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Title page

Article title:

Electroacupuncture versus manual acupuncture in the treatment of plantar fasciitis: study protocol for an upcoming randomized controlled trial

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Abstract

Introduction: Plantar fasciitis is a common cause of heel pain. It may worsen a patient's quality of life, and potentially lead to knee, hip, or lower back problems. Previous studies have shown that electroacupuncture and manual acupuncture are effective treatments for relieving pain in patients with plantar fasciitis. However, little evidence supports the use of one intervention over the other.

Methods and analysis: A total of 92 patients diagnosed with plantar fasciitis will be recruited and randomly assigned to an electroacupuncture group or a manual acupuncture group at a ratio of 1:1. Patients in both groups will receive a 30-min acupuncture treatment (3 times per week) for a total of 12 sessions over 4 weeks. The primary outcome will be the proportion of patients with at least 50% reduction from baseline in the worst pain intensity measured by visual analog scale (0 to 100, higher scores signify worse pain) at first steps in the morning after 4-week treatment. The secondary outcomes will include change in worst pain intensity at first steps in the morning, change in mean pain intensity at first steps in the morning, change in worst pain intensity during the day, change in mean pain intensity during the day, change in the pressure pain threshold, change in ankle-dorsiflexion range of motion, change in Foot and Ankle Ability Measure total score and subscale scores, patients' global improvement assessment, patients' expectations for acupuncture, and safety evaluation. We will perform all statistical analysis following the intention-to-treat principle.

Ethics and dissemination: The study has been approved by our ethics review board (Protocol Approval No. 2018-010-KY). The study findings will be disseminated through presentation at a high-impact medical journal, with online access. We also to plan to present it in select conferences and scientific meetings.

Trial registration: Chinese Clinical Trial Registry identifier: ChiCTR-1800016531, registered 7 June 2018.

Strengths and limitations of this study:

► This study is the first randomized controlled trial comparing electroacupuncture versus manual acupuncture for pain relief in participants with planter fasciitis.

► Strictly standardized endpoints and objective criteria, long-term follow-up, strict quality control, and evaluation of patients' expectations for acupuncture.

► The results might not apply to primary hospital or other countries. Participants and the acupuncturist will not be blinded due to the nature of the study. A placebo/sham/ wait list group was not assigned.

Background

Plantar fasciitis (PF), a common cause of heel pain,[1] is characterized by pain exacerbated with the first walking in the morning or after a long period of rest.[2] In the United States, more than 2 million people per year seek treatment due to heel pain,[3] and approximately 10% of the general population is affected by heel pain during their lives.[4] Excluding conditions such as fat pad atrophy, plantar fibromatosis, and calcaneal stress fracture, symptoms of plantar heel pain are attributed to PF in 80% of patients.[5] Patients ranging in age from 40 to 60 years comprise the largest affected 20-year age group.[6] PF usually occurs unilaterally with bilateral involvement occurring only 30% of the time .[7] Common risk factors known to be associated with PF include obesity, decreased ankle dorsiflexion or shortened/tight achilles tendon, excessive running, pes cavus (high arched foot type), and pes planus (flat foot).[5 6 8] PF may worsen a patient's quality of life,[9] and potentially lead to knee, hip, or lower back problems.

PF likely has multiple etiologies in combination with degeneration and inflammation.[10] The healing time of PF generally varies from 6 to 18 months, although it is a self-limiting condition.[7 11] Drug-therapy (e.g., oral analgesics and corticosteroid injections) and surgery are the two of the most common approaches used in treating PF.[12] However, oral analgesics and corticosteroid injections do not provide sustained pain relief effect,[13] and corticosteroid injections may be associated with plantar fascia rupture and plantar fat pad atrophy.[10] Surgical intervention is indicated only after at least 6 to 12 months of conservative treatment has failed.[14]

Moreover, some patients are resistant to surgery because of fear or cost. There is little convincing evidence available to support various approaches for treating PF.[15]

Acupuncture, a traditional Chinese medicine, has been used to treat a variety of musculoskeletal pain-related conditions (including PF) for thousands of years. Two recent systematic reviews concerning the effectiveness of acupuncture in treating PF have concluded that compared to the evidence available for conventionally used interventions (e.g., stretching, night splints, or dexamethasone), little evidence supports the effectiveness of electroacupuncture (EA) and manual acupuncture (MA) for reducing PF pain. They also state that acupuncture should be included in recommendations for the treatment of PF.[16 17]

EA and MA are the two acupuncture modalities frequently used which may exert different therapeutic effects via different mechanisms related to the characteristics of diseases.[18] EA has been indicated in some cases where treatment with traditional acupuncture has failed. Moreover, it has been demonstrated to produce a faster and better analgesic effect than MA.[19 20]

To our knowledge, until now no randomized controlled clinical research has analyzed the effectiveness of EA versus MA in treating PF. The objective of this study is to assess whether EA was superior to MA in reducing PF pain.

Methods and design

Study design

We will conduct a prospective randomized parallel-group assessor-blinded two-arm trial. The standard protocol items including Recommendations for Interventional Trials (SPIRIT) [21] and the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [22] guidelines were followed during the development of the protocol of this study. The flow chart is shown in Fig. 1 and the time point of assessment is shown in Fig. 2. The study was planned in accordance with the Helsinki Declaration and was approved by the Ethical Committee of the Guang'anmen Hospital, China Academy of Chinese Medical Sciences (No. 2018-010-KY). The trial has been registered at Chinese Clinical Trial Registry. Any modifications to the protocol will be reported and approved by the Ethical Committee of the Guang'anmen Hospital, China Academy of Chinese Medical Sciences and will be communicated with the trial registry, investigators and data monitoring researchers.

Study setting and recruitment

This trial will be performed at Guang'anmen Hospital, China Academy of Chinese Medical Sciences between October 2018 and December 2019. A total of 92 participants will be recruited through posters, hospital webs, and networks. The duration of the study for each participant will be 29 weeks: 1-week baseline, 4-week treatment, and 24-week follow-up.

Randomization and blinding

A 1-week baseline assessment will be needed before randomization. Participants will

be randomly assigned to either the EA or MA group at a ratio of 1:1. To ensure equal distribution in treatment groups, the random block is set to a fixed size of 4. The randomizing scheme will be generated using the Statistics Analysis System (SAS) software created by the Clinical Pharmacological Assessment Center at Guang'anmen Hospital. Random numbers and assigned groups were signed and sealed in an opaque envelope by the staff who produced it and kept by other staff who took no part in this trial. Research assistants who did not participant in the assessment and treatment will open the envelopes according to the sequence numbers. The research assistants will be in charge of recruitment and data collection, and an orthopedist will be in charge of the diagnosis of the participants. Participants and the acupuncturist will not be blinded to the allocation. The efficacy evaluator will be blinded.

Participants

Inclusion criteria:

Participants aged from 18 to 75 years will be included in the study if they meet the diagnostic criteria for PF according to the Orthopaedic Section of American Physical Therapy Association,[23] and conform to all the following conditions for at least 1 month:

(1) Pain localized to the plantar medial aspect of the heel along the insertion of the plantar fascia;

(2) Most noticeable plantar medial heel pain with initial steps after a period of inactivity (e.g., initial steps in the morning) but also worse following prolonged

weight bearing;

(3) Palpation/provocation over the medial calcaneal tuberosity or along the plantar fascia;

(4) Active and passive talocrural dorsiflexion range of motion;

(5) Positive windlass test as well as negative tarsal tunnel tests;

(6) A minimum score of 40 in worst pain intensity at first steps in the morning according to the 100-point visual analog scale (VAS); and

(7) Signed the informed consent prior to inclusion.

Exclusion criteria:

Participants who fulfill any of the following criteria will be excluded:

(1) A history of ankle and foot fracture, surgery or tumor, or have a foot deformity;

(2) A history of plantar fascia rupture, nerve entrapment syndrome, or achilles tendon lesions;

(3) Neurological or systemic diseases including rheumatoid arthritis, diabetes, cardiovascular disorder, severe hepatic/renal insufficiency, or coagulation disorder;

(4) Existing systemic or local infection, or chapped heel skin;

(5) Used local corticosteroid injections in the last 6 months;

(6) Needle-phobic patients or had received EA or MA in the past 4 weeks.

Intervention and comparison

The intervention protocol of this trial is based on the meridian theory of traditional Chinese medicine and the consensus of three acupuncture specialists, it is also used in a systematic review.[16] Acupuncturists who hold an acupuncture license and have at least 1-year of experience in acupuncture will perform the treatment. Disposable acupuncture needle (size 0.30×40 mm) and SDZ-V EA apparatus (all Hwato Brand, Suzhou Medical Appliance Factory, Suzhou, China) will be used in this trial. Acupuncture will be given on the heel pain side. If a subject experienced PF on both sides, the treatment will be performed on both sides with the more serious side evaluated.

EA group

Two Ashi points (the severer tender points over the anteromedial aspect of the heels), Chengshan (BL57), Taixi (KI3) and Kunlun (BL60) were selected in this trial. The location of the acupoints will be based on *Nomenclature and location of acupuncture points*[24] drafted in 2006 by the National Standard of the People's Republic of China (GB/T 12346–2006). After the local skin was routinely sterilized in a prone position, the participants' Ashi points, BL57, KI3, and BL60 will be vertically inserted by the needles to a depth of 10 to 15 mm to the plantar fascia layer. All needles other than Ashi points will be gently stimulated by lifting and thrusting combined with twirling and rotating the needle to reach *de qi* (the sensation of sourness, numbness, swelling and heaviness).[25] Paired alligator clips of the EA apparatus will be attached to the needle holders of the two Ashi points. EA stimulation will last for 30 minutes with a

continuous wave of 2 Hz and current intensity of 0.1 to 1 mA. The current intensity will be increased until the skin around the acupoints shivers. The manipulation on BL57, KI3, and BL60 should be performed every 10 minutes; 3 times in 30 minutes. All needles were removed after 30 minutes and pressure applied using a dry sterilized cotton ball.

MA group

Participants will receive MA at the same points as the EA group, followed by the same manipulation as EA group until *de qi* is reached. However, there will be no electric current attached to the needle holders. During needles retaining, the manipulation on BL57, KI3, and BL60 should be performed every 10 minutes; 3 times in 30 minutes.

Both treatment groups will receive 12 sessions of treatment over a 4-week period after baseline (3 sessions every week). Each session will last for 30 minutes.

Rescue medication

Throughout the trial, participants will be discouraged from taking any medication or other therapy for PF. However, if heel pain is unbearable during the study period, ibuprofen (sustained release type, 300 mg/T) will be allowed for relief up to 600 mg per day (2 T/day) for 3 days. Details of drug use (name, time, frequency, and dosage) will be recorded.

Outcome measures

Primary outcome

The primary outcome will be the proportion of responders after the 4-week treatment. The responder is defined as a participant with a decline (by at least 50%) in the worst pain intensity at first steps in the morning compared with baseline. The pain intensity will be measured using a 100 mm linear visual analog scale (VAS) with 0 representing no pain and 100 the worst imaginable pain. Additionally, the proportion of responders at weeks 16 and 28 will also be assessed.

Secondary outcomes

The secondary outcomes include the following items:

(1) Change in worst pain intensity measured by VAS at first steps in the morning after 4-week treatment, weeks 16 and 28.

(2) Change in mean pain intensity measured by VAS at first steps in the morning after 4-week treatment, weeks 16 and 28.

(3) Change in worst pain intensity measured by VAS during the day (before bed time) after 4-week treatment, weeks 16 and 28.

(4) Change in mean pain intensity measured by VAS during the day (before bed time) after 4-week treatment, weeks 16 and 28.

(5) Change in the pressure pain threshold (PPT) at the most painful spot after 4-week treatment, weeks 16 and 28. PPT, known as the minimal pressure when the sensation of pressure changes to pain,[26] will be measured by a pressure algometer (Fabrication

Enterprises, Inc., White Plains, NY; from 1 kg/cm^2 to 5 kg/cm^2) consisted of a metal probe with a rubber disc (0.5 cm^2) at one end. The pressure applied by pressing the rubber disc to the painful spot perpendicularly moves the needle in the scale at a rate of approximately 0.1 kg/cm^2/s through the metal probe. The mean score of three repeated measurements at the tested location will be used for the main analysis. Thirty seconds was used between each trial. Discomfort felt at values below 1 kg/cm^2 are defined as 0.5 kg/cm^2.

(6) Change in ankle-dorsiflexion range of motion (DFROM) after treatment, weeks 16 and 28: DFROM will be measured for using a digital goniometer (Tangxia Electronic Instrument Factory, Dongguan, from 0° to 360°). Each participant will be asked to sit with the popliteal space at the edge of the table and their knees with 90° of flexion in a completely relaxed station. The axis of the goniometer will be centered over the lateral malleolus and the arms are aligned with the fibular shaft and the head of the fifth metatarsal. The examiner passively moves the ankle into dorsiflexion from a neutral starting position until a firm end feel is elicited.[27] The examiner will measure the ankle-joint angle 3 times at maximum DFROM within 10 seconds between each examination.

(7) Change in FAAM (Foot and Ankle Ability Measure) total score and subscale scores after 4-week treatment, weeks 16 and 28: The FAAM is a 29-item evaluative tool for the function of foot and ankle, which consists of 21-item activities of daily living (ADL) and 8-item sports subscales.[28] Each item score ranges from 0 to 4, with higher scores indicating a higher level of function. The FAAM has a maximum

potential score (116 total, 84 ADL, and 32 Sport subscales). The obtained score (total score, ADL, and sport subscale scores) is divided by the maximum potential score and multiplied by 100 to get a percentage. If the patient cannot respond, it is left blank and is not a part of the final value of the questionnaire. In this trial, we will use the Chinese version of FAAM, which has been reported to have a satisfactory psychometric property.[29]

(8) Patients' global improvement assessment: Patients' global improvement will be assessed by a 7-point self-reporting scale ranging from 1 to 7, where 1 indicates "complete recovery", 2 indicates "obvious improvement", 3 indicates "a little improvement", 4 indicates "no change", 5 indicates "a little worse", 6 indicates "obvious worse", and 7 indicates "vastly worse". The proportions of participants in each category of global improvement assessment will be measured after the 4-week treatment, weeks 16 and 28.

(9) Patients' expectations for acupuncture: We will assess patients' expectation for acupuncture at baseline. It includes three brief questions to investigate whether patients believe that acupuncture treatment will help: "Do you believe acupuncture is effective for treating the illness?", "Do you think acupuncture will be helpful to improve your PF?" and "which acupuncture manipulation do you prefer, MA or EA?". For each question, participants will choose "Yes", "No", or "unclear/whatever" as the answer.

Safety assessment

All adverse events (AEs) will be monitored and reported through the whole trial. AEs will be categorized as treatment-related (e.g., localized hematoma, localized infection, broken needle, fainting, nausea, dizziness, vomiting, or palpitations) or non-treatment-related within 24 hours after their occurrence. Detailed information on AEs and serious adverse events (SAEs)—including the name, onset and end date, intensity, relationship with acupuncture and outcome—will be recorded. Participants are discontinued if the treatments cause aggravation of symptoms. Researchers will immediately report SAEs (e.g., requiring hospitalization, causing disability or impaired ability to work) to the Medical Ethics Committee of Guang'anmen Hospital and suspend the study.

Sample size calculation

The null hypothesis is that the proportion of participants with at least a 50% decrease from baseline in the worst pain intensity (as measured by the VAS at first steps in the morning after the 4-week treatment) will be same for MA and EA. A decline by at least 50% in the pain at first steps was regarded as clinically relevant.[30] The previous studies reported that 73.3% of the participants had at least a 50% decrease in the pain as measured by the VAS at first steps after the 4-week EA treatment,[31] and 44.4% after the 4-week MA treatment.[32] Power was defined as 80% for an alpha of 5%. Accordingly, 92 participants will be required (46 in each group), assuming a

two-tailed test with 10% loss to follow-up.

Statistical analysis

We will use SPSS v20 software (IBM SPSS Statistics; IBM Corp, Somers, NY) to perform all statistical analysis following the intention-to-treat (ITT) principle. The confidence interval will be established at 95%, and the significance level at 0.05. Missing data will be calculated using the actual observational value without imputation if the dropout rate is no more than 10%. For continuous data, the data will be presented as mean ± standard deviation when normally distributed or presented as median (interquartile range) when not normally distributed. The continuous data will be compared between groups using Student's *t*-test and Wilcoxon rank sum test, and the categorical data using the Chi-squared test or Fisher's exact test, as appropriate. Sensitivity analysis will be performed if necessary. A P-value <0.05 will be considered statistically significant.

Quality control

Prior to the trial, all staff will undergo special training on the purpose and content of the trial, treatment strategies, and quality control. Acupuncturists in this trial will have an acupuncture license with at least 1-year of acupuncture experience. Monitors will check case report forms once every week as well as the acupuncture operation during the treatment period. Drop-outs and withdrawals including the reasons will be detailed documented through the trial. Participants' information will be stored in locked file

cabinets at the study sites with limited access; only investigators have the right to access the data. All investigators will always maintain a strict privacy policy to protect confidentiality before, during and after the trial.

Discussion

The results of this study will clarify the effect of EA compared with MA in treating PF. There were several trials assessing EA and MA in the treatment of PF.[31 33 34] The results have already showed that EA or MA coupled with conventional treatments could reduce pain, disabilities, and activity limitations in patients with PF compared with conventional treatments.[31 33]

According to some previous studies, EA can produce a faster and better analgesic effect than MA.[19 20] However, no studies have reported the effect of head-to-head comparison between EA and MA in the treatment of PF. This trial comparing EA with MA could fill a gap in the literature thus helping physical therapists and acupuncturists in their clinical decision-making.

The VAS is one of the most commonly used instruments for assessment of pain and has been validated to detect changes in pain intensity.[35] Moreover, it has also been used in many studies applying acupuncture for PF.[33 34] Because morning pain localized to the plantar medial aspect of the heel is the distinct feature of PF, we will choose the proportion of participant with a decline of at least 50% in the worst pain intensity at first steps in the morning after 4-week treatment compared with baseline as the primary outcome.

The result may help clarify the effect of EA compared with MA on the pain relief of PF. In addition, considering that pain of PF can be categorized as pressure pain, PPT (which will be evaluated by an algometer) could be a reasonable objective secondary outcome to help investigating physiological changes of PF. Moreover, DFROM measured by a digital goniometer and FAAM are well suited for evaluating the effects of acupuncture treatment for PF. These would be supportive of the primary outcome and meaningful for the overall effectiveness evaluation.

Strengths of the study include its strictly standardized endpoints and objective criteria, long-term follow-up, strict quality control, and evaluation of patients' expectations for acupuncture. The trial also has some limitations. First, this is a single-center study conducted at a tertiary A hospital in China and the results might not apply to primary hospital or other countries. Second, participants and the acupuncturist will not be blinded due to the nature of the study, which might bring bias and influence the results. Third, considering ethics and the acceptance of participants, we did not assign a placebo/sham/ wait list group, which could not exclude the placebo effect of acupuncture and a possible spontaneous remission of the PF.

Trial status: No recruitment at the present.

Ethical Approval and Consent to participate The study protocol has received approval from the Institutional Review Boards of Guang'anmen Hospital in China (approval NO. 2018-010-KY, TEL +86-10-88001552), and all investigators will comply with the Helsinki Declaration.

Consent for publication Not applicable.

Availability of data and materials All data are fully available without restriction.

Competing interests The authors declare that they have no competing interests.

Authors' contributions Zhishun Liu is responsible for supervising the clinical study and for communicating important protocol modifications to relevant parties. Weiming Wang and Zhishun Liu conceived the idea and designed this trial. Ruimin Jiao are responsible for the recruitment and treatment of patients. Yan Liu and Jie Zhao are responsible for statistical analysis. This manuscript was drafted by Weiming Wang and revised by Zhishun Liu. All authors read and approved the final draft of the manuscript.

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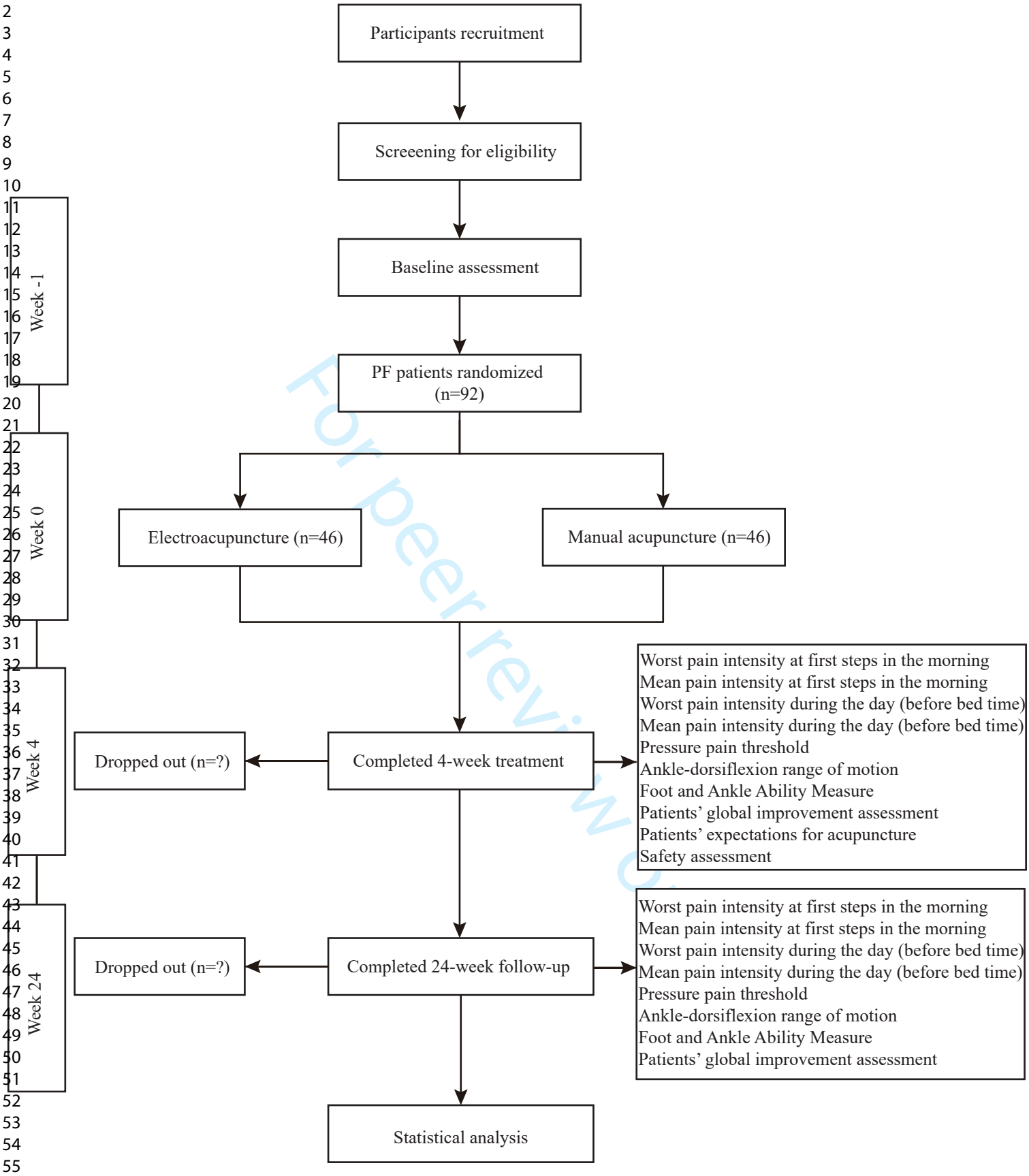

Figure 1. Trial flow diagram

	Study Period				
	Baseline	**Allocation**	**Treatment**	**Follow-up**	
TIME POINT (W, week)			W 4±2d	W 16±3d	W 24±3d
Enrollment					
Eligibility criteria	×				
Demography characteristics	×				
Disease history of PF	×				
Eligibility screen	×				
Informed consent	×				
Allocation		×			
Interventions					
Electroacupuncture			×(weeks1-4)		
Manual acupuncture			×(weeks1-4)		
Assessments					
Worst pain intensity at first steps in the morning	×		×	×	×
Mean pain intensity at first steps in the morning	×		×	×	×
Worst pain intensity during the day (before bed time)	×		×	×	×
Mean pain intensity during the day (before bed time)	×		×	×	×
Pressure pain threshold	×		×	×	×
Ankle-dorsiflexion range of motion	×		×	×	×
Foot and Ankle Ability Measure	×		×	×	×
Patients' global improvement assessment	×		×	×	×
Patients' expectations for acupuncture	×				
Adverse events			×		
Safety assessment			×	×	×

Figure 2: The time point of assessment

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Article title:

Electroacupuncture versus manual acupuncture in the treatment of plantar heel pain syndrome: study protocol for an upcoming randomized controlled trial

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Abstract

Introduction: Plantar heel pain syndrome is a common cause of heel pain. It may worsen a patient's quality of life, and potentially lead to knee, hip, or lower back problems. Previous studies have shown that electroacupuncture and manual acupuncture are effective treatments for relieving pain in patients with Plantar heel pain syndrome. However, little evidence supports the use of one intervention over the other.

Methods and analysis: A total of 92 patients diagnosed with plantar heel pain syndrome will be recruited and randomly assigned to an electroacupuncture group or a manual acupuncture group at a ratio of 1:1. Patients in both groups will receive a 30-min acupuncture treatment (3 times per week) for a total of 12 sessions over 4 weeks. The primary outcome will be the proportion of patients with at least 50% reduction from baseline in the worst pain intensity measured by visual analog scale (0 to 100, higher scores signify worse pain) at first steps in the morning after 4-week treatment. The secondary outcomes will include change in worst pain intensity at first steps in the morning, change in mean pain intensity at first steps in the morning, change in worst pain intensity during the day, change in mean pain intensity during the day, change in the pressure pain threshold, change in ankle-dorsiflexion range of motion, change in Foot and Ankle Ability Measure total score and subscale scores, patients' global improvement assessment, patients' expectations for acupuncture, and safety evaluation. We will perform all statistical analysis following the intention-to-treat principle.

Ethics and dissemination: The study has been approved by our ethics review board (Protocol Approval No. 2018-010-KY). The study findings will be disseminated through presentation at a high-impact medical journal, with online access. We also to plan to present it in select conferences and scientific meetings.

Trial registration: Chinese Clinical Trial Registry identifier: ChiCTR-1800016531, registered 7 June 2018.

Strengths and limitations of this study:

► This study is the first randomized controlled trial comparing electroacupuncture versus manual acupuncture for pain relief in participants with plantar heel pain syndrome.

► Strictly standardized endpoints and objective criteria, long-term follow-up, strict quality control, and evaluation of patients' expectations for acupuncture aiming to reduce the risk of bias.

► Eligible participants will be restricted to those in a tertiary A hospital in China, the results might not apply to primary hospital or other countries.

►Due to the nature of the study, participants and the acupuncturist will not be blinded, which may bring bias and influence the results.

►Considering ethics and the acceptance of participants, a placebo/sham/ wait list group will not be assigned, which could not exclude the placebo effect of acupuncture and a possible spontaneous remission of the plantar heel pain syndrome.

Background

Plantar heel pain syndrome (PHPS), also referred to as plantar fasciitis, is a common cause of heel pain,[1 2] It is characterized by pain exacerbated with the first walking in the morning or after a long period of rest.[3] In the United States, more than 2 million people per year seek treatment due to heel pain,[4] and approximately 10% of the general population is affected by heel pain during their lives.[5] Excluding conditions such as fat pad atrophy, plantar fibromatosis, and calcaneal stress fracture, symptoms of plantar heel pain are attributed to PHPS in 80% of patients.[6] Patients ranging in age from 40 to 60 years comprise the largest affected 20-year age group.[7] PHPS usually occurs unilaterally with bilateral involvement occurring only 30% of the time .[8] Common risk factors known to be associated with PHPS include obesity, decreased ankle dorsiflexion or shortened/tight achilles tendon, excessive running, pes cavus (high arched foot type), and pes planus (flat foot).[6 7 9] PHPS may worsen a patient's quality of life,[10] and potentially lead to knee, hip, or lower back problems.

PHPS likely has multiple etiologies in combination with degeneration and inflammation.[11] The healing time of PHPS generally varies from 6 to 18 months, although it is a self-limiting condition.[8 12] Different approaches are available for the treatment of PHPS, including instrumental-, physical-, drug-, and surgical-therapy.[1] However, definite effects of instrumental- and physical-therapy are still needed to be confirmed. Meanwhile, drug-therapy (e.g., oral analgesics and corticosteroid injections) do not provide sustained pain relief effect,[13] and corticosteroid injections may be associated with plantar fascia rupture and plantar fat pad atrophy.[11] Surgical

-therapy is indicated only after at least 6 to 12 months of conservative treatment has failed.[14] Moreover, some patients are resistant to surgery because of fear or cost. There is little convincing evidence available to support various approaches for treating PHPS.[15]

Even lack of unified standard on the definition of acupuncture, most hold the view that acupuncture is a technique of the stimulation of specific points on the skin by the insertion of needles based on the principles of traditional Chinese medicine.[16] Acupuncture has been used to treat a variety of musculoskeletal pain-related conditions (including PHPS) for thousands of years. Acupuncturists' conceptualisations of PHPS include 'deficient Kidney Qi', 'Bi syndrome' and others.[17] At present, various acupuncture modality such as electroacupuncture and manual acupuncture are available to clinicians. Stimulation of acupuncture points through needling was shown to inducing analgesia via releasing neuropeptides such as enkephalin, dynorphin, β-endorphin and endomorphine.[18] Two recent systematic reviews concerning the effectiveness of acupuncture in treating PHPS have concluded that acupuncture may reduce PHPS pain in the short term and acupuncture should be included in recommendations for the treatment of PHPS[19 20]. Though broader questions such as how practitioners choose between the various approaches in different contexts remain unclear,[17] future research should have a focus on exploring the optimum use of acupuncture for heel pain.[20]

EA and MA are the two acupuncture modalities frequently used which may exert different therapeutic effects via different mechanisms related to the characteristics of

diseases.[21] EA has been indicated in some cases where treatment with traditional acupuncture has failed. Moreover, it has been demonstrated to produce a faster and better analgesic effect than MA.[22 23]

To our knowledge, until now no randomized controlled clinical research has compared the effectiveness of EA with MA in treating PHPS. The objective of this study is to assess whether EA was superior to MA in reducing PHPS pain.

Methods and design

Study design

We will conduct a prospective randomized parallel-group assessor-blinded two-arm trial. The standard protocol items including Recommendations for Interventional Trials (SPIRIT) [24] and the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [25] guidelines will be followed during the development of the protocol of this study. The flow chart is shown in Fig. 1 and the time point of assessment is shown in Fig. 2.

Study setting and recruitment

This trial will be performed at Guang'anmen Hospital, China Academy of Chinese Medical Sciences between October 2018 and December 2019. A total of 92 participants will be recruited through posters, hospital webs, and networks. The duration of the study for each participant will be 29 weeks: 1-week baseline, 4-week treatment, and 24-week follow-up.

Randomization and blinding

A 1-week baseline assessment will be needed before randomization. Participants will be randomly assigned to either the EA or MA group at a ratio of 1:1. To ensure equal distribution in treatment groups, the random block is set to a fixed size of 4. The randomizing scheme will be generated using the Statistics Analysis System (SAS) software created by the Clinical Pharmacological Assessment Center at Guang'anmen Hospital. Random numbers and assigned groups were signed and sealed in an opaque envelope by the staff who produced it and kept by other staff who took no part in this trial. Research assistants who did not participant in the assessment and treatment will open the envelopes according to the sequence numbers. The research assistants will be in charge of recruitment and data collection, and an orthopedist will be in charge of the diagnosis of the participants. Participants and the acupuncturist will not be blinded to the allocation. The efficacy evaluator will be blinded.

Participants

Inclusion criteria:

Participants aged from 18 to 75 years will be included in the study if they meet the diagnostic criteria for PHPS according to the Orthopaedic Section of American Physical Therapy Association,[26] and conform to all the following conditions for at least 1 month:

(1) Pain localized to the plantar medial aspect of the heel along the insertion of the plantar fascia;

(2) Most noticeable plantar medial heel pain with initial steps after a period of

inactivity (e.g., initial steps in the morning) but also worse following prolonged weight bearing;

(3) Palpation/provocation over the medial calcaneal tuberosity or along the plantar fascia;

(4) Active and passive talocrural dorsiflexion range of motion;

(5) Positive windlass test as well as negative tarsal tunnel tests;

(6) A minimum score of 40 in worst pain intensity at first steps in the morning according to the 100-point visual analog scale (VAS); and

(7) Signed the informed consent prior to inclusion.

Exclusion criteria:

Participants who fulfill any of the following criteria will be excluded:

(1) A history of ankle and foot fracture, surgery or tumor, or have a foot deformity;

(2) A history of plantar fascia rupture, nerve entrapment syndrome, or achilles tendon lesions;

(3) Neurological or systemic diseases including rheumatoid arthritis, diabetes, cardiovascular disorder, severe hepatic/renal insufficiency, or coagulation disorder;

(4) Existing systemic or local infection, or chapped heel skin;

(5) Used local corticosteroid injections in the last 6 months;

(6) Needle-phobic patients or had received EA or MA in the past 4 weeks.

Intervention and comparison

The intervention protocol of this trial is based on the meridian theory of traditional Chinese medicine and the consensus of three acupuncture specialists, it is also used in a systematic review.[19] Acupuncturists who hold an acupuncture license and have at least 1-year of experience in acupuncture will perform the treatment. Disposable acupuncture needle (size 0.30×40 mm) and SDZ-V EA apparatus (all Hwato Brand, Suzhou Medical Appliance Factory, Suzhou, China) will be used in this trial. Acupuncture will be given on the heel pain side. If a subject experienced PHPS on both sides, the treatment will be performed on both sides with the more serious side evaluated.

EA group

Two Ashi points (the severer tender points over the anteromedial aspect of the heels), Chengshan (BL57), Taixi (KI3) and Kunlun (BL60) will be selected in this trial. Based on the principles of TCM, the major cause of PHPS is qi and blood deficiency in the kidney meridian. Sometimes PHPS may also associated with qi and blood stasis.[27] Whatever the root cause, stimulation of Ashi points can unblock the qi-blood stagnation and result in alleviating pain.[28] BL57, KI3 and BL60 will be selected to build and supply qi and blood to the local area and kidney as well as to the whole person. The location of the acupoints will be based on *Nomenclature and location of acupuncture points*[29] drafted in 2006 by the National Standard of the People's Republic of China (GB/T 12346–2006). After the local skin was routinely sterilized in a prone position, the participants' Ashi points will be vertically inserted by the

needles to a depth of 10 to 15 mm to the plantar fascia layer. For BL57, KI3, and BL60, needles will be vertically inserted approximately 15 mm. All needles other than Ashi points will be gently stimulated by lifting and thrusting combined with twirling and rotating the needle to reach *de qi* (the sensation of sourness, numbness, swelling and heaviness).[30] Paired alligator clips of the EA apparatus will be attached to the needle holders of the two Ashi points. EA stimulation will last for 30 minutes with a continuous wave of 2 Hz and current intensity of 0.1 to 1 mA. The current intensity will be increased until the skin around the acupoints shivers. The manipulation on BL57, KI3, and BL60 should be performed every 10 minutes; 3 times in 30 minutes. All needles were removed after 30 minutes and pressure applied using a dry sterilized cotton ball.

MA group

Participants will receive MA at the same points as the EA group, followed by the same manipulation as EA group until *de qi* is reached. However, there will be no electric current attached to the needle holders. During needles retaining, the manipulation on BL57, KI3, and BL60 should be performed every 10 minutes; 3 times in 30 minutes.

Both treatment groups will receive 12 sessions of treatment over a 4-week period after baseline (3 sessions every week). Each session will last for 30 minutes.

Rescue medication

Throughout the trial, participants will be discouraged from taking any medication or other therapy for PHPS. However, if heel pain is unbearable during the study period, ibuprofen (sustained release type, 300 mg/T) will be allowed for relief up to 600 mg per day (2 T/day) for 3 days. Details of drug use (name, time, frequency, and dosage) will be recorded.

Outcome measures

Primary outcome

The primary outcome will be the proportion of responders after the 4-week treatment. The responder is defined as a participant with a decline (by at least 50%) in the worst pain intensity at first steps in the morning compared with baseline. The pain intensity will be measured using a 100 mm linear VAS with 0 representing no pain and 100 the worst imaginable pain. Additionally, the proportion of responders at weeks 16 and 28 will also be assessed.

Secondary outcomes

The secondary outcomes include the following items:

(1) Change in worst pain intensity measured by VAS at first steps in the morning after 4-week treatment, weeks 16 and 28.

(2) Change in mean pain intensity measured by VAS at first steps in the morning after 4-week treatment, weeks 16 and 28.

(3) Change in worst pain intensity measured by VAS during the day (before bed time) after 4-week treatment, weeks 16 and 28.

(4) Change in mean pain intensity measured by VAS during the day (before bed time) after 4-week treatment, weeks 16 and 28.

(5) Change in the pressure pain threshold (PPT) at the most painful spot after 4-week treatment, weeks 16 and 28. PPT, known as the minimal pressure when the sensation of pressure changes to pain,[31] will be measured by a pressure algometer (Fabrication Enterprises, Inc., White Plains, NY; from 1 kg/cm^2 to 5 kg/cm^2) consisted of a metal probe with a rubber disc (0.5 cm^2) at one end. The pressure applied by pressing the rubber disc to the painful spot perpendicularly moves the needle in the scale at a rate of approximately 0.1 kg/cm^2/s through the metal probe. The mean score of three repeated measurements at the tested location will be used for the main analysis. Thirty seconds will be used between each trial. Discomfort felt at values below 1 kg/cm^2 are defined as 0.5 kg/cm^2.

(6) Change in ankle-dorsiflexion range of motion (DFROM) after treatment, weeks 16 and 28: DFROM will be measured for using a digital goniometer (Tangxia Electronic Instrument Factory, Dongguan, from 0° to 360°). Each participant will be asked to sit with the popliteal space at the edge of the table and their knees with 90° of flexion in a completely relaxed station. The axis of the goniometer will be centered over the lateral malleolus and the arms are aligned with the fibular shaft and the head of the fifth metatarsal. The examiner passively moves the ankle into dorsiflexion from a neutral starting position until a firm end feel is elicited.[32] The examiner will measure the ankle-joint angle 3 times at maximum DFROM within 10 seconds between each examination.

(7) Change in FAAM (Foot and Ankle Ability Measure) total score and subscale scores after 4-week treatment, weeks 16 and 28: The FAAM is a 29-item evaluative tool for the function of foot and ankle, which consists of 21-item activities of daily living (ADL) and 8-item sports subscales.[33] Each item score ranges from 0 to 4, with higher scores indicating a higher level of function. The FAAM has a maximum potential score (116 total, 84 ADL, and 32 Sport subscales). The obtained score (total score, ADL, and sport subscale scores) is divided by the maximum potential score and multiplied by 100 to get a percentage. If the patient cannot respond, it is left blank and is not a part of the final value of the questionnaire. In this trial, we will use the Chinese version of FAAM, which has been reported to have a satisfactory psychometric property.[34]

(8) Patients' global improvement assessment: Patients' global improvement will be assessed by a 7-point self-reporting scale ranging from 1 to 7, where 1 indicates "complete recovery", 2 indicates "obvious improvement", 3 indicates "a little improvement", 4 indicates "no change", 5 indicates "a little worse", 6 indicates "obvious worse", and 7 indicates "vastly worse". The proportions of participants in each category of global improvement assessment will be measured after the 4-week treatment, weeks 16 and 28.

(9) Patients' expectations for acupuncture: We will assess patients' expectation for acupuncture at baseline. It includes three brief questions to investigate whether patients believe that acupuncture treatment will help: "Do you believe acupuncture is effective for treating the illness?", "Do you think acupuncture will be helpful to

improve your PHPS?" and "which acupuncture manipulation do you prefer, MA or EA?". For each question, participants will choose "Yes", "No", or "unclear/whatever" as the answer.

Safety assessment

All adverse events (AEs) will be monitored and reported through the whole trial. AEs will be categorized as treatment-related (e.g., localized hematoma, localized infection, broken needle, fainting, nausea, dizziness, vomiting, or palpitations) or non-treatment-related within 24 hours after their occurrence. Detailed information on AEs and serious adverse events (SAEs)—including the name, onset and end date, intensity, relationship with acupuncture and outcome—will be recorded. Participants are discontinued if the treatments cause serious aggravation of symptoms, which will include an 80% or more increase of existing heel pain measured by VAS at the end of the first hour after acupuncture. Researchers will immediately report SAEs (e.g., requiring hospitalization, causing disability or impaired ability to work) to the Medical Ethics Committee of Guang'anmen Hospital and suspend the study.

Sample size calculation

The null hypothesis is that the proportion of participants with at least a 50% decrease from baseline in the worst pain intensity (as measured by the VAS at first steps in the morning after the 4-week treatment) will be same for MA and EA. A decline by at least 50% in the pain at first steps was regarded as clinically relevant.[35] The previous

studies reported that 73.3% of the participants had at least a 50% decrease in the pain as measured by the VAS at first steps after the 4-week EA treatment,[36] and 44.4% after the 4-week MA treatment.[37]Power was defined as 80% for an alpha of 5%. Accordingly, 92 participants will be required (46 in each group), assuming a two-tailed test with 10% loss to follow-up.

Statistical analysis

We will use SPSS v20 software (IBM SPSS Statistics; IBM Corp, Somers, NY) to perform all statistical analysis following the intention-to-treat (ITT) principle. The confidence interval will be established at 95%, and the significance level at 0.05. Missing data will be calculated using the actual observational value without imputation if the dropout rate is no more than 10%. For continuous data, the data will be presented as mean ± standard deviation when normally distributed or presented as median (interquartile range) when not normally distributed. The longitudinal continuous data will be compared between groups using repeated-measures ANOVA including group and time*group interaction. The other continuous data will be analyzed Student's *t*-test and Wilcoxon rank sum test, and the categorical data using the Chi-squared test or Fisher's exact test, as appropriate. Sensitivity analysis will be performed if necessary. A P-value <0.05 will be considered statistically significant.

Quality control

Prior to the trial, all staff will undergo special training on the purpose and content of the trial, treatment strategies, and quality control. Acupuncturists in this trial will have an acupuncture license with at least 1-year of acupuncture experience. Monitors will check case report forms once every week as well as the acupuncture operation during the treatment period. Drop-outs and withdrawals including the reasons will be detailed documented through the trial. Participants' information will be stored in locked file cabinets at the study sites with limited access; only investigators have the right to access the data. All investigators will always maintain a strict privacy policy to protect confidentiality before, during and after the trial.

Patient and public involvement

The initial concept of investigating whether EA was superior to MA in reducing PHPS pain was first proposed by a patient who prefer EA rather than MA. No other patients will be in the recruitment and conduct of the study. The burden of the intervention will be assessed by patients themselves. The results will be disseminated to study participants via the website of our hospital.

Ethics and dissemination

The study was planned in accordance with the Helsinki Declaration and was approved by the Ethical Committee of the Guang'anmen Hospital, China Academy of Chinese Medical Sciences (No. 2018-010-KY). The trial has been registered at Chinese Clinical Trial Registry. All the participants will be fully informed about this trial and

given enough time to inquire about details and decide whether to participate or not at first visit. Participants will be asked to sign the informed consent form if they agree to participate. Any modifications to the protocol will be reported and approved by the Ethical Committee of the Guang'anmen Hospital, China Academy of Chinese Medical Sciences and will be communicated with the trial registry, investigators and data monitoring researchers. The study findings will be disseminated through presentation at a high-impact medical journal, with online access. We also plan to present it in select conferences and scientific meetings after the paper about this trial' results published.

Discussion

The results of this study will clarify the effect of EA compared with MA in treating PHPS. There were several trials assessing EA and MA in the treatment of PHPS.[36 38 39] The results have already showed that EA or MA coupled with conventional treatments could reduce pain, disabilities, and activity limitations in patients with PHPS compared with conventional treatments.[36 38]

According to some previous studies, EA can produce a faster and better analgesic effect than MA.[22 23] However, no studies have reported the effect of head-to-head comparison between EA and MA in the treatment of PHPS. This trial comparing EA with MA could fill a gap in the literature thus helping physical therapists and acupuncturists in their clinical decision-making.

The VAS is one of the most commonly used instruments for assessment of pain and has been validated to detect changes in pain intensity.[40] Moreover, it has also been used in many studies applying acupuncture for PHPS.[38 39] Because morning pain localized to the plantar medial aspect of the heel is the distinct feature of PHPS, we will choose the proportion of participant with a decline of at least 50% in the worst pain intensity at first steps in the morning after 4-week treatment compared with baseline as the primary outcome.

The result may help clarify the effect of EA compared with MA on the pain relief of PHPS. In addition, considering that pain of PHPS can be categorized as pressure pain, PPT (which will be evaluated by an algometer) could be a reasonable objective secondary outcome to help investigating physiological changes of PHPS. Moreover, DFROM measured by a digital goniometer and FAAM are well suited for evaluating the effects of acupuncture treatment for PHPS. These would be supportive of the primary outcome and meaningful for the overall effectiveness evaluation.

Strengths of the study include its strictly standardized endpoints and objective criteria, long-term follow-up, strict quality control, and evaluation of patients' expectations for acupuncture. The trial also has some limitations. First, this is a single-center study conducted at a tertiary A hospital in China and the results might not apply to primary hospital or other countries. Second, participants and the acupuncturist will not be blinded due to the nature of the study, which might bring bias and influence the results. Third, considering ethics and the acceptance of participants, we did not assign a placebo/sham/ wait list group, which could not

exclude the placebo effect of acupuncture and a possible spontaneous remission of the PHPS. Fourth, this study mainly focuses on Ashi points, BL57, KI3 and BL60 for PHPS, so that the findings may not be extended to other points for the same condition.

Trial status: No recruitment at the present.

Ethical Approval and Consent to participate The study protocol has received approval from the Institutional Review Boards of Guang'anmen Hospital in China (approval NO. 2018-010-KY, TEL +86-10-88001552), and all investigators will comply with the Helsinki Declaration.

Consent for publication Not applicable.

Availability of data and materials All data are fully available without restriction.

Competing interests The authors declare that they have no competing interests.

Authors' contributions Zhishun Liu is responsible for supervising the clinical study and for communicating important protocol modifications to relevant parties. Weiming Wang and Zhishun Liu conceived the idea and designed this trial. Ruimin Jiao are responsible for the recruitment and treatment of patients. Yan Liu and Jie Zhao are responsible for statistical analysis. This manuscript was drafted by Weiming Wang and revised by Zhishun Liu. All authors read and approved the final draft of the manuscript.

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Figure legends

Figure 1: Trial flow diagram

Figure 2: The time point of assessment

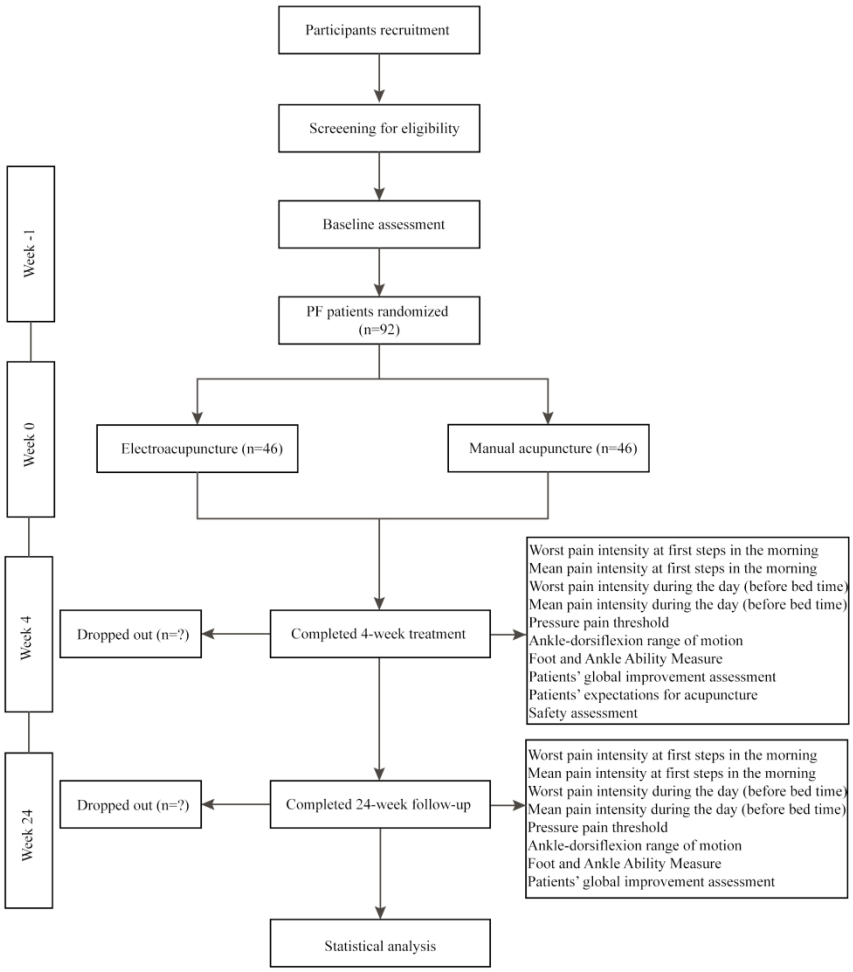

Figure 1. Trial flow diagram

Figure 1: Trial flow diagram

234x277mm (300 x 300 DPI)

	Study Period				
	Baseline	**Allocation**	**Treatment**	**Follow-up**	
TIME POINT (W, week)			W 4±2d	W 16±3d	W 24±3d
Enrollment					
Eligibility criteria	×				
Demography characteristics	×				
Disease history of PF	×				
Eligibility screen	×				
Informed consent	×				
Allocation		×			
Interventions					
Electroacupuncture			×(weeks1-4)		
Manual acupuncture			×(weeks1-4)		
Assessments					
Worst pain intensity at first steps in the morning	×		×	×	×
Mean pain intensity at first steps in the morning	×		×	×	×
Worst pain intensity during the day (before bed time)	×		×	×	×
Mean pain intensity during the day (before bed time)	×		×	×	×
Pressure pain threshold	×		×	×	×
Ankle-dorsiflexion range of motion	×		×	×	×
Foot and Ankle Ability Measure	×		×	×	×
Patients' global improvement assessment	×		×	×	×
Patients' expectations for acupuncture	×				
Adverse events			×		
Safety assessment			×	×	×

Figure 2: The time point of assessment

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210x297mm (300 x 300 DPI)

Table 1

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	3
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1,19
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	17，7

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	No
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	11
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-14

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	NA
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	3

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	20
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.