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

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9 **Electroacupuncture versus manual acupuncture in the treatment of**
10 **plantar fasciitis: study protocol for an upcoming randomized**
11 **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.

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4 **Ethics and dissemination:** The study has been approved by our ethics review board
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6 (Protocol Approval No. 2018-010-KY). The study findings will be disseminated
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8 through presentation at a high-impact medical journal, with online access. We also to
9
10 plan to present it in select conferences and scientific meetings.
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13 **Trial registration:** Chinese Clinical Trial Registry identifier: ChiCTR-1800016531,
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15 registered 7 June 2018.
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18 **Strengths and limitations of this study:**
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20 ▶ This study is the first randomized controlled trial comparing electroacupuncture
21
22 versus manual acupuncture for pain relief in participants with planter fasciitis.
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25 ▶ Strictly standardized endpoints and objective criteria, long-term follow-up, strict
26
27 quality control, and evaluation of patients' expectations for acupuncture.
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30 ▶ The results might not apply to primary hospital or other countries. Participants and
31
32 the acupuncturist will not be blinded due to the nature of the study. A placebo/sham/
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34 wait list group was not assigned.
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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

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3 Moreover, some patients are resistant to surgery because of fear or cost. There is little
4
5 convincing evidence available to support various approaches for treating PF.¹⁵
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8 Acupuncture, a traditional Chinese medicine, has been used to treat a variety of
9
10 musculoskeletal pain-related conditions (including PF) for thousands of years. Two
11
12 recent systematic reviews concerning the effectiveness of acupuncture in treating PF
13
14 have concluded that compared to the evidence available for conventionally used
15
16 interventions (e.g., stretching, night splints, or dexamethasone), little evidence
17
18 supports the effectiveness of electroacupuncture (EA) and manual acupuncture (MA)
19
20 for reducing PF pain. They also state that acupuncture should be included in
21
22 recommendations for the treatment of PF.^{16 17}
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28 EA and MA are the two acupuncture modalities frequently used which may exert
29
30 different therapeutic effects via different mechanisms related to the characteristics of
31
32 diseases.¹⁸ EA has been indicated in some cases where treatment with traditional
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34 acupuncture has failed. Moreover, it has been demonstrated to produce a faster and
35
36 better analgesic effect than MA.^{19 20}
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40 To our knowledge, until now no randomized controlled clinical research has
41
42 analyzed the effectiveness of EA versus MA in treating PF. The objective of this
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44 study is to assess whether EA was superior to MA in reducing PF pain.
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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

1
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3 be randomly assigned to either the EA or MA group at a ratio of 1:1. To ensure equal
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6 distribution in treatment groups, the random block is set to a fixed size of 4. The
7
8 randomizing scheme will be generated using the Statistics Analysis System (SAS)
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10 software created by the Clinical Pharmacological Assessment Center at Guang'anmen
11
12 Hospital. Random numbers and assigned groups were signed and sealed in an opaque
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14 envelope by the staff who produced it and kept by other staff who took no part in this
15
16 trial. Research assistants who did not participant in the assessment and treatment will
17
18 open the envelopes according to the sequence numbers. The research assistants will
19
20 be in charge of recruitment and data collection, and an orthopedist will be in charge of
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22 the diagnosis of the participants. Participants and the acupuncturist will not be blinded
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24 to the allocation. The efficacy evaluator will be blinded.
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33 **Participants**

34 **Inclusion criteria:**

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36 Participants aged from 18 to 75 years will be included in the study if they meet the
37
38 diagnostic criteria for PF according to the Orthopaedic Section of American Physical
39
40 Therapy Association,²³ and conform to all the following conditions for at least
41
42 1 month:
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- 46
47 (1) Pain localized to the plantar medial aspect of the heel along the insertion of the
48
49 plantar fascia;
- 50
51 (2) Most noticeable plantar medial heel pain with initial steps after a period of
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53 inactivity (e.g., initial steps in the morning) but also worse following prolonged
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3 weight bearing;

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

7
8 fascia;

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

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

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

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17 (7) Signed the informed consent prior to inclusion.
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25 **Exclusion criteria:**

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

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

30
31 (2) A history of plantar fascia rupture, nerve entrapment syndrome, or achilles tendon
32 lesions;

33
34 (3) Neurological or systemic diseases including rheumatoid arthritis, diabetes,
35 cardiovascular disorder, severe hepatic/renal insufficiency, or coagulation disorder;

36
37 (4) Existing systemic or local infection, or chapped heel skin;

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

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41 (6) Needle-phobic patients or had received EA or MA in the past 4 weeks.
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52 **Intervention and comparison**

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4 The intervention protocol of this trial is based on the meridian theory of traditional
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6 Chinese medicine and the consensus of three acupuncture specialists, it is also used in
7
8 a systematic review.¹⁶ Acupuncturists who hold an acupuncture license and have at
9
10 least 1-year of experience in acupuncture will perform the treatment. Disposable
11
12 acupuncture needle (size 0.30×40 mm) and SDZ-V EA apparatus (all Hwato Brand,
13
14 Suzhou Medical Appliance Factory, Suzhou, China) will be used in this trial.
15
16 Acupuncture will be given on the heel pain side. If a subject experienced PF on both
17
18 sides, the treatment will be performed on both sides with the more serious side
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23 evaluated.

24 25 26 27 28 **EA group**

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30 Two Ashi points (the severer tender points over the anteromedial aspect of the heels),
31
32 Chengshan (BL57), Taixi (KI3) and Kunlun (BL60) were selected in this trial. The
33
34 location of the acupoints will be based on *Nomenclature and location of acupuncture*
35
36 *points*²⁴ drafted in 2006 by the National Standard of the People's Republic of China
37
38 (GB/T 12346–2006). After the local skin was routinely sterilized in a prone position,
39
40 the participants' Ashi points, BL57, KI3, and BL60 will be vertically inserted by the
41
42 needles to a depth of 10 to 15 mm to the plantar fascia layer. All needles other than
43
44 Ashi points will be gently stimulated by lifting and thrusting combined with twirling
45
46 and rotating the needle to reach *de qi* (the sensation of sourness, numbness, swelling
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48 and heaviness).²⁵ Paired alligator clips of the EA apparatus will be attached to the
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4 continuous wave of 2 Hz and current intensity of 0.1 to 1 mA. The current intensity
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6 will be increased until the skin around the acupoints shivers. The manipulation on
7
8 BL57, KI3, and BL60 should be performed every 10 minutes; 3 times in 30 minutes.
9
10 All needles were removed after 30 minutes and pressure applied using a dry sterilized
11
12 cotton ball.
13
14



18 **MA group**

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20 Participants will receive MA at the same points as the EA group, followed by the
21
22 same manipulation as EA group until *de qi* is reached. However, there will be no
23
24 electric current attached to the needle holders. During needles retaining, the
25
26 manipulation on BL57, KI3, and BL60 should be performed every 10 minutes; 3
27
28 times in 30 minutes.
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33 Both treatment groups will receive 12 sessions of treatment over a 4-week period
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35 after baseline (3 sessions every week). Each session will last for 30 minutes.
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40 **Rescue medication**

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42 Throughout the trial, participants will be discouraged from taking any medication or
43
44 other therapy for PF. However, if heel pain is unbearable during the study period,
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46 ibuprofen (sustained release type, 300 mg/T) will be allowed for relief up to 600 mg
47
48 per day (2 T/day) for 3 days. Details of drug use (name, time, frequency, and dosage)
49
50 will be recorded.
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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

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3 Enterprises, Inc., White Plains, NY; from 1 kg/cm² to 5 kg/cm²) consisted of a metal
4 probe with a rubber disc (0.5 cm²) at one end. The pressure applied by pressing the
5 rubber disc to the painful spot perpendicularly moves the needle in the scale at a rate
6 of approximately 0.1 kg/cm²/s through the metal probe. The mean score of three
7 repeated measurements at the tested location will be used for the main analysis. Thirty
8 seconds was used between each trial. Discomfort felt at values below 1 kg/cm² are
9 defined as 0.5 kg/cm².

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

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40 (7) Change in FAAM (Foot and Ankle Ability Measure) total score and subscale
41 scores after 4-week treatment, weeks 16 and 28: The FAAM is a 29-item evaluative
42 tool for the function of foot and ankle, which consists of 21-item activities of daily
43 living (ADL) and 8-item sports subscales.²⁸ Each item score ranges from 0 to 4, with
44 higher scores indicating a higher level of function. The FAAM has a maximum
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3 potential score (116 total, 84 ADL, and 32 Sport subscales). The obtained score (total
4 score, ADL, and sport subscale scores) is divided by the maximum potential score and
5 multiplied by 100 to get a percentage. If the patient cannot respond, it is left blank and
6 is not a part of the final value of the questionnaire. In this trial, we will use the
7 Chinese version of FAAM, which has been reported to have a satisfactory
8 psychometric property.²⁹
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18 (8) Patients' global improvement assessment: Patients' global improvement will be
19 assessed by a 7-point self-reporting scale ranging from 1 to 7, where 1 indicates
20 "complete recovery", 2 indicates "obvious improvement", 3 indicates "a little
21 improvement", 4 indicates "no change", 5 indicates "a little worse", 6 indicates
22 "obvious worse", and 7 indicates "vastly worse". The proportions of participants in
23 each category of global improvement assessment will be measured after the 4-week
24 treatment, weeks 16 and 28.
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35 (9) Patients' expectations for acupuncture: We will assess patients' expectation for
36 acupuncture at baseline. It includes three brief questions to investigate whether
37 patients believe that acupuncture treatment will help: "Do you believe acupuncture is
38 effective for treating the illness?", "Do you think acupuncture will be helpful to
39 improve your PF?" and "which acupuncture manipulation do you prefer, MA or EA?".
40 For each question, participants will choose "Yes", "No", or "unclear/whatever" as the
41 answer.
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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

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3 two-tailed test with 10% loss to follow-up.
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8 **Statistical analysis** 9

10 We will use SPSS v20 software (IBM SPSS Statistics; IBM Corp, Somers, NY) to
11 perform all statistical analysis following the intention-to-treat (ITT) principle. The
12 confidence interval will be established at 95%, and the significance level at 0.05.
13 Missing data will be calculated using the actual observational value without
14 imputation if the dropout rate is no more than 10%. For continuous data, the data will
15 be presented as mean \pm standard deviation when normally distributed or presented as
16 median (interquartile range) when not normally distributed. The continuous data will
17 be compared between groups using Student's *t*-test and Wilcoxon rank sum test, and
18 the categorical data using the Chi-squared test or Fisher's exact test, as appropriate.
19 Sensitivity analysis will be performed if necessary. A P-value <0.05 will be
20 considered statistically significant.
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40 **Quality control** 41

42 Prior to the trial, all staff will undergo special training on the purpose and content of
43 the trial, treatment strategies, and quality control. Acupuncturists in this trial will have
44 an acupuncture license with at least 1-year of acupuncture experience. Monitors will
45 check case report forms once every week as well as the acupuncture operation during
46 the treatment period. Drop-outs and withdrawals including the reasons will be detailed
47 documented through the trial. Participants' information will be stored in locked file
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3 cabinets at the study sites with limited access; only investigators have the right to
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5 access the data. All investigators will always maintain a strict privacy policy to
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7 protect confidentiality before, during and after the trial.
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10 11 12 13 **Discussion**

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15 The results of this study will clarify the effect of EA compared with MA in treating
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17 PF. There were several trials assessing EA and MA in the treatment of PF.^{31 33 34} The
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19 results have already showed that EA or MA coupled with conventional treatments
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21 could reduce pain, disabilities, and activity limitations in patients with PF compared
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23 with conventional treatments.^{31 33}
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28 According to some previous studies, EA can produce a faster and better analgesic
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30 effect than MA.^{19 20} However, no studies have reported the effect of head-to-head
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32 comparison between EA and MA in the treatment of PF. This trial comparing EA
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34 with MA could fill a gap in the literature thus helping physical therapists and
35
36 acupuncturists in their clinical decision-making.
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41 The VAS is one of the most commonly used instruments for assessment of pain
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43 and has been validated to detect changes in pain intensity.³⁵ Moreover, it has also
44
45 been used in many studies applying acupuncture for PF.^{33 34} Because morning pain
46
47 localized to the plantar medial aspect of the heel is the distinct feature of PF, we will
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49 choose the proportion of participant with a decline of at least 50% in the worst pain
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51 intensity at first steps in the morning after 4-week treatment compared with baseline
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53 as the primary outcome.
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3 The result may help clarify the effect of EA compared with MA on the pain relief
4 of PF. In addition, considering that pain of PF can be categorized as pressure pain,
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6 PPT (which will be evaluated by an algometer) could be a reasonable objective
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8 secondary outcome to help investigating physiological changes of PF. Moreover,
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10 DFROM measured by a digital goniometer and FAAM are well suited for evaluating
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12 the effects of acupuncture treatment for PF. These would be supportive of the primary
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14 outcome and meaningful for the overall effectiveness evaluation.
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20 Strengths of the study include its strictly standardized endpoints and objective
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22 criteria, long-term follow-up, strict quality control, and evaluation of patients'
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24 expectations for acupuncture. The trial also has some limitations. First, this is a
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26 single-center study conducted at a tertiary A hospital in China and the results might
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28 not apply to primary hospital or other countries. Second, participants and the
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30 acupuncturist will not be blinded due to the nature of the study, which might bring
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32 bias and influence the results. Third, considering ethics and the acceptance of
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34 participants, we did not assign a placebo/sham/ wait list group, which could not
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36 exclude the placebo effect of acupuncture and a possible spontaneous remission of the
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38 PF.
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4 **Trial status:** No recruitment at the present.

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6 **Ethical Approval and Consent to participate** The study protocol has received
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8 approval from the Institutional Review Boards of Guang'anmen Hospital in China
9
10 (approval NO. 2018-010-KY, TEL +86-10-88001552), and all investigators will
11
12 comply with the Helsinki Declaration.
13

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15 **Consent for publication** Not applicable.

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

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21 **Competing interests** The authors declare that they have no competing interests.
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25 **Authors' contributions** Zhishun Liu is responsible for supervising the clinical study
26
27 and for communicating important protocol modifications to relevant parties. Weiming
28
29 Wang and Zhishun Liu conceived the idea and designed this trial. Ruimin Jiao are
30
31 responsible for the recruitment and treatment of patients. Yan Liu and Jie Zhao are
32
33 responsible for statistical analysis. This manuscript was drafted by Weiming Wang
34
35 and revised by Zhishun Liu. All authors read and approved the final draft of the
36
37 manuscript.
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46
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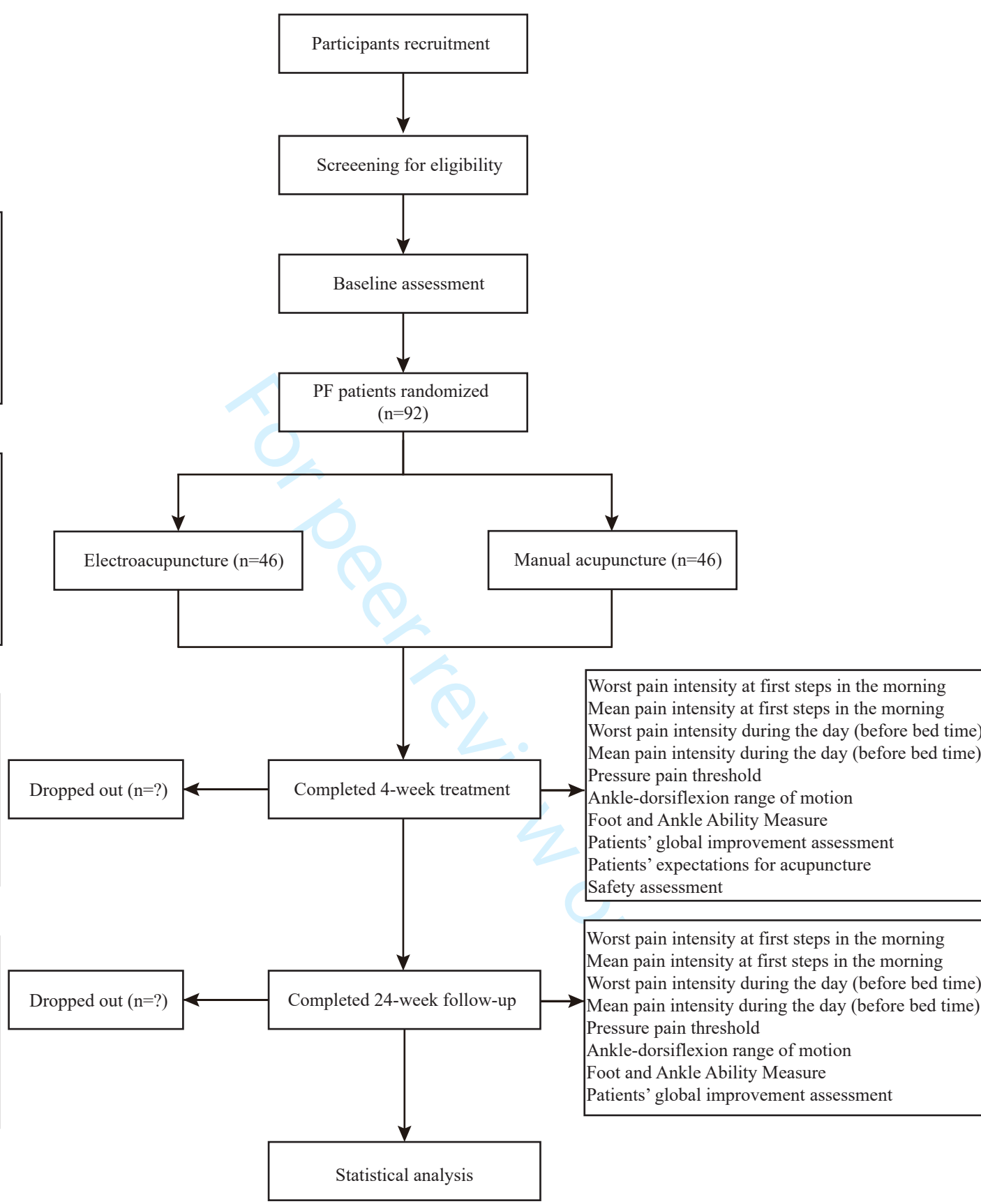


Figure 1. Trial flow diagram

TIME POINT (W, week)	Study Period				
	Baseline	Allocation	Treatment	Follow-up	
			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			×(weeks 1-4)		
Manual acupuncture			×(weeks 1-4)		
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

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-026147.R1
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Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	acupuncture, randomized controlled trial, plantar heel pain syndrome, protocol

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10 4 **Electroacupuncture versus manual acupuncture in the treatment of**
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12 5 **plantar heel pain syndrome: study protocol for an upcoming**
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14 6 **randomized controlled trial**
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21 9 Weiming Wang,¹ Yan Liu,² Jie Zhao,¹ Ruimin Jiao,¹ Zhishun Liu^{1*}
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4 **24 Abstract**

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6 **25 Introduction:** Plantar heel pain syndrome is a common cause of heel pain. It may
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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.

31 Methods and analysis: A total of 92 patients diagnosed with plantar heel pain
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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.

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4 46 **Ethics and dissemination:** The study has been approved by our ethics review board
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6 47 (Protocol Approval No. 2018-010-KY). The study findings will be disseminated
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9 48 through presentation at a high-impact medical journal, with online access. We also to
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12 49 plan to present it in select conferences and scientific meetings.

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14 50 **Trial registration:** Chinese Clinical Trial Registry identifier: ChiCTR-1800016531,
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17 51 registered 7 June 2018.

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20 52 **Strengths and limitations of this study:**

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22 53 ► This study is the first randomized controlled trial comparing electroacupuncture
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25 54 versus manual acupuncture for pain relief in participants with plantar heel pain
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28 55 syndrome.

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30 56 ► Strictly standardized endpoints and objective criteria, long-term follow-up, strict
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33 57 quality control, and evaluation of patients' expectations for acupuncture aiming to
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36 58 reduce the risk of bias.

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38 59 ► Eligible participants will be restricted to those in a tertiary A hospital in China, the
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41 60 results might not apply to primary hospital or other countries.

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46 62 blinded, which may bring bias and influence the results.

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48 63 ► Considering ethics and the acceptance of participants, a placebo/sham/ wait list
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54 65 and a possible spontaneous remission of the plantar heel pain syndrome.

66 **Background**

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

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

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4 88 -therapy is indicated only after at least 6 to 12 months of conservative treatment has

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7 89 failed.¹⁴ Moreover, some patients are resistant to surgery because of fear or cost.

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9 90 There is little convincing evidence available to support various approaches for

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12 91 treating PHPS.¹⁵

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14 92 Even lack of unified standard on the definition of acupuncture, most hold the view

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16
17 93 that acupuncture is a technique of the stimulation of specific points on the skin by the

18
19
20 94 insertion of needles based on the principles of traditional Chinese medicine.¹⁶

21
22 95 Acupuncture has been used to treat a variety of musculoskeletal pain-related

23
24
25 96 conditions (including PHPS) for thousands of years. Acupuncturists'

26
27 97 conceptualisations of PHPS include 'deficient Kidney Qi', 'Bi syndrome' and

28
29
30 98 others.¹⁷ At present, various acupuncture modality such as electroacupuncture and

31
32
33 99 manual acupuncture are available to clinicians. Stimulation of acupuncture points

34
35 100 through needling was shown to inducing analgesia via releasing neuropeptides such as

36
37
38 101 enkephalin, dynorphin, β -endorphin and endomorphine.¹⁸ Two recent systematic

39
40 102 reviews concerning the effectiveness of acupuncture in treating PHPS have concluded

41
42
43 103 that acupuncture may reduce PHPS pain in the short term and acupuncture should be

44
45
46 104 included in recommendations for the treatment of PHPS^{19,20}. Though broader

47
48 105 questions such as how practitioners choose between the various approaches in

49
50
51 106 different contexts remain unclear,¹⁷ future research should have a focus on exploring

52
53
54 107 the optimum use of acupuncture for heel pain.²⁰

55
56 108 EA and MA are the two acupuncture modalities frequently used which may exert

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58
59 109 different therapeutic effects via different mechanisms related to the characteristics of

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4 110 diseases.²¹ EA has been indicated in some cases where treatment with traditional
5
6 111 acupuncture has failed. Moreover, it has been demonstrated to produce a faster and
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9 112 better analgesic effect than MA.^{22 23}
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11
12 113 To our knowledge, until now no randomized controlled clinical research has
13
14 114 compared the effectiveness of EA with MA in treating PHPS. The objective of this
15
16
17 115 study is to assess whether EA was superior to MA in reducing PHPS pain.
18

19 20 117 **Methods and design**

21 22 118 **Study design**

23
24 119 We will conduct a prospective randomized parallel-group assessor-blinded two-arm
25
26
27 120 trial. The standard protocol items including Recommendations for Interventional
28
29 121 Trials (SPIRIT)²⁴ and the Standards for Reporting Interventions in Clinical Trials of
30
31 122 Acupuncture (STRICTA)²⁵ guidelines will be followed during the development of
32
33
34 123 the protocol of this study. The flow chart is shown in Fig. 1 and the time point of
35
36 124 assessment is shown in Fig. 2.
37

38 39 125 40 41 126 **Study setting and recruitment**

42
43 127 This trial will be performed at Guang'anmen Hospital, China Academy of Chinese
44
45 128 Medical Sciences between October 2018 and December 2019. A total of 92
46
47
48 129 participants will be recruited through posters, hospital webs, and networks. The
49
50 130 duration of the study for each participant will be 29 weeks: 1-week baseline, 4-week
51
52 131 treatment, and 24-week follow-up.
53

54 55 132 56 57 58 133 **Randomization and blinding** 59 60

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4 134 A 1-week baseline assessment will be needed before randomization. Participants will
5
6 135 be randomly assigned to either the EA or MA group at a ratio of 1:1. To ensure equal
7
8
9 136 distribution in treatment groups, the random block is set to a fixed size of 4. The
10
11 137 randomizing scheme will be generated using the Statistics Analysis System (SAS)
12
13
14 138 software created by the Clinical Pharmacological Assessment Center at Guang'anmen
15
16
17 139 Hospital. Random numbers and assigned groups were signed and sealed in an opaque
18
19
20 140 envelope by the staff who produced it and kept by other staff who took no part in this
21
22 141 trial. Research assistants who did not participant in the assessment and treatment will
23
24
25 142 open the envelopes according to the sequence numbers. The research assistants will
26
27
28 143 be in charge of recruitment and data collection, and an orthopedist will be in charge of
29
30 144 the diagnosis of the participants. Participants and the acupuncturist will not be blinded
31
32
33 145 to the allocation. The efficacy evaluator will be blinded.
34
35
36 146

147 **Participants**

148 **Inclusion criteria:**

149 Participants aged from 18 to 75 years will be included in the study if they meet the
150 diagnostic criteria for PHPS according to the Orthopaedic Section of American
151 Physical Therapy Association,²⁶ and conform to all the following conditions for at
152 least 1 month:
153 (1) Pain localized to the plantar medial aspect of the heel along the insertion of the
154 plantar fascia;
155 (2) Most noticeable plantar medial heel pain with initial steps after a period of

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4 156 inactivity (e.g., initial steps in the morning) but also worse following prolonged
5
6
7 157 weight bearing;
8
9 158 (3) Palpation/provocation over the medial calcaneal tuberosity or along the plantar
10
11
12 159 fascia;
13
14 160 (4) Active and passive talocrural dorsiflexion range of motion;
15
16
17 161 (5) Positive windlass test as well as negative tarsal tunnel tests;
18
19
20 162 (6) A minimum score of 40 in worst pain intensity at first steps in the morning
21
22 163 according to the 100-point visual analog scale (VAS); and
23
24
25 164 (7) Signed the informed consent prior to inclusion.
26
27
28
29

30 166 **Exclusion criteria:**

- 31
32 167 Participants who fulfill any of the following criteria will be excluded:
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34
35 168 (1) A history of ankle and foot fracture, surgery or tumor, or have a foot deformity;
36
37
38 169 (2) A history of plantar fascia rupture, nerve entrapment syndrome, or achilles tendon
39
40 170 lesions;
41
42
43 171 (3) Neurological or systemic diseases including rheumatoid arthritis, diabetes,
44
45 172 cardiovascular disorder, severe hepatic/renal insufficiency, or coagulation disorder;
46
47
48 173 (4) Existing systemic or local infection, or chapped heel skin;
49
50
51 174 (5) Used local corticosteroid injections in the last 6 months;
52
53 175 (6) Needle-phobic patients or had received EA or MA in the past 4 weeks.
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58 177 **Intervention and comparison**
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4 178 The intervention protocol of this trial is based on the meridian theory of traditional
5
6 179 Chinese medicine and the consensus of three acupuncture specialists, it is also used in
7
8
9 180 a systematic review.¹⁹ Acupuncturists who hold an acupuncture license and have at
10
11 181 least 1-year of experience in acupuncture will perform the treatment. Disposable
12
13
14 182 acupuncture needle (size 0.30×40 mm) and SDZ-V EA apparatus (all Hwato Brand,
15
16
17 183 Suzhou Medical Appliance Factory, Suzhou, China) will be used in this trial.
18
19 184 Acupuncture will be given on the heel pain side. If a subject experienced PHPS on
20
21
22 185 both sides, the treatment will be performed on both sides with the more serious side
23
24
25 186 evaluated.

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27 187

28 29 30 188 **EA group**

31
32 189 Two Ashi points (the severer tender points over the anteromedial aspect of the heels),
33
34 190 Chengshan (BL57), Taixi (KI3) and Kunlun (BL60) will be selected in this trial.
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37 191 Based on the principles of TCM, the major cause of PHPS is qi and blood deficiency
38
39 192 in the kidney meridian. Sometimes PHPS may also associated with qi and blood
40
41
42 193 stasis.²⁷ Whatever the root cause, stimulation of Ashi points can unblock the qi-blood
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45 194 stagnation and result in alleviating pain.²⁸ BL57, KI3 and BL60 will be selected to
46
47
48 195 build and supply qi and blood to the local area and kidney as well as to the whole
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50
51 196 person. The location of the acupoints will be based on *Nomenclature and location of*
52
53 197 *acupuncture points*²⁹ drafted in 2006 by the National Standard of the People's
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55
56 198 Republic of China (GB/T 12346–2006). After the local skin was routinely sterilized in
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59 199 a prone position, the participants' Ashi points will be vertically inserted by the
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4 200 needles to a depth of 10 to 15 mm to the plantar fascia layer. For BL57, KI3, and
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6 201 BL60, needles will be vertically inserted approximately 15 mm. All needles other than
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9 202 Ashi points will be gently stimulated by lifting and thrusting combined with twirling
10
11 203 and rotating the needle to reach *de qi* (the sensation of sourness, numbness, swelling
12
13 204 and heaviness).³⁰ Paired alligator clips of the EA apparatus will be attached to the
14
15 205 needle holders of the two Ashi points. EA stimulation will last for 30 minutes with a
16
17 206 continuous wave of 2 Hz and current intensity of 0.1 to 1 mA. The current intensity
18
19 207 will be increased until the skin around the acupoints shivers. The manipulation on
20
21 208 BL57, KI3, and BL60 should be performed every 10 minutes; 3 times in 30 minutes.
22
23 209 All needles were removed after 30 minutes and pressure applied using a dry sterilized
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25 210 cotton ball.
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35 212 **MA group**

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37 213 Participants will receive MA at the same points as the EA group, followed by the
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39 214 same manipulation as EA group until *de qi* is reached. However, there will be no
40
41 215 electric current attached to the needle holders. During needles retaining, the
42
43 216 manipulation on BL57, KI3, and BL60 should be performed every 10 minutes; 3
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45 217 times in 30 minutes.
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50 218 Both treatment groups will receive 12 sessions of treatment over a 4-week period
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52 219 after baseline (3 sessions every week). Each session will last for 30 minutes.
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57 221 **Rescue medication**

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4 222 Throughout the trial, participants will be discouraged from taking any medication or
5
6 223 other therapy for PHPS. However, if heel pain is unbearable during the study period,
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8
9 224 ibuprofen (sustained release type, 300 mg/T) will be allowed for relief up to 600 mg
10
11 225 per day (2 T/day) for 3 days. Details of drug use (name, time, frequency, and dosage)
12
13
14 226 will be recorded.

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18 19 228 **Outcome measures**

20 21 229 **Primary outcome**

22
23 230 The primary outcome will be the proportion of responders after the 4-week treatment.

24
25 231 The responder is defined as a participant with a decline (by at least 50%) in the worst
26
27 232 pain intensity at first steps in the morning compared with baseline. The pain intensity
28
29 233 will be measured using a 100 mm linear VAS with 0 representing no pain and 100 the
30
31 234 worst imaginable pain. Additionally, the proportion of responders at weeks 16 and 28
32
33 235 will also be assessed.

34 35 236 **Secondary outcomes**

36
37 237 The secondary outcomes include the following items:

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39 238 (1) Change in worst pain intensity measured by VAS at first steps in the morning after
40
41 239 4-week treatment, weeks 16 and 28.

42
43 240 (2) Change in mean pain intensity measured by VAS at first steps in the morning after
44
45 241 4-week treatment, weeks 16 and 28.

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47 242 (3) Change in worst pain intensity measured by VAS during the day (before bed time)
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49 243 after 4-week treatment, weeks 16 and 28.

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4 244 (4) Change in mean pain intensity measured by VAS during the day (before bed time)

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6 245 after 4-week treatment, weeks 16 and 28.

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8
9 246 (5) Change in the pressure pain threshold (PPT) at the most painful spot after 4-week

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11 247 treatment, weeks 16 and 28. PPT, known as the minimal pressure when the sensation

12
13 248 of pressure changes to pain,³¹ will be measured by a pressure algometer (Fabrication

14
15 249 Enterprises, Inc., White Plains, NY; from 1 kg/cm² to 5 kg/cm²) consisted of a metal

16
17 250 probe with a rubber disc (0.5 cm²) at one end. The pressure applied by pressing the

18
19 251 rubber disc to the painful spot perpendicularly moves the needle in the scale at a rate

20
21 252 of approximately 0.1 kg/cm²/s through the metal probe. The mean score of three

22
23 253 repeated measurements at the tested location will be used for the main analysis. Thirty

24
25 254 seconds will be used between each trial. Discomfort felt at values below 1 kg/cm² are

26
27 255 defined as 0.5 kg/cm².

28
29 256 (6) Change in ankle-dorsiflexion range of motion (DFROM) after treatment, weeks 16

30
31 257 and 28: DFROM will be measured for using a digital goniometer (Tangxia Electronic

32
33 258 Instrument Factory, Dongguan, from 0° to 360°). Each participant will be asked to sit

34
35 259 with the popliteal space at the edge of the table and their knees with 90° of flexion in

36
37 260 a completely relaxed station. The axis of the goniometer will be centered over the

38
39 261 lateral malleolus and the arms are aligned with the fibular shaft and the head of the

40
41 262 fifth metatarsal. The examiner passively moves the ankle into dorsiflexion from a

42
43 263 neutral starting position until a firm end feel is elicited.³² The examiner will measure

44
45 264 the ankle-joint angle 3 times at maximum DFROM within 10 seconds between each

46
47 265 examination.

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4 266 (7) Change in FAAM (Foot and Ankle Ability Measure) total score and subscale
5
6 267 scores after 4-week treatment, weeks 16 and 28: The FAAM is a 29-item evaluative
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8
9 268 tool for the function of foot and ankle, which consists of 21-item activities of daily
10
11 269 living (ADL) and 8-item sports subscales.³³ Each item score ranges from 0 to 4, with
12
13
14 270 higher scores indicating a higher level of function. The FAAM has a maximum
15
16 271 potential score (116 total, 84 ADL, and 32 Sport subscales). The obtained score (total
17
18 272 score, ADL, and sport subscale scores) is divided by the maximum potential score and
19
20 273 multiplied by 100 to get a percentage. If the patient cannot respond, it is left blank and
21
22 274 is not a part of the final value of the questionnaire. In this trial, we will use the
23
24 275 Chinese version of FAAM, which has been reported to have a satisfactory
25
26 276 psychometric property.³⁴

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32 277 (8) Patients' global improvement assessment: Patients' global improvement will be
33
34 278 assessed by a 7-point self-reporting scale ranging from 1 to 7, where 1 indicates
35
36 279 "complete recovery", 2 indicates "obvious improvement", 3 indicates "a little
37
38 280 improvement", 4 indicates "no change", 5 indicates "a little worse", 6 indicates
39
40 281 "obvious worse", and 7 indicates "vastly worse". The proportions of participants in
41
42 282 each category of global improvement assessment will be measured after the 4-week
43
44 283 treatment, weeks 16 and 28.

45
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47
48 284 (9) Patients' expectations for acupuncture: We will assess patients' expectation for
49
50 285 acupuncture at baseline. It includes three brief questions to investigate whether
51
52 286 patients believe that acupuncture treatment will help: "Do you believe acupuncture is
53
54 287 effective for treating the illness?", "Do you think acupuncture will be helpful to
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4 288 improve your PHPS?” and “which acupuncture manipulation do you prefer, MA or
5
6 289 EA?”. For each question, participants will choose “Yes”, “No”, or “unclear/whatever”
7
8
9 290 as the answer.
10

11 291

12 292 **Safety assessment**

13
14
15 293 All adverse events (AEs) will be monitored and reported through the whole trial. AEs
16
17 294 will be categorized as treatment-related (e.g., localized hematoma, localized infection,
18
19 295 broken needle, fainting, nausea, dizziness, vomiting, or palpitations) or
20
21 296 non-treatment-related within 24 hours after their occurrence. Detailed information on
22
23 297 AEs and serious adverse events (SAEs)—including the name, onset and end date,
24
25 298 intensity, relationship with acupuncture and outcome—will be recorded. Participants
26
27 299 are discontinued if the treatments cause serious aggravation of symptoms, which will
28
29 300 include an 80% or more increase of existing heel pain measured by VAS at the end of
30
31 301 the first hour after acupuncture. Researchers will immediately report SAEs (e.g.,
32
33 302 requiring hospitalization, causing disability or impaired ability to work) to the
34
35 303 Medical Ethics Committee of Guang’anmen Hospital and suspend the study.
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45 305 **Sample size calculation**

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47
48 306 The null hypothesis is that the proportion of participants with at least a 50% decrease
49
50 307 from baseline in the worst pain intensity (as measured by the VAS at first steps in the
51
52 308 morning after the 4-week treatment) will be same for MA and EA. A decline by at
53
54 309 least 50% in the pain at first steps was regarded as clinically relevant.³⁵ The previous
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4 310 studies reported that 73.3% of the participants had at least a 50% decrease in the pain
5
6 311 as measured by the VAS at first steps after the 4-week EA treatment,³⁶ and 44.4%
7
8
9 312 after the 4-week MA treatment.³⁷Power was defined as 80% for an alpha of 5%.
10
11 313 Accordingly, 92 participants will be required (46 in each group), assuming a
12
13
14 314 two-tailed test with 10% loss to follow-up.
15
16

315

316 **Statistical analysis**

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

329

330 **Quality control**

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4 331 Prior to the trial, all staff will undergo special training on the purpose and content of
5
6 332 the trial, treatment strategies, and quality control. Acupuncturists in this trial will have
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8
9 333 an acupuncture license with at least 1-year of acupuncture experience. Monitors will
10
11 334 check case report forms once every week as well as the acupuncture operation during
12
13
14 335 the treatment period. Drop-outs and withdrawals including the reasons will be detailed
15
16
17 336 documented through the trial. Participants' information will be stored in locked file
18
19 337 cabinets at the study sites with limited access; only investigators have the right to
20
21
22 338 access the data. All investigators will always maintain a strict privacy policy to
23
24
25 339 protect confidentiality before, during and after the trial.

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30 341 **Patient and public involvement**

31
32 342 The initial concept of investigating whether EA was superior to MA in reducing
33
34 343 PHPS pain was first proposed by a patient who prefer EA rather than MA. No other
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36
37 344 patients will be in the recruitment and conduct of the study. The burden of the
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39
40 345 intervention will be assessed by patients themselves. The results will be disseminated
41
42
43 346 to study participants via the website of our hospital.

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48 348 **Ethics and dissemination**

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50 349 The study was planned in accordance with the Helsinki Declaration and was approved
51
52
53 350 by the Ethical Committee of the Guang'anmen Hospital, China Academy of Chinese
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55
56 351 Medical Sciences (No. 2018-010-KY). The trial has been registered at Chinese
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59 352 Clinical Trial Registry. All the participants will be fully informed about this trial and
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4 353 given enough time to inquire about details and decide whether to participate or not at
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6 354 first visit. Participants will be asked to sign the informed consent form if they agree to
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9 355 participate. Any modifications to the protocol will be reported and approved by the
10
11 356 Ethical Committee of the Guang'anmen Hospital, China Academy of Chinese
12
13
14 357 Medical Sciences and will be communicated with the trial registry, investigators and
15
16
17 358 data monitoring researchers. The study findings will be disseminated through
18
19 359 presentation at a high-impact medical journal, with online access. We also plan to
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21
22 360 present it in select conferences and scientific meetings after the paper about this trial'
23
24
25 361 results published.

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27 362

30 363 **Discussion**

31
32 364 The results of this study will clarify the effect of EA compared with MA in treating
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34
35 365 PHPS. There were several trials assessing EA and MA in the treatment of PHPS.^{36 38}
36
37 366 ³⁹ The results have already showed that EA or MA coupled with conventional
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39
40 367 treatments could reduce pain, disabilities, and activity limitations in patients with
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43 368 PHPS compared with conventional treatments.^{36 38}

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45 369 According to some previous studies, EA can produce a faster and better analgesic
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48 370 effect than MA.^{22 23} However, no studies have reported the effect of head-to-head
49
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51 371 comparison between EA and MA in the treatment of PHPS. This trial comparing EA
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54 372 with MA could fill a gap in the literature thus helping physical therapists and
55
56 373 acupuncturists in their clinical decision-making.

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4 374 The VAS is one of the most commonly used instruments for assessment of pain
5
6 375 and has been validated to detect changes in pain intensity.⁴⁰ Moreover, it has also
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8
9 376 been used in many studies applying acupuncture for PHPS.^{38 39} Because morning pain
10
11 377 localized to the plantar medial aspect of the heel is the distinct feature of PHPS, we
12
13
14 378 will choose the proportion of participant with a decline of at least 50% in the worst
15
16
17 379 pain intensity at first steps in the morning after 4-week treatment compared with
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19
20 380 baseline as the primary outcome.

21
22 381 The result may help clarify the effect of EA compared with MA on the pain relief
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24 382 of PHPS. In addition, considering that pain of PHPS can be categorized as pressure
25
26
27 383 pain, PPT (which will be evaluated by an algometer) could be a reasonable objective
28
29
30 384 secondary outcome to help investigating physiological changes of PHPS. Moreover,
31
32
33 385 DFROM measured by a digital goniometer and FAAM are well suited for evaluating
34
35
36 386 the effects of acupuncture treatment for PHPS. These would be supportive of the
37
38 387 primary outcome and meaningful for the overall effectiveness evaluation.

39
40 388 Strengths of the study include its strictly standardized endpoints and objective
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42
43 389 criteria, long-term follow-up, strict quality control, and evaluation of patients'
44
45
46 390 expectations for acupuncture. The trial also has some limitations. First, this is a
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48
49 391 single-center study conducted at a tertiary A hospital in China and the results might
50
51
52 392 not apply to primary hospital or other countries. Second, participants and the
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54
55 393 acupuncturist will not be blinded due to the nature of the study, which might bring
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57
58 394 bias and influence the results. Third, considering ethics and the acceptance of
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60 395 participants, we did not assign a placebo/sham/ wait list group, which could not

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

For peer review only

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3
4 399 **Trial status:** No recruitment at the present.
5

6 400 **Ethical Approval and Consent to participate** The study protocol has received
7
8
9 401 approval from the Institutional Review Boards of Guang'anmen Hospital in China
10
11 402 (approval NO. 2018-010-KY, TEL +86-10-88001552), and all investigators will
12
13
14 403 comply with the Helsinki Declaration.
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16
17 404 **Consent for publication** Not applicable.
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19 405 **Availability of data and materials** All data are fully available without restriction.
20

21
22 406 **Competing interests** The authors declare that they have no competing interests.
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26
27 408 **Authors' contributions** Zhishun Liu is responsible for supervising the clinical study
28
29 409 and for communicating important protocol modifications to relevant parties. Weiming
30
31 410 Wang and Zhishun Liu conceived the idea and designed this trial. Ruimin Jiao are
32
33 411 responsible for the recruitment and treatment of patients. Yan Liu and Jie Zhao are
34
35 412 responsible for statistical analysis. This manuscript was drafted by Weiming Wang
36
37 413 and revised by Zhishun Liu. All authors read and approved the final draft of the
38
39 414 manuscript.
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46
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48
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50
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52
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54
55 420 their editing work.
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4 522 **Figure legends**
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6 523 Figure 1: Trial flow diagram
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9 524 Figure 2: The time point of assessment
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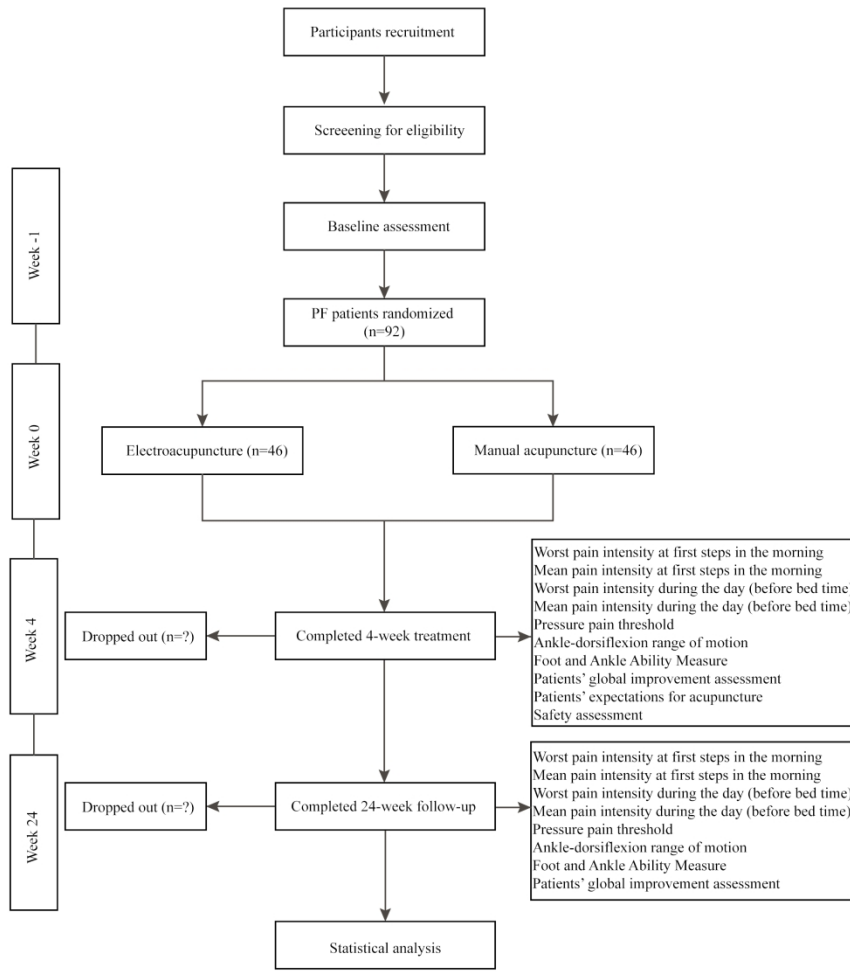


Figure 1. Trial flow diagram

Figure 1: Trial flow diagram
234x277mm (300 x 300 DPI)

TIME POINT (W, week)	Study Period				
	Baseline	Allocation	Treatment	Follow-up	
			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

Figure 2: The time point of assessment

210x297mm (300 x 300 DPI)

Table 1



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
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	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
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5	Protocol	25	Plans for communicating important protocol modifications (eg, changes to	17
6	amendments		eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators,	
7			REC/IRBs, trial participants, trial registries, journals, regulators)	
8				
9	Consent or	26a	Who will obtain informed consent or assent from potential trial participants	7
10	assent		or authorised surrogates, and how (see Item 32)	
11				
12		26b	Additional consent provisions for collection and use of participant data and	NA
13			biological specimens in ancillary studies, if applicable	
14				
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16	Confidentiality	27	How personal information about potential and enrolled participants will be	16
17			collected, shared, and maintained in order to protect confidentiality before,	
18			during, and after the trial	
19				
20	Declaration of	28	Financial and other competing interests for principal investigators for the	20
21	interests		overall trial and each study site	
22				
23				
24	Access to	29	Statement of who will have access to the final trial dataset, and disclosure	16
25	data		of contractual agreements that limit such access for investigators	
26				
27	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for compensation to	NA
28	post-trial care		those who suffer harm from trial participation	
29				
30	Dissemination	31a	Plans for investigators and sponsor to communicate trial results to	17
31	policy		participants, healthcare professionals, the public, and other relevant groups	
32			(eg, via publication, reporting in results databases, or other data sharing	
33			arrangements), including any publication restrictions	
34				
35				
36		31b	Authorship eligibility guidelines and any intended use of professional	20
37			writers	
38				
39		31c	Plans, if any, for granting public access to the full protocol, participant-level	NA
40			dataset, and statistical code	
41				
42				
43	Appendices			
44				
45	Informed	32	Model consent form and other related documentation given to participants	NA
46	consent		and authorised surrogates	
47	materials			
48				
49	Biological	33	Plans for collection, laboratory evaluation, and storage of biological	NA
50	specimens		specimens for genetic or molecular analysis in the current trial and for	
51			future use in ancillary studies, if applicable	
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5 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation &
6 Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.
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