

Acupuncture versus Various Control Treatments in the Treatment of Migraine: A Review of Randomized Controlled Trials from the Past 10 Years

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Background: Migraine is defined as a recurrent headache of moderate to severe intensity that seriously affects the quality of life. Recent clinical trials have confirmed that acupuncture is effective in treating migraine. We aimed to review the effectiveness of acupuncture in the treatment of migraine by comparing treatment and various control groups in accordance with the newly published guidelines for systematic reviews.

Materials and Methods: The following databases were searched for relevant articles published from January 1, 2010 to December 31, 2019: Embase, PubMed, Medline, Cochrane Library, and four Chinese databases. The present review included randomized controlled trials in which acupuncture was the sole treatment or an adjunctive treatment for migraine. Two researchers independently conducted the study selection, data extraction, and quality assessment processes. Disagreements between reviewers were solved by discussion and data reanalysis. The quality of each included study was evaluated using the Cochrane Collaboration risk-of-bias assessment method and the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) checklist.

Results: Forty-nine studies were analyzed and ranked based on the latest STRICTA and Cochrane Collaboration risk-of-bias assessment standards. The analysis revealed that acupuncture reduced headache frequency compared with no treatment (mean difference [MD] = -1.80, $P < 0.00001$, 95% confidence interval [CI] -2.34 to -1.26) and western medicine (MD = -1.75, $P = 0.003$, 95% CI -2.91 to -0.58). Headache frequency did not significantly differ between patients who received real acupuncture versus those who received sham acupuncture (MD = -0.64, $P = 0.24$, 95% CI -1.70 to 0.42).

Conclusion: The present review evaluated the current research on the use of acupuncture for migraine, compared with various control treatments. The evidence for the effectiveness of acupuncture in controlling migraine is still limited due to the low quality of the published studies.

Keywords: acupuncture, migraine, review

Plain Language Summary

Migraine is a common type of primary headache and is the top cause of years of life lived with disability in the 15–49-year age group. It places a huge economic burden on society and families and seriously affects the quality of life of patients. Emerging clinical trials reported that acupuncture effectively treats migraine, mainly manifested as pain relief, reduced frequency and duration of pain, reduced drug dependence, and prevention of recurrence. However, several trials have shown no difference between real and sham acupuncture for migraine treatment. In clinical trials evaluating migraine treatment, the type of control group

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directly affects the conclusion. We reviewed randomized controlled trials published in the past 10 years that evaluated the treatment of migraine with acupuncture versus various controls based on the latest standards for assessing acupuncture safety and effectiveness. The analysis demonstrated that acupuncture achieved better treatment results for migraine than no treatment, waiting-list control, or western medicine but achieved similar treatment results to sham acupuncture. However, the included studies had relatively high risks of bias, so the quality of evidence for the effectiveness of acupuncture as a migraine treatment was low.

Introduction

The 3rd Edition of the International Classification of Headache Disorders (ICHD-3) defines migraine as recurrent headache of moderate to severe intensity lasting 4–72 hours with associated nausea, vomiting, photophobia, or phonophobia.¹ Migraine is one of the most common primary types of headache, affecting 18–18.2% of women and 6–6.5% of men in western developed countries, and approximately 9.3% of the Chinese population.² Migraine is the sixth-most common disabling condition in the world; it causes a huge economic burden on society and families and seriously decreases the patient quality of life.^{2–4}

Acupuncture is a therapeutic technique in which needles are inserted into specific points (acupoints) on the body.^{5,6} As an important component of complementary and alternative medicine, acupuncture has recently gained popularity as a palliative intervention modality.⁷ Emerging reports on clinical trials of acupuncture for migraine have confirmed the effectiveness of acupuncture in treating migraine, mainly manifested as pain relief, reduced frequency and duration of pain, decreased drug dependence, and prevention of recurrence.^{8,9} However, several trials have shown no difference between real acupuncture (RA) and sham acupuncture (SA) in the treatment of migraine,^{10–12} and some reviews reported found that RA and SA are equally effective^{13,14} or that their effect size value is small.¹⁵ In clinical trials evaluating migraine treatment, the choice of control treatment directly affects the trial findings.¹⁶ Furthermore, the review by Linde et al only included randomized controlled trials (RCTs) published before January 2016, and a large number of updated studies been published since 2016.¹⁵ Hence, there is a need for a comprehensive review based on the newest standards to investigate the safety and effectiveness of acupuncture in the treatment of migraine.

The present study was a review of RCTs published between January 1, 2010 and December 31, 2019 that

evaluated the effectiveness of acupuncture in the treatment of migraine in comparison with various types of control treatments. The included studies were ranked in accordance with the latest Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) and Cochrane criteria and evaluated regarding the quality of the methodology, such as treatment and follow-up durations, acupuncture methods, acupoint selection, depth of needle insertion, number of acupuncture sessions, and frequency and duration of treatment sessions.

Materials and Methods

Search Method

The following databases were searched for relevant articles: PubMed, Medline, Cochrane Library, Embase, China National Knowledge Infrastructure, Chongqing VIP Chinese Science and Technology Periodical Database, Wanfang Database, and China Biology Medicine Disc. The interval was from January 1, 2010 to December 31, 2019. The search strategy for the PubMed database is shown in [Table 1](#); it was modified appropriately for other databases.

Selection Criteria

Types of Studies

Inclusion Criteria

1) studies on patients with migraine, 2) RCTs (parallel and/or crossover studies), 3) full articles, and 4) studies published in English or Chinese.

Exclusion Criteria

1) animal studies; 2) nonrandomized or semi-randomized trials; or 3) case reports, abstracts, series, conference reports, comments, and letters.

Types of Participants

Inclusion Criteria

1) patients who had been diagnosed with migraine (diagnostic criteria were not limited), including migraine without aura (MWOA), migraine with aura, chronic migraine (CM), menstrual migraine; and 2) age ≥ 18 years.

Exclusion Criteria

1) healthy volunteers; or 2) pregnant individuals or those currently experiencing menopause.

Types of Acupuncture Interventions

Inclusion Criteria

1) acupuncture treatment such as body acupuncture,

Table I Search Strategy for the PubMed Database

Number	Search Terms
1	Acupuncture. Mesh.
2	Acupuncture. ti, ab
3	Acupuncture therapy. Mesh
4	Acupuncture therapy. ti, ab
5	(acupuncture) and (therapy). ti, ab
6	Acupoint. Mesh.
7	Acupoint. ti, ab
8	Acupuncture*
9	Body acupuncture. ti, ab
10	(body) and (acupuncture). ti, ab
11	Manual acupuncture. ti, ab
12	(manual) and (acupuncture). ti, ab
13	Electroacupuncture. ti, ab
14	(electro) and (acupuncture). ti, ab
15	1 or 2–14
16	Migraine. Mesh.
17	Migraine*. ti, ab.
18	Headache*. ti, ab.
19	16 or 17–18
20	Randomized controlled trial. pt
21	Controlled clinical trial. pt
22	Randomized controlled trials. Mesh.
23	Random allocation. Mesh.
24	Randomized. ti, ab
25	Randomly. ti, ab
26	Double-blind method. Mesh
27	Single-blind method. Mesh
28	Clinical trial. at
29	20 or 21–28
30	15 and 19 and 29

Note: *There is no limit to the number of matches.

Abbreviations: ti, title; ab, abstract; pt, article type.

manual acupuncture, and electroacupuncture; and 2) acupuncture with other concomitant treatments.

Exclusion Criteria

1) exclusive evaluation of acupuncture in specific “micro-systems” (eg, scalp or auricular); 2) methods of acupoint stimulation without needle insertion, including acupressure, laser stimulation, or transcutaneous electrical stimulation; 3) injection of fluids at acupoints or trigger points; or 4) mixed interventions (eg, acupuncture in combination with other therapies) when manual acupuncture or electroacupuncture was not considered the main intervention.

Types of Control Treatments

Inclusion Criteria

1) SA (superficial acupuncture, non-penetrating needles, or insertion simulation at non-acupoints); 2) Chinese herbs;

3) western medicine; 4) no treatment (waiting-list control); 5) usual care; 6) relaxation; 7) self-educational programs; or 8) Tuina.

Types of Outcomes

The inclusion criterion was the measurement of at least one of the followings: 1) headache frequency, 2) pain intensity, 3) response ($\geq 50\%$ frequency reduction documented in a headache diary), or 4) disability or quality of life as assessed with a validated outcome measure.

Exclusion Criteria

1) reported only physiological or laboratory parameters or 2) absence of a complete descriptive data analysis.

Data Analysis

Study Selection

Two trained reviewers (XXN and TT) independently screened the titles and abstracts of the search results to identify all relevant RCTs. After eliminating duplicate records and ineligible studies, the full-text versions of eligible studies were reviewed to determine whether they met the predefined inclusion criteria. When the researchers were unable to reach a consensus, a third reviewer (LLD) made the final judgment.

Data Extraction and Management

Two investigators (XXN and TT) independently extracted information from the included literature and entered the relevant data into a unified data statistics table. The extracted data included the reference ID, first author's surname, publication year, type of migraine, age of patients, type of acupuncture intervention, type of control intervention, sample size of each intervention group, intervention duration, details of randomization, allocation concealment and blinding methods, outcome measures, primary outcomes, adverse events, duration of follow-up, and STRICTA list.¹⁷ When a consensus on data extraction could not be obtained through negotiation, a third investigator (LLD) made the final judgment.

Assessment of Risk of Bias and Study Quality

Two researchers (XL and LL) used the Cochrane Collaboration risk-of-bias assessment method¹⁸ to independently assess the quality of the included literature and complete the STRICTA checklist.¹⁷ The assessed parameters included random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and other possible biases; the final category

included differences between treatment and control groups in the sample size and baseline data. In accordance with the relevant standards listed in the Cochrane Intervention System Assessment Manual, risk of bias was classified as low, high, and unclear. Discrepancies were resolved through discussion; a third investigator (FML) made the final judgment when a consensus on risk assessment could not be reached through discussion.

Results

Included Studies

The initial database searches identified 3334 potentially relevant articles published from January 1, 2010 to December 31, 2019. A total of 1786 duplicates were excluded, and further 1336 articles were removed during the title and abstract screening process. The full-text versions of the remaining 212 studies were reviewed, and 162 more studies were excluded in accordance with the eligibility criteria (Figure 1). A total of 49 studies were finally included.^{8,9,12,19–27,29–65}

Study Characteristics

The study characteristics of the included RCTs are summarized in Table 2. The selection criteria were met by 49 RCTs with a total of 4441 patients (median 76; interquartile range [IQR] 60–90; range 20–476). The annual distribution of the included studies is shown in Figure 2. During the study period, the largest number of studies evaluating acupuncture for migraine was published in 2018.

Migraine Characteristics

Thirteen trials included patients diagnosed with migraine with or without aura, 15 exclusively included patients with MWOA, 4 included patients with CM, 3 exclusively included patients with acute migraine attack, and 14 did not specify the type of migraine. The diagnosis of migraine was made in accordance with the ICHD in 40 studies; of these 40 studies, 27 used the ICHD-2, 5 used the ICHD-3, 1 used the 1998 edition of the ICHD, and 6 did not indicate which ICHD version was used. The diagnosis of migraine was based on the Chinese migraine diagnosis and treatment guidelines in one study,²⁶ while another used the classification and

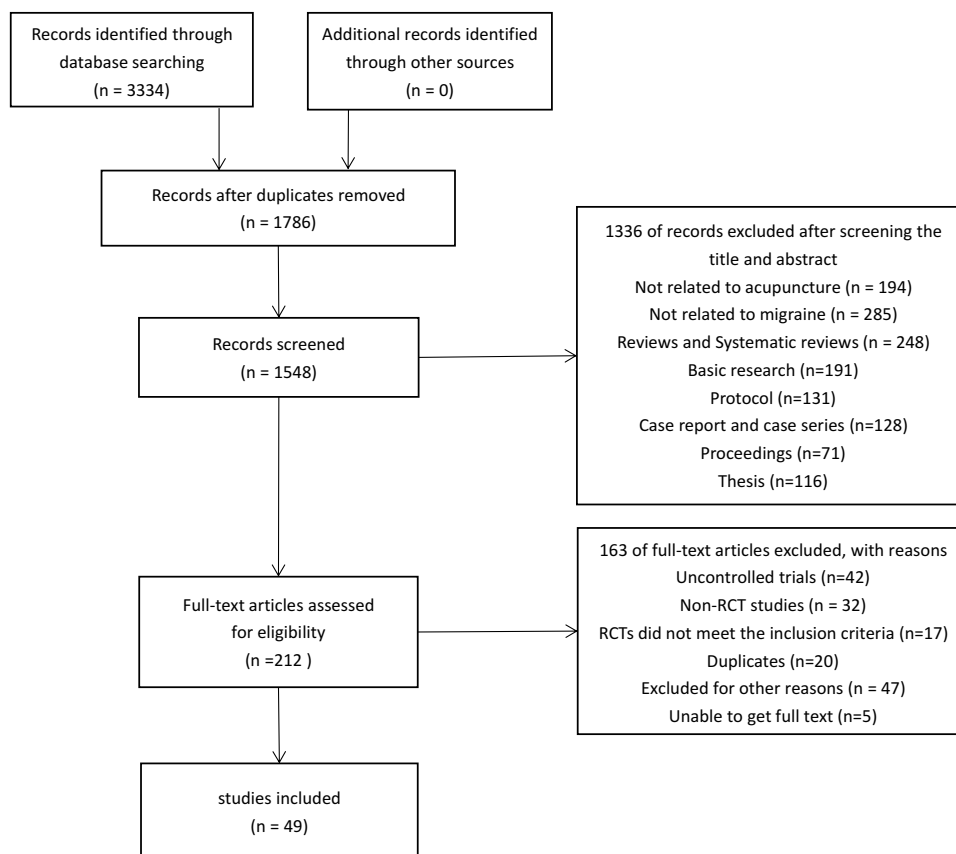


Figure 1 Flow Diagram

Abbreviations: SRs, Systematic reviews; RCT, Randomized Controlled Trial.

Table 2 Study Characteristics

Methods	Design of Trial: Open-Label RCT
Frantisek Musil 2018 ⁹	
Participants	<p>Number of TG/CG: 42/44</p> <p>Condition: migraine with or without aura (ICHD-3)</p> <p>Demographics: age (years): TG:45.6±12.8, CG: 46.5±10.3; 88.37% female</p> <p>Setting: Czech</p> <p>Duration of migraine (years): TG:26.9±12.9 and CG:23.0±14.1</p>
Interventions	<p>TG: Acupuncture CG: WL</p> <p>Acupuncture points: Ascending hyperactivity of liver yang: Fengchi, Taiyang, Shuai Gu. Optional acupuncture points (bilateral) by syndrome: Baihui, Xingjian, Taichong, Taixi, Xuanzhong, and Sanyinjiao; Deficiency of both Qi and blood: Hegu; Optional acupuncture points (bilateral) by syndrome: Baihui, Shang Xing, Zusanli, and Sanyinjiao; Wind phlegm blocking the meridians: Optional acupuncture points (bilateral) by syndrome: Feng Long, Zhongwan, and Yinlingquan; Blood stasis: Optional acupuncture points (bilateral) by syndrome: Sanyinjiao, Xuehai, and Ashi point</p> <p>Number of needles: 9–12</p> <p>Depth of insertion: 10–30 mm</p> <p>Number of treatment sessions: 14 (25 minutes each, twice a week in the first 4 weeks, once a week during weeks 5–8 and once every 14 days during the last month)</p> <p>Duration: 12 weeks</p> <p>Follow-up: 6 months</p>
Adverse event	One mild and common adverse event (Facial hematoma) resolved within 2 days without medication or medical help.
Kenan Tastan 2018 ²⁹	
Participants	<p>Number of TG/CG: 30/30/30</p> <p>Condition:/</p> <p>Demographics: age (years): 33.0 ± 6.9; 71.11% female</p> <p>Setting: Turkey</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Acupuncture CG: Hypnotherapy; Acetaminophen</p> <p>Acupuncture points: bilateral LI4, LU7, SI3, ST6, ST8, ST36, SP6, KI3, TE5, TE18, BL2, BL12, BL60, GB20, LR2, LR3, and Taiyang, and unilateral GV14, GV20, and Yintang points, also ear Shenmen, ear hypothalamus, and ear antidepressant points</p> <p>Number of needles:/</p> <p>Depth of insertion: 0.5 cun</p> <p>Number of treatment sessions: 10 (30 minutes each, 3 times a week)</p> <p>Duration:/</p> <p>Follow-up:/</p>
Adverse event	/
Zhengjie Li 2017 ³⁶	
Participants	<p>Number of TG/CG: 11/11/13/11/16</p> <p>Condition: MWOA (ICHD-2)</p> <p>Demographics: age (years): 21.29; 77.42% female</p> <p>Setting: China</p> <p>Duration of migraine (years): VA1: 5.24, VA2: 5.74, VA3: 5.62, SA: 4.83, WL: 6.11</p>

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	<p>TG: Acupuncture CG: SA; WL</p> <p>Acupuncture points: VA1:Yanglingquan, Qiuxu and Waiguan. VA2:Xiyangguan, Diwuhui and Sanyangluo. VA3:Zusanli, Chongyang and Pianli</p> <p>Number of needles: 6</p> <p>Depth of insertion: 5–15 mm</p> <p>Number of treatment sessions: 20 (20 minutes each, 5 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up:/</p>
Adverse event	/
Bahram Naderinabi 2017 ⁵³	
Participants	<p>Number of TG/CG: 50/50/50</p> <p>Condition: CM (ICHD-3)</p> <p>Demographics: age (years): AG:37.2±7.3, BG:36.8±7.4, CG:37.6±7.4; 68% female</p> <p>Setting: Iran</p> <p>Duration of migraine (years): AG:10.3±5.5, BG:9.2±5.3, CG:9.1±3.9</p>
Interventions	<p>TG: Acupuncture CG: botulinum toxin-A</p> <p>Acupuncture points: The acupuncture points used were mainly the GB41, GB 20, GB 15, GB14, GB10, GB8, LI 4, liver 3, Sanjiao 5, DU20, EX 2, Taiyang for individual migraine associated symptoms</p> <p>Number of needles: 10–12</p> <p>Depth of insertion: 10–15 mm</p> <p>Number of treatment sessions: 30 (Once every 2 days)</p> <p>Duration: 2 months</p> <p>Follow-up: 3 months</p>
Adverse event	The side effects of acupuncture treatment were only bleeding or subcutaneous hematoma formation and the adverse effects of botulinum toxin A included ptosis, facial masking or asymmetry.
Ling Zhao 2017 ⁸	
Participants	<p>Number of TG/CG: 83/80/82</p> <p>Condition: MWOA (ICHD-2)</p> <p>Demographics: age (years): 38.1±14.1; 77.14% female</p> <p>Setting: China</p> <p>Duration of migraine (years): 9.26</p>
Interventions	<p>TG: Electro-acupuncture CG: SA; WL</p> <p>Acupuncture points: Acupuncture on 2 obligatory points, including GB20 and GB8. The 2 other points were chosen according to the syndrome differentiation of meridians in the headache region. The potential acupoints included SJ5, GB34, BL60, SI3, LI4, ST44, LR3, and GB40</p> <p>Number of needles: 4</p> <p>Depth of insertion: 0.3–1 cm</p> <p>Number of treatment sessions: 20 (30 min each, 5 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 20 weeks</p>
Adverse event	Seven patients (5 in the RA group and 2 in the SA group) reported AEs during the 24 weeks.
Yanyi Wang 2015 ¹⁹	

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Participants	<p>Number of TG/CG: 11/11/13/11/16</p> <p>Condition:/(ICHD-2)</p> <p>Demographics: age (years): TG:41.6±14.9 CG:43.8±13.4; 74% female</p> <p>Setting: Australia</p> <p>Duration of migraine (years): TG: 18.4±12.7 CG:21.1±13.3</p>
Interventions	<p>TG: Acupuncture CG: Superficial Needling at Nonacupoints</p> <p>Acupuncture points: Ascending hyperactivity of liver yang: Fengchi, Taiyang, Shuai Gu. Optional acupuncture points (bilateral) by syndrome:Baihui, Xingjian, Taichong, Taixi, Xuanzhong, and Sanyinjiao; Deficiency of both Qi and blood: Hegu; Optional acupuncture points (bilateral) by syndrome: Baihui, Shang Xing, Zusanli, and Sanyinjiao; Wind phlegm blocking the meridians: Optional acupuncture points (bilateral) by syndrome:Feng Long, Zhongwan, and Yinlingquan;Blood stasis: Optional acupuncture points (bilateral) by syndrome: Sanyinjiao, Xuehai, and Ashi point</p> <p>Number of needles: 9–12</p> <p>Depth of insertion: 10–30 mm</p> <p>Number of treatment sessions: 16 (25 minutes each, twice per week for four weeks followed by once per week for another four weeks, then once every two weeks for four weeks, then once per month for another two months.)</p> <p>Duration: 20 weeks</p> <p>Follow-up: 1 year</p>
Adverse event	/
Mehran Rezvani 2014 ³²	
Participants	<p>Number of TG/CG: 40/40</p> <p>Condition:/(ICHD-2)</p> <p>Demographics: age (years): TG:35.4 ± 9.5 CG:35.5 ±10; 68.75% female</p> <p>Setting: Iran</p> <p>Duration of migraine (years): TG:5.4 ± 4 CG:5.8 ± 3.6</p>
Interventions	<p>TG: Acupuncture CG: Yamamoto new scalp acupuncture</p> <p>Acupuncture points: On the basis of clinical symptoms and traditional Chinese physical examination and diagnosis, several points from the LI4, ST8, ST36, BL2, GB14, TB5, GB8, tai yang, SI3, BL10, BL60, GB20, LIV3, KID1, DU20, si shen cong, LU7, SP6, LIV2, ST36, and REN6 acupuncture points were selected.</p> <p>Number of needles:/</p> <p>Depth of insertion: 10–15 mm</p> <p>Number of treatment sessions: 18 (30 minutes each, 3 times a week)</p> <p>Duration: 8 weeks</p> <p>Follow-up: 4 weeks</p>
Adverse event	/
Mingxiao Yang 2014 ⁵²	
Participants	<p>Number of TG/CG: 10/10/10</p> <p>Condition: MWOA (ICHD)</p> <p>Demographics:/</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	TG: Electro-acupuncture CG: SE; WL Acupuncture points: Luxi, San Yangluo, and Xi Yangguan Number of needles: 6 Depth of insertion: 15–30 mm Number of treatment sessions:/ Duration:/ Follow-up:/
Adverse event	/
Ling Zhao 2014 ⁵¹	
Participants	Number of TG/CG: 40/40 Condition: MWOA (ICHD-2) Demographics: age (years): TG:33.35±11.69 CG: 33.23±9.73; 71.25% female Setting: China Duration of migraine (years): TG: 10.58±7.40 CG: 9.93±5.73
Interventions	TG: Electro-acupuncture CG: SE Acupuncture points: Bilateral Waiguan, Fengchi, Yanglingquan, and Qiuxu Number of needles: 8 Depth of insertion: 25–35 mm Number of treatment sessions: 32 (30 minutes each, 4 times a week) Duration: 8 weeks Follow-up: 0
Adverse event	One case in the RA group suffered acupuncture fainting during acupuncture treatment
Mohsen Foroughipour 2014 ³³	
Participants	Number of TG/CG: 50/50 Condition: MWOA Demographics: age (years): 36.5; 59% female Setting: Iran Duration of migraine (years):/
Interventions	TG: Acupuncture CG: Superficial Needling at Nonacupoints Acupuncture points:/ Number of needles:/ Depth of insertion:/ Number of treatment sessions: 12 (30 minutes each, 3 times a week) Duration: 4 weeks Follow-up: 4 months
Adverse event	/
E Facco 2013 ⁵⁶	
Participants	Number of TG/CG: 50/50 Condition: MWOA (ICHD-2) Demographics: age (years): TG: 40 CG:34; 65.85% female Setting: Italy Duration of migraine (years): TG: 4 CG:4

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	<p>TG: Acupuncture CG: Valproic acid</p> <p>Acupuncture points: For exogenous syndromes the following acupoints were used: GB20, St8 (directing the needle towards GB8), EX-HN5, plus GB8, BL12, BL60, in wind-cold syndrome, TE5 and GV14 in wind-heat syndrome, and St40, SP6 and CV12 in wind-dampness syndrome. The endogenous syndromes were hyperactivity of liver yang (a), obstruction of middle jiao due to damp-phlegm (b), deficiency of kidney essence (c), stagnation of qi and blood (d). The acupoint selection in these syndromes was the following: a) GB8,20,38 St8 (towards GB8), LR3,4, EX-HN5; b) St8 (towards GB8), St40, SP9, GV23 (towards GV20), CV12, EX-HN5; c) GB12,20, BL10,12,23 KI3; d) GB8,20, SP6,10, LR3, EX-HN5, plus ashi points on GB channel</p> <p>Number of needles:/</p> <p>Depth of insertion: According to classical prescription for each acupoint</p> <p>Number of treatment sessions: 20 (30 minutes each, twice a week, with one-week rest between the two courses.)</p> <p>Duration: 11 weeks</p> <p>Follow-up: 6 months</p>
Adverse event	No event
Jie Yang 2012 ⁴⁹	
Participants	<p>Number of TG/CG: 10/10/10</p> <p>Condition: MWOA (ICHD)</p> <p>Demographics: age (years): 32.87 ± 8.71; 60% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Electro-acupuncture CG: SE; WL</p> <p>Acupuncture points: Waiguan, Yang Lingquan, and Fengchi</p> <p>Number of needles: 6</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions:/(30 minutes each)</p> <p>Duration:/</p> <p>Follow-up:/</p>
Adverse event	/
Lin-Peng Wang 2012 ³⁹	
Participants	<p>Number of TG/CG: 75/75</p> <p>Condition: Acute attack (ICHD-2)</p> <p>Demographics: age (years): TG: 37.8 ± 10.6 CG: 38.6 ± 12.6; 86.67% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Acupuncture CG: SA</p> <p>Acupuncture points: The obligatory points included Baihui, Shenting, Touwei, Shuaigu, and Fengchi. According to different syndromes, additional points could be chosen individually: Waiguan and Yanglingquan for Shaoyang headache (TE-GB); Hegu and Neiting for Yangming headache (LI-ST); Kunlun and Houxi for Taiyang headache (SI-BL); Taichong and Qixu for Jueyin headache (PC-LR); Neiguan for nausea and vomit ing; and Taichong for dysphoria and susceptibility to rage</p> <p>Number of needles: 10–12</p> <p>Depth of insertion: 10–15 mm</p> <p>Number of treatment sessions: 1 (30 minutes each)</p> <p>Duration: 1 day</p> <p>Follow-up: 3 day</p>
Adverse event	Seven patients (three in RA group, four in SA group) reported mild AE during the study period.

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Ying Li 2012 ¹²	
Participants	Number of TG/CG: 121/119/118/118 Condition: Migraine with or without aura (ICHD) Demographics: age (years): 36.9±12.3; 82.77% female Setting: China Duration of migraine (years): 8.18
Interventions	TG: Electro-acupuncture CG: SE Acupuncture points: Shaoyang-specific acupuncture: Waiguan, Yanglingquan, Qixu, Fengchi; Shaoyang- nonspecific acupuncture: Luxi, Sanyangluo, Xiyangguan, Diwuhui; Yangming-specific acupuncture: Touwei, Pianli, Zusanli, Chongyang Number of needles: 4 Depth of insertion: 0.3–2 cun Number of treatment sessions: 20 (30 minutes each, once per day for five consecutive days followed by a two-day break) Duration: 4 weeks Follow-up: 3 months
Adverse event	37 patients (7.8%) experienced 42 adverse events during the study period
Thomas-Martin Wallasch 2012 ⁴⁶	
Participants	Number of TG/CG: 18/17 Condition: (ICHD-2) Demographics: age (years): TG:37.2±9.6 CG:39.3±11.7; 88.57% female Setting: Germany Duration of migraine (years): TG: 16.8±11.2 CG:18.5±10.9
Interventions	TG: Acupuncture CG: SA Acupuncture points: Hegu, Zusanli, Waiguan, Zulinqi, Houxi, Shenmai, Baihui (DU20), Fengchi, Taiyang, Sizhukong, Taichong, Taixi Number of needles: 12 Depth of insertion: / Number of treatment sessions: 8 (30 minutes each, once a week) Duration: 8 weeks Follow-up: 12 weeks
Adverse event	/
C-P Yang 2011 ⁶²	
Participants	Number of TG/CG: 33/33 Condition: CM (ICHD-2) Demographics: age (years): TG:47.6±7.4 CG:48.1±6.4; 89.39% female Setting: China Duration of migraine (years): TG: 13.2±3.5 CG:13.5±4.5
Interventions	TG: Acupuncture CG: topiramate Acupuncture points: bilateral Cuanzhu, Fengchi, Taiyang and midline Yintang Number of needles: 7 Depth of insertion: Standard to each point according to classic acupuncture point Number of treatment sessions: 24 (30 minutes each, twice a week) Duration: 12 weeks Follow-up: 0
Adverse event	In the RA group, side effects were reported by 6% of the patients

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Lin-Peng Wang 2011 ³¹	
Participants	<p>Number of TG/CG: 70/70</p> <p>Condition: (ICHD-2)</p> <p>Demographics: age (years): TG: 39.2 ± 10.9 CG: 39.9 ± 13.1; 85% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Acupuncture plus placebo medication CG: flunarizine plus SA</p> <p>Acupuncture points: The obligatory points included Baihui, Shenting, Benshen, Shuaigu, and Fengchi. Additional points were chosen individually depending on different syndromes: Waiguan and Yanglingquan for Shaoyang headache (TE-GB); Hegu and Neiting for Yangming headache (LI-ST); Kunlun and Houxi for Taiyang headache (SI-BL); Taichong and Qixu for Jueyin headache (PC-LR); Neiguan for nausea and vomiting, and Taichong for dysphoria and susceptibility to rage</p> <p>Number of needles: 10–12</p> <p>Depth of insertion: 10–15 mm</p> <p>Number of treatment sessions: 12 (30 minutes each, 3 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 12 weeks</p>
Adverse event	A total of 12 patients (5 in the acupuncture group, 7 in the control group) reported mild adverse effects during the study period.
Qin 2019 ²⁰	
Participants	<p>Number of TG/CG: 19/19</p> <p>Condition: MWOA (ICHD-3)</p> <p>Demographics: age (years): 18–43; 62.5% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Acupuncture CG: SA</p> <p>Acupuncture points: Bilateral headache points, located at the midpoint of the anterior depression of the 1st and 2nd metatarsal joint of the dorsum of the foot</p> <p>Number of needles: 2</p> <p>Depth of insertion: 25–40 mm</p> <p>Number of treatment sessions: 20 (Immediately release the needle when it reaches the sense of discharge and numbness, 5 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 4 weeks</p>
Adverse event	/
Guan 2019 ⁵⁴	
Participants	<p>Number of TG/CG: 65/65/65</p> <p>Condition: Migraine with or without aura (ICHD)</p> <p>Demographics: age (years): TG: 45.98 ± 10.30 CG1: 44.16 ± 9.82 CG2: 46.44 ± 10.24; 68.89% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG: 0.80 CG1: 0.73 CG2: 0.84</p>

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	<p>TG: Acupuncture CG: flunarizine hydrochloride</p> <p>Acupuncture points: The obligatory points included Baihui, Sishencong, Benshen, Shenting. Additional points were chosen individually depending on different syndromes: Guanyuan, Qihai, Zusanli for deficiency of both Qi and blood; Fenglong, Yinlingquan, for Phlegm; Taichong, Xingjian for Liver Yang hyperactivity; Xuehai, Gesu for Qi and blood stasis.</p> <p>Number of needles:/</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions: 20 (30 minutes each)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 12weeks</p>
Adverse event	/
Du 2019 ⁶⁵	
Participants	<p>Number of TG/CG: 33/34</p> <p>Condition: Migraine with or without aura (the Chinese migraine diagnosis and treatment guidelines)</p> <p>Demographics: age (years): TG: 55.74±5.28 CG: 56.58±6.14; 47.76% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG: 12.68±9.25 CG: 13.54±8.83</p>
Interventions	<p>TG: Acupuncture+ traditional Chinese herbal medicine CG: Tongqiao Huoxue Tang</p> <p>Acupuncture points: Baihui, Touwei, Taiyang, Neiguan, Xuehai, Qihai, Xuanlu, Waiguan, Shuaigu, Zulinqi</p> <p>Number of needles:/</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions: 21 (25–30 minutes each, Once a day)</p> <p>Duration: 3 weeks</p> <p>Follow-up: 0</p>
Adverse event	/
Hou 2019 ⁵⁷	
Participants	<p>Number of TG/CG: 40/40</p> <p>Condition:/</p> <p>Demographics: age (years): TG:45.01±1.89 CG:44.39±1.33; 57.5% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Acupuncture CG: flunarizine hydrochloride</p> <p>Acupuncture points: Baihui, Taiyang, Touwei, Sun, Zhengying, Zhongzhu, Xiaxi, Hegu and Taichong</p> <p>Number of needles:/</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions: 14 (20 minutes each, Once a day)</p> <p>Duration: 2 weeks</p> <p>Follow-up: 0</p>
Adverse event	/
Shen 2019 ³⁸	
Participants	<p>Number of TG/CG: 35/35</p> <p>Condition: CM (/)</p> <p>Demographics: age (years): TG:48.1±2.3 CG:48.3 ± 2.1; 45.71% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG:6.1±3.0 CG:6.4 ± 3.3</p>

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	TG: Acupuncture CG: SA Acupuncture points: Qiuxu, Jiaosun, Yanglingquan Number of needles:/ Depth of insertion:/ Number of treatment sessions: 20 (30 minutes each, 5 times a week) Duration: 4 weeks Follow-up: 0
Adverse event	One case of hematoma occurred in the RA group, 2 cases of hematoma 2 cases of needle stagnation occurred in the SA group
Zhang 2019 ⁵⁹	
Participants	Number of TG/CG: 24/24 Condition:/ Demographics: age (years): TG:36.85±3.47 CG:36.91±3.38; 60.42% female Setting: China Duration of migraine (years): TG:0.75±0.21 CG:0.81±0.19
Interventions	TG: Acupuncture CG: ergotamine caffeine Acupuncture points: Bilateral Shuaigu, Touwei, Taiyang, Hegu, Zhongzhu, Taichong, Zulinqi, Qubin, Jiaosun, Baihui, Zusanli, Xuanzhong, Waiguan. Number of needles:/ Depth of insertion:/ Number of treatment sessions: 30 (20–30 minutes each, Once a day) Duration: 1 month Follow-up: 0
Adverse event	/
Yu 2019 ⁴⁴	
Participants	Number of TG/CG: 43/40 Condition:/(ICHD-2) Demographics: age (years): TG:37. 17 ± 7. 68 CG:36. 81 ± 8. 02; 73.75% female Setting: China Duration of migraine (years): TG:2. 25 ± 1. 34 CG:2. 27 ± 1. 26
Interventions	TG: Acupuncture CG: SA Acupuncture points: Jiaosun, Fengchi, Waiguan, Yanglingquan and Qiuxu Number of needles:/ Depth of insertion:/ Number of treatment sessions: 1 (30 minutes each) Duration: 1 day Follow-up: 24 h
Adverse event	5 patients had adverse reactions, including 3 cases in the RA group (2 cases of fainting + 1 case of local bleeding), and 2 cases in the SA group (1 case of fainting + 1 case of local bleeding). Patients with fainting can recover after lying down and taking the needles out, and local bleeding is treated with local compression to stop bleeding. No serious adverse reactions occurred during the entire study.

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Cheng 2019 ²⁶	
Participants	<p>Number of TG/CG: 60/60</p> <p>Condition:/(the classification and diagnosis of headache disorders published in the Journal of Neurology and Neurorehabilitation)</p> <p>Demographics: age (years): TG: 37.8 ± 10.6 CG: 38.6 ± 12.6; 63.33% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG: 3.44 ± 1.03 CG: 3.42 ± 1.02</p>
Interventions	<p>TG: Acupuncture+ traditional Chinese herbal medicine CG: Banxia Baizhu Tianma Tang</p> <p>Acupuncture points: Tianyou, Tianrong, Yifeng, Fengchi, Tianding, Taiyang, Hegu, Shuaigu, Taichong</p> <p>Number of needles:/</p> <p>Depth of insertion: 0.5–1.2 cun</p> <p>Number of treatment sessions: 20 (30 minutes each, 5 times a week)</p> <p>Duration: 1 month</p> <p>Follow-up: 0</p>
Adverse event	0
Wang 2018 ⁶¹	
Participants	<p>Number of TG/CG: 40/40</p> <p>Condition:/</p> <p>Demographics: age (years): TG: 35.4 ± 3.5 CG: 36.4 ± 3.2; 53.75% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG: 0.6 ± 0.2 CG: 0.5 ± 0.3</p>
Interventions	<p>TG: Acupuncture CG: carbamazepine</p> <p>Acupuncture points: Shuaigu, Qubin, Tou wei, Jiaosun, Taiyang, Baihui, Hegu, Zusanli, Zhongzhu, Xuanzhong, Taichong, Waiguan, Zulinqi.</p> <p>Number of needles:/</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions: 28 (20–30 minutes each. Once a day)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 0</p>
Adverse event	/
Peng 2018 ⁵⁵	
Participants	<p>Number of TG/CG: 32/30</p> <p>Condition: MWOA (ICHD-2)</p> <p>Demographics: age (years): TG: 32.84 ± 8.51 CG: 33.65 ± 8.85; 72.58% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG: 4.44 ± 2.86 CG: 4.37 ± 2.71</p>
Interventions	<p>TG: Electroacupuncture CG: flunarizine hydrochloride</p> <p>Acupuncture points: Bilateral Qiuxu, Fengchi, Waiguan, Yanglingquan</p> <p>Number of needles: 8</p> <p>Depth of insertion: 15–20 mm</p> <p>Number of treatment sessions: 12 (30 minutes each, 3 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 0</p>
Adverse event	/

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Zhuo 2018 ⁶⁴	
Participants	Number of TG/CG: 30/30 Condition:/ Demographics: age (years): TG:27.9±12.6 CG:29.4±13.5; 78.33% female Setting: China Duration of migraine (years):/
Interventions	TG: Acupuncture+ flunarizine hydrochloride CG: flunarizine hydrochloride Acupuncture points:/ Number of needles:/ Depth of insertion:/ Number of treatment sessions:/ Duration: 1 month Follow-up: 0
Adverse event	/
Cong 2018 ²⁷	
Participants	Number of TG/CG: 60/60 Condition:/(ICHD) Demographics: age (years): TG:43.5±2.53 CG:42.3±2.58; 55.83% female Setting: China Duration of migraine (years): TG:2.24±0.86 CG:2.21±0.79
Interventions	TG: Acupuncture+ flunarizine hydrochloride+ nimodipine CG: flunarizine hydrochloride, nimodipine Acupuncture points: Baihui, Taiyang, Shuaigu, Xuanlu, Touwei, Fengchi, Waiguan, Taichong, Zulinqi, Hegu, Sanyinjiao. Number of needles:/ Depth of insertion:/ Number of treatment sessions:/(30 minutes each, Once a day) Duration: 8 weeks Follow-up: 0
Adverse event	In the treatment group, 1 case of dizziness and 2 cases of gastrointestinal reactions occurred; in the control group, 3 cases of dizziness, 5 cases of gastrointestinal reactions, and 1 case of arrhythmia, all improved without treatment
Ma 2018 ³⁴	
Participants	Number of TG/CG: 89/89 Condition: MWOA with acute attack (ICHD-3) Demographics: age (years): TG:36.25 ± 4.29 CG:36.00 ± 3.89; 43.43% female Setting: China Duration of migraine (years): TG:3.14 ± 1.49 CG:3.41±1.23
Interventions	TG: Acupuncture CG: Superficial Needling at Nonacupoints Acupuncture points: Baihui, Sishencong, Shenting, Yintang, Shuaigu, Quze, Ququan and Taichong Number of needles:/ Depth of insertion: 25 mm Number of treatment sessions: 12(30 minutes each, 3 times a week) Duration: 4 weeks Follow-up: 0
Adverse event	0

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Xu 2018 ³⁵	
Participants	<p>Number of TG/CG: 30/30</p> <p>Condition: Migraine with or without aura (ICHD-2)</p> <p>Demographics: age (years): TG:45.07±2.34 CG:50.80±1.89; 81.67% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG:10.93±1.45 CG:13.57±1.43</p>
Interventions	<p>TG: Acupuncture CG: Superficial Needling at Nonacupoints</p> <p>Acupuncture points: Taiyang, Sizhukong, Jiaosun, Shougu, Fengchi, Waiguan, Zu Linwei (Bilaterally), A Shi point</p> <p>Number of needles:/</p> <p>Depth of insertion: 10–40 mm</p> <p>Number of treatment sessions: 12 (20 minutes each, 2 times a week)</p> <p>Duration: 6 weeks</p> <p>Follow-up: 6 weeks</p>
Adverse event	0
Yang 2018 ⁵⁸	
Participants	<p>Number of TG/CG: 21/21</p> <p>Condition: Migraine with or without aura (ICHD-2)</p> <p>Demographics: age (years): TG:34.5±3.3 CG:31.4±2.8; 82.05% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Acupuncture CG: flunarizine hydrochloride</p> <p>Acupuncture points: Main points: Shuaigu, Touwei, Taiyang, Fengchi.</p> <p>Auxiliary points: Liver-yang hyperactivity plus Xingjian, Taichong; Phlegm turbidity upper disturbance plus Yinlingquan, Fenglong; Heat plus Xuanzhong, Waiguan, Quchi; Qi stagnation and blood stasis plus Geshu, Sanyinjiao, Xuehai; liver and kidney yin deficiency plus Sanyinjiao, Taixi.</p> <p>Number of needles:/</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions:/(30 minutes each, 2–3 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 24 weeks</p>
Adverse event	A total of 7 patients under the acupuncture group had minor subcutaneous bleeding, no hematoma, ecchymosis, etc. No serious adverse events occurred, only 1 person fell off due to their own reasons, and no subjects withdrew from the test due to adverse events; 9 patients in the drug group experienced adverse events Among them, 7 of them reduced the dose of medication, including 3 people with drowsiness, 2 with constipation, 1 with depression, and 1 with myalgia; 2 people withdrew from the trial due to intolerable adverse reactions (drowsiness).
Wang 2017 ³⁷	
Participants	<p>Number of TG/CG: 19/19</p> <p>Condition: MWOA (ICHD-3)</p> <p>Demographics: age (years): 18–43; 52.63% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	TG: Acupuncture CG: SA Acupuncture points: Bilateral headache points, located at the midpoint of the anterior depression of the 1st and 2nd metatarsal joint of the dorsum of the foot Number of needles: 2 Depth of insertion: 25–40 mm Number of treatment sessions: 20 (Immediately release the needle when it reaches the sense of discharge and numbness, 5 times a week) Duration: 4 weeks Follow-up: 4 weeks
Adverse event	/
Liang 2016 ²⁵	
Participants	Number of TG/CG: 30/30 Condition: CM (ICHD-2) Demographics: age (years): TG:46.5 CG:44.5; 65% female Setting: China Duration of migraine (years):/
Interventions	TG: Acupuncture CG: SA Acupuncture points: Bilateral Yanglingquan, Jiaosun, Qiuxu, Waiguan Number of needles: 8 Depth of insertion: 0.3–1.5 cun Number of treatment sessions: 20 (30 minutes each, 5 times a week) Duration: 4 weeks Follow-up: 0
Adverse event	/
Meng 2015 ⁴⁰	
Participants	Number of TG/CG: 30/30 Condition: MWOA with acute attack (ICHD-2) Demographics: age (years): TG:32. 65 ± 12. 73 CG:30. 09 ± 13. 39; 66.67% female Setting: China Duration of migraine (years): TG:4.13 ± 3.38 CG:4.50 ± 4.05
Interventions	TG: Acupuncture CG: SA Acupuncture points: Taiyang through Shuaigu and Toulinqi through Muchuang on the affected side, Bilateral Waiguan, Zhongzhu. Number of needles: 6 Depth of insertion:/ Number of treatment sessions: 20 (60 minutes each, 5 times a week) Duration: 4 weeks Follow-up: 0
Adverse event	/
Huang 2015 ²¹	
Participants	Number of TG/CG: 10/10 Condition: MWOA (ICHD-2) Demographics: age (years): TG:28 ±4 CG:29 ±5; 55% female Setting: China Duration of migraine (years): TG:3. 3 ±1. 2 CG:2. 8 ± 0. 9

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	TG: Acupuncture CG: SA Acupuncture points: Jiaosun, Waiguan, Yanglingquan, Qixu on the affected side Number of needles: 4 Depth of insertion:/ Number of treatment sessions: 10 (Once a day) Duration: 12 day Follow-up: 0
Adverse event	/
Zhang 2015 ⁵⁰	
Participants	Number of TG/CG: 55/55 Condition: MWOA (ICHD-2) Demographics: age (years): TG:24±3 CG:25±3; 52.73% female Setting: China Duration of migraine (years): TG: 4.2±3.5 CG: 3.7±3.1
Interventions	TG: Electroacupuncture CG: SE Acupuncture points: Fengchi, Waiguan, Sugu, Yanglingquan Number of needles: 8 Depth of insertion: 13–40 mm Number of treatment sessions: 1 (30 minutes each) Duration: 1 day Follow-up: 8 hours
Adverse event	0
Yang 2014 ⁴⁷	
Participants	Number of TG/CG: 30/30/30 Condition: Migraine with or without aura (ICHD-2) Demographics: age (years): TG:38.89±12.88 CG1:38.66±11.43 CG2:42.58±11.98; 53.33% female Setting: China Duration of migraine (years): TG:3.18±3.93 CG1:4.79±3.65 CG2:7.35±7.77
Interventions	TG: Acupuncture CG: SA Acupuncture points: Bilateral Taiyang, Fengchi, Waiguan, Yanglingquan, Qixu Number of needles: 10 Depth of insertion:/ Number of treatment sessions: 1 (30 minutes each) Duration: 1 day Follow-up: 24 h
Adverse event	0
Chang 2013.08.01 ²²	
Participants	Number of TG/CG: 30/30 Condition: Migraine with or without aura (ICHD-2) Demographics: age (years): TG:27.4 CG:25; 57.63% female Setting: China Duration of migraine (years): TG:6 CG:5.6

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	TG: Acupuncture CG: SA Acupuncture points: Jiaosun, Waiguan, Yanglingquan, Qixu Number of needles: 8 Depth of insertion: 0.3–1.5 cun Number of treatment sessions:/(30 minutes each) Duration: 4 weeks Follow-up: 0
Adverse event	/
Zhang 2013 ⁴⁵	
Participants	Number of TG/CG: 30/30 Condition: Migraine with or without aura (ICHD-2) Demographics: age (years): TG:28.83 ± 7.57 CG:26.86 ± 6.66; 57.63% female Setting: China Duration of migraine (years):/
Interventions	TG: Acupuncture CG: SA Acupuncture points: Jiaosun, Waiguan, Yanglingquan, Qixu Number of needles: 8 Depth of insertion: 0.3–1.5 cun Number of treatment sessions: 20 (30 minutes each, 5 times a week) Duration: 4 weeks Follow-up: 0
Adverse event	/
Liu Mi 2013 ⁴²	
Participants	Number of TG/CG: 30/30/30 Condition: Migraine with or without aura (ICHD-2) Demographics: age (years): TG:38.89±12.88 CG1:38.66±11.43 CG2:42.58±11.98; 52.5% female Setting: China Duration of migraine (years): TG:3.18±3.93 CG1:4.79±3.65 CG2:7.35±7.77
Interventions	TG: Acupuncture CG: SA Acupuncture points: Bilateral Jiaosun, Fengchi, Waiguan, Yanglingquan, Qixu Number of needles: 10 Depth of insertion: 0.3–1.5 cun Number of treatment sessions: 1 (30 minutes) Duration: 1 day Follow-up: 24 h
Adverse event	/
Wang 2013 ³⁰	
Participants	Number of TG/CG: 76 Condition: Migraine with or without aura (ICHD-2) Demographics: age (years): 38.2±9.5; 76.32% female Setting: China Duration of migraine (years): 18.2±9.5

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Interventions	<p>TG: Acupuncture CG: bloodletting</p> <p>Acupuncture points: Local acupoint selection according to the meridian: Sizhukong, Sugu, Sun, Fengchi; remote acupoint selection (bilateral acupoints): Hegu, Lieqie, Taichong, Zu Linwei; internal medicine syndrome selection (bilateral acupoint selection): phlegm stasis plus Zhongwan, Fenglong, Yinlingquan, Xuehai, Geshu; Liver-yang hyperactivity plus Ganshu, Yanglingquan, Qiuxu, Taixi.</p> <p>Number of needles:/</p> <p>Depth of insertion: 25–35 mm</p> <p>Number of treatment sessions: 1 (30 minutes)</p> <p>Duration: 1 day</p> <p>Follow-up: 24 h</p>
Adverse event	/
Chang 2013.04.10 ²³	
Participants	<p>Number of TG/CG: 30/29</p> <p>Condition: Migraine with or without aura (ICHD-2)</p> <p>Demographics: age (years): TG:28.83±7.57 CG:26.86±6.66; 66.10% female</p> <p>Setting: China</p> <p>Duration of migraine (years): TG:3.71±2.24 CG:3.96±2.64</p>
Interventions	<p>TG: Acupuncture CG: SA</p> <p>Acupuncture points: Bilateral Jiaosun, Waiguan, Yanglingquan, Qiuxu</p> <p>Number of needles: 8</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions: 20 (30 minutes each, 5 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 1 months</p>
Adverse event	/
Lin 2013 ⁴⁸	
Participants	<p>Number of TG/CG: 30/29</p> <p>Condition: Migraine with or without aura (ICHD-2)</p> <p>Demographics: age (years):/; 66.10% female</p> <p>Setting: China</p> <p>Duration of migraine (years):/</p>
Interventions	<p>TG: Acupuncture CG: SA</p> <p>Acupuncture points: Bilateral Jiaosun, Waiguan, Yanglingquan, Qiuxu</p> <p>Number of needles: 8</p> <p>Depth of insertion:/</p> <p>Number of treatment sessions: 20 (30 minutes each, 5 times a week)</p> <p>Duration: 4 weeks</p> <p>Follow-up: 1 month</p>
Adverse event	/

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Liu Zhao 2013 ⁴³	
Participants	Number of TG/CG: 30/30/30 Condition: Acute attack (ICHD-2) Demographics: age (years): TG:38.89±12.88 CG1:38.66±11.43 CG2:42.58±11.98; 53.33% female Setting: China Duration of migraine (years): TG:3.18±3.93 CG1:4.79±3.6 CG2:7.35±7.77
Interventions	TG: Acupuncture CG: SA Acupuncture points: Bilateral Jiaosun, Fengchi, Waiguan, Yanglingquan, Qixu Number of needles: 10 Depth of insertion:/ Number of treatment sessions: 1 (30 minutes) Duration: 1 day Follow-up: 24 h
Adverse event	0
Liu 2012 ⁴¹	
Participants	Number of TG/CG: 30/30 Condition: Acute attack (ICHD-2) Demographics: age (years): TG:38.89±12.88 CG1:38.66±11.43 CG2:42.58±11.98; 53.33% female Setting: China Duration of migraine (years): TG:3.18±3.93 CG1:4.79±3.6 CG2:7.35±7.77
Interventions	TG: Acupuncture CG: SA Acupuncture points: Bilateral Jiaosun, Fengchi, Waiguan, Yanglingquan, Qixu Number of needles: 10 Depth of insertion:/ Number of treatment sessions: 1 (30 minutes) Duration: 1 day Follow-up: 24 h
Adverse event	0
Wu 2011 ⁶³	
Participants	Number of TG/CG: 30/30 Condition: MWOA (ICHD-2) Demographics: age (years): TG:39.6 ±9.7 CG:39.1 ±10.2; 66.67% female Setting: China Duration of migraine (years): TG:16.2 ±7.9 CG:15.4 ±9.1
Interventions	TG: Acupuncture CG: flunarizine hydrochloride Acupuncture points: A Shi, Baihui, Taiyang, Shuaigu, Fengchi, Benshen, Lieque Number of needles:/ Depth of insertion: 13–25 mm Number of treatment sessions: 24 (30 minutes each, 6 times a week) Duration: 4 weeks Follow-up: 0
Adverse event	/

(Continued)

Table 2 (Continued).

Methods	Design of Trial: Open-Label RCT
Sheng 2010 ²⁴	
Participants	Number of TG/CG: 40/40 Condition:/(1998 edition of the ICHD) Demographics: age (years): 37; 51.52% female Setting: China Duration of migraine (years):/
Interventions	TG: Acupuncture+ flunarizine hydrochloride CG: flunarizine hydrochloride Acupuncture points: Fengchi, Touwei, Taiyang, Ashi Number of needles:/ Depth of insertion:/ Number of treatment sessions: 28 (30 minutes each, Once a day) Duration: 4 weeks Follow-up: 0
Adverse event	/
Geng 2010 ⁶⁰	
Participants	Number of TG/CG: 30/30 Condition:/(1988 edition of the ICHD) Demographics: age (years): TG:13–68 CG:16–69; 55% female Setting: China Duration of migraine (years): TG:0.17–9.33 CG:0.25–11.75
Interventions	TG: Acupuncture CG: nimodipine Acupuncture points: Fengfu, Fengchi, Taiyang, Laogong, Hegu, Zulinwei, Baihui Number of needles:/ Depth of insertion:/ Number of treatment sessions: 12 (30 minutes each, Once a day) Duration: 12 days Follow-up: 0
Adverse event	/

Abbreviations: TG, treatment group; CG, control group; RCT, randomized controlled trial; ICHD, international classification of headache disorders; MWOA, migraine without aura; VA, verum acupuncture; RA, true acupuncture; SA, sham acupuncture; WL, waiting list; CM, chronic migraine; AE, adverse event.

diagnosis of headache disorders published in the Journal of Neurology and Neurorehabilitation.²⁷ The remaining seven studies did not specify the diagnostic criteria.

Patient Characteristics

The present review only included studies with adult patients (≥ 18 years of age), and the mean age was 37.35 years (median 37.1; IQR 33–40.04). The proportion of females ranged from 45.71% to 88.57% (median 66.1%; IQR 55–74%). The course of migraine ranged from 2 months to 26.9 years (median 5.11; IQR 3.835–10.255).

Acupuncture Intervention Characteristics

The treatment intervention was acupuncture alone in 38 trials, electroacupuncture in 6, acupuncture plus conventional

western medicine in 3, and acupuncture plus traditional Chinese herbal medicine in 2. The number of treatment sessions ranged from 1 to 32 (median 20; IQR 10–20), and treatment frequency ranged from 1 to 7 times per week (median 3; IQR 1–5). The treatment period ranged from 1 to 20 weeks (median 4; IQR 2–4). The duration of each acupuncture session ranged from 20 to 60 minutes (median 30; IQR 30–30); six studies did not report the duration of treatment, and the needle was removed immediately after the attainment of Deqi (an internal compound sensation of soreness, tingling, fullness, aching, cool, warmth, heaviness, and a radiating sensation at and around acupoints) in two studies. The duration of follow-up ranged from 4 to 52 weeks (median 12; IQR 4–20) in 18 studies. The follow-up duration was not specified

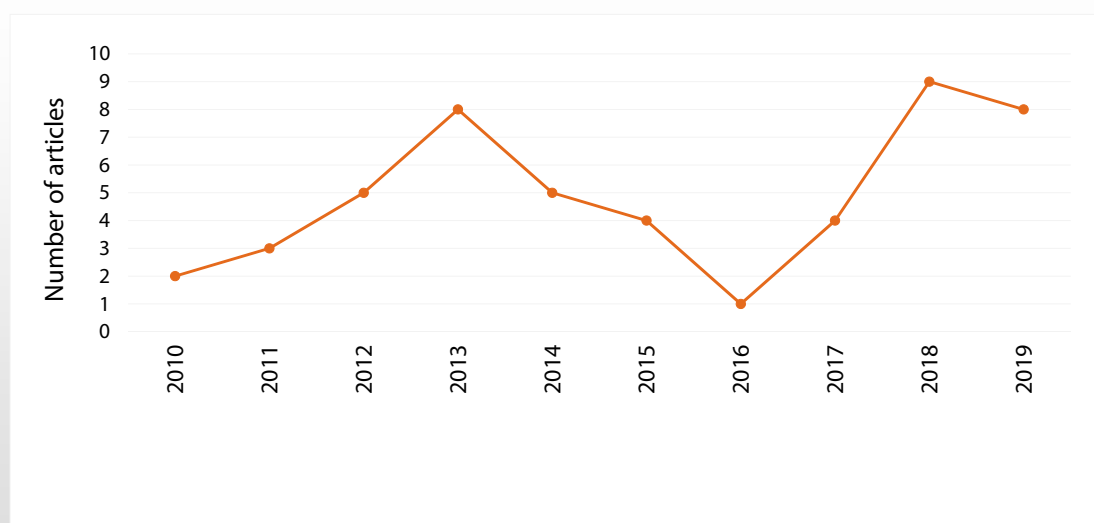


Figure 2 Annual distribution of the included studies evaluating acupuncture for migraine.

in 3 studies, and 28 studies did not perform any follow-up. Most studies did not specify the exact number of needle insertions, especially in individualized interventions.

Control Intervention Characteristics

The control intervention most commonly used in the included RCTs was SA comprising either needle puncture at sham locations (eg, sham points, pseudo points, inactive points) or sham insertions (eg, superficial insertion, pseudo insertion, or electroacupuncture without electric stimulation).²⁸ Twenty-two studies used SA at sham points as a control intervention, of which 4 used superficial acupuncture and 18 performed puncture at the same depth as the RA intervention. Six studies used sham electroacupuncture at sham points. Fifteen trials used conventional pharmacological therapies (eg, flunarizine hydrochloride, nimodipine, carbamazepine, ergotamine caffeine, botulinum toxin A, topiramate, acetaminophen, or valproic acid). Two studies used traditional Chinese medicine (TCM) prescriptions as a control intervention. Five studies used waiting-list control. Other control interventions (all one study each) included hypnotherapy,²⁹ bloodletting,³⁰ flunarizine hydrochloride plus needling at non-acupoints,³¹ and Yamamoto new scalp acupuncture.³²

Risk of Bias

Figure 3 shows the risk of bias in each of the six domains for all included studies. Only one-fifth of the included studies were assessed as high-quality; the remaining studies were classified as having a high risk of bias. Most studies explicitly reported the randomization method, while 15 studies failed to provide a detailed description. Allocation concealment was appropriately employed in 18 RCTs via the use of sealed envelopes or by computer, but the remaining trials did not provide information about allocation concealment. Acupuncturists in all trials and patients in 31 trials were not blinded to the intervention due to the unique nature of acupuncture, while the other 18 trials were single-blind. In 34 studies, the outcome assessors were not blinded, suggesting a risk of measurement bias. In addition, only 18 RCTs reported the number of drop-outs and reasons. In all included studies, the treatment and control groups had comparable baseline data and sample sizes; however, only six of the included studies provided the details of the sample size calculation. A summary of the risk of bias in each of the included trials is presented in Figure 4.

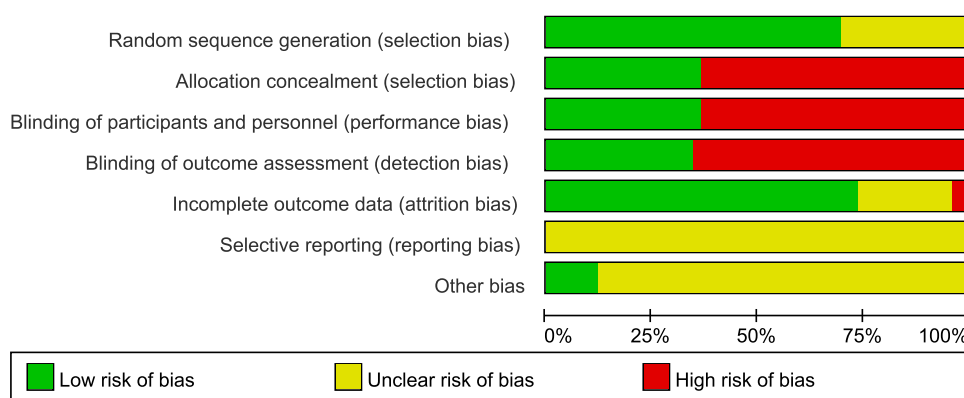


Figure 3 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Outcomes of the Acupuncture and Control Groups

Acupuncture versus Superficial Needling at Non-Acupoints

Four RCTs used superficial or minimal needling at non-acupoints as a control treatment. One study showed that the RA group had significantly fewer migraine days, less severe migraines, more responders, and an increased pressure pain threshold than the SA group at the end of treatment, and these differences were maintained after 3 months but not at 12 months.¹⁹ One study reported that the number of migraine attacks was significantly lower in the RA group than the control group after 1 month of treatment and during post-treatment months 2, 3, and 4.³³ Two studies reported that RA significantly decreased the visual analogue scale (VAS) pain score after treatment.^{34,35}

Acupuncture versus Deep Needling at Non-Acupoints

Deep needling at non-acupoints was performed as a control intervention in 18 RCTs. The included patients had MWOA in four studies, CM in two, and acute migraine attack in five, while seven studies did not mention the type of migraine. Patients with MWOA showed a significant improvement in the VAS pain score and frequency of migraine attacks after acupuncture treatment.^{20,36,37} Among patients with CM, those in RA groups showed an improved VAS pain score after treatment.^{25,38} For patients with acute migraine attack, RA achieved a greater effect in reducing headache-related pain in accordance with the VAS score,³⁹⁻⁴¹ earlier onset and longer duration of headache relief,⁴² and greater clinical effectiveness⁴³ immediately after the end of the treatment compared with the control intervention. Of the studies that did not mention the migraine type, three reported that the RA group achieved a significant decrease in headache intensity,

VAS pain score, and Migraine-Specific Quality of Life Questionnaire score,^{22,44,45} one reported a more significant decrease in the number of days with migraine headache in the RA group, while placebo acupuncture achieved a smaller decrease in migraine frequency and no significant decrease in the duration of migraine attack;⁴⁶ and three found greater effectiveness in the RA group than the control group.^{23,47,48}

Electroacupuncture versus Sham Electroacupuncture

Six RCTs used sham electroacupuncture as a control intervention. Of these, three showed a greater reduction in the frequency of migraine attacks⁸ and headache intensity^{49,50} in the true electroacupuncture group (EG) than in the sham electroacupuncture group (SEG). However, three RCTs demonstrated significant reductions compared with baseline in both the EG and SEG in the VAS pain score, frequency of migraine attacks, number of days with migraine, and Headache Impact Test-6 score.^{12,51,52} Furthermore, the reduction in pain intensity did not significantly differ between the EG and SEG.^{12,51,52}

Acupuncture versus Western Medicine

Twelve trials compared the effectiveness of acupuncture versus western medicine including flunarizine hydrochloride, nimodipine, carbamazepine, ergotamine caffeine, botulinum toxin A, topiramate, acetaminophen, and valproic acid. Five trials evaluated the pain intensity and demonstrated that acupuncture achieved a significantly greater decrease in the VAS pain score (compared with acetaminophen,²⁹ botulinum toxin A,⁵³ and flunarizine hydrochloride^{54,55}) and a significantly greater decrease in the pain intensity and pain relief score (compared with valproic acid⁵⁶). Five studies showed that the total effective rate of the acupuncture group was higher than that of the western medicine group (versus flunarizine hydrochloride,^{57,58} ergotamine caffeine,⁵⁹ nimodipine,⁶⁰ and carbamazepine⁶¹).

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bahram Naderinabi 2017	?	?	?	?	?	?	?
Chang 2013.04.10	?	?	?	?	?	?	?
Chang 2013.08.01	?	?	?	?	?	?	?
Cheng 2019	?	?	?	?	?	?	?
Cong 2018	?	?	?	?	?	?	?
C-P Yang 2011	?	?	?	?	?	?	?
Du 2019	?	?	?	?	?	?	?
E Facco 2013	?	?	?	?	?	?	?
Frantisek Musil et al 2018	?	?	?	?	?	?	?
Geng 2010	?	?	?	?	?	?	?
Guan 2019	?	?	?	?	?	?	?
Hou 2019	?	?	?	?	?	?	?
Huang 2015	?	?	?	?	?	?	?
Jie Yang 2012	?	?	?	?	?	?	?
Kenan Tastan 2018	?	?	?	?	?	?	?
Liang 2016	?	?	?	?	?	?	?
Lin 2013	?	?	?	?	?	?	?
Ling Zhao 2014	?	?	?	?	?	?	?
Ling Zhao 2017	?	?	?	?	?	?	?
Linpeng Wang 2011	?	?	?	?	?	?	?
Linpeng Wang 2012	?	?	?	?	?	?	?
Liu 2012	?	?	?	?	?	?	?
Liu Mi 2013	?	?	?	?	?	?	?
Liu Zhao 2013	?	?	?	?	?	?	?
Ma 2018	?	?	?	?	?	?	?
Mehran Rezvani 2014	?	?	?	?	?	?	?
Meng 2015	?	?	?	?	?	?	?
Mingxiao Yang 2014	?	?	?	?	?	?	?
Mohsen Foroughipour 2015	?	?	?	?	?	?	?
Peng 2018	?	?	?	?	?	?	?
Qin 2019	?	?	?	?	?	?	?
Shen 2010	?	?	?	?	?	?	?
Shen 2019	?	?	?	?	?	?	?
Thomas-Martin Wallasch 2012	?	?	?	?	?	?	?
Wang 2013	?	?	?	?	?	?	?
Wang 2017	?	?	?	?	?	?	?
Wang 2018	?	?	?	?	?	?	?
Wu 2011	?	?	?	?	?	?	?
Xu 2018	?	?	?	?	?	?	?
Yang 2014	?	?	?	?	?	?	?
Yang 2018	?	?	?	?	?	?	?
Yanyi Wang 2015	?	?	?	?	?	?	?
Ying Li 2012	?	?	?	?	?	?	?
Yu 2019	?	?	?	?	?	?	?
Zhang 2013	?	?	?	?	?	?	?
Zhang 2015	?	?	?	?	?	?	?
Zhang 2019	?	?	?	?	?	?	?
Zhengjie Li 2017	?	?	?	?	?	?	?
Zhuo 2018	?	?	?	?	?	?	?

Figure 4 Risk of bias summary: review authors' judgements about each risk of bias item for each included.

Another RCT reported a significantly larger decrease in the mean monthly number of moderate/severe headache days in the acupuncture group compared with the topiramate group.⁶²

One study showed that the acupuncture group achieved significantly higher scores than the medication group for physical functioning, role-physical, and bodily pain using the Short-Form Health Survey.⁶³

Acupuncture Plus Western Medicine versus Western Medicine Alone

Three trials reported that acupuncture plus western medicine had a greater effect than western medicine alone in reducing the frequency, duration, and degree of headaches.^{24,27,64}

Acupuncture Plus Traditional Chinese Herbs versus Traditional Chinese Herbs Alone

Two trials reported that acupuncture plus herbs was more effective than herbs alone.^{26,65} One demonstrated that both the acupuncture and control groups achieved a significantly lower headache index and Hamilton Depression Scale score after treatment compared with baseline, and scores in the acupuncture group were significantly lower than those in the control group.³²

Acupuncture versus Waiting-List Control

Two RCTs indicated that pain intensity based on the VAS score was significantly reduced after acupuncture treatment compared with baseline, while there was no significant change in pain intensity in the waiting-list control groups.^{49,52} One study showed a greater reduction in the frequency of migraine attacks in the acupuncture compared with the waiting-list control group.⁸ Another trial reported that the number of migraine days was reduced in both the acupuncture and waiting-list control groups; however, the acupuncture group achieved a significantly greater reduction in the number of migraine days and a significantly greater number of responders to treatment than the waiting-list control group.⁹

Acupuncture versus Hypnotherapy

One trial compared the effect of acupuncture with hypnotherapy and concluded that both treatments were effective in treating migraine headaches.²⁹

Traditional Acupuncture versus Other Acupuncture Methods

In TCM, acupuncture includes bloodletting, fire needling, plum needling, cupping, and other acupuncture methods.

One study compared the effects of traditional Chinese acupuncture versus Yamamoto new scalp acupuncture on migraine and reported that both groups showed similar decreases in the frequency and severity of migraine attacks, nausea, the need for rescue treatment, and work absence rate;³² both groups also showed similar improvements in recovery from headache and ability to continue daily activities 2 hours after treatment.³² One trial that compared acupuncture with bloodletting reported that acupuncture achieved a greater reduction in headache intensity based on the VAS score.³⁰

Meta-Analysis

Real Acupuncture versus Sham Acupuncture

We conducted a meta-analysis of the effect of treatment on headache frequency reported in nine trials. There was significant heterogeneity ($I^2 = 92\%$, $P < 0.00001$), so a random-

effects model was used (Figure 5). Headache frequency did not significantly differ between patients treated with RA versus SA ($n = 999$, mean difference [MD] = -0.64 , $P = 0.24$, 95% confidence interval [CI] -1.70 to 0.42). However, as there was significant heterogeneity between trials and a risk of bias due to a lack of blinding (four trials) and allocation concealment (four trials), the evidence regarding the effect of treatment on headache frequency was considered to be low quality (Figure 6).

Real Acupuncture versus No Acupuncture

Three trials compared acupuncture with waiting-list control. There was no heterogeneity ($I^2 = 0\%$, $P = 0.37$), so a fixed-effects model was used (Figure 7). Acupuncture had a better treatment effect for migraine than waiting-list control ($n = 268$, MD = -1.80 , $P < 0.00001$, 95% CI -2.34 to -1.26). Although there was a risk of bias because of

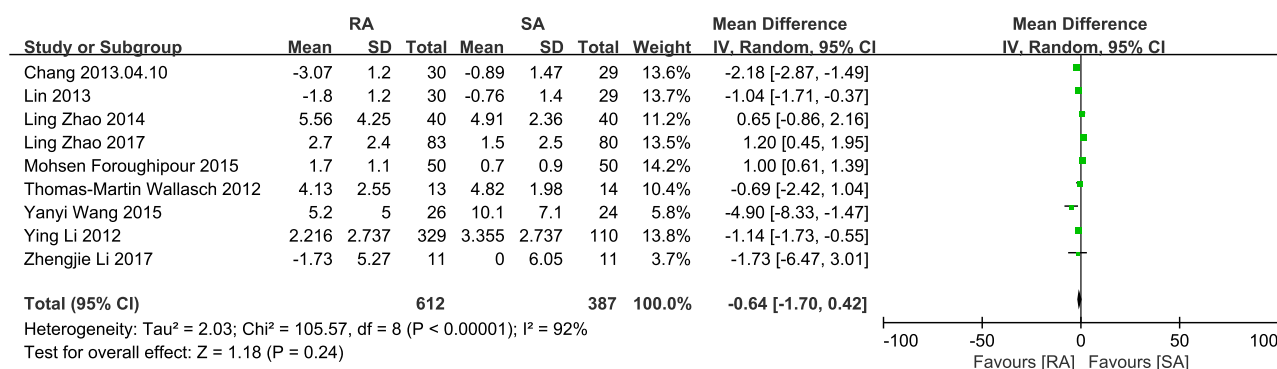


Figure 5 Forest plot of comparison: I RA vs. SA, outcome: headache frequency.

acupuncture compared to sham acupuncture for people with migraine

Patient or population: people with migraine

Settings: inpatient care or outpatient care

Intervention: acupuncture

Comparison: sham acupuncture

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Sham acupuncture	Acupuncture				
headache frequency		The mean headache frequency in the intervention groups was 0.64 lower (1.7 lower to 0.42 higher)		999 (9 studies)	⊕⊕⊕⊕ low ^{1,2}	

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Nearly half of the studies did not describe the random method and allocation concealment, and were not blinded to analysts

² pronounced heterogeneity of study results ($I^2 = 92\%$; $\chi^2 = 105.57$; P value < 0.00001)

Figure 6 Summary of evidence of comparison: I RA vs. SA, outcome: headache frequency.

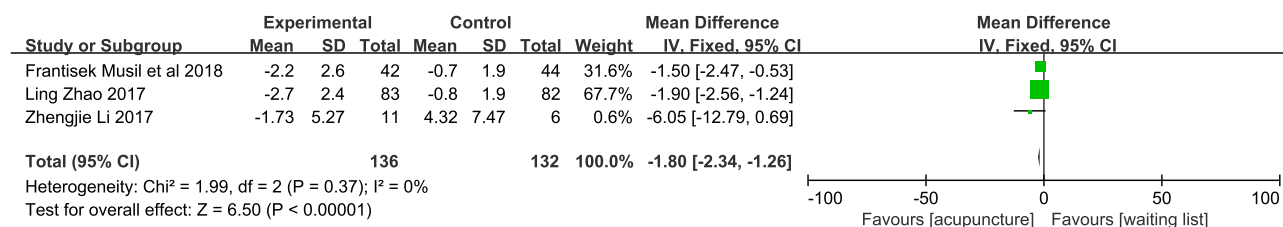


Figure 7 Forest plot of comparison: 2 acupuncture vs. waiting list, outcome: headache frequency.

a lack of blinding in two trials and lack of allocation concealment in one trial, the evidence regarding the effectiveness of acupuncture versus waiting-list control was considered to be moderate quality because of the highly consistent findings in the three trials (Figure 8).

Real Acupuncture versus Western Medicine

Four trials were included in the meta-analysis. Acupuncture resulted in a significantly greater reduction in migraine frequency than western medicine ($n = 445$, $MD = -1.75$, $P = 0.003$, 95% CI -2.91 to -0.58 ; Figure 9). However, three of the four studies had a risk of bias because of a lack of allocation concealment and blinding, so the evidence was considered to be low quality (Figure 10).

Discussion

Migraine is a common primary headache disorder that is one of the most disabling conditions. In 2016, migraine was experienced by nearly 1.04 billion individuals⁶⁶ and accounted for 45.1 million years of life lived with disability in 2016, representing an increase of 51.2% from 29.8 million years of life lived with disability in 1990.⁶⁶ The present review summarized the clinical research of acupuncture treatment of migraine over the past 10 years and compared its effectiveness with various control interventions. Several trials using different control treatments consistently demonstrated that acupuncture was more effective than other therapies. Acupuncture had a better treatment effect for migraine than no treatment, waiting-list control, or routine care compared with placebo acupuncture. Acupuncture was more effective for migraine

Author(s):
 Date: 2020-05-15
 Question: Should acupuncture vs no treatment be used in people with migraine?
 Settings: inpatient care or outpatient care
 Bibliography:

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture	No treatment	Relative (95% CI)	Absolute		
headache frequency (Better indicated by lower values)												
3	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	136	132	-	MD 1.8 lower (0 higher to 1.26 lower)	⊕⊕⊕⊕ MODERATE	CRITICAL

[†] One of the three articles has risk bias such as allocation concealment and blind

Figure 8 Summary of evidence of comparison: 2 acupuncture vs. waiting list, outcome: headache frequency.

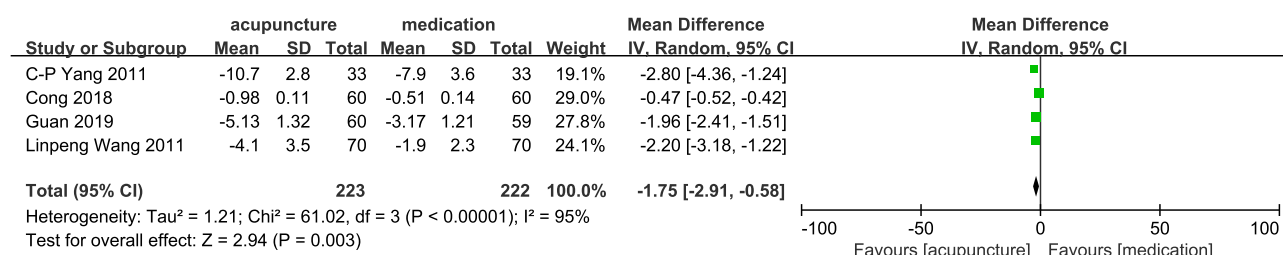


Figure 9 Forest plot of comparison: 3 acupuncture vs. western medicine, outcome: headache frequency.

acupuncture compared to western medicine for people with migraine						
Patient or population: people with migraine						
Settings: inpatient care or outpatient care						
Intervention: acupuncture						
Comparison: western medicine						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Western medicine	Corresponding risk Acupuncture				
headache frequency		The mean headache frequency in the intervention groups was 1.75 lower (2.91 to 0.58 lower)		445 (4 studies)	⊕⊕⊕⊕ low ^{1,2}	
*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).						
CI: Confidence interval;						
GRADE Working Group grades of evidence						
High quality: Further research is very unlikely to change our confidence in the estimate of effect.						
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.						
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.						
Very low quality: We are very uncertain about the estimate.						
¹ Three-quarters of studies have risk of bias such as allocation concealment and blind						
² pronounced heterogeneity of study results (I ² = 95%; Chi ² = 1.27; P value < 0.00001)						

Figure 10 Summary of evidence of comparison: 3 acupuncture vs. western medicine, outcome: headache frequency.

than positive controls (guideline-recommended pharmacotherapies). Furthermore, acupuncture seems to have a lower risk of adverse events than pharmacotherapy. There was no difference between SA and RA, especially electroacupuncture versus sham electroacupuncture.

Nearly 50% of the included trials used SA as a control. SA mainly comprised needling at non-acupoints with the same frequency and duration as in the RA group, but in some SA comprised needle insertion into acupoints not related to migraine treatment. In trials that used penetrating SA, acupuncture had a smaller effect size than that reported in trials using non-penetrating SA.⁶⁷ This is because the factors affecting acupuncture efficacy are mainly divided into specific and non-specific factors.⁶⁸ The specific factors include acupuncture point selection, needle selection, needle manipulation, and stimulation intensity and time. The non-specific factors include the placebo effect of acupuncture, treatment environment, social factors, cultural factors, non-psychological factors such as natural disease regression, and the use of a non-parallel intervention. The placebo effect is produced by factors such as patient recognition,^{69,70} expectation,^{70,71} attention,^{72,73} preference, and doctor–patient communication.^{74–77} Promotion of the placebo effect results from doctors’ statements,^{78,79} expectations,^{78–81} and diagnosis during treatment^{74,82} and via indirect adjustment of the patient’s psychology by the treatment environment.^{83–85} The effect of SA is also related to the stimulation of local nerve fibers. Experimental and clinical studies have reported that needling at non-acupoints in animals induces analgesia,⁸⁶ and that the anti-inflammatory effect of electroacupuncture is lost when the nerve fibers supplying the stimulated area (dermatome) are damaged.⁵ Superficial

needling can stimulate nerve fibers within the dermatome of real acupoints, and non-penetrating needles can stimulate nerve terminals underneath the acupoints, as these areas have higher electrical conductivity than the surrounding tissues⁸⁷ and become hypersensitive in certain pathological conditions.^{88–90} The importance of acupoint specificity using an optimized experimental design remains to be demonstrated.

Previous reviews indicate that studies with poor methodological quality tend to report false-positive results.^{91–93} This statement is broadly consistent with our finding that most low-quality trials reported better clinical outcomes in the RA group than in the SA group or other control groups, suggesting that these studies may include false-positive results. As shown in Figure 3, nearly two-thirds of the included studies had a high risk of bias in three domains (allocation concealment, blinding of patients and personnel, and blinding of outcome assessors). Although almost all included studies were RCTs, few explicitly described the randomization method and allocation concealment. Allocation concealment is the most effective way to avoid bias as it eliminates the bias caused by the researcher’s personal subjective desired trial outcome.⁹⁴ The treatment effect of studies with unconcealed or imperfectly concealed allocation schemes is exaggerated by 30–40%.⁹⁵ Blinding is an important safeguard against bias, particularly when assessing subjective outcomes.⁹⁶ Due to the unique nature of acupuncture manipulation, it is difficult to blind the acupuncturists. However, the blinding of data collectors and outcome analysts reduces the impact of subjective factors,⁹⁷ and this was done in almost all high-quality studies included in this review.

The present study has some limitations. 1) The literature search was limited to articles published in Chinese or English, which excluded studies published in other languages (eg, Japanese, Korean, and German). This language limitation may have introduced biased outcomes. 2) Furthermore, the risk of bias in the assessment varied between studies based on the authors' subjective views and diligence. 3) Bias may have resulted from variations between studies, including the use of different control interventions, treatment sessions, frequency and duration of treatments, acupoints, the stage and type of migraine, and blinding of outcome assessors. As TCM does not advocate the use of a one-size-fits-all acupuncture regimen, the standardization of results is always an issue in such research.⁹⁸ 4) We focused on the comparison of acupuncture with different types of control treatment, but there were deficiencies in the systematic review methodology, and a meta-analysis was only conducted for headache frequency as the treatment outcome. However, the present study also had some strengths. In contrast to the systematic review published in 2016,¹⁵ we evaluated the effect of acupuncture on migraine prevention and its therapeutic effect on acute migraine attacks.

Conclusions

The present results demonstrate that acupuncture reduces the symptoms of migraine and improves the quality of life. The meta-analysis revealed that acupuncture reduces headache frequency more than no treatment and western medicine, but the quality of evidence was low. RA did not have any advantages over SA. To achieve international recognition of the effect of acupuncture in treating migraine, there is a need for more multi-center, large-sample, RCTs that use world-recognized evaluation methods and curative effect standards⁹⁹ to develop standard criteria for selecting acupoints and creating treatment protocols. In addition, future migraine research should focus on reporting the minimal clinically important difference; although statistically significant changes often occurred after intervention, the significant change had minimal clinical significance in some cases.¹⁰⁰ Future research is also required to evaluate the effect of various acupuncture intervention times for different stages of migraine (eg, period of migraine attack and remission), the long-term effects of acupuncture treatment, and differences between results obtained by manual acupuncture versus electroacupuncture. Moreover, the mechanism of acupuncture for migraine should be further investigated to provide a reliable basis for its wider use.

Finally, as the evaluation criteria for the efficacy of migraine treatment differed between trials, the results could not be directly compared. Future trials should use internationally recognized outcome indicators.

Abbreviations

CI, confidence interval; EG, electroacupuncture group; IQR, interquartile range; MD, mean difference; RA, real acupuncture; RCT, randomized controlled trial; SA, sham acupuncture; SEG, sham electroacupuncture group; TCM, traditional Chinese medicine; VAS, visual analogue scale.

Data Sharing Statement

The data can be requested from the corresponding author.

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Author Contributions

All authors contributed to data analysis, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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