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Effectiveness of Acupuncture Combined with Tuina Therapy for Headache: a Systematic Review and Meta-analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Support - No support.

Review stage at the time of initial registration - Data analysis.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 November 2026 and was last updated on 24 November 2026.

INTRODUCTION

Review question / Objective To evaluate the therapeutic efficacy of acupuncture combined with Tuina therapy compared with conventional pharmacological treatment in individuals presenting with headache.

Rationale Acupuncture and Tuina therapy are widely applied in Traditional Chinese Medicine for pain management; however, a systematic evaluation comparing their combined application against conventional pharmacological treatments for headache symptoms remains necessary to provide robust clinical evidence.

Condition being studied The PICO (population, intervention, comparison, outcome) setting of the current meta-analysis included: (1) P: individuals presenting with headache; (2) I: acupuncture combined with Tuina therapy; (3) C: conventional pharmacological treatment; and (4) O: changes in headache-related symptoms.

METHODS

Search strategy Two independent authors (YC-Hsu and PW-Wang) conducted electronic searches in PubMed, Cochrane Library, ClinicalTrials.gov, and China National Knowledge Infrastructure (CNKI) databases using the following keywords: ("Acupuncture" OR "Needle Acupuncture" OR "Electroacupuncture" OR "Auricular Acupuncture" OR "Abdominal Acupuncture" OR "Umbilical Acupuncture" OR "Laser Acupuncture" OR "Low-level Laser Therapy" OR "Photobiomodulation Therapy" OR "Catgut Embedding" OR "Catgut Implantation" OR "Thread Embedding" OR "Thread Implantation" OR "Acupotomy") AND ("Tuina" OR "Massage" OR "Manipulation" OR "Manual Therapy") AND ("Headache" OR "Migraine") from the earliest available records in each database through December 31, 2025. No language restrictions were applied.

Participant or population Individuals presenting with headache.

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Intervention Acupuncture combined with Tuina therapy (with Tuina based on TCM theories including acupuncture points and meridians).

Comparator Conventional pharmacological treatment.

Study designs to be included Randomized controlled trials.

Eligibility criteria Studies were included if they met the following criteria: (1) RCTs involving human participants, (2) quantitative assessment of headache symptoms performed before and after acupuncture and Tuina therapy, and (3) headache assessments or pain score data reported both before and after the intervention. Studies were excluded if they: (1) were non-randomized controlled trials, (2) administered only acupuncture or only Tuina therapy, (3) utilized other TCM interventions such as Chinese Herbal Medicine or herbal patching, (4) applied Tuina therapy based on anatomical principles rather than TCM theories including acupuncture points and meridians, (5) employed a non-pharmacological comparator, (6) lacked quantitative assessment of headache, (7) were ongoing studies, or (8) enrolled participants that overlapped with previously published trials.

Information sources Electronic searches were conducted in PubMed, Cochrane Library, ClinicalTrials.gov, and China National Knowledge Infrastructure (CNKI) through December 31, 2025. In addition, manual searches and reviews of citation sources of screened articles were performed.

Main outcome(s) The primary outcome was the effective rate of headache improvement following treatment. Because the definition of "effective rate" varied across studies (with some stratifying responses into cured, markedly effective, or improved), while "non-effective" (defined as a symptom score reduction of less than 20% from baseline) was consistently defined, the effective rate was calculated as 100% minus the non-effective rate by author consensus (YC-Hsu, PW-Wang). The effective rate was quantified using risk ratios (RRs).

Additional outcome(s) Secondary outcomes included headache-related assessments such as pain severity (Visual Analogue Scale [VAS] and Present Pain Intensity [PPI]), headache duration, frequency of attack, and quality of life. These continuous outcomes were quantified using the mean difference (MD) when studies employed the same measurement scale, and the standardized mean difference (SMD) when different measurement scales were used across studies.

Data management Title and abstract screening was conducted by two independent authors (YC-Hsu and PW-Wang) with eligibility determined by consensus; a third reviewer (HR-Yen) was consulted to resolve disagreements.

Quality assessment / Risk of bias analysis To investigate the methodological quality of recruited studies, we used the Cochrane risk-of-bias tool for randomized trials, version 2 (RoB 2), which consisted of 6 main items: randomization process, intervention adherence, missing outcome data, outcome measurement, selective reporting, and overall risk of bias. In the intervention adherence section of RoB 2, there are two options for literature assessment: intention-to-treat (intervention assignment) or per-protocol (intervention adherence). In this meta-analysis, we chose the per-protocol evaluation, since it fits the design of our included studies.

Strategy of data synthesis Statistical analyses were performed using Comprehensive Meta-Analysis software (Version 3; Biostat, Englewood, NJ, USA). Given the anticipated clinical and methodological variability among the included patient cohorts, a random-effects model was predefined to synthesize all pooled estimates. All statistical tests were two-sided, with significance established at $p < 0.05$. We used risk ratios (RRs) and their associated 95% confidence intervals (CIs) to evaluate the primary outcomes (i.e., effective rates). Model stability and the influence of individual studies were tested via leave-one-out sensitivity analyses. The secondary outcomes (i.e., frequency, PPI, quality of life, severity, and VAS) were evaluated with Hedges' g and 95% CIs. For the incidence of adverse events, pooled odds ratios (ORs) and 95% CIs were estimated. Between-study heterogeneity was quantified using Cochran's Q test and the I2 index, where values approximating 25%, 50%, and 75% represented mild, moderate, and substantial heterogeneity, respectively. Potential publication bias was appraised through visual inspection of funnel plot asymmetry.

Subgroup analysis Not applicable.

Sensitivity analysis To confirm the robustness of the meta-analysis, the sensitivity analyses were performed using one-study removal method to see if there was a significant change in the summary effect size after removing a particular trial from the analysis.

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Language restriction No language limit.

Country(ies) involved Taiwan.

Keywords Headache, acupuncture, Tuina, systematic review, meta-analysis.

Contributions of each author

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