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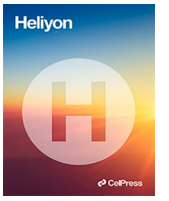

Research article

Durable effects of acupuncture for tension-type headache: A systematic review and meta-analysis

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ABSTRACT

Background: Acupuncture may be effective in treating tension-type headache (TTH). The durability of its effects after treatment completion remains inconclusive.
Methods: We searched multiple databases and references from previous reviews for randomized controlled trials (RCTs) which investigated the effectiveness of acupuncture for TTH. We assessed the methodological quality of RCTs using the Cochrane Risk of Bias 2.0 (RoB 2) tool. Primary outcome was response rate, defined as the proportion of participants who reported at least a 50% reduction in monthly headache days from baseline after completion of treatment. Secondary outcomes included headache days, headache intensity, and analgesic use. Safety outcomes were also evaluated.
Results: A total of seven RCTs involving 3,221 participants with frequent episodic and chronic TTH were included. Individuals receiving acupuncture reported a significantly higher response rate versus sham acupuncture (SA) immediately and at 1–6 months after completion of treatment ($P<0.05$). Compared with SA, post-treatment results of headache days and headache intensity appeared consistent on the whole, showing associations favoring acupuncture. However, no significant reduction in analgesic use was found post-treatment. Acupuncture showed no superiority over physical training or relaxation training in headache days and headache intensity. Moreover, no serious adverse events associated with acupuncture were reported.
Conclusion: Limited evidence suggested that acupuncture might provide durable post-treatment effects in the management of frequent episodic and chronic TTH for up to 6 months compared with SA,with no severe treatment-related adverse events reported.

1. Introduction

Tension-type headache (TTH) is the most common type of primary headache disorder, characterized by recurrent episodes of mild to moderate headache that typically presents bilaterally as a pressing or tightening sensation [1]. Risk factors for TTH include a lack of relaxation after work, sleeping disorder, depression, anxiety, a history of migraine, medication overuse, and female sex [2–5]. Currently, the exact pathophysiology of TTH is not fully understood. The potential pathophysiological mechanisms underlying TTH encompass genetic factors, peripheral and central mechanisms [2]. Peripheral mechanisms involving myofascial trigger points and

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vascular abnormalities may induce peripheral sensitization of nociceptors [2]. Central mechanisms include central sensitization of nociceptive pathways and alteration in descending pain modulation [2]. Frequent TTH can cause significant disability and decrease quality of life with enormous socio-economic impacts [6–8]. The estimated global prevalence of TTH is 26.0% (95% confidence interval [CI] 22.7–29.5) [9], making it a major public health concern. Individuals aged 15–49 years bear the greatest burden in terms of years lived with disability (YLD) due to TTH [10].

The diagnosis of TTH depends on clinical criteria outlined in the third edition of the International Classification of Headache Disorders (ICHD-3) by the International Headache Society (IHS), which categorizes TTH into three subtypes based on the frequency of headaches: infrequent episodic (headaches for <1 day/month on average [<12 days/year]), frequent episodic (headaches for 1–14 days/month on average for >3 months [≥12 and <180 days/year]), and chronic (headaches for ≥15 days/month on average for >3 months [≥180 days/year]) [1]. Frequent episodic and chronic TTH are associated with higher disability and are more challenging to treat compared to infrequent episodic TTH [10–12].

The treatment of TTH involves a comprehensive management approach, including patient education, non-pharmacological therapy, and medication [2,13,14]. For prophylactic treatment of TTH, it is recommended to begin with non-pharmacological interventions including acupuncture [14]. Non-pharmacological treatment for TTH such as psycho-behavioral treatment (e.g. cognitive-behavioral therapy, biofeedback, and relaxation training) can be time-consuming and there is no convincing high-quality evidence regarding their effects nor standard treatment guideline [2,14]. Prophylactic pharmacotherapies include amitriptyline, mirtazapine and venlafaxine; they should be continued for an additional 6 months or more after achieving satisfactory therapeutic effects and it may come with considerable side-effects [2,13–15]. For acute medication use or symptomatic treatment, aspirin and/or acetaminophen are the recommended first-line options, with caffeine combinations or nonsteroidal anti-inflammatory drugs (NSAIDs) being second-choice options [2]. However, there is a risk for side effects and overuse of analgesics may lead to medication-overuse headache and worsen patients' status. Moreover, evidence for durable effects of current treatment for TTH is scarce.

Acupuncture has been widely practiced for primary headaches including TTH. Previous randomized controlled trials (RCTs) [16–18] and systematic reviews [19,20] have suggested its effectiveness on TTH though solid conclusions cannot be drawn. Acupuncture has shown to reduce headache days posing minimal risk of adverse events [16–18]. The National Institute for Health and Care Excellence (NICE) guideline recommends offering chronic TTH patients a course of up to 10 sessions of acupuncture to help prevent future attack [21]. The durable effects of acupuncture are defined as the effects persist after completion of treatment (post-treatment), which may facilitate the prevention of TTH. However, the durability of acupuncture's effects on TTH remains inconclusive and relevant evidence is sparse. Therefore, we conducted this systematic review and meta-analysis. The objective of this work was to investigate whether acupuncture can provide durable benefits for TTH patients by focusing on outcomes measured after the completion of treatment. Our findings might guide clinical decision-making, the development of guidelines, and future research.

2. Methods

This systematic review and meta-analysis was performed in adherence to the protocols outlined in the Cochrane Handbook for Systematic Reviews of Interventions version 6.4 [22]. We arranged our reports in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline [23]. The review was prospectively registered with PROSPERO (CRD42023467192).

2.1. Inclusion and exclusion criteria

Studies were eligible if: (1) the study design was a parallel RCT published in English or Chinese; (2) the participants were patients aged 18 or older diagnosed with TTH; (3) the intervention group received acupuncture treatment which involves needle insertion at acupoints, pain points or trigger points, with or without electrical stimulation or needle retention, including dry needling and acupuncture performed at specific micro-system such as scalp or ear; (4) the control group received sham acupuncture (SA), no treatment, usual care, pharmacological therapy, and cognitive therapy; (5) the outcomes included at least one of the following outcomes measured at or after 3 months following completion of treatment: response rate (defined as the proportion of participants who reported at least a 50 % reduction in monthly headache days from baseline), headache days, and headache intensity.

Studies were excluded if: (1) they were dissertations, conference articles, trial registries, or ongoing trials; (2) the study enrolled participants diagnosed with different types of headaches (e.g. chronic headache which may involve patients with migraine and patients with TTH) without reporting separate results for TTH patients; (3) the intervention group received treatment at acupoints without skin penetration, such as acupressure, laser acupuncture, or transcutaneous electrical stimulation; (4) the intervention group received acupoint injection or acupuncture combined with herbal medicine; (5) the participants received maintained treatment during the follow-up period; (6) they compared acupuncture with herbal medicine or other forms of acupuncture therapy.

2.2. Search methods

We conducted a thorough search of PubMed, EMBASE, Web of Science, and the Cochrane Central Register of Controlled Trials, as well as Chinese databases including China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBM), and WanFang Database from their inception to September 26, 2023. The search was conducted on September 26, 2023. We also examined the references of prior reviews concerning acupuncture for TTH. We utilized Endnote X9 (Clarivate) for citation management. The search strategy was presented in Table S1 in the supplementary material.

2.3. Literature selection and data extraction

Two review authors independently screened the available records to identify eligible trials following the aforementioned criteria. Two independent researchers systematically extracted data from the included RCTs using standardized forms in Excel 2019. The extracted dataset comprised key information including first author, study location, publication year, basic demographics of the participants, sample size, methods, intervention details, outcomes, time points of follow-up, and adverse events. In cases where data were presented graphically, we used GetData Graph Digitizer software (version 2.25) to extract the raw data whenever possible. If necessary, we attempted to contact the original authors to obtain missing or additional data. Any discrepancies or disagreements were resolved through discussion and consensus.

2.4. Outcomes

Data analysis was conducted using a monthly time frame, where a duration of four weeks was considered equivalent to one month. The outcomes were assessed at multiple time points following completion of treatment, including immediately, at 1 month, 2 months, 3 months, and subsequent intervals thereafter. The primary outcome was response rate. The secondary outcomes included monthly headache days, headache intensity, and analgesic use. Safety outcomes were also evaluated.

2.5. Assessment of risk of bias

Two researchers independently assessed the methodological quality of the included studies using the Cochrane Risk of Bias 2.0 (RoB 2) tool [24]. This tool considers five key domains of bias: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of reported results. Each study was evaluated within these domains, and an overall assessment of the risk of bias was categorized into three classifications: “low” for studies with minimal risk of bias across all domains, “some concerns” for studies displaying substantial risk of bias across multiple domains, and “high” for studies exhibiting high risk of bias in at least one domain.

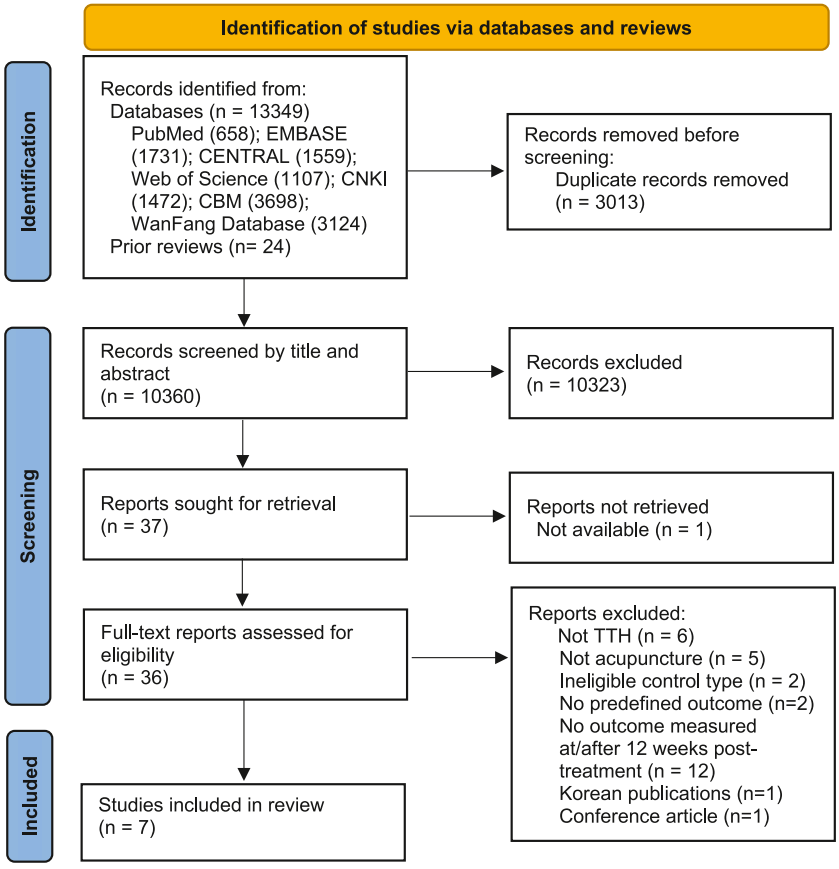

Fig. 1. Flow diagram of the identification of eligible studies.

Table 1
Characteristics of the included studies.

Study Location Center	Age Mean ± SD, years Female,%	Intervention				Control		Observation period, months	Measurement time points	Key outcome measurements
		Treatment	Sessions, n Time per session (min)	Duration, weeks	N	Type	N			
Tavola 1992 [29] Italy Single-center	32.9 ± 11.6 87%	Acupuncture	8 20 min	8	15	SA: non-acupoints in the same regions	15	15	4-week baseline period, 4 and 8 weeks of treatment, 1, 6 and 12 months after completion of treatment	Headache score; duration, frequency, andintensity of headache, analgesic use, response rate
Karst 2001 [27] Germany Single-center	48.1 ± 14.1 55%	Acupuncture	10 30 min	5	34	SA: non-penetrating placebo needle at the same acupoints	35	7.25	Immediately, 6 weeks and 5 months after treatment termination	Number of headache days per month, analgesic use, pain intensity, site and duration of headache attacks, VAS, CGI
Melchart 2005 [17] Germany Multicenter	42.7 ± 13.3 74%	Acupuncture	12 30 min	8	132	SA: superficial needling at non-acupoints	63	7	4-week baseline, 12 weeks and 21–24 weeks after randomization	Headache days, headache intensity, analgesic use, duration of headache, headache score, global intensity rating
Söderberg 2006 [30] Sweden Multicenter	37.5[a] 81%	Acupuncture	12 30 min	12	30	Physical training Relaxation training	30 30	10.5–11	4 weeks before, immediately after, and 3 and 6 months after the treatment period	Headache intensity, headache-free days, headache-free periods
Endres 2007 Germany Multicenter	39.1 ± 11.8 78%	Acupuncture	10[b] 30 min	6	209	SA: superficial needling at distant non-acupoints	200	7.5	At the end of the 4-week baseline, 6 weeks, 3 months and 6 months after randomization	Response rate, number of headache days per 4 weeks, von Korff chronic pain grading scale, global patient rating
Schiller 2021 [28] Germany Single-center	38.7 ± 13.3 78%	Acupuncture	12 30 min	6	24	Usual care	24	6	Baseline, 3 and 6 months after intervention start	Pain intensity, headache frequency, response rate, headache duration, medication use
		Acupuncture + MT	12 Acupuncture: 30 min; MT: 60 min	6	24	MT	24			
Zheng 2022 [18] China Single-center	43.1 ± 12.6 72%	Acupuncture	20 30 min	8	110	SA: superficially needling at the same acupoints	108	9	Every 4 weeks	Response rate, number of headache days, headache intensity, acute medication use

Note: SD, Standard Deviation; min, minute; N, the number of participants; SA, sham acupuncture; VAS, visual analog scale; CGI, clinical global impressions; MT, medical training (a combination of strength, endurance, flexibility and coordination training).

[a] The standard deviation (SD) of the age in this study was unavailable.

[b] If there is a moderate response, an additional 5 sessions may be scheduled.

2.6. Data synthesis and statistical analysis

Data synthesis and statistical analysis were all performed in R software (version 4.1.1) [25] using the meta package [26]. For the calculation of response rate, we used the number of patients randomized to a group as the denominator and considered patients with missing data as non-responders. For continuous measures, we utilized intention-to-treat (ITT) analyses with imputed missing values whenever possible; otherwise, we analyzed the available data only. We performed meta-analysis by statistically combining and summarizing the results of included studies to obtain a pooled estimate. The results of meta-analysis were illustrated using forest plots. The effect estimates for categorical variables were expressed using risk ratio (RR). As regarding safety outcomes, given that the number of events was generally very low, we calculated odds ratios (OR) rather than risk ratios. Risk ratios/odds ratios greater than 1 indicate a higher likelihood of events occurring in the acupuncture group compared to control. The effect estimates for continuous variables were expressed as mean differences (MD) or standardized mean differences (SMD). We reported pooled effect estimates along with their respective 95% confidence intervals (CIs). We also conducted the Chi^2 test for heterogeneity and calculated the I^2 statistic as a measure of heterogeneity among the included studies. If I^2<50%, indicating low to moderate heterogeneity, we used fixed-effects estimates for the pooled effect; otherwise, we reported random-effects estimates owing to substantial heterogeneity across the studies. Due to the limited number of trials available for each comparison, we did not assess publication bias.

3. Results

3.1. Characteristics of included studies

A total of 7 RCTs were identified from 13,373 citation records. The process of study selection was illustrated in Fig. 1, and the excluded studies with reasons were listed in Table S2. The included studies were published between 1992 and 2022 involving 3,221 participants. The key characteristics of the studies were detailed in Table 1. Four trials were conducted in Germany [16,17,27,28], one in Italy [29], one in Sweden [30], and one in China [18]. Three out of the seven trials were multi-centered trials [16,17,30].

One study [29] enrolled 30 TTH patients according to the criteria of the Ad Hoc Committee on Classification of Headache [31], while the remaining studies adopted the IHS criteria [1]. According to baseline headache days presented in the seven trials and the IHS criteria, all the participants enrolled had frequent episodic and/or chronic TTH. Two trials clearly reported they only included patients with chronic TTH [18,30], while the remaining trials enrolled both frequent episodic and chronic TTH patients. The observation period, including baseline period (1 month), ranged from 6 to 15 months. Four studies were two-armed trials which compared acupuncture with SA [16,18,27,29]. One study [30] had three arms and one had four arms [28]. The study by Melchart et al. [17] also included three groups: acupuncture, minimal acupuncture, and waiting list group. However, the waiting list group received acupuncture 12 weeks after randomization, and thus this arm was excluded from the analysis.

Patients received 8–20 sessions of acupuncture treatment delivered by qualified and experienced acupuncturists over 5–12 weeks. The details of acupuncture treatment protocol were presented in Table S3. As regarding the regimen of acupuncture treatment, all trials used a combination of local acupoints on the head and distal acupoints (located away from the area of symptoms or discomfort, head in this case), with GB20 (*Fengchi*) being the most frequently used acupoints. GB20 is located in the anterior region of the neck, inferior to the occipital bone, in the depression between the origins of sternocleidomastoid and the trapezius muscles. Deqi sensation was achieved in the acupuncture group across all included trials.

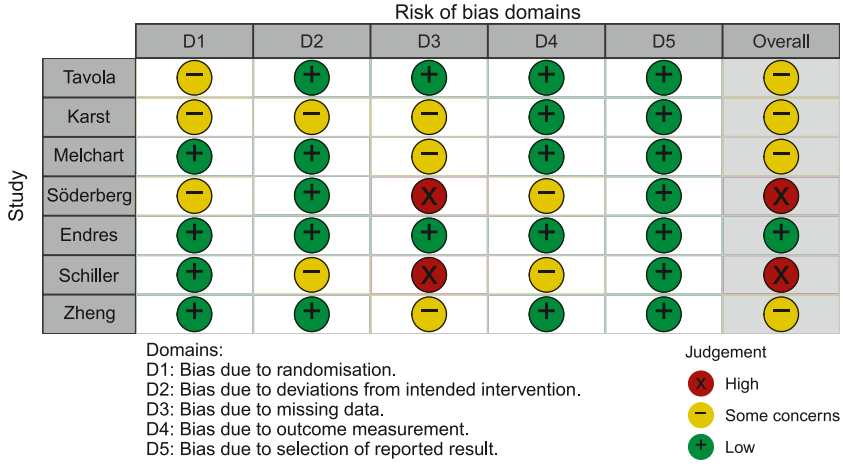

Fig. 2. Risk of bias summary.

3.2. Risk of bias

Among the included trials, two trials were judged to have a low risk of bias, three trials were judged to have some concerns, and two trials were judged to have a high risk of bias (Figs. 2 and 3). In terms of the randomization process, three trials were judged to have some concerns due to insufficient information on random sequence generation and allocation concealment, although no significant baseline differences between groups were observed [27,29,30]. For deviations from intended interventions, two trials were judged to have some concerns [27,28,30]. Karst and colleagues [27] did not use ITT analyses. Schiller et al. [28] claimed to have performed ITT analyses where possible but the results were poorly reported, making it unclear which part of the results were based on ITT population. As for missing data, five trials were judged to have some concerns or a high risk of bias after comprehensive consideration. The number of participants completed the last follow-up versus the number at randomization in each trial was 55/69 (80%) [27], 170/190 (90%) [17], 55/90 (61%) [30], 80/96 (83%) [28], 174/218 (80%) [18] respectively. Additionally, the number of and reason for dropouts were not balanced between groups, and these five trials did not report whether the result was biased by missing outcome data or perform any relevant analyses. For the domain of outcome measurement, two trials had some concerns because participants were not blinded and knowledge of the assigned intervention may have influenced participant-reported outcomes [28,30].

3.3. Acupuncture versus SA

3.3.1. Response rate

Compared to SA, acupuncture showed a significantly higher ($P<0.05$) response rate up to 6 months after completion of treatment. The association favoring acupuncture was observed at 1 months (RR 1.56, 95% CI 1.24 to 1.96), 3 months (RR 1.41, 95% CI 1.11 to 1.79), 6 months (RR 1.36, 95% CI 1.09 to 1.71) after completion of treatment (Fig. 4). However, at 12 months post-treatment, the effect estimate was statistically insignificant based on a small sample sized trial (1.50, 0.53 to 4.26, $P=0.45$) (Fig. 4).

3.3.2. Headache days

Overall, acupuncture reduced headache days up to 6 months after completion of treatment comparing to SA. The headache days decreased significantly ($P<0.05$) immediately (MD −3.36, 95% CI −4.76 to −1.96) and at 1.5 months (MD −2.14, 95% CI −3.52 to −0.76), 2 months (MD −4.70, 95% CI −5.09 to −4.31), 3 months (MD −4.86, 95% CI −5.24 to −4.48), 4.5 months (MD −2.40, 95% CI −3.80 to −1.00), 5 months (MD −3.55, 95% CI −6.97 to −0.13), and 6 months (MD −4.73, 95% CI −5.17 to −4.29) after the completion of acupuncture treatment, whereas no significant difference was observed at 1 month (MD −3.03, 95% CI −8.44 to 2.38) or 4 months (MD −3.29, 95% CI −7.73 to 1.15) post-treatment (Fig. 5).

3.3.3. Headache intensity

Pooled data indicated that acupuncture provided significantly alleviation versus SA in headache intensity from 3 to 6 months after treatment termination on the whole. Significant reduction ($P<0.05$) in headache intensity was observed at 3 months (SMD −0.32, 95% CI −0.59 to −0.06), 4 months (SMD −0.28, 95% CI −0.49 to −0.08), 5 months (SMD −0.34, 95% CI −0.57 to −0.11), and 6 months (SMD −0.43, 95% CI −0.70 to −0.16) post-treatment, while no superior improvements in headache intensity were found immediately (SMD 0.17, 95% CI −0.07 to 0.40) and at 1 month (SMD −0.01, 95% CI −0.21 to 0.20), 1.5 months (SMD −0.11, 95% CI −0.29 to 0.07), 2 months (SMD −0.13, 95% CI −0.40 to 0.13), 4.5 months (SMD −0.17, 95% CI −0.37 to 0.03) after treatment termination (Fig. 6).

3.3.4. Analgesic use

The results indicated that acupuncture did not reduce analgesic use compared to SA up to 12 months after completion of treatment (Fig. 7). Results of the proportion of participants with analgesic use showed similar results, with no significant association favoring acupuncture was observed up to 6 months post-treatment (Fig. S1).

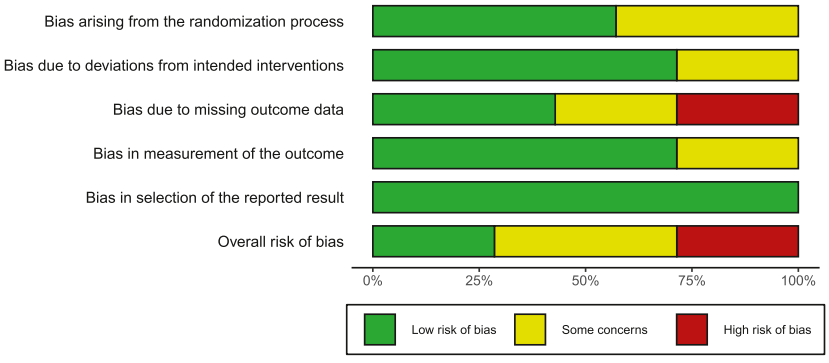

Fig. 3. Risk of bias graph.

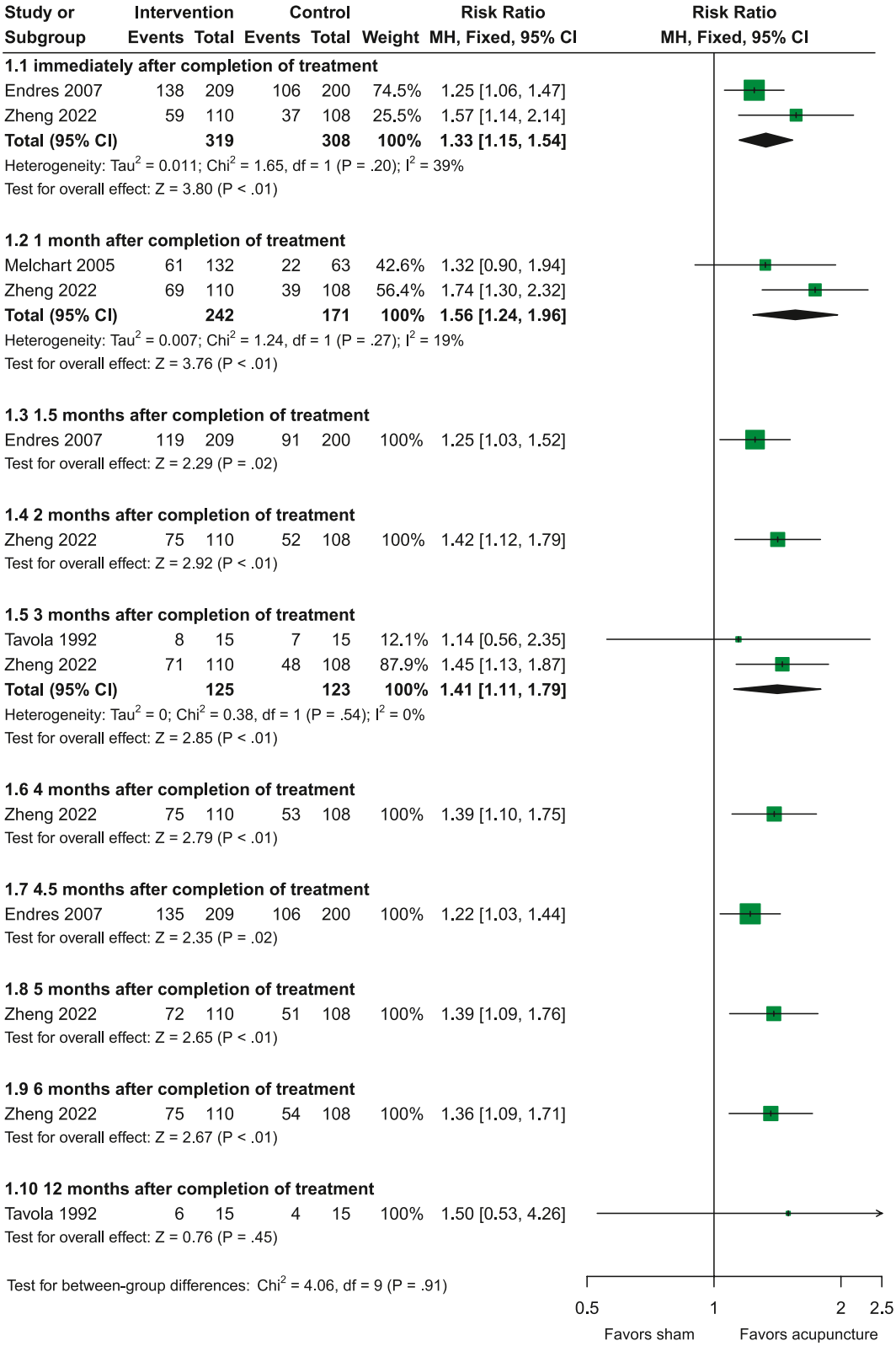

Fig. 4. Acupuncture versus sham acupuncture outcome 1: response rate.

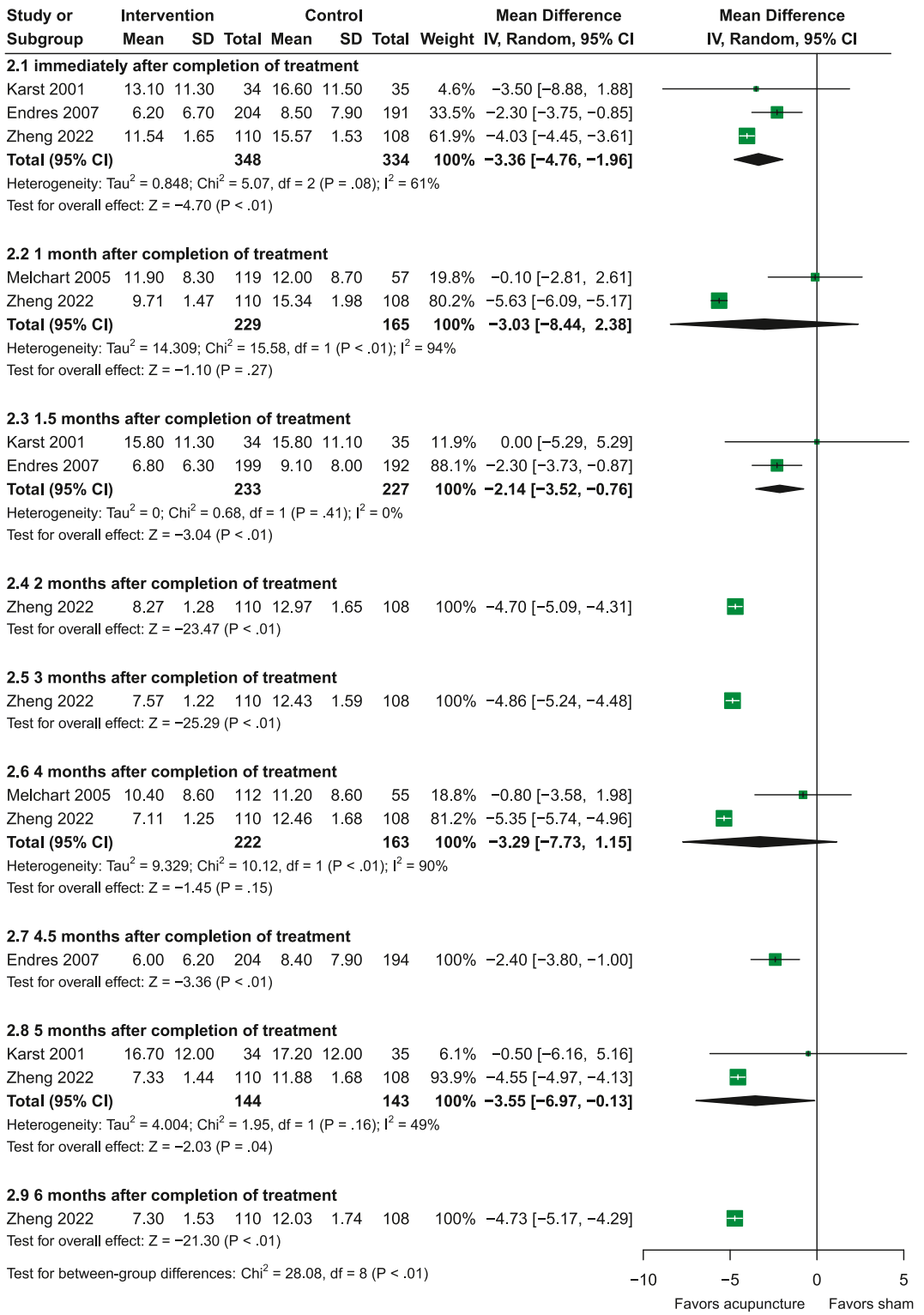

Fig. 5. Acupuncture versus sham acupuncture outcome 2: headache days.

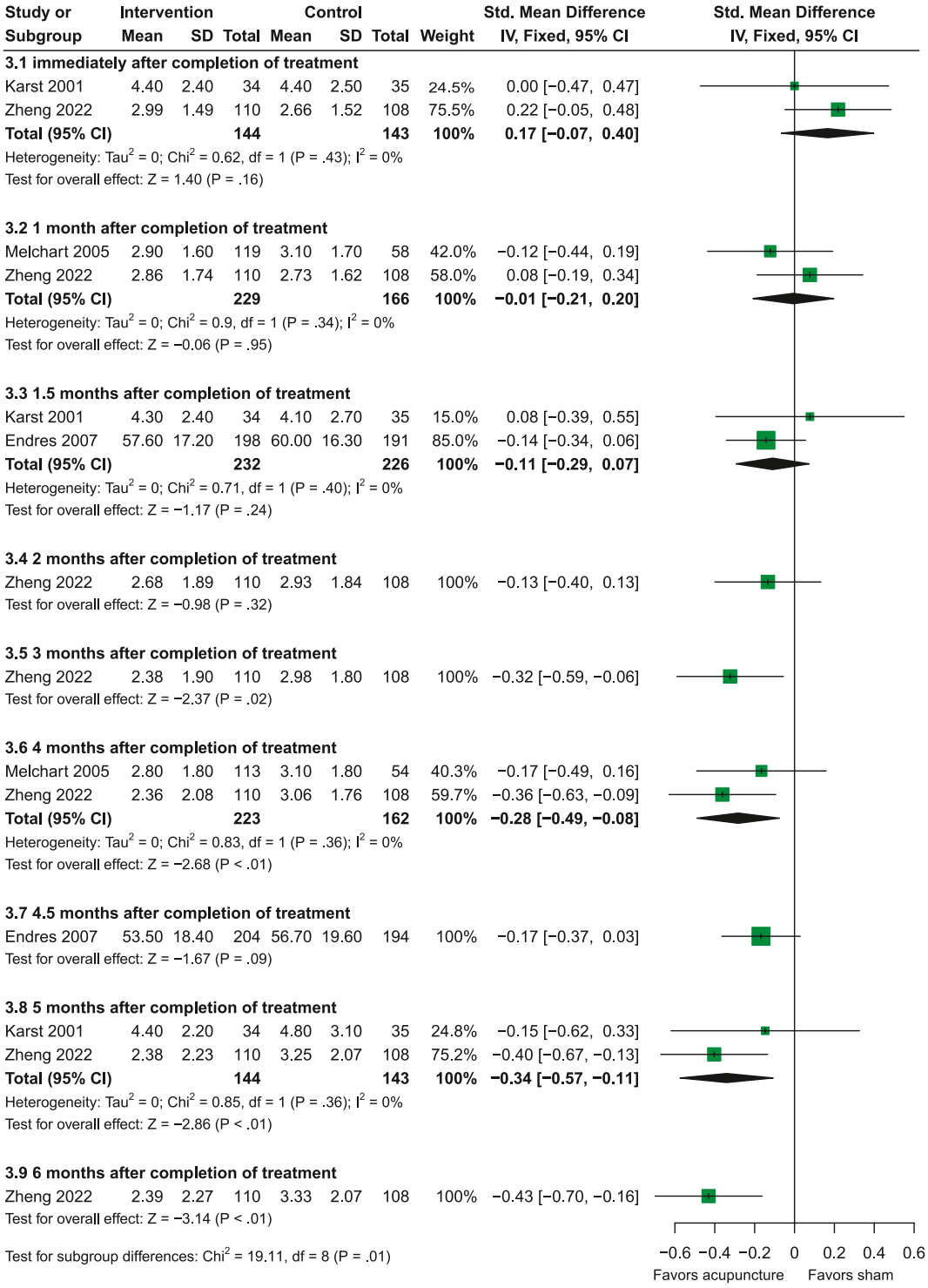

Fig. 6. Acupuncture versus sham acupuncture outcome 3: headache intensity.

3.4. Acupuncture versus physical training or relaxation training

One three-armed trial [30] compared acupuncture to physical training and relaxation training with 30 participants in each group. However, this trial did not report on response rate or safety outcomes. The number of headache-free periods and headache-free days were reported instead of the number of headache days. Outcomes were measured at 4 weeks before, immediately after, and 3 and 6

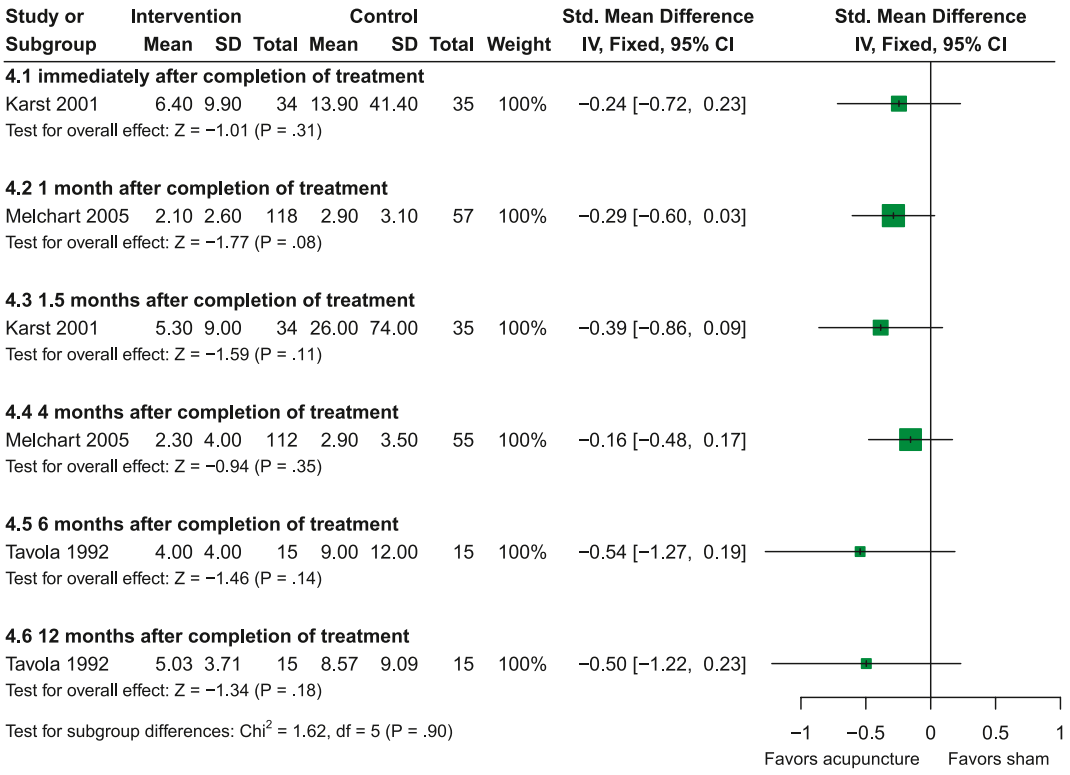

Fig. 7. Acupuncture versus sham acupuncture outcome 4: analgesic use.

months after the treatment. Continuous variables were presented with mean, median and range, so pooled effect size estimates cannot be calculated. No significant difference was found between the acupuncture and physical training groups in headache intensity, headache-free periods and headache-free days at both 3 and 6 months post-treatment [30]. Compared with acupuncture, the relaxation training group showed a significantly higher number of headache-free periods ($P<0.05$) and headache-free days ($P<0.01$) immediately after the last treatment. However, there was no significant difference between the relaxation training and acupuncture groups in headache intensity, headache-free periods or headache-free days at other time points.

3.5. Other comparisons

One trial [28] enrolled 96 adult patients with frequent episodic and chronic TTH and randomized them into four groups, usual care, acupuncture, medical training (MT, a combination of strength, endurance, flexibility, and coordination training), and combination of acupuncture and MT with 24 participants in each group. Outcomes were presented as a change in scores from baseline. However, the results presented should be interpreted with caution due to some methodological shortcomings. Only 80 of 96 (83%) participants completed the six-month follow-up. The author reported that all analyses were performed on an ITT-basis where possible, but it was unclear which part of the results were based on ITT population. Since the exact number of participants measured for each outcome were unclear, we cannot pool the effect size estimates. Only the combination therapy significantly reduced headache intensity compared to usual care at 3-month follow-up. No between-group differences were found in response rate, headache frequency, mean duration of headache episodes, and analgesic intake at the same time point. At 6 months follow-up, significantly higher response rates were found in all intervention groups compared with usual care, whereas no between-group differences were observed regarding other outcomes [28].

3.6. Safety

In trials comparing acupuncture with SA, four trials involving 703 patients [16,17,27,29] documented the number of participants dropping out due to adverse events. Only one such dropout was reported [17,28], which was due to intolerance of the needling. One trial documented adverse events in 23 patients (out of 132 patients) receiving acupuncture versus 11 patients (out of 63 patients) receiving SA, resulting in an insignificant OR of 1.00 (95% CI 0.45 to 2.20) (Fig. S2). Pooled results of adverse events also showed no statistically significant difference (OR 1.15, 95% CI 0.58 to 2.28, I^2=0%, 2 trials, 413 participants) (Fig. S2). All the adverse events reported were mild and resolved without requiring additional medical management, such as subcutaneous hematoma and pain at the penetration site. According to the trial by Schiller et al. [28], one patient in the acupuncture group withdrew from the trial due to fear

of acupuncture. Mild side effects were reported in a total of 25 cases, with 13 occurring in the acupuncture group, two in the MT group, and 10 in the combination group. The most common side effects were acute worsening of symptoms (five in the acupuncture group, one in the MT group, and six in the combination group) and hematoma (six in the acupuncture group, one in the combination group).

4. Discussion

In this study, we conducted data analyses using a monthly time frame, focusing on the measurement taken after completion of treatment to examine whether acupuncture has sustainable effects in treating TTH. Our results showed that acupuncture led to a higher response rate versus SA up to 6 months after completion of treatment. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) guideline recommends a threshold of 25% for minimal clinically important difference (MCID) for RR [32]. Pooled effect estimates of the primary outcomes, i.e. response rate, met the threshold at all time points except 4.5 months post-treatment. This suggests that acupuncture may provide clinically relevant improvement for TTH patients, and the benefit may persist for 6 months. The post-treatment results of acupuncture versus SA in headache days and headache intensity appeared consistent on the whole, showing association favoring acupuncture. However, no significant reduction of analgesic use was observed in the acupuncture group compared with SA post-treatment. These results indicate that the effects of acupuncture might be sustained for 6 months after completion of treatment. Moreover, no severe treatment-related adverse events were reported.

For the outcome of headache days at 1 month and 4 months post-treatment in acupuncture versus SA, analysis of data from two trials [17,18] yielded an insignificant effect estimate with considerable heterogeneity. Similar results were observed for the outcome of headache intensity at 1 month and 4 months post-treatment. The trial by Melchart et al. [17] reported that the improvements of headache days and headache intensity seen in the acupuncture and minimal acupuncture groups sustained throughout the follow-up period with no significant between-group difference. Similarly, according to the trial by Karst et al. [27], headache intensity and headache days decreased significantly from baseline ($P<0.001$) immediately, and at 6 weeks and 5 months after completion of treatment without significant difference between the acupuncture and SA (blunt needle placing at the same acupoints) groups. The strong and lasting response to SA was both intriguing and confounding, as it was designed to be a placebo intervention.

Our main findings align with the cumulative evidence that acupuncture demonstrates a modest and durable effects in various types of chronic pain including headache [19,33,34]. Linde et al. found that TTH patients receiving acupuncture reported a significant higher response rate than those receiving SA at three to four months (RR 1.27, 95% CI 1.09 to 1.48) and five to six months (RR 1.17, 95% CI 1.02 to 1.35) after randomization [19]. Furthermore, a recent review demonstrated that the effect of acupuncture for episodic migraine persisted for at least three months following treatment completion [33]. A prior individual patient data meta-analysis including 39 trials with 20,827 patients demonstrated that acupuncture was superior to both SA and no acupuncture control in treating chronic pain including headache, with effects potentially persisting for at least 12 months [34]. However, we did not find the effects sustained over 12 months due to insufficient information.

Moreover, acupuncture might have the potential to reduce analgesic use. Although no significant difference was found between acupuncture and SA in analgesic use post-treatment, there was a trend favoring acupuncture. Additionally, one trial showed that the number of patients with no medication use increased in the acupuncture group (n=28) versus SA group (n=17) [16]. Another study also reported that the number of patients discontinued acute medication use was higher in the acupuncture group (n=7) than SA group (n=3) at 24 weeks after completion of treatment [18].

Overall, the observed lasting effects of acupuncture compared to SA appear relatively consistent. However, due to the limited number of trials included, it is important to note that future studies could potentially result in significant revisions to our estimates. Moreover, the existing evidence is insufficient to evaluate the comparative durable effectiveness of acupuncture against other treatment options. Only one included trial [30] compared acupuncture with physical and relaxation training, while another trial [28] compared acupuncture with usual care and MT. Therefore, further studies with large sample sizes and rigorous methodologies, and diverse comparison groups are necessary to provide a comprehensive evaluation of the effects of acupuncture for TTH and its durability.

It is worthwhile to compare the durable effects of acupuncture with pharmacotherapy, but no such comparison was identified in our study. As regarding pharmacological preventive treatment for TTH, the tricyclic antidepressant amitriptyline is considered as first-line option, followed by mirtazapine and venlafaxine as second and third options [2]. However, the effects of these prophylactic drugs may be limited and treatment may be complicated by side effects including dizziness, somnolence, weight gain, and gastrointestinal disorders [2,14,35–38]. Evidence of high quality showed that acupuncture was comparable to amitriptyline in number of patients needed to treat for a patient to have a beneficial outcome (number needed to treat [NNT], 11 vs 12) with a higher number of patients needed to treat for a patient to have an adverse event (number needed to harm [NNH], acupuncture vs amitriptyline, 20 vs 2 [1.6 to 2.6]) [14,19,39]. The NNH for mirtazapine (NNH=4) and venlafaxine (NNH=6) were also higher than acupuncture [40–42]. These findings suggest that acupuncture is an effective treatment modality with a good safety profile, potentially serving as an alternative to pharmacological options. Nevertheless, further research is required to directly compare the durable effects of acupuncture and pharmacotherapy for TTH.

The potential durable effects of acupuncture for TTH may have a positive influence on both individuals and society. By providing sustained relief, acupuncture may improve an individual's functional capacity, enhance their overall well-being, and improve their productivity. As a non-pharmacological treatment option, it may reduce reliance on medication, potentially decreasing the risk of medication-overuse headache and healthcare costs. The durability of the effects of acupuncture may allow for ongoing management of the disease and reduce the need for frequent treatment, hopefully making it cost-effective.

This review possesses several strengths. We conducted a comprehensive search of both English and Chinese databases, and

examined the durable effects of acupuncture on TTH by analyzing all available outcomes measured following the completion of treatment. This approach affords a comprehensive summary of existing evidence, potentially informing clinical decision-making and facilitating the formulation of evidence-based guidelines. Additionally, we discerned methodological constraints in previous investigations, thereby providing valuable insights for future studies.

There are several limitations in this review. First, we did not take ongoing trials or trial registries into consideration. Second, due to an insufficient number of trials to analyze, publication bias was not assessed. Third, the loss to follow-up may lead to potential impact on the effect size estimates. Fourth, limited trials were included in this review with low sample sizes and overall risk of bias with some concerns, which may undermine the certainty of the evidence. Therefore, our findings should be interpreted with caution. Future trials with rigorous study design and long-term follow-up are warranted.

5. Conclusion

Acupuncture might provide durable effects compared with SA in managing frequent episodic and chronic TTH for 6 months after treatment completion without severe adverse events. However, the evidence is of limited certainty. Future studies with rigorous design are needed to further investigate the durability of the effects of acupuncture for TTH.

Data availability statement

Data were included in this article and supplementary materials.

Ethical approval statement

Not applicable.

CRediT authorship contribution statement

He Chen: Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Hangyu Shi:** Writing – original draft, Visualization, Software, Formal analysis. **Shuai Gao:** Writing – original draft, Visualization, Software, Formal analysis. **Jiufei Fang:** Writing – original draft, Visualization, Software. **Xinkun Liu:** Writing – original draft, Visualization, Software. **Zhishun Liu:** Writing – review & editing, Supervision, Conceptualization.

Declaration of competing interest

The authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e32174.

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