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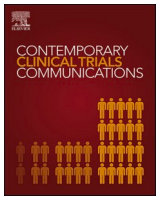

Comparing different session regimens of electroacupuncture for chronic plantar fasciitis: Study protocol for a randomized clinical trial

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ABSTRACT

Background: Plantar fasciitis (PF) is one of the most common causes of plantar heel pain, and previous studies found that acupuncture is effective for relieving pain in patients with PF. Nevertheless, the impact of different sessions of electroacupuncture on PF has not been investigated through randomized, controlled trials.
Methods/design: This is a two parallel-group, assessor-blinded, randomized controlled trial, consisting of a four-week treatment phase followed by a 12-week follow-up. Eighty patients with chronic PF will be recruited and randomly allocated to receive 12 (three sessions per week; the multiple electroacupuncture weekly treatment group (group M)) or four (one session per week; single electroacupuncture weekly treatment group (group S)) sessions of electroacupuncture treatment in a 1:1 ratio. The primary outcome to be studied is the response rate, defined as a minimum of 50 % improvement in most severe pain intensity with first steps in the morning, compared with baseline. We will perform all analyses based on the intention-to-treat principle, with differences considered significant when the P value < 0.05 on a two-sided basis.
Discussion: This prospective trial will provide high-quality evidence on evaluating the efficacy and safety of different electroacupuncture sessions (one session per week versus three sessions per week) for chronic PF. This study aims to contribute in produce up-to-date, rigorous evidence on the most effective frequency of electroacupuncture in managing chronic PF.
Trial registration Clinicaltrials.gov Identifier: NCT06284993. Registered on February 17, 2024.

1. Background

Plantar fasciitis (PF) is one of the most common causes of heel pain, typically characterized by a sharp pain in the plantar aponeurosis, specifically near the insertion site close to the medial process of the calcaneal tuberosity [1,2]. One in ten people is expected to develop PF in their lifetime [3]. A comprehensive internet-panel survey conducted among adults in the United States revealed a population-based prevalence of self-reported PF with pain in the last month of 0.85 percent [4]. Approximately one million patients are diagnosed with this disease each year in the United States [5]. PF was originally thought to be an acute inflammatory disease, but patient samples revealed it to be a chronic degenerative process caused by diverse factors, including repetitive stresses, vascular and metabolic disorders, excess free radicals, high temperatures, genetic factors, and medical conditions such as rheumatoid arthritis and spondyloarthropathies [6]. PF may be associated with impaired health-related quality of life, including reduced functioning, poor perceived health status, and social isolation [7]. Additionally, the annual cost associated with PF was recently found to be $284 million in the United States [8].

The first-line treatments recommended by guidelines for PF consist of physical therapy (including manual therapy, stretching, and others),

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pharmacological therapy (consisting of corticosteroids or platelet-rich plasma), and surgical treatment [1,9]. However, the definite effects of physical therapy still require confirmation. Pharmacological treatments, such as local corticosteroid injections, provide only short-term relief [10]. Some studies indicate that the relief provided by corticosteroid injections lasts up to one month, while others show that efficacy diminishes after six months [11,12]. Surgical treatment is generally advised six to 12 months after unsuccessful conservative treatment, albeit with the drawback of higher costs, post-surgery recovery time, and patient apprehension [13].

Electroacupuncture is one of the most common complementary alternative therapies to treat pain-related diseases, especially musculoskeletal pain [14–16], and recent guidelines recommend dry needling as a treatment for relief of plantar fasciitis, with a level of evidence of B (Moderate-certainty evidence) [1]. Although dry needling differs from acupuncture in its theoretical basis, therapeutic apparatus, technical operation, and scope of indications [17,18], the American Alliance for Professional Acupuncture Safety also believes that dry needling falls under the umbrella of acupuncture, but under a different name [19]. In addition, systematic reviews suggest that acupuncture can be a safe and effective treatment for PF, although there is no recommended course of treatment in these reviews, and two- and four-week courses were used in most of the included trials [20–22]. We previously showed that a four-week intervention of both electroacupuncture and manual acupuncture resulted in improved pain outcomes in patients with PF [23].

As one of the dose components of acupuncture, the total number/frequency of acupuncture is a crucial factor influencing its efficacy [24,25]. Needling trials with negative results had a significantly lower frequency of treatment compared to those yielding positive results [26]. Furthermore, acupuncture once a week can be helpful in conditions such as simple obesity, functional dyspepsia, and overactive bladder in women[27–29]. There is no universally accepted standard frequency of treatment for many conditions, including PF. In China, patients with chronic diseases usually receive three to five acupuncture treatments per week [30]. However, in most previous trials, individuals with chronic diseases received one to two sessions per week [31]. An increase in the number of acupuncture sessions means an increase in the pain, time, and financial investment associated with the acupuncture process [32]. Therefore, it is critical to optimize the number of treatments for electroacupuncture to ensure the effectiveness and feasibility of the treatment while avoiding increased patient burden. Accordingly, we designed the current trial to compare the effects of different numbers of electroacupuncture sessions (one session per week versus three sessions per week) in a randomized controlled trial (RCT) for the treatment of chronic PF. The hypothesis is that a single session per week compared with three sessions per week of electroacupuncture treatment over a total of four weeks of treatment will provide similar pain relief in chronic PF.

2. Methods

2.1. Study design

This will be a parallel-design, assessor-blinded, randomized trial with a 1:1 allocation ratio. The study is designed to adhere to the standard protocol items including the Recommendations for Interventional Trials [33] and the Standards for Reporting Interventions in Clinical Trials of Acupuncture [34] guidelines. The study flow diagram and treatment schedule are presented in Figs. 1 and 2, respectively.

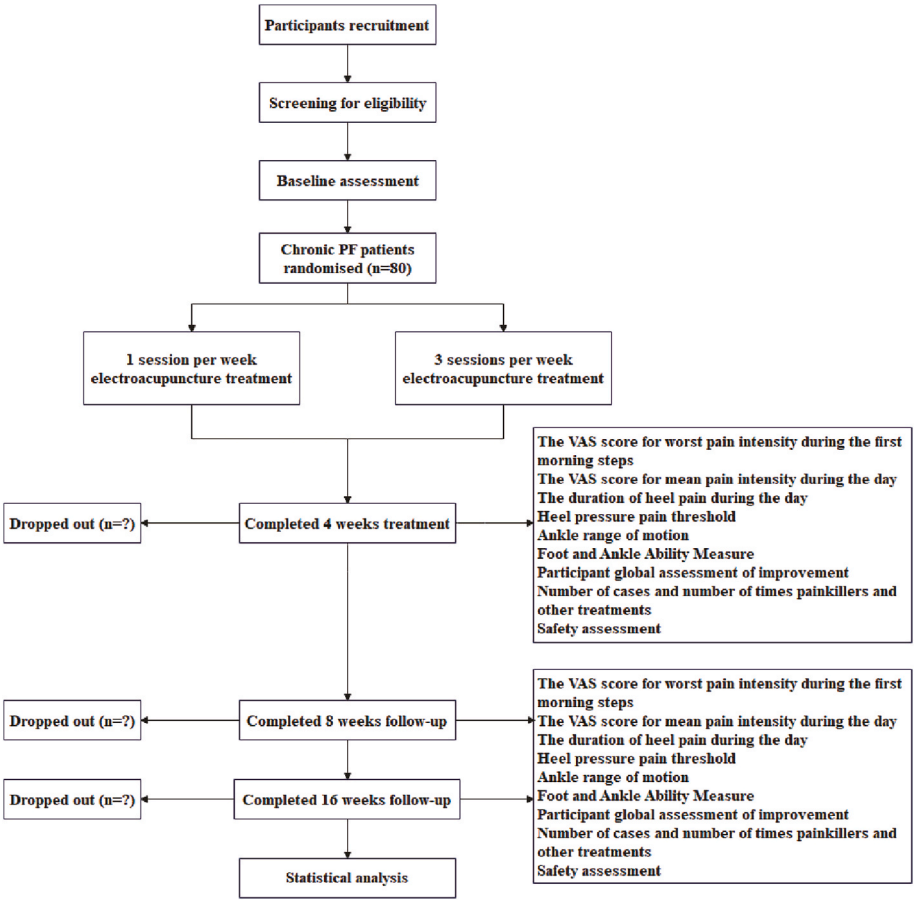

Fig. 1. The study flow diagram.

Stage	Screening/baseline	Period of regular treatment (weeks)	Follow-up period (weeks)	
Visits	**1**	**2**	**3**	**4**
TIME POINT (W, week)	W 0	W 4+2d	W 8+2d	W 16+2d
Enrollment				
Inclusion/ exclusion criteria	X			
Demography information	X			
Disease history of plantar fasciitis	X			
Eligibility screen	X			
Informed consent	X			
Allocation		X		
Intervention				
The more frequent acupuncture treatment group (Group M)		X（weeks 1-4)		
The less frequent acupuncture treatment group (Group L)		X（weeks 1-4)		
Assessment				
The VAS score for worst pain intensity during the first morning steps	X	X	X	X
The VAS score for mean pain intensity during the day	X	X	X	X
Heel pressure pain threshold	X	X	X	X
Ankle range of motion	X	X	X	X
Foot and Ankle Ability Measure	X	X	X	X
Participant global assessment of improvement		X	X	X
Number of cases and number of times painkillers and other treatments	X	X	X	X
Participants' expectation towards acupuncture	X			
Safety assessment		X	X	X

Fig. 2. The treatment schedules.

2.2. Study setting, recruitment, and ethics

Study recruitment will be conducted at Guang'anmen Hospital, China Academy of Chinese Medical Sciences, and a total of 80 patients diagnosed with chronic PF will be recruited to the protocol. The study has been approved by the medical ethical review committee of Guang'anmen Hospital, China Academy of Chinese Medical Sciences (No. 2023-214-ky) [see Additional file 1]. Patients will be recruited through multiple channels, including WeChat (a social networking site), outpatient units, and print advertisements. People interested in study participation will be invited to contact the clinical research coordinator (CRC) by telephone. The CRC will conduct a preliminary participants screening, assessing inclusion and exclusion criteria, and then, if appropriate, schedule a face-to-face baseline visit with a physical and rehabilitation medicine senior specialist. All eligible patients will provide written informed consent [see Additional file 2]. The CRC will thoroughly discuss all study details, including the purpose, procedures, time commitment, and potential risks and benefits associated with participation, obtaining written informed consent from potential participants. Patient record confidentiality will be strictly protected through provision, upon enrollment, of a unique randomization number, which will be the sole direct identifier on all case report forms (CRF).

2.3. Randomization and blinding

The randomized protocol will be prepared by the Key Laboratory of Chinese Internal Medicine of Ministry of Education, Dongzhimen Hospital. The randomization sequence with variable block size (four, or six) will be generated using the PROC PLAN process statement of SAS software. Group M will be scheduled to receive three sessions per week, while group S will be scheduled for one session per week. Participants will be numbered 1–80 according to their order of enrollment, and the random assignment group corresponding to the inclusion order will be obtained, that is, 40 participants in each of the two groups.

A sequentially numbered, opaque, sealed envelope system will be used to conceal allocations. The randomization scheme is designed in advance by persons not participating in this study, the inclusion sequence number will be pasted on the surface of the envelope, and the random numbers and groups will be sealed in an opaque envelope for random assignment and concealment. Randomization envelopes and assignments will be the responsibility of a dedicated person who is not involved in treatment and evaluation. As only the frequency of needling differs between the two groups, it is not possible to blind the acupuncturists and participants, and the evaluators and data analysts will be blinded to the group allocation.

2.4. Diagnostic criteria

Following the Orthopedic Section of American Physical Therapy Association clinical practice guidelines for heel pain and PF [1], the following clinical signs or symptoms are consistent with a diagnosis of PF based on history and clinical examination.

(1) The pain is located in the middle of the heel or in a location where it migrates along the middle of the plantar fascia;
(2) The pain is most pronounced with the first few steps taken after a period of stillness (e.g., in the morning) and worsens after sustained weight bearing;
(3) Sensitivity/pain during palpation of the middle calcaneal tuberosity or the middle transition area of the plantar fascia;
(4) Limited range of active and passive dorsiflexion of the ankle joint;
(5) Positive windlass test; and
(6) Negative tarsal tunnel tests.

For inclusion in the study, they must meet all of the following inclusion criteria and not fulfill any of the exclusion criteria.

2.5. Inclusion criteria

(1) Patients with a diagnosis of chronic PF with a disease course of ≥ six months;
(2) The most painful heel pain in the morning is Visual Analogue Scale (VAS; 0 indicating no pain and 100 indicating maximal pain) ≥ 40 mm on a 100 mm VAS;
(3) Patients between the ages of 18 and 75 years;
(4) Patients should be conscious, free from mental disorders, and without serious heart, liver, or kidney diseases; and
(5) Willing to sign the informed consent form.

2.6. Exclusion criteria

(1) History of calcaneal tuberosity fracture/calcaneal stress fracture/calcaneal contusion/plantar fascia rupture;
(2) History of ankle or foot surgery;
(3) Achilles tendon enthesis lesion/tarsal tunnel syndrome/medial calcaneal nerve entrapment/nerve injury;
(4) Systemic or local infection, severe cracked heel, foot deformity (e.g., high arched feet, flat feet, foot valgus);
(5) Systemic diseases (e.g., obligatory spondylitis, rheumatoid arthritis, seronegative arthritis, autoimmune system diseases, tumors, diabetes) and other situations judged by the investigators not to be suitable for the clinical trial;
(6) Pregnant women; patients with severe combined cardiac, hepatic, renal, hematopoietic, and patients with cardiac pacemakers, and patients with severe poor general nutritional status;
(7) Cognitive impairment, inability to understand the content of the scale evaluation;
(8) Topical steroid injection or oral steroid use in the past six months;
(9) Patients with a known fear of acupuncture or who have been treated with acupuncture in the past eight weeks.

2.7. Interventions

2.7.1. The multiple electroacupuncture weekly treatment group (group M)

The electroacupuncture protocol was developed by consensus of three experts based on the meridian theory of Traditional Chinese Medicine (TCM) and was used in our previous trial [35]. Licensed acupuncturists with more than two years of acupuncture experience will perform the treatment. In this trial, we will apply needles to two Ashi points (the two most severely tender points in the area of greatest sensitivity over the anteromedial aspect of the heels, based on the participant's reported pain with palpation) as well as the *Chengshan* (BL57), *Taixi* (KI3), and *Kunlun* (BL60) acupoints (Fig. 3. And Table 1). The position of the aforementioned acupoints will be based on the nomenclature and location of acupuncture points [36] designated by the National Standard of the People's Republic of China (GB/T 12346-2021). Sterile, disposable, stainless-steel needles (Hwato brand; Suzhou Medical Appliance Factory, Suzhou, China; 0.25 mm × 40 mm) will be used. With the patient lying prone, the local skin will be sterilized per routine,

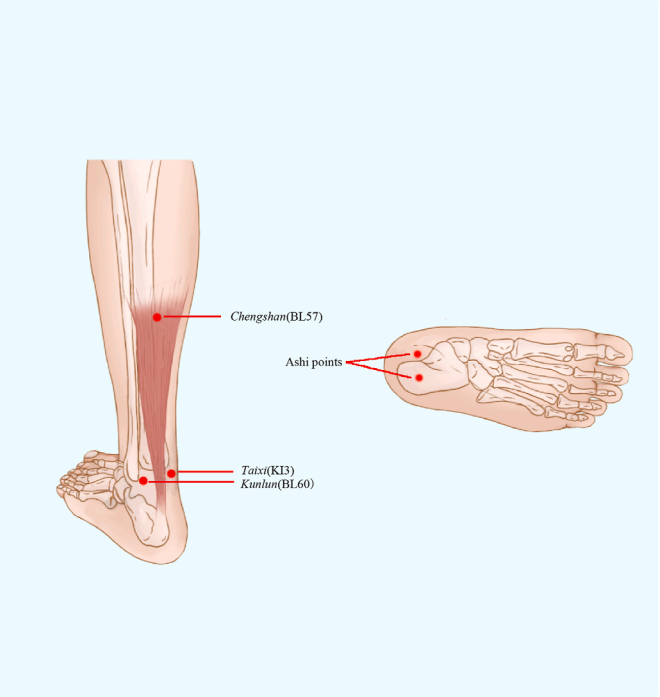

Fig. 3. Locations of acupoints
Sterile disposable stainless steel acupuncture needles (Hwato brand; Suzhou Medical Appliance Factory, Suzhou, China; 0.25 mm × 40 mm) will be used in both groups.

Table 1
Similarities and differences between the multiple electroacupuncture weekly treatment group (Group M) and the single electroacupuncture weekly treatment group (Group S).

Items	Group M	Group S
Similarities		
Area of points stimulated	Lower limb	
Kinds of points stimulated	Acupoints	
Location of points stimulated	2 Ashi points with BL57, KI3 and BL60	
Types of needles	Sterile disposable stainless-steel needles[a]	
Size of needle	Size 0.25 × 40 mm	
Depth of penetration, mm	10-15 (Ashi), 15–20 (BL57, KI3 and BL60)	
Number of acupoints (on each side)	5	
Number of needles (on each side)	5	
Needle retention, min	30	
Angle of needing, °	90	
De qi	Yes	
Connection of the electroacupuncture instrument[b]	Yes	
Parameters of the electroacupuncture	Continuous wave, 10Hz, current intensity 0.5 mĀ2 mA, and the patient can tolerate it.	
Lifting, inserting, twisting, and turning	Three times (10 s each time) every 10 min	
Differences		
Number of sessions	12	4
Additional visits	0	8

[a] Produced by Hwato brand, Suzhou Medical Appliance Factory, Suzhou, China.
[b] Hwato brand electronic needle therapy instrument, SDZ-V type, Suzhou Medical Supplies Factory Co.

Ashi points will be perpendicularly inserted into the plantar fascia layer with a depth of approximately 15–20 mm, depending on the location. Acupoints BL57, KI3, and BL60 will be punched perpendicularly to a depth of 10–15 mm into the skin. All needles except the Ashi points will

be manually stimulated with small, equal manipulations of lifting, thrusting, twirling, and rotating to achieve De qi (a sensation including soreness, numbness, distention, and heaviness) [37], and the practitioner perceives needle sinking and tightness. The electroacupuncture instrument (Hwato brand electronic needle therapy instrument, SDZ-V type, Suzhou Medical Supplies Factory Co.) will be connected to the needle handle of BL57 and BL60 respectively, and the parameters of the electroacupuncture will be: continuous wave, 10Hz; current intensity, 0.5 mÃ2 mA; and to patient tolerance. During the needle retention period, except for BL57 and BL60, which are connected to the electroacupuncture instrument, for Ashi points and KI3, the acupuncturists will perform a small and uniform twisting technique three times every 10 min, and a total of three times within 30 min.

Before removing the needle, the acupuncturist will gently rotate the needle handle until it is sufficiently lubricated for easy removal. After removing the needle, the acupuncturist will grasp a sterilized cotton ball with the left hand and apply gentle pressure to the electroacupuncture site, while the right hand twists the needle slightly and gradually withdraws it. Subsequently, pressure will be applied to the needle hole post-removal to mitigate the risk of bleeding. If participants suffer pain bilaterally, the acupuncturists will treat both sides and evaluate the side presenting with more severe pain at baseline.

2.7.2. The single electroacupuncture weekly treatment group (group S)

The treatments for group S are similar to those of group M, with the only difference being the number of electroacupuncture sessions weekly (once per week). During the treatment period, in addition to the electroacupuncture sessions, patients will be visited twice a week by telephone or in person, for a total of eight visits. If the content of the visit aligns with the established efficacy evaluation visit in the program, it will be carried out as planned. Otherwise, the patient will be asked about the progress of their condition since the previous treatment, use of any rescue medications, and other relevant information. Information obtained that does not involve changes in relevant indicators of the study does not need to be recorded.

The electroacupuncture will last for 30 min and will be performed three sessions per week or one session per week for a total of 12 or four sessions in four consecutive weeks. Participants in both groups will be treated and evaluated separately. Participants in both groups will receive the same health education prior to treatment, including foot braking, changing poor footwear habits (e.g., avoiding flip-flops and flat shoes), using heel footwear, and avoiding standing for prolonged periods and not walking barefoot during the 17-week study period.

2.8. Rescue medication

During the trial, participants will not be permitted to take any medication or other treatment. However, if the pain for a participant in either group is severe and unbearable, ibuprofen (200 mg tablets, Xiuzheng Pharmaceutical Group Co., Ltd, China) will be permitted every four to 6 h (not more than four times per 24 h) for three days as needed. Drug details (name, dosage, and frequency) will be recorded. Pain VAS evaluation should not be performed 48 h before ibuprofen tablets, and the evaluation time point should be delayed if already used, and the pain within 48 h of administration of rescue medication will not be involved in the assessment.

3. Outcomes

3.1. Primary outcome

The primary outcome is the response rate at four weeks of treatment, defined as a minimum of 50 % improvement in the worst pain intensity during the first morning steps at four weeks of treatment compared with the baseline. This trial will be analyzed using the mean of the worst pain level VAS from the previous three days.

Pain intensity will be measured using a 0–100 VAS, with 0 indicating no pain and 100 indicating maximal pain. Participants who must resort to additional treatments other than the permitted rescue medication will be classified as non-responders. In addition, the responder rate at eight weeks and 16 weeks of follow-up will also be assessed.

3.2. Secondary outcomes

The secondary outcomes are as follows.

(1) Change from baseline in the VAS score for worst pain intensity during the first morning steps at four weeks of treatment, eight weeks of follow-up, and 16 weeks of follow-up.

Patients will indicate their pain intensity on the VAS by marking a point, and the distance from 0 mm to this point will determine the pain score. The mean of the worst pain intensity during the first morning steps during the previous three days will be determined.

(2) Change from baseline in the VAS score for mean pain intensity during the day at four weeks of treatment, eight weeks of follow-up, and 16 weeks of follow-up. The average VAS score of daily heel pain over the past three days will be assessed.
(3) Change from baseline in the duration of heel pain during the day at four weeks of treatment, eight weeks of follow-up, and 16 weeks of follow-up. The study will measure the average number of hours of daytime heel pain over the last three days while participants maintain their normal daily activities.
(4) Change from baseline in heel pressure pain threshold (PPT) at four weeks of treatment, eight weeks of follow-up, and 16 weeks of follow-up. PPT is defined as the minimum pressure detected when the sensation of pressure first changes to a sensation of pain [38].

PPT will be tested with a pressure algometer (Fabrication Enterprises, White Plains, NY; from 1 kg/cm^2 to 5 kg/cm^2) using a metal probe with a 0.5 cm^2 rubber disc, performed by a trained researcher. PPT will be measured with the participant lying supine in a relaxed position with the affected foot hanging over the edge of the bed. When measuring the PPT, the rubber disc will be placed perpendicularly on the painful spot, and pressure will be applied at a rate of approximately 0.1 $kg/cm^2/s$ through the metal probe of the pressure algometer. Participants will be asked to report when the initial pain sensation occurs, and the readings of the algometer will be recorded. The score will be determined by averaging three repeated measurements with 30 s between each trial. All values below 1 kg/cm^2 will be reported as 0.5 kg/cm^2.

(5) Change from baseline in ankle range of motion (AROM) at four weeks of treatment, eight weeks of follow-up, and 16 weeks of follow-up.

The examiner will measure the AROM, including dorsiflexion and plantar flexion with the knee extended, using a digital goniometer (Tangxia Electronic Instrument Factory, Dongguan, from 0° to 360°). For the extended-knee assessment, the participant will be seated on a treatment table with the knees fully extended (0°) and the feet hanging off the end of the table. The axis of the goniometer will be placed at the lateral malleolus. The stationary arm will be placed parallel to the center of the fibular head and the moving arm placed parallel to the fifth metatarsal. The ankle will be passively moved from a neutral starting position into dorsiflexion and plantar flexion until a firm end feel is elicited [39], and the readings of the goniometer will be recorded. The mean score of three trials, with 10s between each examination, will be calculated and used for analysis.

(6) Change from baseline in Foot and Ankle Ability Measure (FAAM) total score and subscale scores at four weeks of treatment, eight weeks of follow-up, and 16 weeks of follow-up.

The FAAM is a self-reported outcome instrument designed to assess physical functioning in patients with foot and ankle-related injuries, and consists of a 29-item questionnaire divided into two subscales: a 21-item Activities of Daily Living (ADL) subscale, and an eight-item exercise subscale [40]. Each item is scored on a 0–4 point Likert scale ranging from zero (unable to do) to four (no difficulty at all), with higher total scores indicating a higher level of function. The FAAM has a maximum potential score of 116 (84 ADL and 32 sport subscales). The score obtained (total, ADL, and sport subscale scores) is divided by the maximum potential score and multiplied by 100 to obtain a percentage. If the patient does not respond to a question, that specific question will be left blank and not be a part of the final value of the questionnaire. In this trial, we will use the previously validated Chinese version of the FAAM [41].

(7) Participant global assessment of improvement at the end of weeks four, eight, and 16. The evaluation of overall clinical impact from the participants' perspective will be divided into seven grades, assessed by patients at three timepoints: the end of the four-week treatment, and at eight and 16 weeks of follow-up. The improvement will be scaled from one (complete recovery) to seven (vastly worse), with two being obvious improvement, three being a little improvement, four being no change, five being a little worse and six being obviously worse. Although the scale's validity has not been verified in patients with PF, it has been shown to provide credible validity in some musculoskeletal disorders including osteoarthritis, rheumatoid arthritis, inflammatory synovitis [42].
(8) Number of cases and number of times painkillers and other treatments usage for relief of PF pain were recorded at baseline and at the end of weeks four, eight, and 16.
(9) Participants' expectation towards acupuncture at baseline: at baseline, participants in both groups will be asked the following questions: "Do you think acupuncture will be helpful to improve your chronic PF?" "Do you think Group M will help you improve your chronic PF?" "Do you think Group S will help you improve your chronic PF?" Participants will choose one of the following answers: "Yes", "No", or "Unclear", and will be asked "Which treatment do you prefer?" Participants will choose one of the following answers: "Group M″, "Group S″, or "Indifferent".

3.3. Safety assessment

The adverse events (AEs) throughout the study will be recorded and described as electroacupuncture-related AEs and non-electroacupuncture-related AEs. Electroacupuncture-related AEs include fainting, broken needle, unbearable pain during electroacupuncture (VAS $\geq$7, using VAS from 0 (no pain) to 10 (worst pain imaginable)) and other unintended signs or symptoms after electroacupuncture (e.g., localized hematoma or infection, nausea, dizziness, vomiting, headache, palpitations). Detailed information on AEs including the name, onset, end date, intensity, correlation with electroacupuncture, and outcomes will be documented in the CRF. Investigators will immediately report serious AEs (e.g., requiring hospitalization, causing disability, or impaired ability to work) within 24 h to the Medical Ethics Committee of Guang'anmen Hospital, and stop the clinical trial until further instruction is given.

3.4. Sample size calculation

Based on relevant clinical studies, we determined that a $\geq$50 % reduction in the VAS score for worst pain intensity during the first morning steps from baseline would be considered clinically significant [43]. The primary outcome of this trial is the percentage of the number of cases with $\geq$50 % reduction in the VAS score for worst pain intensity during the first steps in the morning from baseline at the end of the fourth week of treatment. Based on the relevant literature [21], we predicted that after four weeks of treatment, the percentage of cases with $\geq$50 % reduction in the VAS score for worst pain intensity during the first steps in the morning from baseline would be 55 % in group M [23], and 24 % in group S. Therefore, in this study, the sample size was calculated using PASS software, taking $\alpha = 0.05$ and $\beta = 0.2$, which yielded $n = 36$. Allowing for a 10 % dropout rate, 40 cases will be needed in each group, for a total of 80 cases.

3.5. Statistical analysis

We will use SAS, version 9.4 (SAS Institute), or Stata, version 15.1 (StataCorp), to perform all statistical analysis, following the intention-to-treat (ITT) principle. The ITT population includes all randomized patients. For the safety assessment, the safety set will be used, which includes all randomized patients who have received at least one safety evaluation after treatment. We will impute missing primary outcome data using multiple imputation techniques under the "missing at random" assumption for the ITT population, and we will not impute missing secondary outcome data. For continuous data, the data will be presented as mean $\pm$ SD when normally distributed or presented as median (IQR) when not normally distributed. Longitudinal continuous data will be compared between groups using repeated-measures analysis of variance (ANOVA), including group and time-group interaction. Other continuous data will be analyzed using Student's t-test and the Wilcoxon rank-sum test, and categorical data using the χ^2 test or Fisher's exact test, as appropriate. Sensitivity analysis will be performed for the primary outcome if necessary. A 2-sided *P*-value less than 0.05 will be considered statistically significant.

3.6. Quality control

Before beginning the trial, all researchers involved in the study will undergo comprehensive training, which will include instruction on the procedural steps and methodologies for project implementation, the criteria for diagnosing participants and determining inclusion and exclusion, the proper evaluation of the CRF and various scales, as well as guidelines for their completion, and the techniques for administering electroacupuncture. Throughout the treatment phase, researchers will conduct weekly assessments of CRFs and monitor the administration of electroacupuncture. The raw data for this study consists of the CRF, informed consent documentation, clinical records, and original laboratory test results, all of which will be required to be verifiable. The CRF will be completed manually by the researcher, collected at regular intervals, and entered into the database using a two-person double-entry system.

4. Discussion

This prospective study is a block-randomized, two-group, parallel-controlled, randomized controlled trial. Although several reviews and RCTs of acupuncture for PF have been published [44,45], there are no RCTs of different frequencies of electroacupuncture for PF. Hence, in this trial, we propose to investigate the impact of varying frequencies of electroacupuncture for chronic PF, specifically examining whether electroacupuncture performed once a week demonstrates comparable efficacy in decreasing pain intensity associated with chronic PF compared with electroacupuncture performed three times a week over a four-week period, with 12 weeks of follow-up.

The strengths of this study include that this trial will, for the first time, investigate the difference in efficacy between different frequencies of electroacupuncture for chronic PF. Simultaneously, an additional two

visits per week will be conducted for Group S, controlling for possible differences in efficacy due to differences in the frequency of contact between the patient and the physician. Additionally, a recent study suggests a potential association between prolonged standing and the pathogenesis of PF [46]. Consequently, as part of our trial assessing the efficacy of the intervention on patients' return to daily life/work, we will evaluate the duration of heel pain during the day over the three days prior to the visit, while participants maintain their usual lifestyle and work habits. This particular secondary outcome measure has not been employed in previous trials.

There are several limitations in this trial. First, it is not feasible to implement blinding for either acupuncturists or participants, a common obstacle in non-pharmacological interventional trials that has the potential to introduce bias. Second, the limited 12-week follow-up period impairs assessment of electroacupuncture's long-term effects on chronic PF. Third, while our study provides insights into the efficacy of specific electroacupuncture points, it does not offer information on personalized treatment approaches. Fourth, the treatment rate per week assessed in the study only represents one aspect of the dosage components of acupuncture. Factors such as the number of needles, intensity of stimulation, and other dosage variables that could impact the effectiveness of acupuncture in treating this disease are not examined. Additionally, as this will be a clinical trial focused on dose response [47], it did not include a placebo electroacupuncture group or another form of control.

This study aims to investigate the effectiveness of once per week versus three times per week electrotherapy in individuals with chronic PF to reduce the discomfort caused by needle insertion and alleviate patient financial and time burdens. In the practice of electroacupuncture, treatments given less often may have reduced efficacy [48], while excessively high numbers of treatments per week can result in tolerance, increased treatment expenses, and prolonged treatment time that impede the widespread acceptance of electroacupuncture therapy and reduce its cost-effectiveness. The findings obtained from this preliminary investigation will inform the decision whether to commence a more thorough randomized controlled trial examining the impact of how often electroacupuncture should be given. This study aims to produce up-to-date, rigorous evidence on the most effective dosing of electroacupuncture in managing chronic PF. As a result, we will be able to improve the refinement and uniformity of electroacupuncture protocols to guide the management of chronic PF.

Ethics approval and consent to participate

The study has been approved by the Institutional Review Boards of Guang'anmen Hospital in China (approval no. 2023-214-ky, Tel +86-10-88001552), and all investigators have complied with the Helsinki Declaration.

Consent for publication

Not required.

Availability of data and materials

Data are available upon reasonable request.

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CRediT authorship contribution statement

Jiaxiang Shi: Writing – original draft. **Ruimin Jiao:** Writing – original draft. **Yan Liu:** Formal analysis, Data curation. **Xinkun Liu:** Investigation. **Yingxin Sun:** Investigation. **Hangyu Shi:** Investigation. **Ning Gao:** Investigation. **Zhishun Liu:** Supervision. **Jun Liang:** Writing – review & editing. **Weiming Wang:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2024.101355.

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