Journal of Pain Research

Dovepress
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STUDY PROTOCOL

The Effectiveness of Acupuncture on Myofascial Trigger Points Versus Traditional Chinese Medicine Acupoints for Treating Plantar Fasciitis With Low Back Pain: A Study Protocol for a Randomised Clinical Trial

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Background: Plantar fasciitis is a common cause of heel pain, often associated with a higher rate of low back pain. This increased disability rate in low back pain may be correlated with reduced foot and ankle function. While both acupuncture and trigger point dry needling have been reported as potentially effective treatments for plantar fasciitis, the quality of evidence is currently low. Acupuncture at trigger points might be a promising treatment for plantar fasciitis, though there is a lack of evidence supporting its effectiveness. This trial aims to compare the effectiveness of acupuncture at trigger points versus Traditional Chinese Medicine (TCM) acupoints in the treatment of participants with plantar fasciitis and low back pain.

Methods: The trial will be a single-centre, parallel two-group, randomised controlled trial with 62 participants allocated in a 1:1 ratio to either the trigger point group or the TCM acupoint group. Patients with plantar fasciitis and low back pain will be enrolled in this trial. Eligible participants will receive acupuncture for 30 minutes per session over 8 total sessions, with a 12-week follow-up period. The primary outcome measure will be the change from baseline in the worst first-step pain intensity in the morning after treatment. Secondary outcomes include changes from baseline in foot and low back pain, foot and low back function, plantar fascia thickness, and participants' self-reported global improvement. Statistical analysis will be conducted using a two-sided test with a significance level of 0.05 and 95% confidence intervals.

Clinical Trial Registration: This trial has been registered at the Chinese Clinical Trial Registry. Registration number: ChiCTR2300067552. Registration date: 1 January 2023.

Keywords: acupuncture, trigger point, plantar fasciitis, low back pain, randomised clinical trial

Background

Plantar fasciitis is a common cause of varying degrees of in heel pain and functional loss.[1,2] It is related to repetitive microtrauma of the plantar fascia.[2,3] Short-term increases in body weight, being overweight, and physical activity are also risk factors for plantar fasciitis.[4] Although no long-term complications have been reported, participants may experience persistent symptoms after the initial onset.[4,5] These symptoms may lead to a decrease in physical activity, which may result in weight gain. In turn, the weight gain can exacerbate the symptoms or make recovery more difficult.[4]

Initial treatments for plantar heel pain, such as stretching, taping, or manual physical therapy, may provide short-term (1 week to 4 months) pain relief and may improve foot function. NSAIDs can also be used as initial treatments for mild-to-moderate pain, but they may cause adverse effects.[6–9] Night splints, corticosteroid local injections, and extracorporeal shock wave therapy can be used for persistent pain. Night splints are recommended for participants with plantar fasciitis

Received: 22 August 2024
Accepted: 21 January 2025
Published: 28 January 2025

who consistently experience pain with the first step in the morning, and they require a long treatment period.[10] Local corticosteroid injection is not typically recommended as a first-line treatment.[11] Extracorporeal shock wave therapy can reduce heel pain in participants with chronic plantar fasciitis, although there is no significant difference in overall heel pain improvement.[12] Weight gain and inactive due to plantar heel pain could worsen plantar fasciitis.[4] Thus, it is important to treat plantar fasciitis rather than neglect it.[4] However, no treatments with a high level of evidence are available for plantar fasciitis, although several treatments, such as stretching and orthotics, have a moderate level of evidence supporting their use.[4] Although most participants with plantar fasciitis will resolve their symptoms within 12 months or after various treatments, 11% of participants with plantar heel pain experience recurrent pain and function loss.[4]

Acupuncture is one of the therapies based on ancient Chinese philosophy and commonly involves manual stimulation of the needles. Traditional acupuncture involves the insertion of needles into acupoints located on meridians and to achieve a *deqi* sensation, such as numbness, fullness, warmth, or soreness, either locally or radiating along a certain meridian.[13] Dry needling involves inserting needles in myofascial trigger points. The use of needling can involve acupuncture needles or any other type of injection needle without any liquid.[14] Both acupuncture and trigger point dry needling can also be used to treat plantar fasciitis. These techniques involve the insertion of needles into the body to reduce pain and promote healing.[14] Dry needling typically targets body trigger points to treat musculoskeletal conditions, while acupuncture focuses on acupoints to treat a variety of diseases.[13,14] Trigger points associated with heel pain are found in the flexor digitorum brevis and quadratus plantae muscles of the foot, as well as in the soleus muscles in the calves.[15] One study indicated that trigger point dry needling may reduce pain, but the degree of reduction may not be clinically significant.[16] Another study suggested that dry needling may reduce heel pain more effectively than methyl-prednisolone acetate injections after more than three months in adults.[17] A meta-analysis showed that dry-needling might be effective in reducing the heel pain due to plantar fasciitis and low back pain.[18–20] However, due to limited evidence, whether dry needling is recommended for patients with plantar fasciitis remains controversial.[20–22] Acupuncture alone, or combined with conventional therapies (eg, ice therapy, non-steroidal anti-inflammatory drugs, and stretching) may improve pain in the short term in participants with plantar fasciitis and low back pain.[3,23,24]

The secondary costs and health problems caused by plantar fasciitis and low back pain also need to be considered. A cross-sectional study found that participants with plantar heel pain were more likely to have low back pain (74% of patients with plantar heel pain also had low back pain, compared to 37% of patients without low back pain; odds ratio = 5.2, P = 0.009).[25] In addition, higher low back pain disability was correlated with reduced foot and ankle function. Thus, treatments targeting both locations may be warranted to improve the management of plantar fasciitis.[25]

However, to the best of our knowledge, there is no detailed evidence indicating whether acupuncture at trigger points and acupoints is effective in treating patients with both plantar fasciitis and low back pain. This randomized clinical trial aims to explore the effectiveness of acupuncture at trigger points and acupoints in treating participants with plantar fasciitis and low back pain.

Methods

Study Design

This is a single-centre, prospective, parallel, participant and assessor-blinded randomised controlled trial with a 1:1 allocation ratio. The protocol will be developed according to the Recommendations for Interventional Trials and the Standards for Reporting Interventions in Clinical Trials of Acupuncture guidelines.[26] The Study Flowchart and the Study Schedule are shown in Figure 1 and Table 1.

Study Setting and Recruitment

This trial will be conducted at the Affiliated Hospital of Guizhou Medical University from April 2023 to October 2025. A total of 62 participants with plantar fasciitis and low back pain will be recruited from the outpatient and inpatient departments. The study duration for each participant will be 15 weeks, which includes 1 week for baseline assessment, 2 weeks for treatment, and 12 weeks for follow-up.

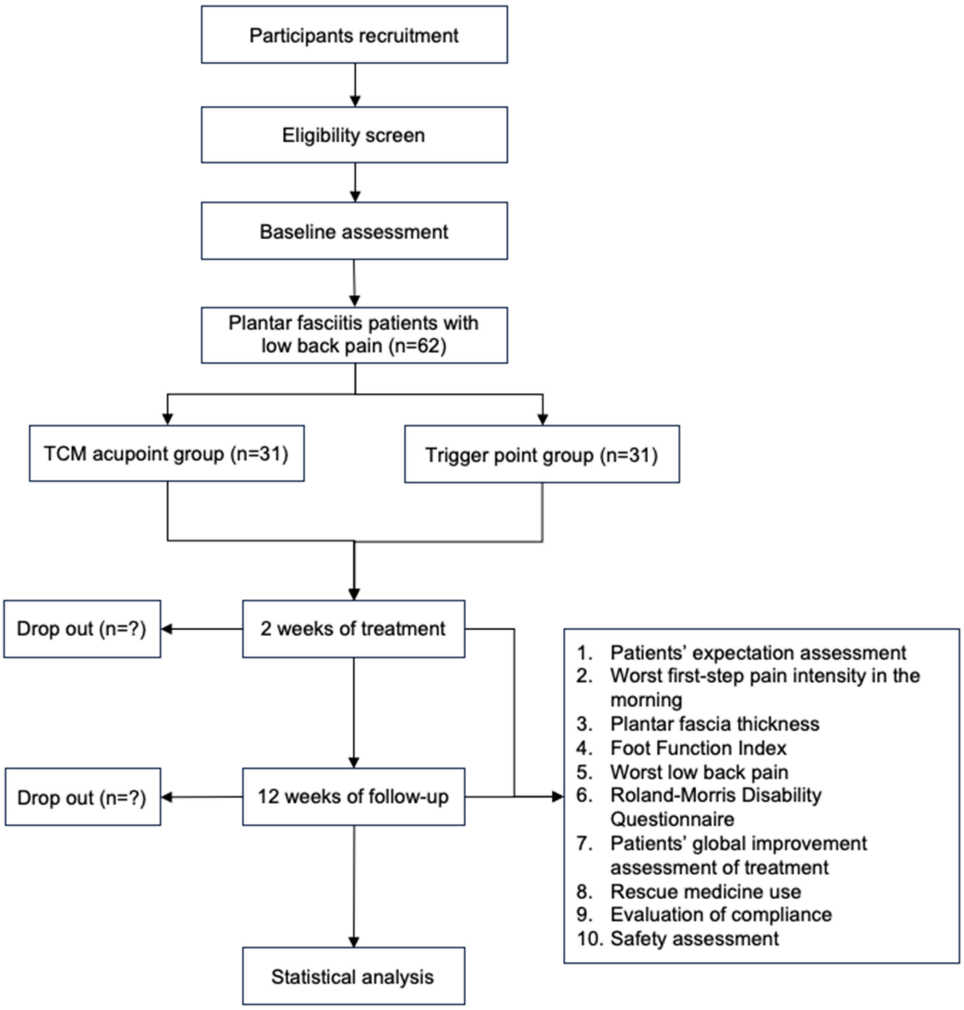

Figure 1 Study flowchart.

Randomisation and Blinding

Random numbers will be generated using the Randomisation Allocation System for Single-centre Clinical Research at the Affiliated Hospital of Guizhou Medical University. Randomisation and allocation will be managed by a research assistant, who will not be involved in the trial intervention or evaluation. Participants will be randomly allocated to either the trigger point group or the TCM acupoint group in a 1:1 ratio. Participants, outcome evaluators, and data analysts will be blinded. Due to the nature of acupuncture treatment, the acupuncturist cannot be blinded. Random numbers will be stored in opaque, sealed envelopes. The envelopes containing the random numbers will be charged with a trial assistant who will not participate in the treatment or outcome assessment. For participant blinding, both groups will be asked whether they have pain points in the lower leg, lower back, or foot to prevent participants from identifying which group they have been allocated to.

Participants

Sixty-two participants with plantar fasciitis and low back pain will be enrolled in this study. The participants will be informed of the potential benefits and risks associated with this trial. An orthopedic surgeon will diagnose plantar fasciitis and assess whether participants meet the inclusion criteria or are subject to exclusion. Informed consent will be obtained before participants are included. Participants will be free to withdraw from the trial at any time. Participants will be included only if they meet all of the inclusion criteria and do not meet any of the exclusion criteria.

Table 1 Study Schedule

	Study Period					
	Baseline	**Allocation**	**Treatment**		**Follow-up**	
Time point	Week 0	Week 0	Week 1	Week 2	Week 7	Week 14
Enrollment						
Eligibility criteria	×					
Informed consent	×					
Allocation		×				
Interventions						
Acupuncture on trigger points			×	×		
Acupuncture on acupoints			×	×		
Assessments	×					
X-ray of foot	×					
First-step pain			×	×		
Plantar fascia thickness	×		×	×		
Foot Function Index (FFI)	×		×	×	×	×
The worst low back pain intensity	×		×	×	×	×
Roland-Morris Disability Questionnaire (RMDQ)	×		×	×	×	×
Patients' expectation assessment	×					
Patients' global improvement assessment			×	×	×	×
Safety assessment			×	×	×	×
Rescue medicine use			×			
Adverse events			×			
Compliance evaluation			×			

Diagnose Criteria

According to the American Physical Therapy Association, diagnosis will be based on medical history and physical examination,[22] which includes the following criteria:

1. Worst plantar heel pain on the first-step, which decreases with activity;
2. Plantar heel pain that worsens after a period of inactivity or prolonged weight-bearing;
3. Plantar heel pain associated with recent weight gain;
4. Positive windlass test.

Inclusion Criteria

1. Patients with plantar fasciitis and plantar heel pain at least 3 points on a 0–10 numeric pain scale;
2. Participants who are accompanied by low back pain without limitation of pain intensity;
3. Age between 18 and 60 years;
4. Ability to adhere to the study protocol, sign the informed consent form, and voluntarily participate in the trial.

Exclusion Criteria

1. Foot deformities (eg, flat feet, strephexopodia, strephenopodia, etc.);
2. Lateral X-ray of the foot showing the formation of large osteophytes;
3. Lumbar deformities (eg, severe lumbar disc herniation, lumbar spondylolisthesis, lumbar scoliosis, etc.);
4. Low back pain accompanied by radiating pain in the lower extremities;
5. Spinal or foot tumours, acute fractures, or a history of fractures;
6. Endocrine disease or autoimmune diseases (such as type 1 or 2 diabetes, rheumatoid arthritis, respiratory issues, or severe osteoporosis, etc.);
7. Lumbosacral radiculopathy or peripheral radiculopathy of the ankle joint;
8. Skin infection at the acupuncture site;
9. Blood system disorders or major systemic diseases.

Interventions

Trigger Point Group

An acupuncturist with an acupuncture license and at least five years of clinical experience will be responsible for performing the treatment. Trigger points identification will follow *The Trigger Point Therapy Workbook*.[15] Disposable acupuncture needles (Hwato disposable needles, Suzhou Medical Appliance Factory, Suzhou, China, size 0.30×40mm) will be used in this trial. Participants in the trigger point group will receive acupuncture at trigger points on the gastrocnemius, soleus, and quadratus plantae. Participants with low back pain will receive acupuncture at the trigger points on the psoas major, gluteus medius, and soleus. Treatment will be administered in the prone position. The skin at the local sites will be routinely sterilised before acupuncture treatment. Each trigger point will be needled vertically to a depth of 20–35mm, adjusted for the participant's body type. Each acupuncture session will last 30 minutes, followed by three times of even twisting and lifting at 10-minute intervals to achieve *deqi*. The needles will be removed after 30 minutes, and a sterile cotton ball will be used to apply pressure to prevent bleeding.

TCM Acupoint Group

The acupuncture regimen in the TCM acupoint group is developed by experts consensus based on the TCM meridian theory.[27] The acupoints used in this group will be determined according to the National Standard of the People's Republic of China (GB/T 12,346–2006). Participants in the TCM acupoint group will receive acupuncture at Chenshan (BL57), Taixi (KI3), Kunlun (BL60), and Jiaji (EX-B2) in prone position. Each acupoint will be needled vertically to a depth of 20–35mm, based on the participant's physique, and manipulated with three times of even twisting and lifting.

Participants in both groups will receive the same acupuncture technique, with the only difference being the insertion points. If bilateral pain is experienced, both sides will be treated with acupuncture. Participants in both groups will receive a total of 8 acupuncture sessions over two weeks, followed by a 12-week follow-up period. Participants will be treated separately to prevent interaction between them. Additionally, participants in both groups will be advised not to engage in strenuous activities during the trial.

Rescue Medication

Other medications or interventions will not be encouraged during this trial. However, if participants experience intolerable pain in their lumbar or plantar heel areas, ibuprofen sustained-release tablets (0.3g per tablet) will be allowed as rescue medication. Participants will be informed that ibuprofen can be taken up to twice a week, with a maximum daily dose of 1.2g. Any use of rescue medication will be recorded. If participants take rescue medication before baseline assessment, the measurements will be postponed by 72 hours.

Outcome Measures

Primary Outcome

The primary outcome will be the change from baseline in the worst first-step pain intensity in the morning after 8 sessions of treatment, compared between the two groups. First-step plantar heel pain in the morning and the worst low back pain will be evaluated using the Numeric Pain Rating Scale[28] (NPRS, 0–10) at weeks 0, 1, 2, 7, and 14. The NPRS is an 11-point scale scored from 0 to 10, where a score of 0 indicates no pain, and a score of 10 indicates unbearable pain. Participants will be asked to select a value that represents the worst pain they have experienced for plantar heel pain and low back pain in the past week. If participants experience bilateral pain, both sides will be treated, and the more severe side will be used for evaluation. The minimal important difference for the first-step pain will be defined as a change of 1.9 points on the 10-point NPRS after treatment [29].

Secondary Outcomes

1. Changes in plantar fascia thickness from baseline at weeks 1 and 2 between the two groups. Ultrasound will be used to evaluate plantar fascia thickness at weeks 0, 1, and 2. One ultrasonographer will be responsible for conducting ultrasound examination to avoid bias.
2. Change from the baseline in the worst first-step pain measured by the NPRS in weeks 1, 2, 7, and 14, compared between the two groups;
3. Changes from baseline in each subcategory of the Foot Function Index (FFI)[29] at weeks 0, 1, 2, 7, and 14 between the two groups. The FFI is a self-report scale that measures foot pain and function, consisting of 23 items that evaluate foot pain and function over the past week. The questionnaire has three subcategories: foot pain, difficulty in movement, and limitation of motion. Participants rate each item from 0 to 10, with higher scores indicate worse function. Minimal clinically important differences (MCID) for the pain subscale, the disability subscale, the activity subscale, and the total score are 12.3 points, 6.7 points, 0.5 points, and 6.5 points, respectively.[30]
4. Changes from the baseline in the FFI total score at weeks 0, 1, 2, 7, and 14, compared between the two groups;
5. Changes from baseline in the worst low back pain measured by the NPRS at weeks 0, 1, 2, 7, and 14, compared between the two groups;
6. Changes from baseline in the Roland-Morris Disability Questionnaire (RMDQ)[31] score at weeks 0, 1, 2, 7, and 14, compared between the two groups. The RMDQ is a self-report questionnaire that containing 24 items related to the impact of low back pain. Each item is followed by "due to low back pain" to clarify the context. Participants will rate each item based on their low back condition over the past week.
7. Participants' Global Improvement Assessment of treatment in both groups. Participants will rate their perception of treatment efficacy after 1 and 2 weeks of treatment at 7 and 14 weeks of follow-up. The evaluation will use a 7-point Likert scale, ranging from "markedly improved" to "markedly worse", encompassing the following levels: markedly improved, moderately improved, slightly improved, no change, slightly worse, moderately worse, and markedly worse.
8. Rescue medicine use. Participants who experience intolerable plantar heel pain or low back pain may use rescue medication if necessary. Any use of rescue medication will be recorded in detail, including the name, dosage, timing, and frequency of use. Pain intensity will be assessed before and after rescue medication use.
9. Evaluation of compliance. Compliance will be evaluated based on the number of treatment sessions participants actually received versus the number they were supposed to receive.
10. Participants' expectation assessment. Participants' expectation will be assessed using the Stanford Expectations of Treatment Scale before the acupuncture session.[32] The scale includes six questions related to the treatment that participants are about to receive. Three positive and three negative questions about their expectations for acupuncture. A seven-point Likert-type response scale will be used: (1) "strongly disagree", (2) "moderately disagree", (3) "slightly disagree", (4) "neither agree nor disagree", (5) "slightly agree", (6) "moderately agree", and (7) "strongly agree".

Safety Assessment

Any adverse events reported by participants, acupuncturists, or outcome assessors that occur during the trial period will be recorded in the case report form in detail. Adverse events will be categorized as treatment-related or non-treatment-related. Detailed information regarding the adverse events will include the name, onset date and time, intensity, relationship to acupuncture, outcomes, and relief date and time. The intensity of adverse events will be evaluated using an 11-point numerical rating scale (0 to 10 points), with a higher number indicating more severe events. Any serious adverse events will be reported to the principal investigator and the Medical Ethics Committee of Guizhou University of Medicine.

Sample Size Calculation

Based on relevant trials, assuming that after 8 sessions of acupuncture treatment, the NPRS scores for the two groups with the most severe first-step pain in the morning are reduced by an average of 3.63 ± 1.23 points and 3.45 ± 1.32 points from baseline.[33,34] The minimum clinically important difference in the NPRS score was considered to be 0.8 points between the two groups after treatment, which was used as the non-inferior cut-off value.[30] PASS 11.0 software was used for sample size calculation. With $\alpha = 0.05$ and $\beta = 0.2$, and accounting for a 15% drop-out rate, 31 participants will be needed for each group, for a total of 62 participants in the trial.

Statistical Analysis

Data will be analyzed according to the intention-to-treat principle. Missing data will be imputed using by multiple imputation. A two-sided test will be conducted at a significance level of 0.05, with a 95% confidence interval (CI). Between-group differences in pain intensity, functional scores, and plantar fascia thickness will be analyzed using Analysis of Covariance (ANCOVA) or a nonparametric test, depending on the normality of the data. General linear regression will be used to assess whether there is a correlation between the primary outcome and participant expectations. The success of the blinding method will be evaluated using the χ^2 test. Means and standard deviations (SDs) or means with 95% CIs will be used to present continuous data if it is normally distributed. Medians and interquartile ranges will be used to present continuous data for non-normal distributions. Categorical data will be presented as frequencies and percentages.

Quality Control

All the investigators will undergo specialized training regarding the trial content, treatment procedures, and objectives to ensure quality control. Myofascial trigger point identification will be taught by a physician from the Department of Pain Management. Acupuncture will be performed by Ziling Huang, who has obtained a certificate in Traditional Chinese Medicine and has over five years of acupuncture practice. The case report form will first be filled out on paper and then entered into Microsoft Excel® by two independent researchers. Data monitoring and validation will be conducted regularly conducted throughout the study. The case report forms and consent forms will be stored in the Department of Acupuncture at the Affiliated Hospital of Guizhou Medical University, with limited access authority for 3 years after publication. Original clinical information will not be accessed without the principal investigator's permission.

Participant and Public Involvement

No participant was involved in the design of this study.

Ethics and Dissemination

The study was approved by the Ethics Committee of the Affiliated Hospital of Guizhou Medical University and has been registered at the Chinese Clinical Trial Registry (Registration number: ChiCTR2300067552). This trial will be conducted in accordance with the principles of the Declaration of Helsinki. Informed consent must be obtained before randomization. Participants have the right to withdraw their informed consent at any time during the trial, with or without providing a reason for their withdrawal. Any modifications or changes to the protocol must be agreed upon co-researchers and re-approved by the Ethics Committee of the Affiliated Hospital of Guizhou Medical University. The results of this study will be submitted for publication in a peer-reviewed medical journal following data analysis.

Discussion

Several trials and reviews have shown that acupuncture and dry needling at trigger points are effective for treating plantar fasciitis and low back pain.[19,20] However, the comparison of needling at trigger points versus acupoints for treating plantar heel pain, low back pain, or both conditions has not been explored. To the best of our knowledge, this is the first clinical trial in which acupuncture is used to treat both plantar fasciitis and low back pain simultaneously. This study will provide evidence on whether acupuncture at trigger points and Traditional Chinese Medicine acupoints is effective in relieving plantar heel pain with low back pain. Additionally, there is a lack of studies to comparing acupuncture at trigger points with traditional acupuncture.

This study aims to evaluate the effectiveness of acupuncture applied to both acupoints and trigger points for treating participants with plantar fasciitis and low back pain. The assessment will include the intensity of pain and function in both the plantar heel and low back, as well as the thickness of the plantar fascia. Due to the inherent nature of acupuncture, any type of needle insertion or stimulation of the skin can produce biological effects, which makes it challenging to effectively blind the acupuncture procedure. This challenge is why traditional acupuncture points have been chosen as a control group to compare against acupuncture at trigger points. The objective is to discern the differences in outcomes between these two approaches.

In this study, the NPRS will be used to measure the subjective intensity of pain. This scale can be completed in less than three minutes without any prior training. Furthermore, it has excellent test–retest reliability, as well as inter-rater and intra-rater reliability.[35] MCID is also established for many types of pain.[36,37] The first-step pain intensity, measured by the NPRS, will be used as the primary outcome. First-step pain intensity is a meaningful subjective outcome measure for participants with plantar heel pain and has been used in many trials related to plantar fasciitis.[18,21] Additionally, the thickness of the plantar heel fascia will be measured as an objective outcome to provide further insights into the anatomical changes in the plantar fascia before and after acupuncture treatment.

The FFI measures the impact of foot pathology on individual function by assessing pain, disability, and activity restriction. It is a self-reported outcome, and participants can complete the ratings in 5–10 minutes without training. The FFI was originally developed in English and was translated and adapted into Chinese in 2017. It has demonstrated excellent test–retest reliability, as well as inter-rater and intra-rater reliability.[38,39] The MCID for plantar fasciitis has been established for each subscale. The MCID for the pain subscale, the disability subscale, the activity subscale, and the total score are 12.3 points, 6.7 points, 0.5 points, and 6.5 points, respectively.[40]

The Roland-Morris Disability questionnaire is a 24-item self-report questionnaire that assesses low back function. Each item is worth one point, and the total score is calculated by adding up the number of items reported by the participant. Therefore, the total score can range from 0 to 24 (with 0 indicating no disability and 24 indicating severe disability). The MCID for the RMDQ is defined as a change of 5 points, which represents the smallest change that is clinically important for participants with low back pain after 3–6 weeks of treatment.[31] A Chinese version of this questionnaire is also available.

This trial also faces several challenges. Due to a lack of epidemiological investigations, the incidence of participants with both plantar fasciitis and low back pain may be low. Additionally, risk factors for plantar heel pain, such as obesity and heavy physical labor, are difficult to eliminate, which may lead to a higher risk of recurrence.

This study has several limitations that must be acknowledged. First, the trial will be conducted in Guiyang, Guizhou, and most participants will be recruited from this region, limiting the diversity of the sample. Second, due to the specific nature of acupuncture and the manipulation methods, blinding of the acupuncturist is not possible.

Abbreviations

TCM, Traditional Chinese Medicine; NPRS, Numeric Pain Rating Scale; FFI, Foot Function Index; MCID, Minimal clinical important difference; RMDQ, Roland-Morris Disability Questionnaire.

Trial Status

Participant recruitment began on January 1, 2024.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study has been approved by the Ethics Committee of the Affiliated Hospital of Guizhou Medical University (approval number: 2022083k). Participants must sign an informed consent form before randomization. They will be permitted to withdraw their informed consent with or without providing any reasons at any time during the trial.

Author Contributions

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

Funding

This trial is funded by the Doctoral Research Initiation Fund Project of the Affiliated Hospital of Guizhou Medical University (fund number gyfybsky-2022-49).

Disclosure

The authors declare that they have no competing interests in this work.

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