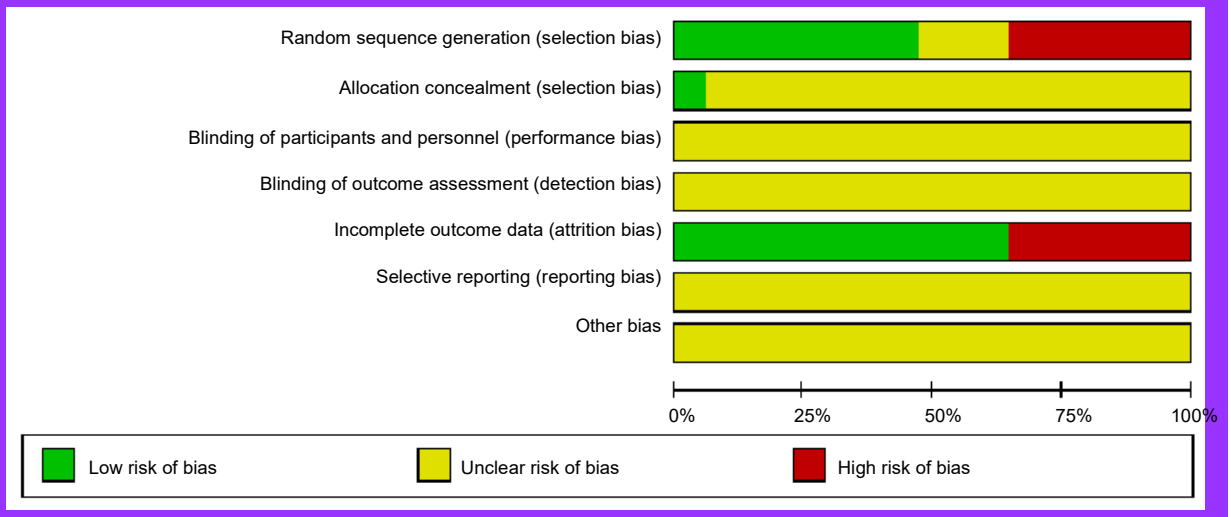

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Meta-analysis

Acupuncture compares with Western medicine for climacteric depression

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Abstract

The aim of this study was to assess the clinical efficacy and safety of acupuncture for climacteric depression. Two reviewers searched major databases independently. The quality assessment and data analysis were evaluated by Cochrane reviews 5.3.0. Seventeen clinical trials were included, contained 1,369 cases. Meta-analysis of acupuncture comparing with medicine showed that: a) Affective rate: [OR = 1.44, 95% CI (1.02, 2.04)], the difference had statistically significance; b) HAMA score : [MD = -2.12, 95% CI (-2.85, -1.40)], the difference had statistically significance; c) HAMD score: The difference of the 2nd week, 4th week, 6th week, 8th week, or 12th week was not statistically significant; d) Kupperman score: [MD = -5.05, 95% CI (-11.94, 1.84)] showed no statistical significance; e) Incidence of adverse events of acupuncture (2.7%) was significantly less than the control group (20%). In conclusion acupuncture will help to improve depressive symptoms of climacteric and decrease adverse reactions.

Introduction

Climacteric depression is caused by decline and even disappearance of the ovarian function. It is emergence of a series of emotional depression, anxiety and stress as the main symptom, accompanied by insomnia, physical discomfort, autonomic dysfunction and other symptoms. In recent years, the clinical data shows that the incidence of climacteric depression has an increasing trend (Shi et al., 2007), which is up to 46%. However, the pathogenesis of this disease is not very clear. Therefore, the treatment of climacteric depression has caused more and more attention.

Western medicine treatment had achieved certain effectiveness by using anti-depression and hormone replacement therapy. However, hormone therapy had more contraindications, adverse effects and increased incidence rate of endometrial cancer, breast cancer and so on. Currently, there were many domestic and international clinical trials on acupuncture for climacteric depression, but the clinical trials exist reporting differences, that convincing evidence was limited, and lack of relevant systematic reviews.

In view of this, we analyzed studies on simple acupuncture compared to Western medicine for climacteric depression according to Cochrane systematic review of the research method to investigate the efficacy and safety of acupuncture treatment of this disease.

Materials and Methods

Inclusion criteria

Type of study

Randomized controlled trials (RCTs); or only men-

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tioned literature, "randomized controlled", "randomized", "random" and other words. Whether blinded, language had no limitation.

Studied

Age, sources of cases were not restricted; clear diagnostic criteria was needed.

Interventions

The treatment group used simple acupuncture treatment (needle materials, acupuncture-points, implementation techniques, needle retention time and treatments procedure were not limited); the control group with Western medicine (drug type had no limitation).

Outcomes

Main outcome measure was effective rate. Secondary outcomes were Hamilton Depression Rating Scale (HAMD) reduction rate, HAMD scale score, HAMA score, KMI score, etc). Reduction rate criteria: HAMD score reduction rate = [(total score before treatment - after treatment score) / pre-treatment score] × 100%, recovery: HAMD reduction rate ≥75%; markedly: HAMD score reduction rate ≥ 50%; effective: HAMD reduction rate ≥25%; remission: HAMD reduction rate <25%.

Safety: TESS (side effects scale) score, the incidence of adverse events.

Exclusion criteria

The subjects were other diseases associated with climacteric depression; or substance dependence, schizophrenia, dementia; or patients with bipolar disorder; duplicate detection or published literature; or review articles; or animal literature; or treatment group interventions combine acupuncture with Traditional Chinese Medicine or Western medicine.

Search strategy

Computer retrieval: Searched China National Knowledge Infrastructure (1979-), Chinese Biomedical Literature Database (1979-), VIP database (1989-), Wan-Fang Database (1998-), Chinese Clinical Trial Register (ChiCTR), The CNKI included the China Academic Journals Literature Database, China Proceedings of Conference Full-text Database, China Master-Doctoral dissertation Full-text Database, PubMed (1966-), EMbase (1980-) and the Cochrane Library.

Manual search: "Traditional Chinese Medicine", "Traditional Chinese Medicine in English," "Chinese Acupuncture" and so on.

Search terms were "Acupuncture" and "Climacteric Depression". Took the appropriate search strategies and search query according to all types of database features. Language had no restriction. All search time ended up to January 2015.

Literature selection and data extraction

Studies were selected by two reviewers independently. The titles and abstracts from the electronic searches were scrutinized firstly. Excluded the studies which meeting the exclusion criteria obviously. Read the literature integrality that was likely to meet inclusion criteria to determine whether truly met the inclusion standards. Studies published in different languages were categorized as foreign literatures. Data were extracted by two reviewers independently.

Extraction of information includes study design, interventions and methods, measure of results, methodology content such as concealment and blinding, etc. Any disagreements about inclusion were resolved by a third reviewer. If the full text could not be obtained, we should contact with the author to obtain it. In case of duplicate publication, the most recent and complete versions were selected.

Evaluation of the quality

Quality assessment in accordance with the Cochrane handbook for methodological quality of included studies was conducted to assess the risk of bias. Evaluation criteria include: a) random sequence generation; b) allocation concealment; c) blinding of participants and personnel; d) blinding of outcome assessment; e) incomplete outcome data; f) selective reporting; g) other sources of bias. 'Low risk' represented a low risk of bias. 'Ligh risk' represented a high risk of bias. 'Unclear risk' represented an unclear risk of bias.

Statistical analysis

All statistical analyses were performed using RevMan 5.3.0 (Cochrane Collaboration, UK) software. The odds ratio (OR) and 95% confidence interval (95% CI) were taken as the efficacy of statistics of count data (dichotomous variables); using the mean difference (MD) when measurement and expression were the same; if different measurement scales or research time highly variable results were inconsistent, then using standardized mean difference (SMD); heterogeneity of treatment effects was evaluated statistically using chi-square test. When sufficiently similar between the study ($p \geq 0.10$; $I2 \leq 50\%$), using a fixed effect model analysis, on the contrary, using the random model analysis, and consideration of the possible merger causes (such as different treatment methods, evaluation of results from different time) to take heterogeneous subgroup analysis. Where it was not appropriate to conduct meta-analysis, study data were presented descriptively. When more than five included studies, using the funnel plot verify the existence of publication bias. $p<0.05$ was considered statistically significant.

Results

Main study characteristics

The literature search yielded 355 citations, which included 74 English database and 281 Chinese database detected by reading literature titles, abstracts and full-text. After elimination of duplicate documents, review and studies which were not available to meet the study inclusion criteria, 17 articles (Chi and Zou, 2011; Ding and liu, 2007; Li and Zhou, 2007; Ma and Liu, 2009; Qian et al., 2007; Qiang, 2008; Shi et al., 2007; Xing, 2011; Zhou, 2004; Zhou, 2007a; Zhou, 2007b; Zhou et al., 2007; Zhou, 2009; Zhou and Chen, 2009; Zhou and Wang, 2009; Zheng et al., 2010; Zhang, 2013) were included a total of 1369 women met the inclusion criteria for our review. There were two identical Chinese and English literature, according to the principle of preference, included 15 Chinese literature, 2 English literature. Specific literature search process shown in Figure 1.

Characteristics of included studies

Characteristics of the included studies were showed in Table I.

Type

17 RCTs were used in parallel designs. There were no multi-center RCT.

Subjects

Subjects were either outpatient or inpatient. 15 trials were diagnosed by the CCMD-3-R; 2 trials by the CCMD-2-R; 1 trial by "Obstetrics and Gynecology" perimenopausal depression diagnosis; 1 trial by the 1994 WHO perimenopausal definition; 1 trial by The "Chinese Medicine Clinical Research Guidelines" syndrome diagnostic criteria in perimenopausal women; 12 trials by the HAMD; 8 trials by Kupperman Index (KMI, climacteric symptom score); 1 trial by TCM standard reference in 1994 the state drug administration issued a "TCM syndrome diagnostic efficacy of the standard" before all relevant depressive disease and menopause diagnostic criteria for disorders; 1 trial by TCM standard reference China association of integrative medicine 1991 professional committee of depressive episodes of mental illness syndrome type diagnostic criteria; 1 trial by TCM Standard reference "TCM syndrome diagnostic efficacy standards," State administration of traditional 1995 release of "Melancholia" to develop.

Interventions

The experimental group was simple acupuncture therapy whereas oral medicine was used in the control group. 14 trials used prozac, 1 trial used premarin, 1 trial used hormone replacement with fluoxetine, 1 trial used premarin with medroxyprogesterone.

Measure of outcomes

3 trials used Kupperman score; 14 trials HAMD score; 4

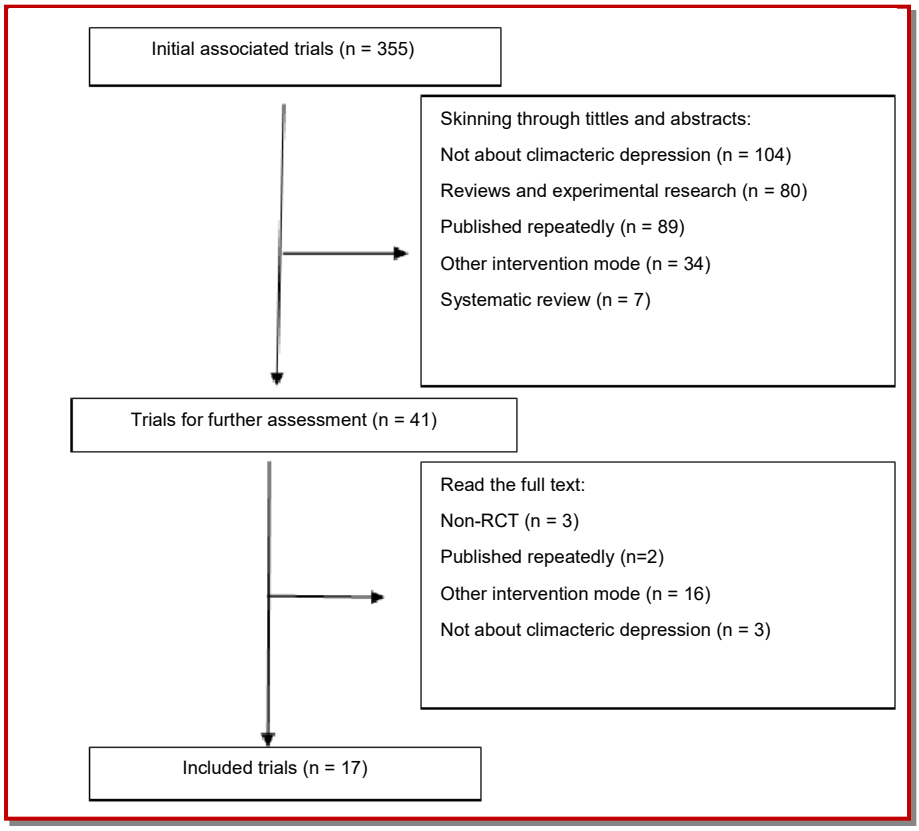

Figure 1: literature selection process for the systematic review

trials HAMA score; 11 trials used efficient and effective rate; 8 trials reported adverse reactions, included 2 trails used the TESS score.

Quality of the included literatures

According to the Cochrane Collaboration recommended bias risk assessment methods, included 17 studies had different levels of bias (Figure 2, 3).

Randomization methods

In all of 17 included studies, 3 trials reported random number table, 2 trials reported the treatment order, 2 trials reported computer generated sequence, 4 trials reported ballot randomization method, and the remaining 6 trials mentioned only random words.

Allocation concealment

Only 1 trial mentioned allocation concealment methods, and the remaining 16 trials were not mentioned.

Blinded

Seventeen trials were not mentioned in a blinded usage.

Drop out, lose track

Six trials described the drop out of the cases and the rest were not described.

Selective reporting and other biases

Seventeen studies were not mentioned.

Analysis of results

Effective rate

Eleven studies reported the effective rate. There was no significant heterogeneity ($p = 0.26 > 0.10$, $I^2 = 19\% < 50\%$). Using the fixed effects model, pooling of the results from the 11 trials showed significant difference between the experimental group and the control group (OR = 1.44, 95% CI (1.02, 2.04), Z = 2.05 ($p<0.01$)

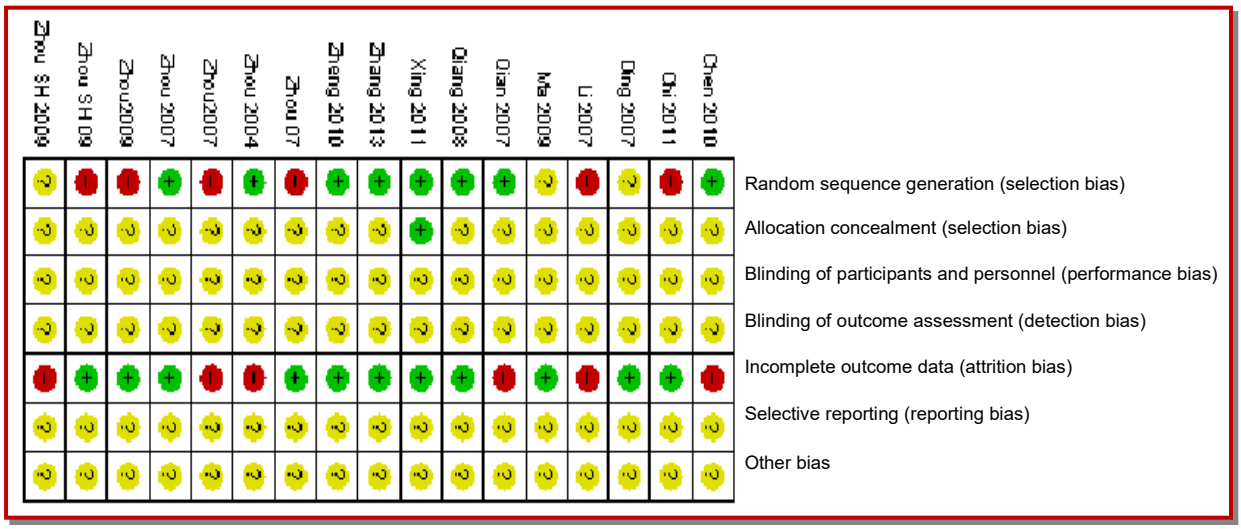

Figure 2: Summary of risk of bias assessment

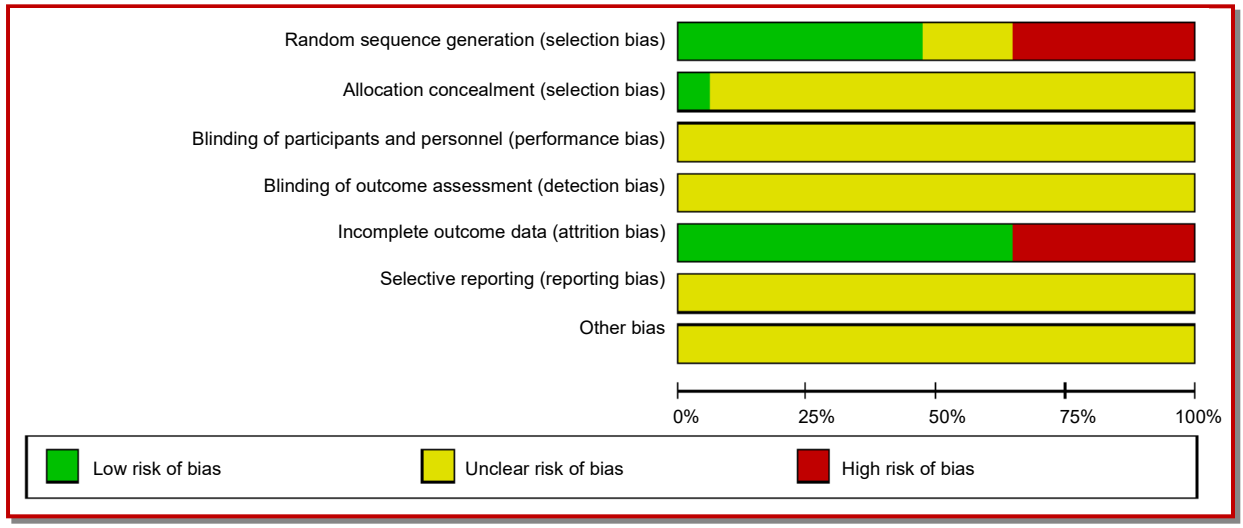

Figure 3: Risk of bias graph

Table I

Characteristics of included studies

Included studies	Case		Period of treatment	Type of intervention		Outcome measure
	Active group	Control group		Active group	Control group	
Li and Zhou, 2007	30	28	6 weeks	Acupuncture	Prozac	E2、FSH
Xing, 2011	120	120	6 weeks	Acupuncture	Prozac	effective rate，HAMD score
Chi and Zou, 2011	30	30	4 weeks	Acupuncture	Prozac	effective rate, HAMD score, adverse effect
Zhou, 2009	30	28	6 weeks	Acupuncture	Prozac	effective rate, HAMD score, HAMA score
Zhou, 2007	30	30	6 weeks	Acupuncture	Prozac	effective rate, HAMD score, adverse effects
Ma and Liu, 2009	30	30	8 weeks	Acupuncture	Prozac	effective rate, HAMD score, adverse effects
Qian, 2007	33	30	6 weeks	Acupuncture	Prozac	HAMD score, adverse effects
Zhang, 2013	94	94	3 months	Acupuncture	Premarin	HAMD score, 、LH,E2、FSH，adverse effects
Zhou and Chen, 2009	30	30	6 weeks	Acupuncture	Prozac	HAMD reduction rate, HAMA score
Zhou and Hao, 2007	30	28	6 weeks	Acupuncture	Prozac	effective rate, DA、NE、HAMD score, 5-HIAA
Qiang, 2008	30	30	6 weeks	Acupuncture	Prozac	effective rate, HAMD score
Chen and Zhou, 2010	30	28	6 weeks	Acupuncture	Prozac	effective rate, HAMD score, HAMA score,
Zheng et al., 2010	30	30	3 months	Acupuncture	HRT+fluoxetine	HAMD score, LH,FSH,E2, adverse effects, KMI score, effective rate, adverse effects,
Ding and Liu, 2007	39	39	4 weeks	Acupuncture	Prozac	HAMD score, KMI score
Zhou, 2007	30	30	6 weeks	Acupuncture	Prozac	E2, FSH
Zhou, 2004	30	28	6 weeks	Acupuncture	Prozac	HAMD score, HAMD reduction rate, LH, FSH, E2,DA, NE,5-HIAA,HAMA score, adverse effects, KMI score, effective rate, adverse effects
Zhou and Wang, 2009	60	30	3 months	Acupuncture	Premarin+ progesterone	HAMD score, E2, effective rate, adverse effects

(Figure 4, 5). The results showed that the effective rate of the experimental group was higher than the controlled group.

HAMA scores

For HAMA scores, data were available from 4 trials, both acupuncture compared with Western medicine. As the inconsistency measurements time, we used sub-group analyses. According to the measurement time, divided into three subgroups: first 2 weeks, 4th week and 6th week. The first 2 weeks when the meta-analysis showed that the two groups had statistically significant differences in HAMA scores [MD = -1.79, 95% CI (-3.37, -0.21)]. In the 4th week, meta-analysis showed that the two groups had statistically significant differences in HAMA scores [MD = -1.64, 95% CI (-2.77, -0.51)]. In the 6th week, meta-analysis showed that the two groups had statistically significant differences in HAMA scores [MD = -2.85, 95% CI (-4.04, -1.66)] (Figure 6).

HAMD scores

For HAMD scores, data were available from 13 trials, both acupuncture compared with Western medicine. As the inconsistency measurements time, there was a large heterogeneity ($p<0.10$, $I^2>50\%$), we used random effects model and subgroup analyzes. There were 5 subgroups according to the measurement time: the first 2 weeks, 4th weeks, 6th weeks prozac group, 8th weeks, 12th weeks. In the first 2 weeks of prozac group, 8 trials were include, when meta-analysis showed that the two groups had no significant difference [MD = 1.79, 95% CI (-0.74, 4.32)]. In the 4th weeks of prozac group, 10 trials were included, when meta-analysis showed that the two groups had no significant difference [MD = 1.39, 95% CI (- 1.15, 3.93)]. In the 6th weeks of prozac group, 8 trials were included, when meta-analysis showed that the two groups had no significant difference [MD = 1.22, 95% CI (-0.17, 2.61)]. In the 8 weeks, 2 trials were included, when meta-analysis showed that the two

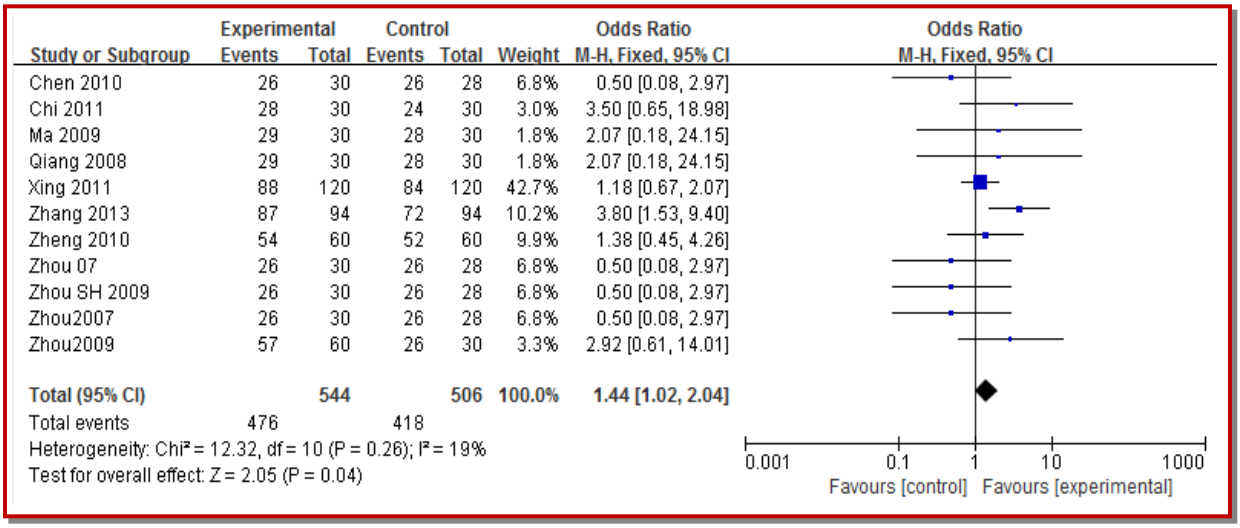

Figure 4: Meta-analysis of the studies evaluating effective rate of acupuncture

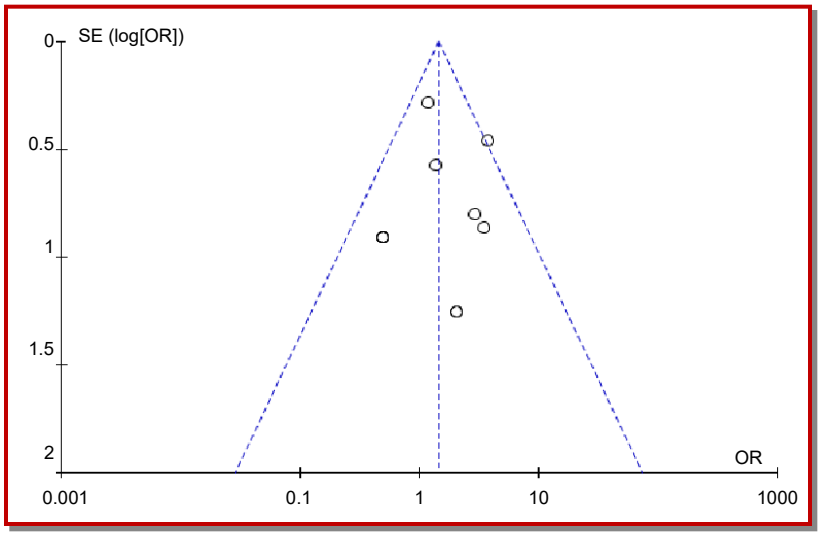

Figure 5. Funnel picture of bias involving comparison of effective rate of acupuncture

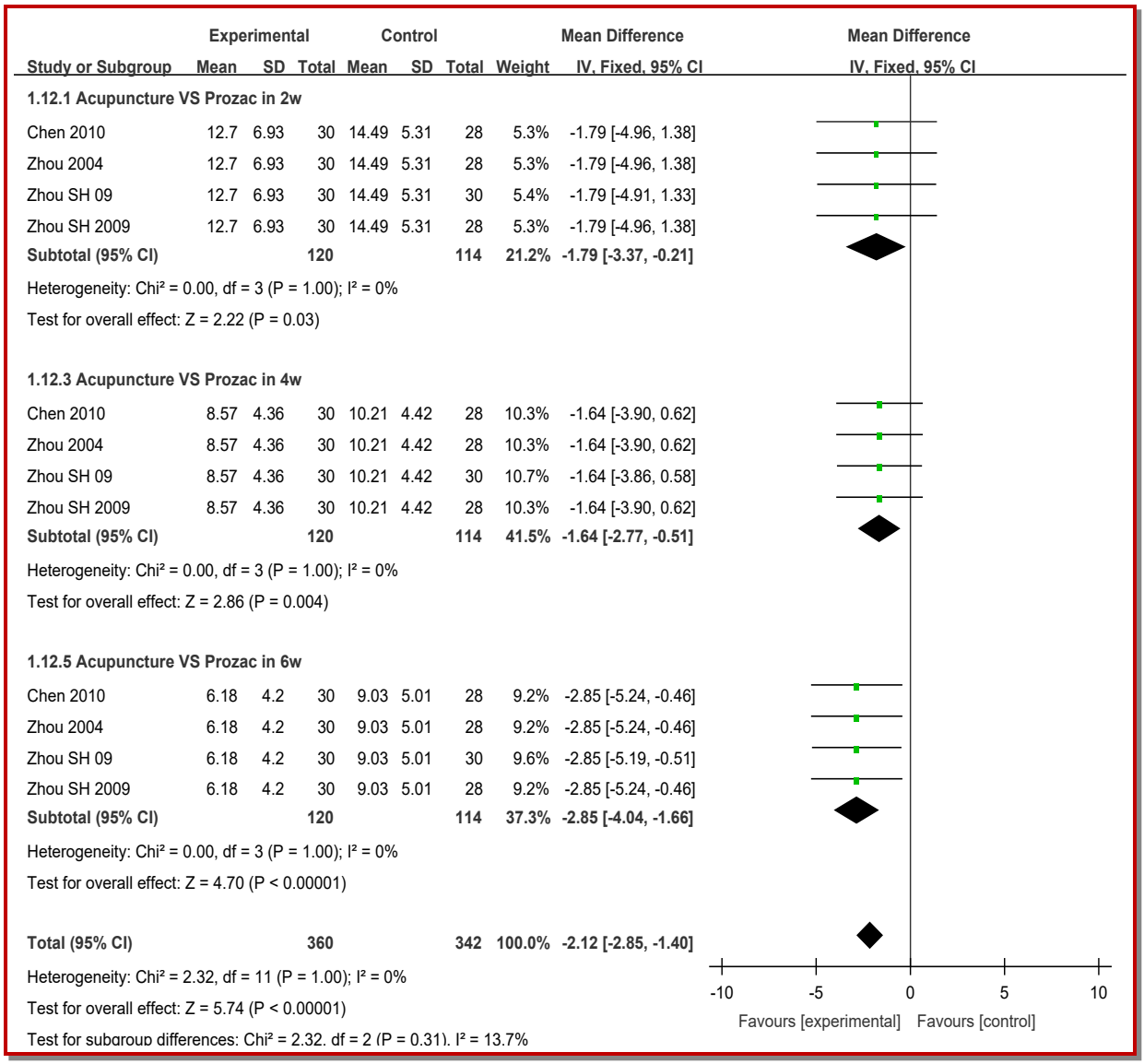

Figure 6: Meta-analysis of the studies evaluating HAMA scores of acupuncture

groups had no significant difference [MD = -0.33, 95% CI (-1.4, 0.75)]. In the 12 weeks, 2 trials were included, when meta-analysis showed that the two groups had no significant difference [MD = -1.13, 95% CI (-3.22, 0.95)] (Figure 7, 8).

KMI score

For KMI scores, data were available from 3 trials, both acupuncture compared with Western medicine. There has significant heterogeneity ($p<0.00001$, $I^2=96\%$). Using the random effects model, pooling of the results from the 3 trials showed no significant difference between the experimental group and the controlled group (MD = -5.05,95%CI(-11.94,1.84), Z = 1.44 (p = 0.15). The results showed that there was no difference in declining the KMI score between the experimental group and the controlled group (Figure 9).

Adverse reactions

Eight trials reported the occurrence of adverse reactions, 2 trials used TESS score. The remaining 6 trials reported the number of adverse reactions and described the symptoms.

Among 367 cases of patients receiving acupuncture treatment, 10 cases (2.7%) had adverse reactions. There were two cases of adverse reactions happened in 1 trial. There were four cases of acupuncture pain happened in 2 trial. There were three cases of poor appetite and one case of insomnia in 1 trial.

Among 330 cases of medically treated patients, 66 cases (20%) had adverse reactions. In 2 trials, 3 participants felt dizzy, 6 participants felt nauseous. In 3 trials, there were 19 cases of adverse reactions happened. In 1 trial, there were five cases of dizziness, four cases of nausea and vomiting, three cases of lethargy. In the HRT plus fluoxetine group, there were five cases of dizziness, three cases of diarrhea, three cases of somnolence, two cases of leucorrhea increase and one case of tremor. In 1 trial, five cases of nausea and one case of hypertension.

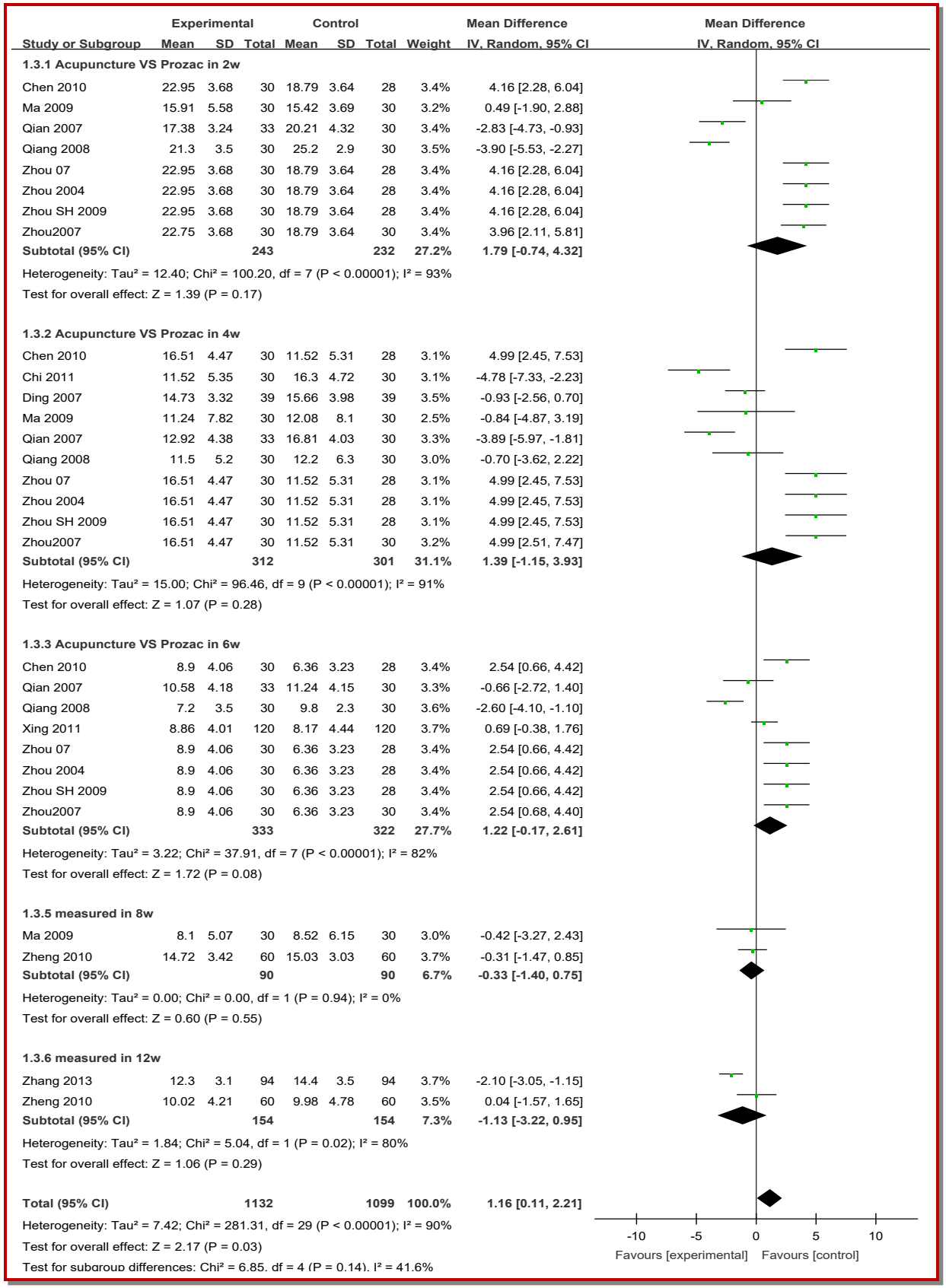

Figure 7: Meta-analysis of the studies evaluating HAMD scores of acupuncture

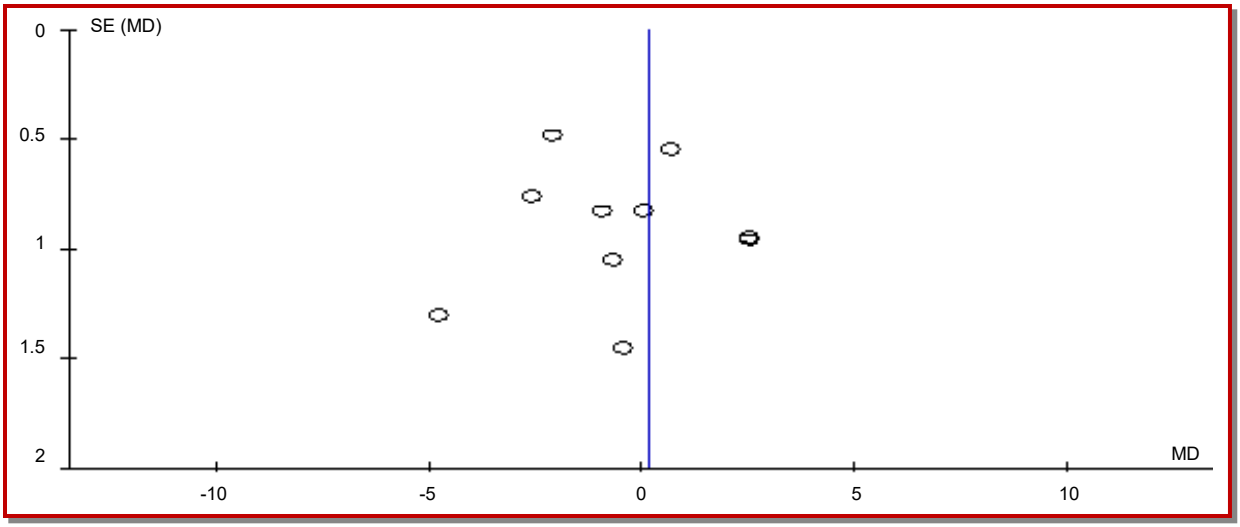

Figure 8: Funnel picture of bias involving comparison of HAMD scores of acupuncture

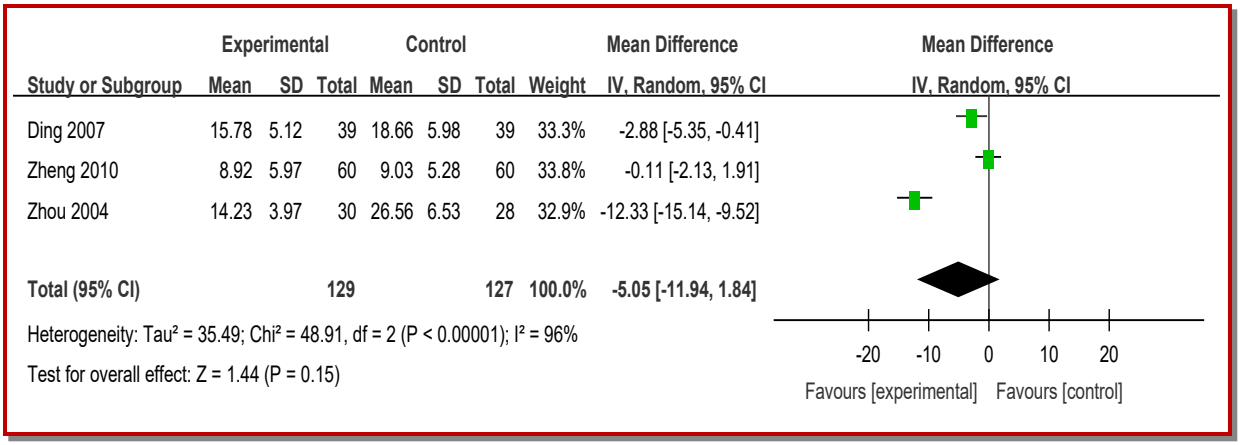

Figure 9: Meta-analysis of the studies evaluating KMI score of acupuncture

The incidence of adverse events, the incidence of adverse events of acupuncture (2.7%) was significantly less than the comparison group (20%).

Discussion

The study included 17 randomized controlled trials, the majority of the included trials was not high quality. No one test for multi-center study, 3 trials reported random number table, 2 trials reported the treatment order, 2 trials reported computer generated sequence, 4 trials reported ballot randomization method, and the remaining 6 trials mentioned only random words. At the same time, only 1 trial mentioned allocation concealment methods, 6 trials describes the drop out of the cases. In addition, 6 trials did not mention baseline in the literature, the remaining 11 studies were consistent account of baseline data.

Comparison of efficacy

The efficiently and HAMA score meta-analysis results were in favor of the experimental group. There was no difference in declining the HAMD scores and KMI score between the experimental group and the controlled group. The result may be was in the cause of significant heterogeneity such as different evaluation of results from different time, randomization, blinding and other methodological heterogeneity. Therefore, according to the evaluation results suggest that the efficacy of acupuncture treatment of climacteric depression is likely better than Western medicine. But the funnel picture of comparing acupuncture with Western medicine, which was asymmetrically distributed, cause this is the reason for the existence of a possible asymmetry publication bias and the low quality of research.

Therefore, in future studies, we can design a rigorous large sample, multi-center, and strictly enforce the allocation concealment and blinding evaluation of randomized controlled trials to validate the hypothesis, if confirmed, acupuncture can be used as an alternative and security interventions.

Adverse reactions

Acupuncture and antidepressant treatment of depression in women had a good effect, and the two

treatments had equally effective in improving HAMD score. There had no significant adverse reactions in treatment group, but slight adverse reactions at the beginning of treatment were found in the control group. This indicating there were higher security in acupuncture treatment.

Limitations of this review

In this study, in the implementation of the random method, blinding, etc were not stringent enough, it induced to methodological heterogeneity. In addition, incidence of adverse events couldn't reflect the adverse effects of the trials comprehensively and standard side effect scale should be used for the assessment of safety in the further study. Besides, only one study reported the efficacy of follow-up, and the lack of studies have reported recurrence or related information is not detailed enough conclusive.

Innovation

In this review, different kinds of medications (fluoxetine, premarin, etc.) and different observation time points were compared separately. It can effectively reduce the methodological heterogeneity and improve the reliability of the evaluation results.

Conclusion

Limited evidence suggests acupuncture treatment will help to improve depressive symptoms of climacteric, and fewer adverse reactions appear, but more high quality RCTs still need to be further confirmed.

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Conflict of Interest

The authors have declared that no competing interests exist.

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