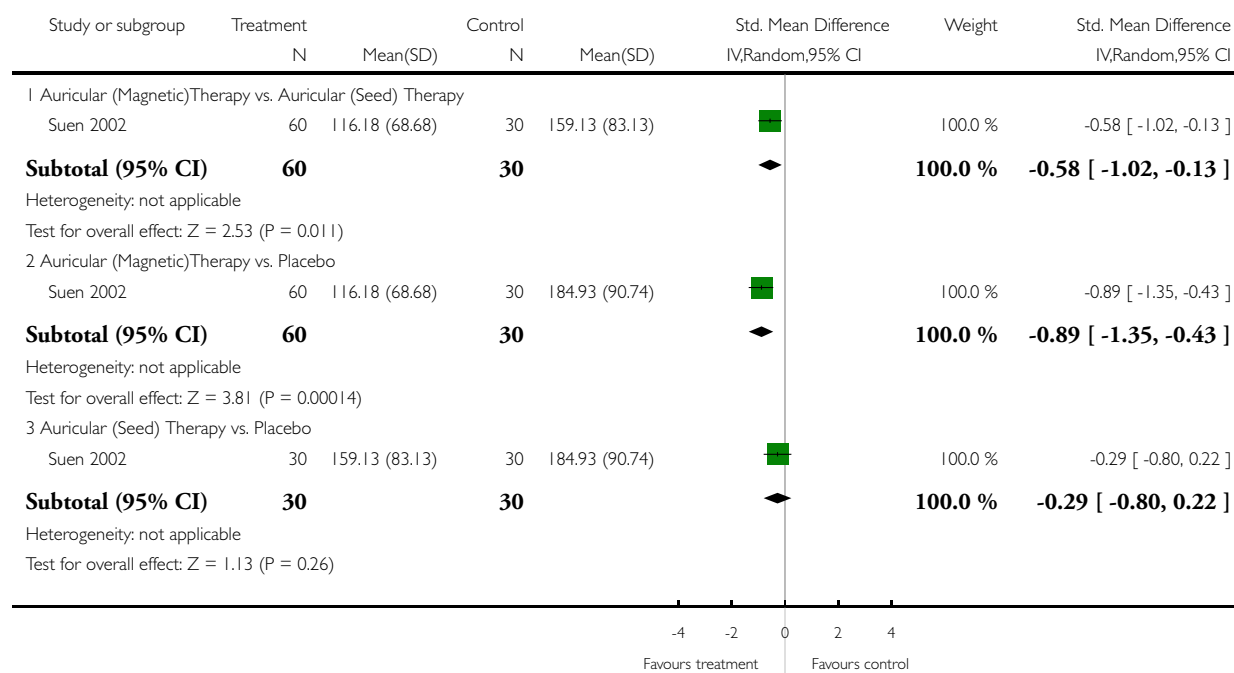


Analysis 1.8. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 8 Post-treatment Total Wake-time (in min) as measured by Actigraphy.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 8 Post-treatment Total Wake-time (in min) as measured by Actigraphy

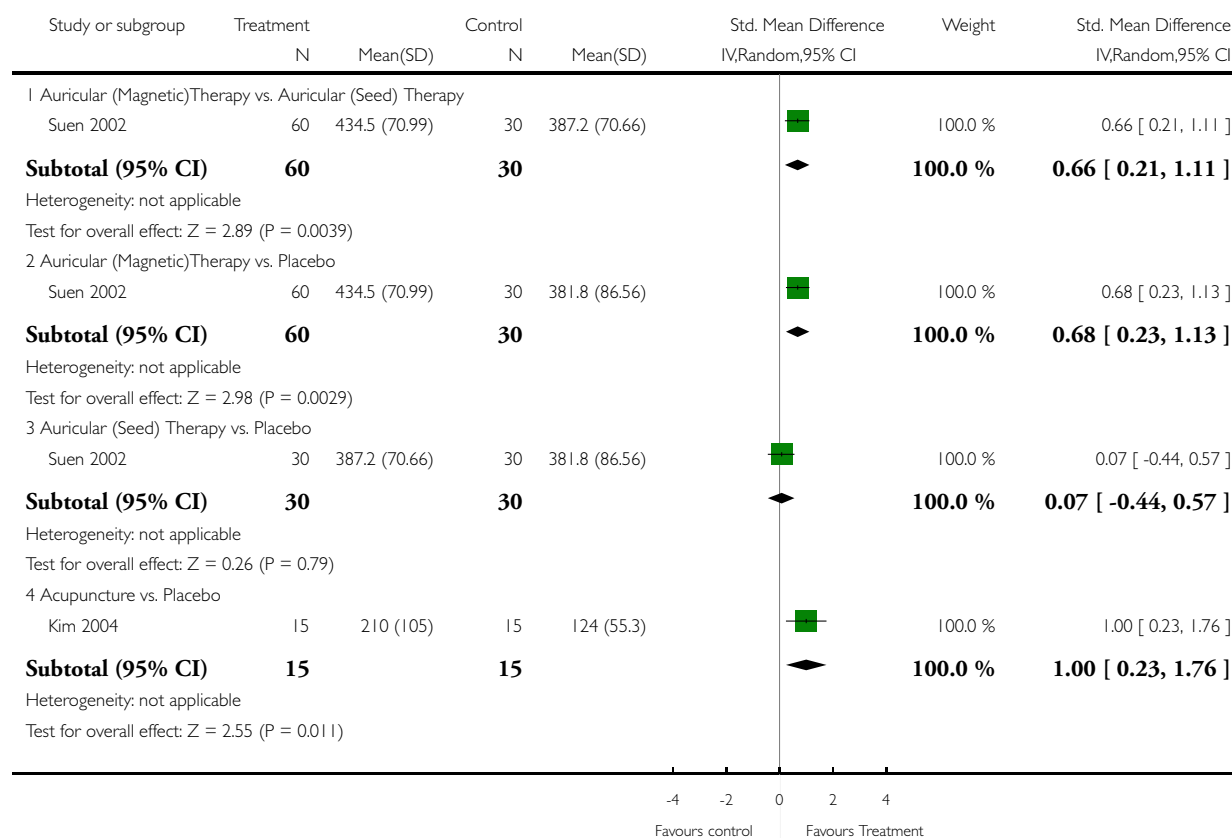


Analysis 1.9. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 9 Post-treatment Total Sleep Duration (in min).

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 9 Post-treatment Total Sleep Duration (in min)

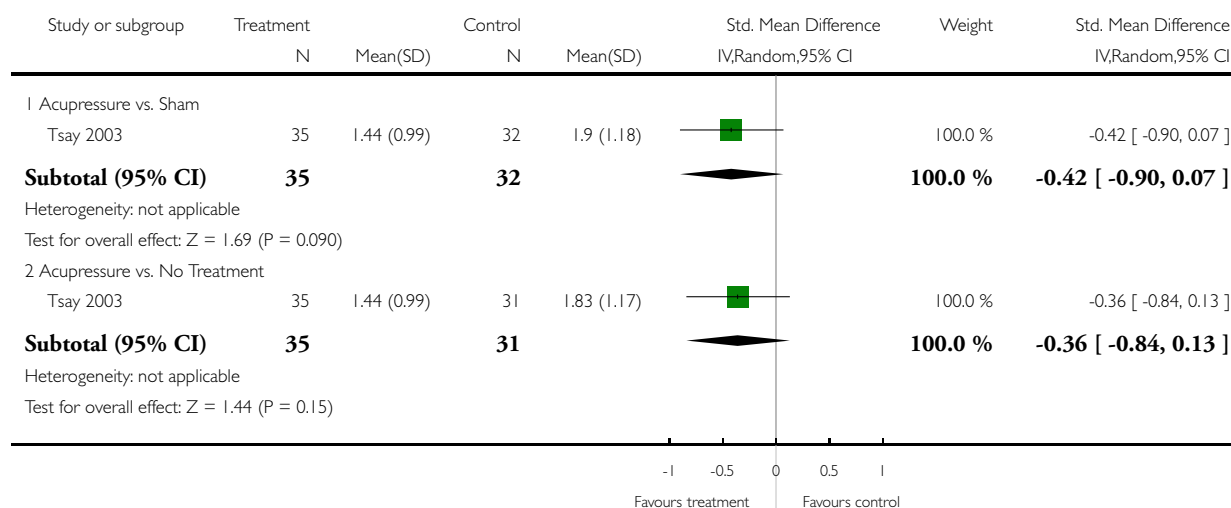


Analysis 1.10. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 10 Post-treatment Total Sleep Duration Score.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 10 Post-treatment Total Sleep Duration Score

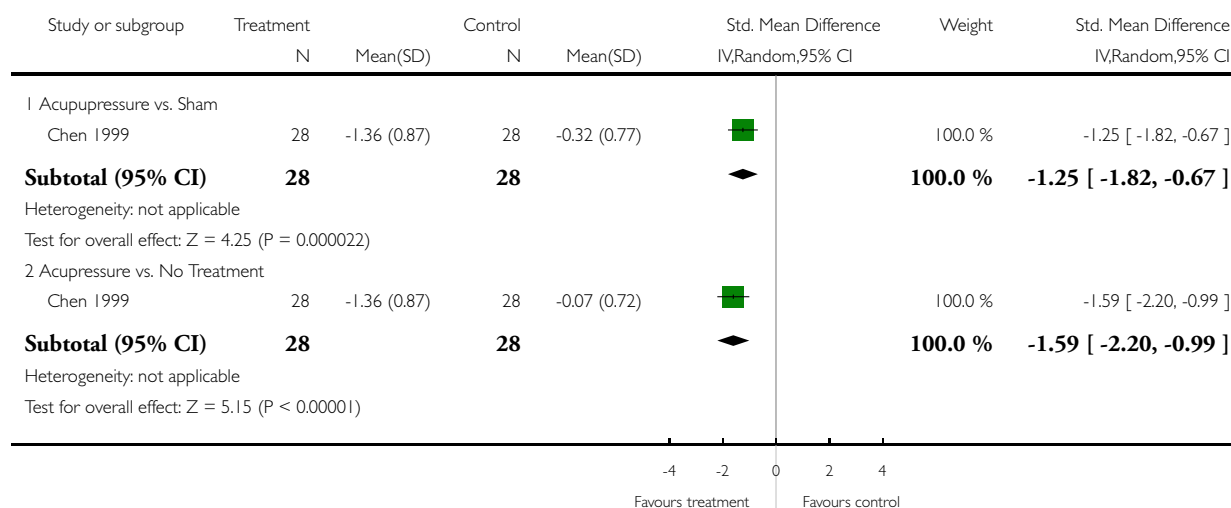


Analysis 1.11. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 11 Change in Total Sleep Duration Score.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 11 Change in Total Sleep Duration Score

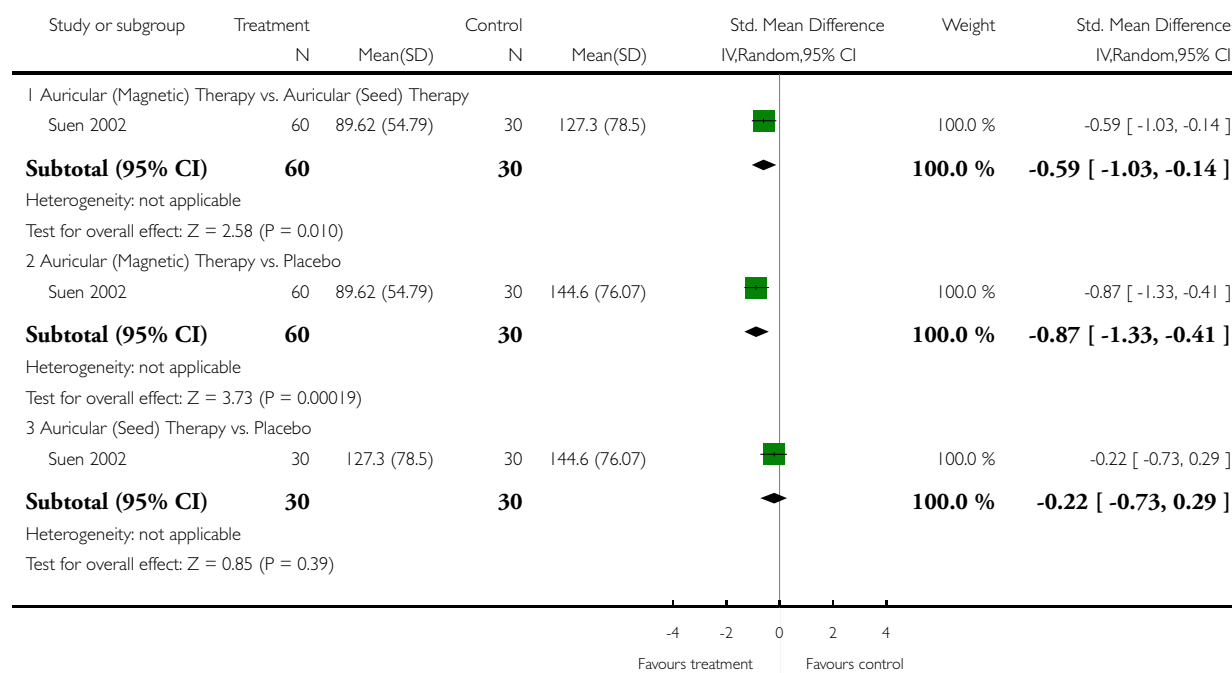


Analysis 1.12. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 12 Post-treatment Wake After Sleep Onset (in min) as measured by Actigraphy.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 12 Post-treatment Wake After Sleep Onset (in min) as measured by Actigraphy

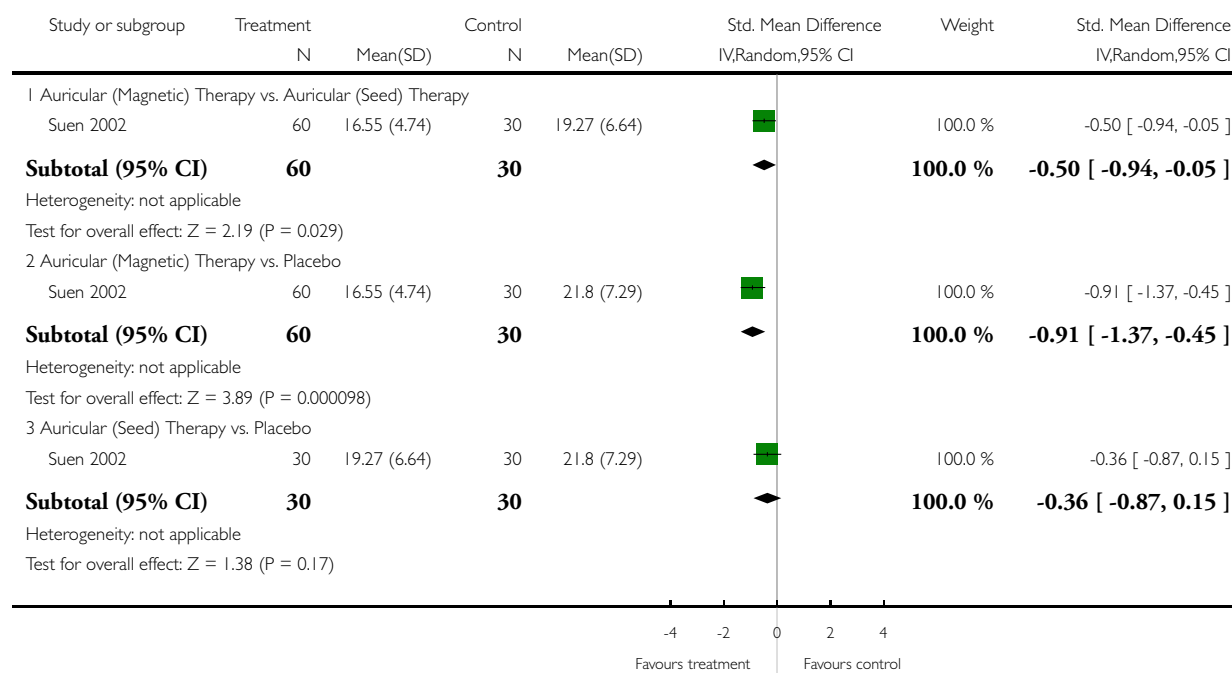


Analysis 1.13. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 13 Post-treatment number of mid-sleep awakenings as measured by actigraphy.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 13 Post-treatment number of mid-sleep awakenings as measured by actigraphy

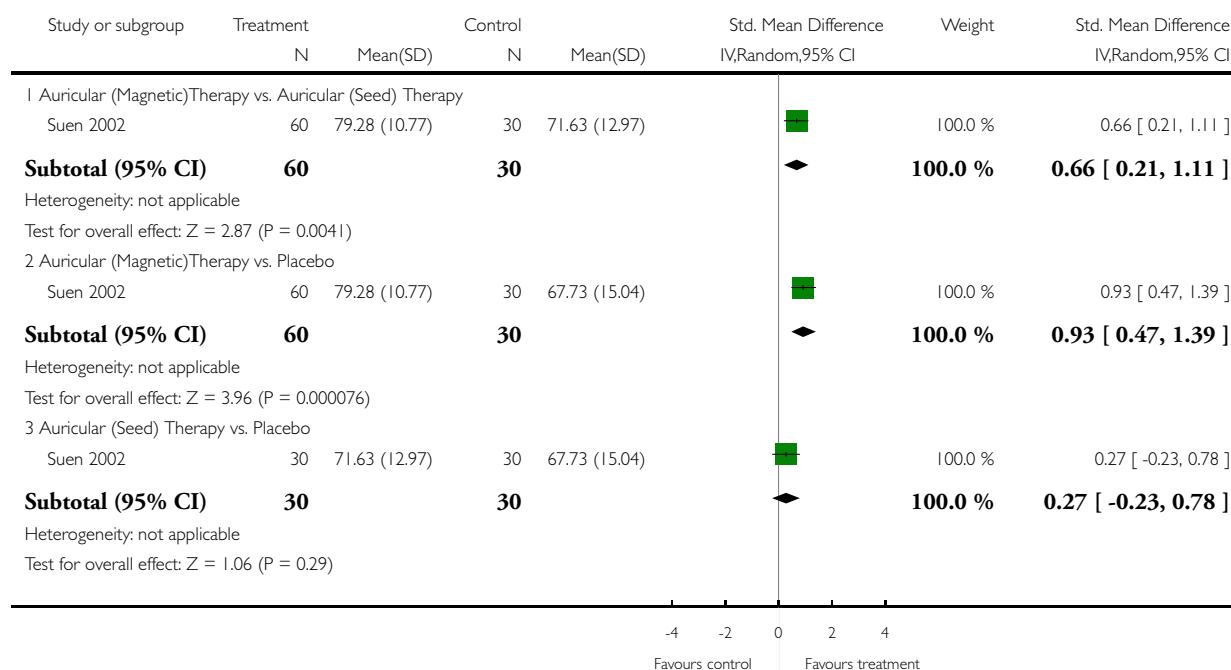


Analysis 1.14. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 14 Post-treatment Sleep Efficiency as measured by Actigraphy.

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 14 Post-treatment Sleep Efficiency as measured by Actigraphy

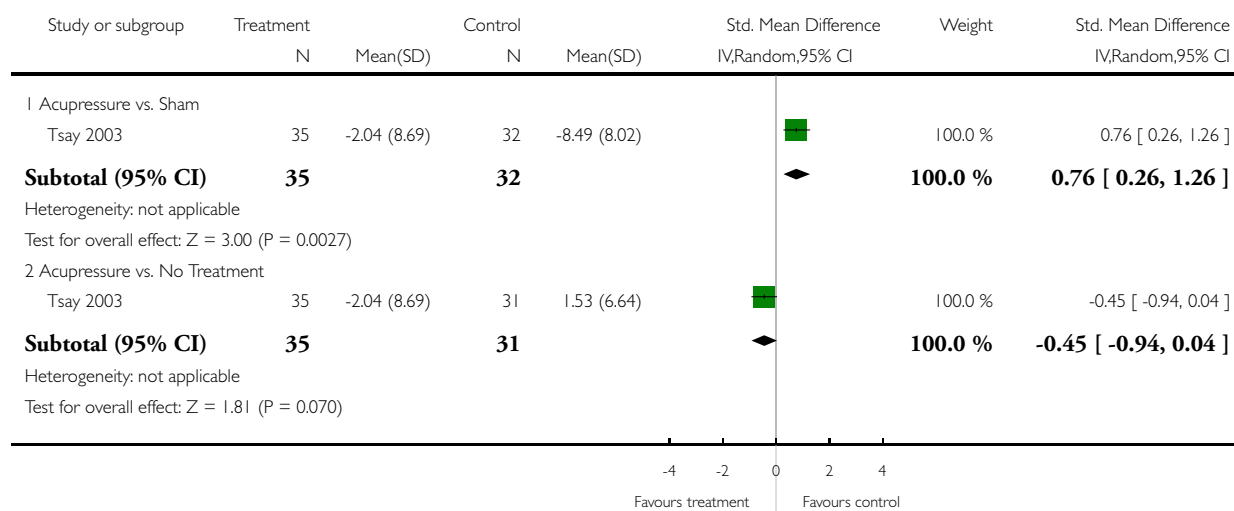


Analysis 1.15. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 15 Change in QoL Score (Physical component).

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 15 Change in QoL Score (Physical component)

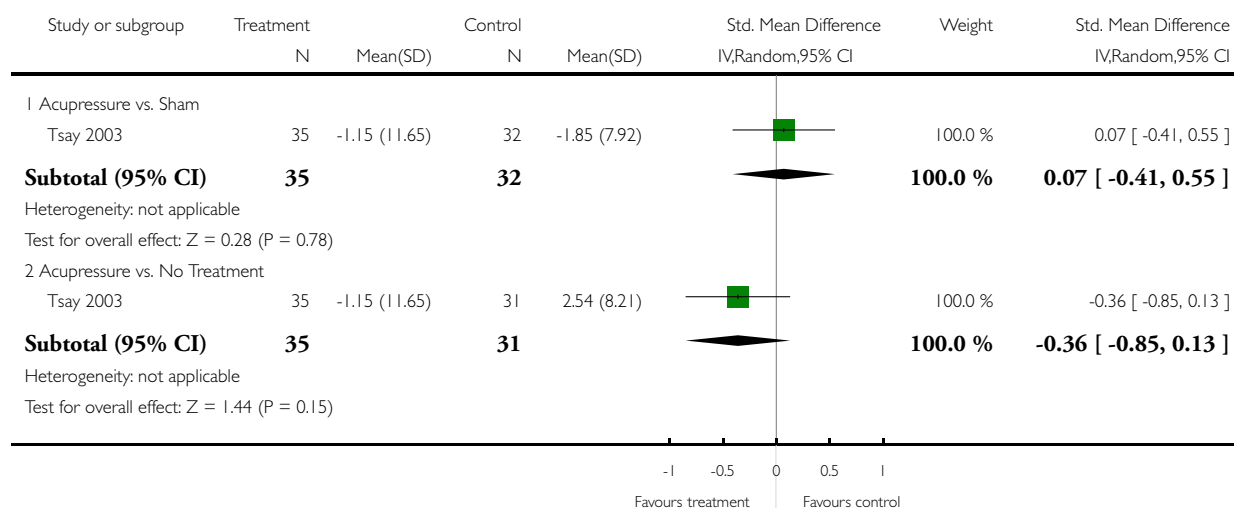


Analysis 1.16. Comparison 1 Acupuncture or its variants alone versus no or sham or placebo treatment, Outcome 16 Change in QoL Score (Mental component).

Review: Acupuncture for insomnia

Comparison: 1 Acupuncture or its variants alone versus no or sham or placebo treatment

Outcome: 16 Change in QoL Score (Mental component)

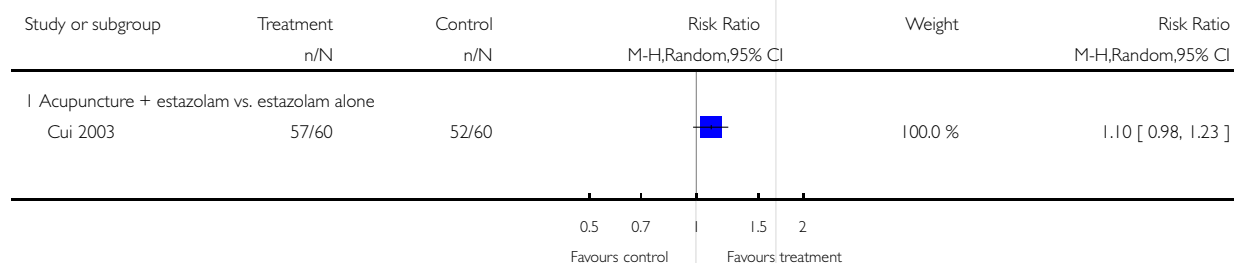


Analysis 2.1. Comparison 2 Acupuncture or its variants plus another treatment versus the same other treatment alone, Outcome 1 Self-rated improvement of insomnia.

Review: Acupuncture for insomnia

Comparison: 2 Acupuncture or its variants plus another treatment versus the same other treatment alone

Outcome: 1 Self-rated improvement of insomnia

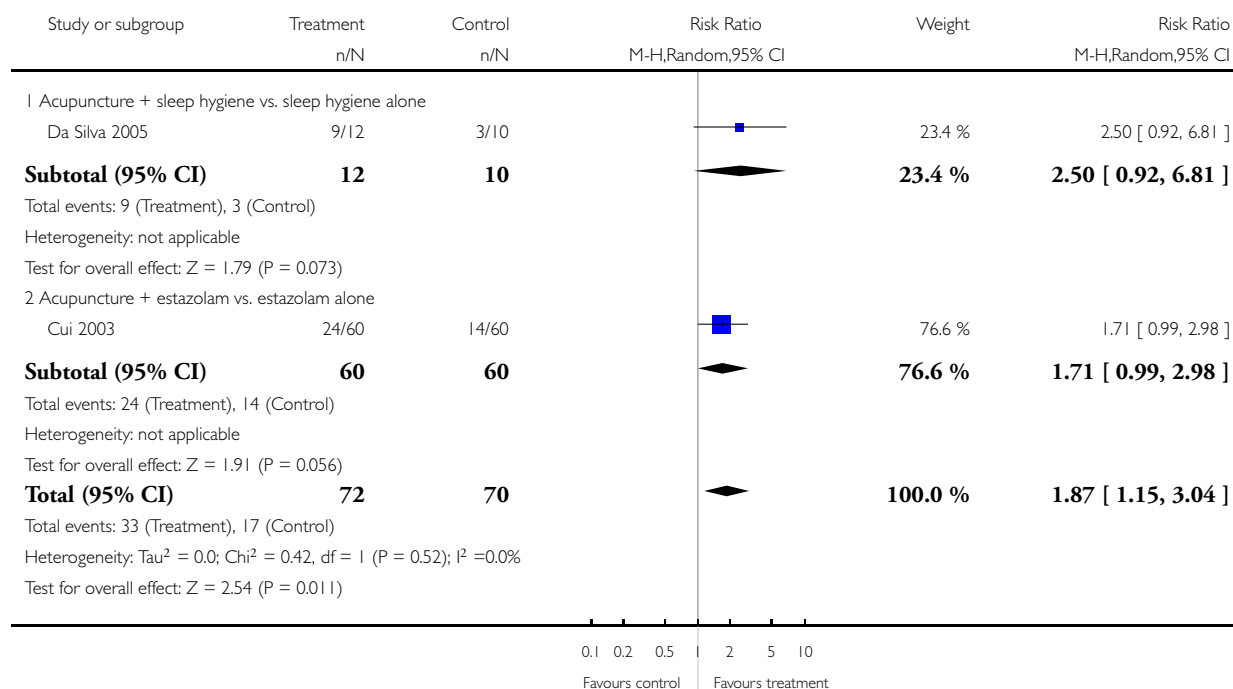


Analysis 2.2. Comparison 2 Acupuncture or its variants plus another treatment versus the same other treatment alone, Outcome 2 Self-rated improvement of insomnia by >=50%.

Review: Acupuncture for insomnia

Comparison: 2 Acupuncture or its variants plus another treatment versus the same other treatment alone

Outcome: 2 Self-rated improvement of insomnia by >=50%

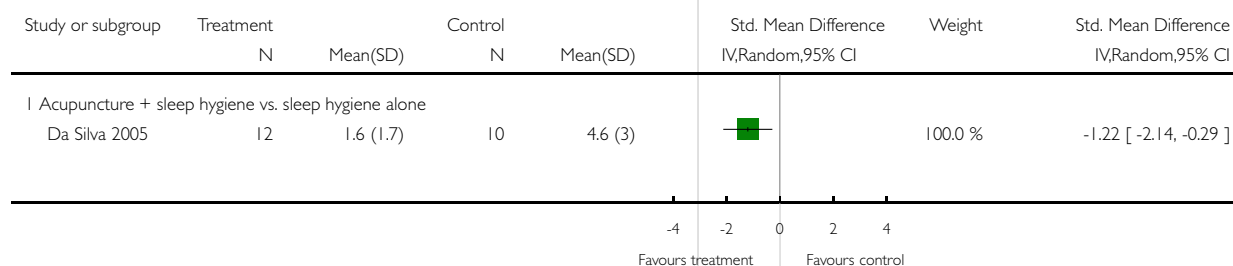


Analysis 2.3. Comparison 2 Acupuncture or its variants plus another treatment versus the same other treatment alone, Outcome 3 Post-treatment Sleep Quality Score.

Review: Acupuncture for insomnia

Comparison: 2 Acupuncture or its variants plus another treatment versus the same other treatment alone

Outcome: 3 Post-treatment Sleep Quality Score

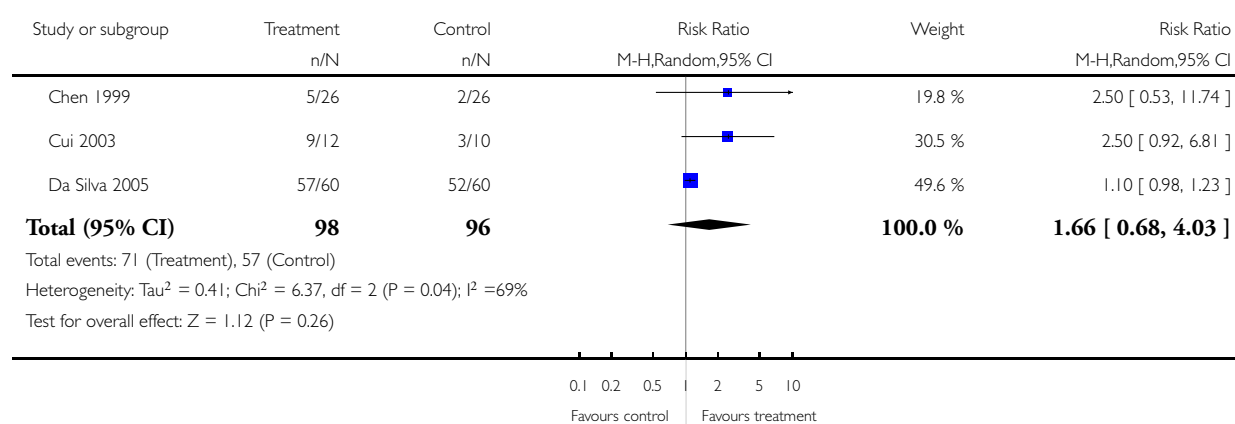


Analysis 3.1. Comparison 3 Effect size of acupuncture or its variants, Outcome 1 Relative likelihood of acupuncture or its variants in self-rated improvement of insomnia.

Review: Acupuncture for insomnia

Comparison: 3 Effect size of acupuncture or its variants

Outcome: 1 Relative likelihood of acupuncture or its variants in self-rated improvement of insomnia



WHAT'S NEW

Last assessed as up-to-date: 23 March 2007.

31 October 2008	Amended	Converted to new review format.
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HISTORY

Protocol first published: Issue 3, 2005

Review first published: Issue 2, 2007

24 March 2007	New citation required and conclusions have changed	Substantive amendment
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CONTRIBUTIONS OF AUTHORS

Cheuk DKL: protocol development, searching for trials, quality assessment of trials, data extraction, data input, data analyses, development of final review, corresponding author.

Yeung J: protocol development, searching for trials, quality assessment of trials, data extraction, data input, data analyses, development of final review.

Chung CF: development of final review.

Wong V: protocol development, development of final review.

DECLARATIONS OF INTEREST

None known.

INDEX TERMS

Medical Subject Headings (MeSH)

*Acupuncture Therapy; Acupressure [methods]; Randomized Controlled Trials as Topic; Sleep Initiation and Maintenance Disorders [*therapy]

MeSH check words

Humans