

Efficacy and Safety of Integrated Traditional Chinese and Western Medicine for Acute Ankle Sprain: A Systematic Review and Meta-Analysis

INPLASY2026100065

doi: 10.37766/inplasy2026.10.0065

Received: 14 October 2026

Published: 14 October 2026

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ADMINISTRATIVE INFORMATION**Support** - No support.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2026100065**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 October 2026 and was last updated on 14 October 2026.**INTRODUCTION**

Review question / Objective ****Objective**:**
RTo systematically assess the efficacy and safety of integrated traditional Chinese-Western medicine versus Western-medicine-alone therapy for patients with acute ankle sprain (AAS).

****PICOS****

- ****Population (P)**:** Patients diagnosed with acute ankle sprain (AAS); excluding those with chronic ankle instability, ankle fractures, or Grade III ligamentous injuries.
- ****Intervention (I)**:** Integrated traditional Chinese and Western medicine (conventional Western-medicine care plus TCM interventions e.g., herbal medicine (oral/topical/fumigation-washing), acupuncture, manipulative therapy).
- ****Comparator (C)**:** Western-medicine-alone treatment, including RICE / PRICE / POLICE

protocols, NSAIDs, and standard physical management for acute ankle sprain.

- ****Outcomes (O)**:** Primary outcomes: total effective rate, pain intensity (VAS), ankle function (AOFAS score), ankle swelling (ankle-circumference change). Secondary outcome: adverse-event incidence.
- ****Study design (S)**:** Randomized controlled trials (RCTs).

Condition being studied Acute ankle sprain (AAS) is a common orthopaedic and sports-related soft-tissue injury, mostly triggered by external ankle trauma that damages peri-ankle ligaments, tendons and surrounding structures. It accounts for up to 30 % of all lower-limb injuries, with high recurrence risk among people who have suffered prior ankle sprains.

Typical clinical manifestations include sharp local pain, tissue swelling, joint stiffness and restricted ankle mobility, which interfere with patients' daily activities and work performance. Without timely and appropriate treatment, around 74 % of patients

may develop persistent residual symptoms such as lingering pain, swelling, reduced muscle strength and joint instability, known as chronic ankle instability. Severe ligament rupture may even require surgical repair and potentially impair occupational function.

Clinically, AAS excludes grade-III complete ligament rupture and concurrent ankle fracture. In traditional Chinese medicine theory, acute ankle sprain falls under “ankle tendon injury”, whose core pathogenesis is qi stagnation and blood stasis: traumatic injury disrupts normal qi-blood circulation, leading to blood extravasation, stasis accumulation and subsequent local pain and swelling. Current Western-medicine conservative management follows the RICE or updated POLICE principle together with non-steroidal anti-inflammatory drugs for symptom control, yet it has limitations in preventing chronic sequelae and long-term functional impairment.

METHODS

Participant or population This review included participants diagnosed with **acute ankle sprain (AAS)** according to explicit diagnostic criteria. Eligible participants were patients with recent-onset ankle ligament soft-tissue injury, without ankle fracture or Grade III complete ligament rupture. Participants with ankle injury lasting longer than one month, chronic ankle instability or chronic ankle pain were excluded.

The included RCTs mainly enrolled young-to-middle-aged adults (predominant age range 23-50 years). All primary studies were conducted in China. No restrictions were applied regarding gender. Total pooled participants across 41 included trials were 3326 patients (1669 experimental-group participants, 1657 control-group participants).

Intervention The intervention evaluated in this review is **integrated traditional Chinese-Western medicine therapy for acute ankle sprain (AAS)**. This combined therapy consists of standard Western-medicine baseline management plus additional traditional Chinese medicine (TCM) treatments.

The underlying Western-medicine component includes conventional acute-ankle-sprain care following RICE, PRICE or POLICE principles, non-steroidal anti-inflammatory drugs (oral or topical), and routine physical therapy. Added TCM modalities varied across included RCTs, covering topical herbal applications, herbal

fumigation-washing, oral herbal prescriptions, acupuncture, and TCM manipulative therapies. Multiple TCM modalities could be used alone or in combination within the experimental group. Oral herbal preparations with undefined compositions were excluded.

Treatment durations of the integrated interventions ranged from 2 days to 21 days; 14-day treatment courses were most frequently reported, followed by 7-day regimens.

Comparator The comparator in this review is **Western-medicine-only treatment for acute ankle sprain (AAS)**.

Control group interventions consisted of standard conservative Western-medicine management for acute ankle sprain, including injury-management protocols following RICE, PRICE or POLICE principles, non-steroidal anti-inflammatory drugs (oral or topical NSAIDs), and relevant physical therapy. No additional traditional Chinese medicine therapies (e.g., herbal preparations, acupuncture, manipulative treatments) were permitted for comparator participants.

Treatment duration in comparator arms ranged from 2 days to 21 days, matching the timeframes used in the corresponding integrated-therapy experimental groups across included RCTs.

Study designs to be included Only **randomized controlled trials (RCTs)** are eligible for this review. Non-randomised studies, quasi-RCTs, case reports, case series, reviews, conference abstracts without full-text data and observational studies are excluded. Included RCTs must report extractable outcome data comparing integrated traditional Chinese-Western medicine versus Western-medicine-alone for acute ankle sprain. Only **randomized controlled trials (RCTs)** are eligible for this review. Non-randomised studies, quasi-RCTs, case reports, case series, reviews, conference abstracts without full-text data and observational studies are excluded.

Eligibility criteria Beyond PICOS-defined population, intervention, comparator, outcome and study-design criteria, additional inclusion and exclusion criteria are specified below.

****Additional inclusion criteria****

1. Full-text publications must be obtainable, with extractable quantitative or qualitative outcome data.

2. Trials were published from database inception up to May 8, 2026, in Chinese or English language.

****Additional exclusion criteria****

1. Duplicate publications of the same trial.
2. Trials recruiting patients with ankle fractures or Grade III complete ligamentous injuries.
3. Participants suffering ankle sprain lasting > 1 month, presenting chronic ankle instability or chronic ankle pain.
4. Interventions containing oral herbal medicines with undefined compositions.
5. Studies reporting data as median-interquartile range that cannot be converted to mean $\pm$ standard deviation, containing obvious logical data errors or missing key verifiable information.

Information sources Electronic databases will be searched from inception up to 8 May 2026, covering both Chinese-language and English-language resources.

English databases: PubMed, Embase, Cochrane Library.

Chinese databases: CNKI, VIP, Wanfang.

Reference lists of included full-text articles will be manually screened to identify additional potentially eligible studies. Where key data are missing from published reports, we will attempt to contact original study authors for supplementary information. Trial registers and grey-literature sources are not routinely searched for this review.

Main outcome(s) ****Primary-efficacy outcomes****

1. Total effective rate (dichotomous outcome, effect measure: risk ratio (RR) with 95% CI): comprehensive therapeutic response after completion of the scheduled treatment course.
2. Pain intensity: measured by Visual Analogue Scale (VAS; continuous outcome, effect measure: mean difference (MD) with 95% CI), assessed post-treatment.
3. Ankle function: evaluated by American Orthopaedic Foot and Ankle Society (AOFAS) score (continuous outcome, MD with 95% CI), measured at post-treatment time-points.
4. Ankle swelling: reflected by change in ankle circumference (continuous outcome, MD with 95% CI), compared after intervention.

****Safety outcome****

5. Adverse-event incidence (dichotomous outcome, RR with 95% CI): number of participants experiencing adverse reactions during treatment follow-up.

Outcomes are assessed at the end of each study's intervention period (treatment durations ranging 2-21 days). Studies reporting median-interquartile range without convertible mean-SD data were excluded from quantitative meta-analysis and handled descriptively.

Quality assessment / Risk of bias analysis The Cochrane-recommended ****Risk of Bias 2.0 (ROB 2.0)**** tool was used to assess risk of bias for included randomized controlled trials. Five evaluation domains were covered: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result.

Each domain was judged as low risk of bias, some concerns, or high risk of bias. Overall risk-of-bias judgements were generated by the ROB 2.0 built-in algorithm: overall low risk required all domains to be low risk; some concerns applied if at least one domain showed some concerns with no high-risk domains; overall high risk occurred if any single domain was rated high risk.

Two reviewers independently completed assessments; disagreements were resolved by discussion or consultation with a third reviewer. Assessment outputs were presented in supplementary risk-of-bias summary and proportion figures.

Strategy of data synthesis All statistical analyses were performed using Stata 15.0. Dichotomous outcomes were pooled using risk ratio (RR) with 95% confidence intervals (CIs); continuous outcomes used mean difference (MD) with 95% CIs.

Heterogeneity was assessed via Cochran Q test ($\alpha = 0.1$) and I^2 statistic. Fixed-effects model was applied for low heterogeneity ($P \geq 0.1$, $I^2 \leq 50\%$); random-effects model was used for substantial heterogeneity ($P < 0.1$, $I^2 > 50\%$). Studies reporting medians-interquartile ranges that could not convert to mean $\pm$ SD, or containing uncorrectable logical data errors, were excluded from meta-analysis and described narratively.

Pre-specified subgroup analyses explored heterogeneity sources according to intervention duration, comparator type and overall risk-of-bias rating. Univariate meta-regression (REML method) used sample size and mean age as covariates to detect heterogeneity moderators.

Sensitivity analyses tested the robustness of pooled results. For outcomes with ≥ 10 studies, funnel plots and Egger's test assessed publication bias (two-tailed $P > 0.05$ regarded as no significant publication bias).

Subgroup analysis Pre-specified subgroup analyses were planned to explore potential sources of statistical heterogeneity. Subgroup stratification factors included: (1) intervention duration (≤ 7 days versus > 7 days); (2) comparator intervention type (with versus without topical medications); (3) overall risk-of-bias rating (low risk, some concerns, high risk).

Pooled effect sizes were compared across subgroups for pain (VAS) and ankle function (AOFAS) outcomes. After stratification, substantial heterogeneity ($I^2 > 50\%$) persisted in most subgroups. Only the high-risk-of-bias subgroup showed markedly reduced heterogeneity (VAS: $I^2 = 0\%$; AOFAS: $I^2 = 48.8\%$). No statistically significant differences in effect magnitudes were detected between any subgroups (all $P > 0.05$). These findings indicated that the three predefined factors could not explain the observed heterogeneity. All subgroup results were presented in supplementary forest plots.

Sensitivity analysis Sensitivity analyses were performed to test the robustness of pooled meta-analysis results. Analyses were carried out for all quantitative pooled outcomes including total effective rate, VAS pain score, AOFAS ankle-function score, ankle swelling and adverse-event incidence.

The sensitivity analysis approach relied on iteratively omitting individual studies one-by-one to assess whether removing any single trial substantially altered the pooled effect size, confidence interval or statistical significance.

After exclusion of individual studies, no material changes were observed for any pooled estimates. Pooled effect directions, magnitude and statistical significance remained stable across all outcomes, demonstrating that the meta-analytic findings were robust and not driven by any single included study. Results of sensitivity analyses were presented in corresponding supplementary figures for each outcome.

Country(ies) involved China.

Keywords Acute ankle sprain; Integrative traditional Chinese and Western medicine; Efficacy; Meta-analysis.

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