Journal of Pain Research

Dovepress
Taylor & Francis Group

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STUDY PROTOCOL

Electroacupuncture Combined with Diclofenac Emulgel for Post-Traumatic Ankle Osteoarthritis: A Randomized Controlled Trial Protocol

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Purpose: Post-traumatic ankle osteoarthritis (PTAOA) is a common chronic condition associated with persistent pain, functional limitation, and reduced quality of life. Electroacupuncture (EA) has shown potential as a non-pharmacological intervention for osteoarthritis, but high-quality evidence in PTAOA remains limited. This study aims to evaluate the efficacy and safety of EA combined with topical diclofenac emulgel in patients with PTAOA and to explore potential inflammatory mechanisms.

Patients and Methods: This is a single-center, randomized, sham-controlled superiority trial. A total of 78 patients with PTAOA will be randomly assigned in a 1:1 ratio to either the EA group or the sham acupuncture (SA) group. Both groups will receive topical diclofenac emulgel (2 g per dose, twice daily) for 4 weeks, together with standardized education regarding PTAOA management. Participants in the EA and SA groups will receive 20 treatment sessions over 4 weeks. The primary outcome is the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale (AOFAS). Secondary outcomes include the Short-Form McGill Pain Questionnaire (SF-MPQ), Foot and Ankle Ability Measure (FAAM), 36-Item Short Form Health Survey (SF-36), musculoskeletal ultrasound findings, and serum levels of TNF-α, IL-6, and IL-1β. Clinical outcomes will be assessed at baseline, week 2, week 4, and week 8, while musculoskeletal ultrasound and serum inflammatory markers will be assessed at baseline and week 4.

Discussion: This study will provide more comprehensive evidence regarding the efficacy and safety of EA combined with topical diclofenac emulgel for PTAOA and may help clarify its potential anti-inflammatory effects.

Trial registration Registry: International Traditional Medicine Clinical Trial Registry (ITMCTR), No. ITMCTR2025001585; registered on 24 July 2025.

Keywords: electroacupuncture, post-traumatic ankle osteoarthritis, diclofenac emulgel, TNF-α, IL-6, IL-1β

Introduction

Ankle osteoarthritis (OA) is a chronic degenerative disease that is common, frequent and refractory in middle-aged and elderly people. Recent studies have shown that about 7% of the world's population is affected by OA with more than 500 million people suffering from it.[1] PTAOA is the predominant form of the case of ankle OA, accounts for 70–78%,[2,3] which is also the main cause of foot and ankle pain in patients over 50-year-old. Joint pain, dorsiflexion and toe flexion, joint swelling or deformity are the main clinical manifestations of PTAOA; X-ray examination (weight-bearing position) shows subchondral bone sclerosis, osteophyte formation, narrowing of joint space and even deformity[4] in PTAOA patients, who have a previous history of ankle trauma such as ankle fracture and ligamentous sprain. Research indicates

https://doi.org/10.2147/JPR.S601713
Received: 6 February 2026
Accepted: 23 April 2026
Published: 11 May 2026

that the incidence of PTAOA is gradually affecting younger individuals, especially among young people who are passionate about sports.[5] Therefore, the threat posed by PTAOA to humans is rapidly increasing, making research on it urgent and crucial.

There are currently no treatment guidelines for the ankle OA, the similarity of the conditions and the impairment of pain, physical and emotional function in ankle,[6] knee[7] and hip[8] OA suggest that similar approaches may be effective in managing these conditions. However, ankle OA is mainly secondary to trauma[9,10] due to the differences in cartilage structure and biology between the ankle and knee,[5] whose chondrocytes respond differently to abnormal mechanical stress and some inflammatory factors from other joints. The inflammatory environment caused by ankle fractures is believed to accelerate the degenerative process throughout the ankle joint. Additionally, ligament instability and laxity of the ankle soft tissue supporting structures increase joint contact pressure leading to degenerative lesions. Therefore, it is important not to extrapolate findings at the knee to the ankle.

Currently, treatment for ankle OA consists of surgical and conservative treatment. Conservative treatment includes lifestyle modifications, pharmacological therapy, physical therapy, and joint injections. Pain medications such as paracetamol and non-steroidal drugs are commonly prescribed as the first-line drugs for OA patients,[11–13] while medications have uncertain benefits and potential risks of adverse effects. Although it has been suggested that intra-articular injection[14,15] and surgery[16] may relieve symptoms of OA, a subset of patients hesitate to undergo these procedures due to concerns about the risk of complications.

Non-steroidal anti-inflammatory drugs (NSAIDs) are currently effective for improving pain in OA patients, especially diclofenac. However, they require long-term administration and carry a series of side effects affecting the gastrointestinal tract, cardiovascular system, and kidneys; in particular, for elderly patients with other comorbidities who require concurrent administration of other medications, this increases the risk of adverse reactions or drug interactions, which some patients cannot tolerate.[17,18] Topical NSAIDs are recommended as first-line treatment for osteoarthritis pain according to the Chinese guideline for diagnosis and treatment of osteoarthritis (2021 edition).[19] Compared with systemic administration, topical treatment with diclofenac diethylamine emulsion offers numerous advantages, such as direct action on the site of pain, reduced systemic exposure, a lower incidence of related side effects, and improved safety.[20,21]

Non-drug therapies for the treatment of mild to moderate PTAOA have attracted more and more attention. Acupuncture is a traditional therapy with thousands of years of development in China. As a comprehensive or adjunctive therapy, acupuncture is widely used in pain management, particularly for musculoskeletal disorders, where it can significantly alleviate patients' pain and swelling due to its anti-inflammatory and analgesic properties, offering advantages such as good tolerability and a low risk of serious adverse effects. EA, the type of acupuncture which has been found to have persistent analgesic effects on chronic pain,[22] is recommended for research by National Institute for Health and Clinical Excellence. Some studies[23–25] suggested that acupuncture may be effective for PTAOA; however, the evidence is limited and reflects a lack of high-quality investigations.

The persistent inflammatory microenvironment following joint trauma is considered a key link in the progression of PTAOA from mechanical injury to structural degeneration. Studies indicate that ankle fractures and chronic instability following ankle sprains are the primary risk factors for PTAOA.[26] Meanwhile, studies have shown that a persistent inflammatory microenvironment remains within the ankle following joint injury.[27–29] After ankle fracture, fibrous scar tissue tends to accumulate within the joint; this tissue possesses high catabolic and inflammatory activity, and its long-term detrimental effects on cartilage degeneration are closely associated with the occurrence and development of PTAOA. The association between pro-inflammatory cytokines and joint function or pain levels has also been confirmed.[30] The pro-inflammatory cytokines TNF-α, IL-6, and IL-1β in fibrous scar tissue, acting as major catabolic cytokines responsible for cartilage destruction, participate in the occurrence and development of OA.[16,31–34] Therefore, these three biomarkers possess both inflammatory significance and biological relevance related to structural degeneration.

Persistent inflammation after ankle trauma is considered a key contributor to the progression of post-traumatic ankle osteoarthritis (PTAOA), linking mechanical injury to ongoing cartilage degeneration and symptom persistence. Previous studies have suggested that EA may have analgesic and anti-inflammatory effects in osteoarthritis; however, high-quality evidence in PTAOA remains limited. Therefore, this randomized, sham-controlled superiority trial aims to determine whether EA combined with topical diclofenac emulgel provides greater improvement in ankle function and symptoms

than sham EA combined with topical diclofenac emulgel in patients with PTAOA. In addition, this study will explore whether the clinical effects of EA are accompanied by changes in serum TNF-α, IL-6, and IL-1β levels.

Material and Methods

Study Design

This study is a single-center, two-arm, randomized, sham-controlled superiority trial conducted in China. A total of 78 patients with post-traumatic ankle osteoarthritis (PTAOA) will be randomly assigned in a 1:1 ratio to either the EA group or the sham EA group. The total study duration for each participant will be 8 weeks, including 4 weeks of treatment and 4 weeks of follow-up. The study protocol has been approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (Approval No. BZYSY-2025YJSKTPJ-24), the original protocol was show up detaily in Additional File 1. This protocol is reported in accordance with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT),[35] as detailed illustrated in Table 1. The SPIRIT checklist is provided in Additional file 2.

Study Site

Recruitment from orthopedic outpatient clinics targeting post-traumatic cases post-ankle fracture/sports injury. Recruitment, intervention and follow up will be conducted at the third Hospital Affiliated to Beijing University of

Table 1 SPIRIT Schedule

	Study Period				
	Enrolment	**Allocation**	**Post-Allocation**		**Close-Out**
Timepoint	Week −1	0	Week 2	Week 4	Week 8
Enrolment					
Eligibility screen	X				
Informed consent	X				
(List other procedures) Preparation period					
Allocation		X			
Interventions:					
Electroacupuncture & Diclofenac Diethylamine Emulgel		X◄———	———	———►X	
Sham acupuncture and Diclofenac Diethylamine Emulgel		X◄———	———	———►X	
Assessments:					
AOFAS*		X	X	X	X
FAAM		X	X	X	X
SF-MPQ		X	X	X	X
SF-36		X	X	X	X
Musculoskeletal Ultrasound		X		X	
Collect venous blood		X		X	
Combine medications		X◄———	———	———	———►X
Adverse event		X◄———	———	———	———►X

Notes: Indicators: *, primary outcome. X, required. ↔, continuous delivery of interventions and assessments.
Abbreviations: AOFAS, American Orthopedic Foot and Ankle Society Ankle-Hindfoot Scale; FAAM, Foot and Ankle Ability Measure; SF-MPQ, simplified McGill Pain Questionnaire; SF-36, Short for 36 Dimensions.

https://doi.org/10.2147/JPR.S601713

Chinese Medicine. Recruitment will occur in outpatient departments, interventions and follow-up will take place in certain rooms within the hospital.

Participants

Diagnostic Criteria

Patients, refer to the diagnostic criteria for AOA in the China Osteoarthritis Diagnosis and Treatment Guidelines (2024 Edition, CODTG),[4] will be required to meet the following requirements: (1) Weight-bearing pain in the ankle joint; (2) limited joint dorsiflexion and toe flexion; (3) Joint swelling and deformity; (4) X-ray (standing position) within 12 months shows subchondral osteosclerosis, osteophyte formation, joint space narrowing and even deformity; (5) Diagnosis confirmed if above criteria met, excluding other etiologies (eg., rheumatoid OA). Diagnosis will be performed by hand and foot surgeons.

Inclusion Criteria

Patients will be eligible for inclusion if they meet all of the following criteria: (1) meet the diagnostic criteria for PTAOA; (2) meet the traditional Chinese medicine (TCM) syndrome diagnosis of Gu Bi, a TCM pattern characterized by chronic joint pain, stiffness, and functional limitation, according to the relevant diagnostic standard;[36] (3) have a history of ankle trauma, such as ankle fracture or sports-related injury; (4) have radiographic findings within the previous 12 months consistent with Takakura stage I, II, or III disease; in this study, these stages are operationally defined as early- to middle-stage PTAOA;[37] (5) aged 18–75, any gender; (6) are able to understand the study procedures and are willing to provide written informed consent (Consent form was shown in detail in Additional file 3).

Exclusion Criteria

Patients will not be recruited if any of the following are met: (1) on other pain relief treatments or have stopped the drug for less than 2 weeks; (2) received acupuncture treatment for ankle OA in the last 6 months; (3) ankle arthritis caused by gout, rheumatism, autoimmune diseases and other reasons; (4) systolic blood pressure ≥ 180mmHg and/or diastolic blood pressure ≥ 110mmHg; (5) have implanted medical devices such as pacemakersor metal implants in the body; (6) severe acute or chronic organic or neuropsychiatric disorder; (7) disorders of coagulopathy (eg., hemophilia).

Allocation

Patients will be allocated and randomly divided into the EA group and the SA group in a 1:1 ratio. Random sequences will be programmed by an independent statistician using SPSS 25.0 software, and are assigned randomly using opaque envelopes, which contain a slip of paper with the random sequence on the inside, and a sequence number on the outside. To conceal randomization, the random sequences and opaque envelopes used are stored in a locked location. Eligible patients, after signing the informed consent form, will be required to complete a Case Report Form (CRF) containing information such as name, gender, age, medical history, etc., for baseline demographic assessment.

Blinding

Patients, outcome evaluators and statistical analysts will be unaware of assigned treatments, due to the differences between the two therapies, blinding by the therapist is not feasible. Sham EA mimics EA appearance to maintain patient blinding.

Recruitment

Seventy-eight PTAOA patients will be planned to recruit from the Third Hospital Affiliated to Beijing University of Chinese Medicine in our study. Eligible participants will be recruited through outpatient clinics, WeChat, hospital bulletin boards and nearby posters, and get the adequate explanation about the informed consent form before signing it. All participants retain the right to withdraw their consent at any time, and we will protect the privacy of all subjects.

Interventions

Both the EA group and SA group will be administered the Diclofenac Diethylamine Emulge (trade name Voltaren, GSK Consumer Healthcare SARL, specification: 20g/stick). Topical application twice daily, 2 g per dose, for 4 weeks. The trial intervention will be administered by licensed acupuncturists from the Third Hospital Affiliated to Beijing University of Chinese Medicine, registered with the Chinese Medical Practitioners Registration Authority, possessing at least three years of clinical experience. To ensure consistency in the implementation of the intervention, the acupuncturists conducting the trial will participate in training sessions on the trial methodology and intervention protocol.

For patients with unilateral PTAOA, treatment will be performed on the affected side, which will be defined as the assessment side. For patients with bilateral ankle osteoarthritis, treatment will be administered to both sides, with the more severely affected side being evaluated. Any other treatments that may affect symptoms are prohibited during the trial period, including medication (eg., opioids) and physical therapy (massage, hydrotherapy, etc). With the aim of helping patients to better understand the condition, participants will be provided education about PTAOA, diagnosis and symptoms, risk factors, prevention measures and pain management of PTAOA, international guidelines and evidence-based management, consistent with OARSI guidelines.[5] Additionally, patients with a Body Mass Index (BMI) >25 will be encouraged to lose weight.

Electroacupuncture

Patients in the EA group will receive treatment 5 times a week, which has been confirmed by previous study[25] as the better frequency for 4 weeks (a total 20 sessions).

A standardized method for selecting acupoints will be adopted. The prescription was formulated based on clinical experience and reviews. The standardized prescription contains: Yanglingquan (GB34), Xuanzhong (GB39), Qiuxu (GB40), Zhongfeng (LR4), Kunlun (BL60), Shenmai (BL62), Taixi (KI3), Zhaohai (KI6), Zusanli (ST36), Jiexi (ST41), Shangqiu (SP5), Sanyinjiao (SP6), an Ashi point (the point where the patient feels the most pain) are fixed points in this study, which means they will be chosen for all patients. Positioning of all acupoints follows World Health Organization's Standard Acupuncture Locations. Further details regarding EA are provided in Table 2 and Additional File 1. The locations of the acupoints, corresponding needle types, and insertion depths are shown in Table 3.

De qi refers to the complex sensations of soreness, distention, heaviness, and numbness when acupuncture needles stimulate acupoints.

Sham Acupuncture

In the SA group, the acupoints prescription is the same as in the EA group. After local disinfection, a circular bandage will be applied over the acupoint. The acupuncture needle will only superficially insert into the bandage (2–3 mm in depth) without piercing the skin and needle manipulation for De qi, which are considered ineffective; this is the standard practice for sham control groups in acupuncture research.[38] The electric needle will be connected at the same position with only 0.1 mA adjusted, simulating the appearance and feel of EA treatment, but not providing actual electrical stimulation. A total of 20 times of sham acupuncture will be received.

Table 2 Details of the Electroacupuncture Intervention

Item	Parameter
Needling instrument	Length: 25–40 mm, diameter: 0.25–0.30 mm; Xin xinglin, Beijing, China
Retaining time	30 min
Treatment sessions	20
Frequency	5 times a week
Manipulation	After the needle inserted, lift, thrust and thrill smoothly for at least 5s to achieve De qi.
Electrical acupoints	Wire 1: ST 41 and SP 5. Wire 2: KI 3 and KI 6. Wire 3: BL 62 and BL 60. Wire 4: GB 40 and GB 39.
Electric parameter	Continuous wave. The current will be increased slowly from zero to the degree which the participant can feel but tolerate.

Table 3 Acupoints' Locations, Corresponding Needle Type and Depth of Insertion

Name	Location	Needle Type	Depth of Insertion
Qiuxu (GB 40)	Anterior and inferior to the external malleolus, in the depression on the lateral side of the tendon of the long extensor muscle of digitus.	0.25 × 25mm	13–20mm
Xuanzhong (GB 39)	On the fibular aspect of the leg, anterior to the fibula, 3 cun proximal to the prominence of the lateral malleolus.	0.30 × 40mm	25–40mm
Kunlun (BL 60)	On the posterolateral aspect of the ankle, in the depression between the prominence of the lateral malleolus and the calcaneal tendon.	0.25 × 25mm	13–20mm
Shenmai (BL 62)	In the depression directly below the lateral malleolus, posterior to the peroneal tendons.	0.25 × 25mm	8–13mm
Shangqiu (SP 5)	In the depression distal and inferior to the medial malleolus, midway between the tuberosity of the navicular bone and the tip of the medial malleolus.	0.25 × 25mm	13–20mm
Sanyinjiao (SP 6)	On the tibial aspect of the leg, posterior to the medial border of the tibia, 3 cun superior to the prominence of the medial malleolus.	0.30 × 40mm	25–40mm
Taixi (KI 3)	On the posteromedial aspect of the ankle, in the depression between the prominence of the medial malleolus and the calcaneal tendon.	0.25 × 25mm	13–20mm
Zhaohai (KI 6)	In the depression below the tip of the medial malleolus.	0.25 × 25mm	8–13mm
Zusanli (ST 36)	3 cun directly below Dubi (ST 35), one finger-breadth lateral to the anterior border of the tibia.	0.30 × 40mm	25–40mm
Jiexi (ST 41)	In the center of the transverse crease of the condylar articulation of dorsum of foot directly upward the second toe, in the depression between the tendons of the long extensor muscle of hallux and of digitus.	0.25 × 25mm	13–20mm
Zhongfeng (LR 4)	With the ankle dorsiflexed, this point is anterior to the medial malleolus, midway between Shanggiu (SP 5) and Jiexi (ST 41), in the depression on the medial side of the tendon of the tibialis anterior muscle.	0.25 × 25mm	13–20mm
Yanglingquan (GB 34)	On the fibular aspect of the leg, in the depression anterior and distal to the head of the fibula.	0.30 × 40mm	25–40mm
Ashi point	The point where the patient feels most pain.	Depends on the location	

Outcomes

Primary Outcome

American Orthopedic Foot and Ankle Society Ankle-Hindfoot Scale (AOFAS)[39] is a measure of ankle symptoms, function and quality of life, consist of pain (40 points), function (50 points), and gait (10 points). The total score is 100 points. A higher score indicates better ankle joint function: Excellent (90–100), Good (75–89), Fair (50–74), Poor (<50).

Secondary outcomes

The secondary outcomes include the Short-form of McGill pain questionnaire (SF-MPQ), Foot and Ankle Ability Measure (FAAM), the MOS item short from health survey (SF-36) and a biological indicator outcome.

SF-MPQ

This study employed the simplified McGill Pain Questionnaire (SF-MPQ) scoring system[40], streamlining the original complex evaluation process and incorporating Visual Analogue Scale (VAS) content to better align with clinical practice, include: Pain Rating Index (PRI, 45 points), Present Pain Intensity (PPI, 10 points), Visual Analogue Scale (VAS, 5 points), and Total Score (T, 60 points). Higher scores indicate greater pain severity and intensity.

FAAM

Foot and Ankle Ability Measure (FAAM)[41–43] is a tool for assessing ankle joint function, primarily performance during various activities. It consists of the Daily Activities subscale (21 scoring items) and the Sports Activities subscale (7 scoring

items), with response options based on a 5-point Likert scale (ranging from 4 to 0 points). Scores for each subscale range from 0% (lowest function) to 100% (highest function), with higher scores indicating better ankle joint function.

SF-36

36-Item Short Form Health Survey (SF-36)[44] is a multi-item tool widely used to measure quality of life and self-perceived health in target populations. SF-36 scores are represented by numbers ranging from 0 to 100, with higher numbers indicating better health status among respondents.

Musculoskeletal Ultrasound

Doppler is an established technique for identifying active synovitis and has been shown to correlate well with clinical disease activity within a joint. Ultrasound is able to visualize synovitis, joint effusion and soft tissue edema, while providing real-time observation of morphological features on the surfaces of human muscles, ligaments, bursae, cartilage, and bones, as well as nerve and soft tissue lesions. It accurately identifies the anatomical location of lesions and assesses their severity. The criteria for assessing ankle lesions are based on the definitions and grading standards for ultrasound lesions[45] established by the Outcome Measurement in Rheumatoid Arthritis and Connective Tissue (OMERACT) organization.

Serum

Patient blood will be collected and centrifuged at 3000 rpm for 15 minutes to obtain serum. ELISA will be used to measure the levels of TNF-α, IL-6 and IL-1β in the patient's serum.

Adverse Events

Common adverse reactions associated with EA include pain, localized hematoma, infection, and dizziness. Common adverse events associated with NSAIDs include dermatitis, rash, pruritus, edema, or scaling. Adverse events will be graded per CTCAE v5.0. The trial will be suspended in case of serious adverse events, which will be reported to IRB within 24 h.

Data Management

Initial data will be meticulously recorded on the Case Report Form (CRF) by the assessor responsible for outcome evaluation. Any supplementary information or modifications must be confirmed by the researcher's signature. The completed CRF will be saved separately by two independent researchers and uploaded to the ResMan Research Manager system (http://www.medresman.org.cn/uc/index.aspx). The clinical trial research assistant will conduct weekly monitoring activities via the website to improve trial quality. All original data will be stored for five years after the study concludes, enabling readers to obtain this information by contacting the corresponding author (excluding patient identification information).

All investigators at clinical research sites will undergo joint training by the principal investigators to ensure the trial's implementation. The withdrawal or lost-to-follow-up cases will be clearly documented during the trial.

Sample Size

This study is designed as a superiority trial with the AOFAS as the primary efficacy outcome. Based on previous clinical evidence, a between-group difference of more than 11 points in the AOFAS total score was considered clinically meaningful. The sample size was calculated using PASS 2021 software with a 1:1 allocation ratio. Assuming 90% power, a two-sided significance level of 0.05, and allowing for a 10% dropout rate, 39 participants are required per group, resulting in a total sample size of 78 participants.

Statistical Analysis

All statistical analyses will be performed using SPSS 25.0. Baseline characteristics will be summarized descriptively. Continuous variables will be presented as mean (standard deviation) for normally distributed data or median (interquartile range) for non-normally distributed data, and categorical variables will be presented as frequencies and percentages.

The primary analysis will follow the intention-to-treat principle. For repeated outcome measures, including AOFAS, SF-MPQ, FAAM, and SF-36, linear mixed-effects models will be used to assess between-group differences over time, with treatment group, time, and group-by-time interaction included in the model and baseline values entered as covariates where appropriate. For multiple secondary outcomes, Bonferroni-adjusted comparisons will be applied as needed to control the inflation of type I error. Missing outcome data will be handled using multiple imputation under the missing-at-random assumption. Effect sizes will be reported as appropriate, and all statistical tests will be two-sided with a significance level of 0.05.

Dissemination of Results

The study results will be published in peer-reviewed journals and presented at domestic and international conferences. If this is available from the corresponding author.

Discussion

PTAOA is a serious condition that is associated with high disability rates and low quality of life,[6] accompanied by severe pain resulting in a tremendous negative impact on patients' physical and mental health. Acupuncture can effectively alleviate joint pain and improve function in patients with OA, while demonstrating a high safety profile.[4] It is recommended for conditional use in the treatment of OA patients. Our study is an initial and necessary step to confirm the efficacy of EA therapy, combined with NSAIDs treatment for AOA.

Limited research has explored the application of EA in PTAOA, with only three studies reporting acupuncture as an adjunctive intervention. Jiang C et al 2024[18] compared the differences in the Ankle Osteoarthritis Scale (AOS), AOFAS and the 3D Motion Analysis System between the EA group and the strength training group in AOA patients, and confirmed that EA can effectively relieve pain and promote the recovery of normal gait. Deng ZX et al 2024[19] compared warm needle moxibustion (WNM) therapy combined with Platelet Rich Plasma (PRP) in PTAOA patients, both the WNM and PRP groups showed significant improvements in VAS scores, AOFAS scores, joint range of motion and serum IL-1β and TNF-α, with the WNM group demonstrating superior efficacy to the PRP group. Jiang T 2019[20] compared a combined intervention of EA and sodium hyaluronate (SH) intraarticular injection with SH injection alone. The study reported the prominent improvements in pain at 3 and 6 mouths post-treatment in the combined intervention group compared to the SH injection group.

While these acupuncture interventions have been demonstrated the efficacy to ankle pain and functional activities, it's lack of reports on the specific nature and severity of pain, ankle joint mobility, and quality of life following acupuncture treatment. In our trial, EA combined with NSAIDs is recommended for the treatment of musculoskeletal pain associated with osteoarthritis. Besides, this study will have several advantages: participants were randomly assigned to intervention measures, the assignment was concealed, and researchers evaluating outcome measures and conducting data analysis will be unaware of participant groupings. All intervention details are designed to realistically simulate the clinic, responding to real situations in clinical practice. Since the main symptoms of PTAOA are joint dysfunction and weight-bearing pain, using joint dysfunction as the primary outcome will clearly elucidate the difference in symptom improvement between the two interventions, including, in addition to self-reported outcomes, objective functional tests and indicators that can objectively describe treatment efficacy. At the same time, we will also attempt to explore the potential mechanism of EA treatment for PTAOA by detecting serum inflammatory factors TNF-α, IL-6 and IL-1β in PTAOA patients.

The results of the study will provide a specific basis for the treatment of PTAOA with non-pharmacological therapies. One limitation of this study is that treating physicians cannot be blinded, potentially leading to bias in results. Researchers maintain a neutral stance on different therapies, which can reduce bias in the study design. Another limitation is that although sham acupuncture was used as a control to minimize the placebo effect, the unique characteristics of acupuncture treatment make it extremely difficult to completely eliminate the influence of the placebo effect, which may lead to certain biases in the evaluation of the actual therapeutic effects of EA. For PTAOA, a chronic condition, an 8-week evaluation may not be sufficient to provide a comprehensive understanding. Definitive conclusions about the long-term effects between the two interventions require further real-world studies and long-term follow-up.

Study Status

This trial is currently recruiting participants. The first participant was enrolled on 9 April 2025, and recruitment is expected to be completed by April 2026. The primary and secondary outcomes remained unchanged between the ethics-approved protocol and the registered protocol.

Abbreviations

AOFAS, American Orthopedic Foot and Ankle Society Ankle-Hindfoot Scale; AOS, Ankle Osteoarthritis Scale; CODTG, China Osteoarthritis Diagnosis and Treatment Guidelines; CRF, Case Report Form; EA, electroacupuncture; FAAM, Foot and Ankle Ability Measure; PRP, Platelet Rich Plasma; SA, sham acupuncture; SF-MPQ, simplified McGill Pain Questionnaire; SH, sodium hyaluronate; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; WNM, warm needle moxibustion.

Data Sharing Statement

The supporting data for this study is available from the corresponding author, Professor Qin and Wei, upon reasonable request.

Ethics Approval and Consent to Participate

All procedures in this study will be conducted in strict accordance with the ethical principles outlined in the Declaration of Helsinki (revised in October 2013). This research protocol has been reviewed and approved by the Third Hospital Affiliated to Beijing University of Chinese Medicine (Ethics Approval No.: BZYSY-2025YJSKTPJ-24). Study findings will be published in peer-reviewed academic journals.

Acknowledgments

Appreciation to every participant in the trial and every personnel in recruitment sites for their contributions.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This study is supported by the Beijing Science Fund (No. 7232026) and the Beijing Municipal Traditional Chinese Medicine Science and Technology Development Fund (No. BJZYYB-2025-12). The funding agencies will not participate in the conduct of this trial or the interpretation of its results, nor will it be involved in any decisions regarding the publication of research findings.

Disclosure

Dr Dan-Dan Xie reports grants from the Beijing Municipal Traditional Chinese Medicine Science and Technology Development Fund, grants from the Beijing Science Fund, during the conduct of the study. Dr Lina Qin reports grants from the Beijing Science Fund (No. 7232026), grants from the Beijing Municipal Traditional Chinese Medicine Science and Technology Development Fund (No. BJZYYB-2025-12), outside the submitted work. The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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