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STUDY PROTOCOL

Acupuncture for Rapid Pain Relief and Restoration of Motor Function in Acute Lateral Ankle Sprains: A Randomized Controlled Trial Protocol Based on Infrared Thermography

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Purpose: Acute lateral ankle sprain (ALAS) is a prevalent clinical sports injury disease, rapid relief of symptoms and return to normal functional activity are urgent needs of ALAS patients. The aim of this study is to observe the immediate therapeutic effect of acupuncture on ALAS patients in the short term and to evaluate the efficacy at different time points through a multidimensional assessment system, which is expected to provide a simple, rapid, safe and effective therapeutic option for ALAS patients.

Patients and Methods: This is a single-center, prospective, randomized clinical trial. About 177 eligible ALAS patients will be randomly assigned in a 1:1:1 ratio to the Group A, Group B and Group C. All three groups of patients will be professionally instructed to move their ankle joints in different directions. Group A will receive real acupuncture treatment and Group B will receive sham acupuncture treatment. Each group will receive one treatment of 10 minutes.

Planned Outcomes: The primary outcome is the change in pain intensity 10 minutes after treatment compared to before treatment, measured using the visual analog scale (VAS). Secondary outcomes will include pain VAS scores at 0, 1, 3 minutes of treatment; Range of motion (ROM) scores for ankle joint mobility and changes in Infrared Thermography (IRT) of the area of ankle pain at 0, 1, 3, 10 minutes of treatment. Other outcomes include the blinding assessment, the expected treatment effect assessment, and the rescue analgesia rate. The statistical analysis of this trial will be performed using SPSS software.

Conclusion: The results of this study may provide evidence-based medical evidence for the treatment of ALAS with acupuncture, and it is expected that the findings of this study will provide a simple, rapid, safe and effective treatment option for patients with ALAS.

Keywords: acupuncture, infrared thermography, acute lateral ankle sprain, rapid efficacy, randomized controlled trial

Introduction

Acute lateral ankle sprain (ALAS) is a common sports injury.[1] Epidemiological data show that the annual incidence rate in the general population is around 2.1 to 3.2 cases per 1000 people, lateral ankle sprains account for 85% of ankle injuries and around 40% of sports injuries.[2] This disease is usually associated with excessive stretching or tearing of the ligaments of the ankle joint due to various factors. The main clinical manifestations are pain and dysfunction of the ankle joint, which seriously affect the patient's work and life.[3] Alarmingly, patients suffering from acute lateral ankle sprains who do not receive prompt and effective treatment are at increased risk of long-term instability and re-injury.[4] Therefore, rapid pain relief and recovery of mobility become the main needs of patients seeking medical treatment.

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Currently, the latest evidence-based clinical guidelines do not recommend a definitive treatment for lateral ankle sprains. Acute clinical management primarily involves the RICE method (rest, ice, compression, elevation) or the POLICE method (protection, proper weight-bearing, ice, compression, elevation), supplemented by Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) to alleviate local pain and swelling. However, the evidence supporting these methods is limited, and NSAIDs not only cause gastrointestinal reactions but also delay natural healing.[5] This makes it challenging for patients to receive timely and effective treatment during acute exacerbations.

Acupuncture, as an important clinical complementary and alternative therapy, has shown significant potential in the treatment of acute pain disorders.[6–8] Several clinical studies have shown that acupuncture can effectively relieve the pain of patients with ankle sprain and improve their mobility.[9,10] A systematic review and meta-analysis evaluated the evidence for acupuncture treatment of acute ankle sprains, suggesting its efficacy and safety.[10] However, studies on the immediate efficacy of acupuncture in the treatment of ALAS are limited and further validation is still needed. This study selected a 10-minute treatment duration based on comprehensive clinical considerations and existing evidence. Patients with ALAS often seek rapid pain relief and recovery of basic functional mobility, making timely intervention critical in such acute care settings. Previous studies have shown that acupuncture provides rapid analgesic effects for various acute pain conditions.[11,12] In clinical practice, we have also observed that a single 10-minute acupuncture session can significantly alleviate symptoms in some patients. Therefore, this trial aims to observe the immediate analgesic and functional recovery effects of acupuncture on acute lateral ankle sprains after 10 minutes.

In addition, Infrared Thermography (IRT) is a non-invasive, radiation-free, highly sensitive, and user-friendly tool that objectively reflects local microcirculation and inflammation, and has been widely used to assess various pain conditions.[13–16] Relevant studies have shown that IRT can detect inflammation-related temperature changes,[17–21] which often correlate positively with Visual Analog Scale (VAS) scores, supporting its role as an objective pain indicator. IRT provides objective physiological evidence that complements or validates subjective reports. Therefore, in this study, we use acupuncture treatment for 10 minutes and add IRT to sensitively capture pain changes in order to assess the rapid efficacy of acupuncture in ALAS and to provide a safe and effective treatment option for patients.

Methods

Study Design and Setting

This study is a randomized controlled trial designed to evaluate the effects of acupuncture on pain relief and functional recovery in ALAS within 10 minutes. The study will be conducted from March 2025 to December 2027 at the outpatient department of the Second Affiliated Hospital of Yunnan University of Traditional Chinese Medicine. About 177 patients aged 18 to 60 with ALAS will be recruited. Participants will be randomly assigned in a 1:1:1 ratio to the Group A, Group B, and Group C. All participants will receive a treatment session of 10 minutes. This research protocol is designed according to the Standard Protocol: The research protocol is designed according to the Standard Protocol for Interventional Trials (SPIRIT 2013) and follows the principles of the Declaration of Helsinki[22] (Supplementary Material 1). This study was approved by the Ethics Committee of the Second Affiliated Hospital of Yunnan University of Traditional Chinese Medicine (2025-002) and registered with the International Traditional Medicine Clinical Trial Registry (ITMCTR2025000599).

The flowchart is shown in Figure 1. The schedule of enrollment, intervention, and assessment is detailed in Table 1.

Recruitment Strategies and Enrollment

All participants will be recruited from the outpatient clinics of the Second Affiliated Hospital of Yunnan University of Traditional Chinese Medicine and the Kunming community through online and offline channels such as WeChat, website and notice. Physicians with more than 5 years of clinical experience will be screened according to strict inclusion and exclusion criteria to assess participants' eligibility. Eligible participants will sign a written informed consent form prior to randomization into groups (Supplementary Material 2). Participants will have the right to withdraw from the study at any time and will not be required to provide a reason, and we will ensure the confidentiality of all participants.

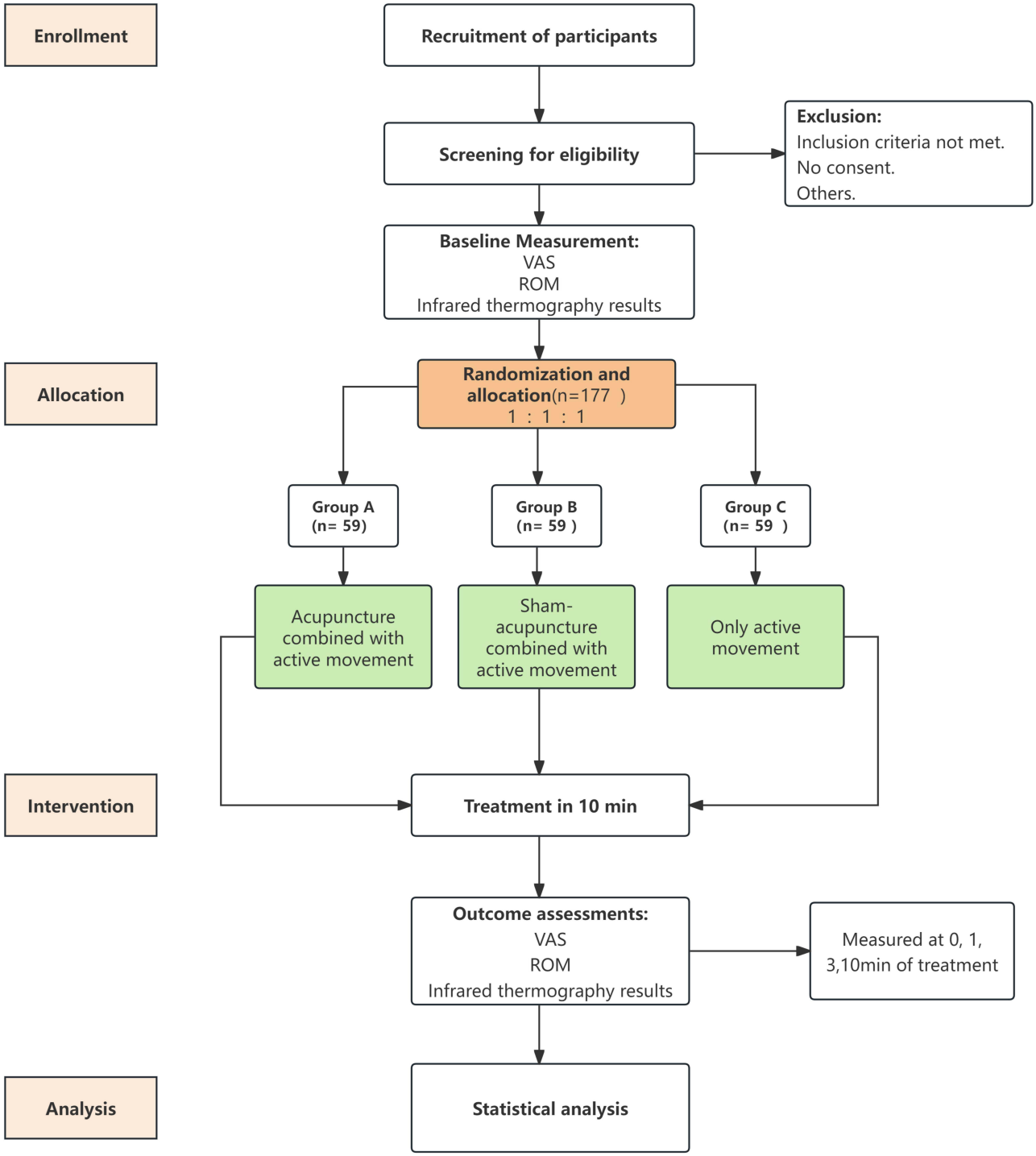

Figure 1 Flow diagram.

Eligibility Criteria

Diagnostic Criteria

Developed with reference to the American Physical Therapy Association Orthopaedic Branch International Classification of Functioning, Disability and Health Clinical Practice Guideline for Sprained Ankle Ligaments (2021 edition)[23] and the Diagnosis and Treatment Standards for Traditional Chinese Medicine issued by the State Administration of Traditional Chinese Medicine:[24]

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Table 1 Study Schedule for Data Measurements

Items	Baseline Period (Minutes)	Treatment Period (Minutes)		
Study Period:				
Timepoint	0	1	3	10
Enrolment:				
Eligibility screen	x			
Sign informed consent	x			
Inclusion/exclusion criteria	x			
Randomisation	x			
Interventions:				
Group A		x	x	x
Group B		x	x	x
Group C		x	x	x
Assessments:				
VAS	x	x	x	x
ROM	x	x	x	x
Infrared thermography results	x	x	x	x
Treatment effect expectancy	x			
Satisfaction evaluation				x
Blind evaluation				x
Rescue analgesia rate				x
Safety evaluation				x
Compliance evaluation				x
Participants Safety:				
AEs		x	x	x

Abbreviations: VAS, visual analogue scale; ROM, range of motion; Group A, acupuncture combined with active movement group; Group B, sham acupuncture combined with active movement group; Group C, active movement group; AEs, adverse events.

(1) History of clear trauma to the ankle;
(2) A sprained ankle joint has obvious tenderness or subcutaneous ecchymosis, accompanied by swelling, pain, limited weight-bearing and limping;
(3) Restricted joint movement;
(4) Ottawa principle negative, X-ray examination did not show any fractures or dislocations.

Inclusion Criteria

Qualified individuals who satisfy the designated prerequisites will be included in the research:

(1) Meets the diagnostic criteria for an ankle sprain;
(2) ALAS meeting Grade I or II criteria (Supplementary Material 3) under clinical evaluation standards;[25]

(3) 4 ≤ VAS scores ≤ 9;
(4) Course of illness ≤ 72 h;
(5) Age 18–60 years;
(6) Voluntary participation in this study and signing of the informed consent form.

Exclusion Criteria

Individuals will be ineligible for the study if they:

(1) ALAS meeting Grade III criteria (Supplementary Material 3) under clinical evaluation standards, with a torn or broken tendon or ligament, or joint instability;
(2) Previous history of other diseases that may affect the results of this study;
(3) Female patients who are currently pregnant or breastfeeding;
(4) Patients with severe hypertension, diabetes, coronary heart disease, malignant tumors, coagulation disorders or other chronic internal diseases;
(5) Patients with severe mental illness or other neurological diseases that cause cognitive and communication disorders;
(6) Those with ulcers, trauma or other skin diseases on the treatment area;
(7) Those with a history of fainting from acupuncture, a clear history of adverse reactions to acupuncture, or allergies to the material of the needles or the disinfectant;
(8) Those who have received other treatments for ALAS shortly before the start of the study;
(9) Currently participating in other clinical studies.

Standard for Elimination and Shedding

(1) Cases that do not meet the inclusion criteria and have been misclassified should be excluded;
(2) Participants with poor compliance who withdrew from the treatment course on their own;
(3) Cases in which the trial is discontinued due to serious adverse reactions or complications that made it inappropriate to continue treatment.

Randomization and Blinding

To minimize selection bias, the randomization process for this study was performed by an independent researcher not involved in the trial. Random numbers were generated using SPSS 28.0 (IBM, Chicago, IL, license code: f56b44b8d8e3562ad8a2) and sealed in opaque, sequentially numbered envelopes, which were prepared in advance. After consenting to participate, each participant selected an envelope and was assigned a group and corresponding intervention based on the serial number inside. The assigned number was recorded by the independent researcher in the case report forms (CRFs), ensuring allocation concealment until the moment of assignment. To maintain blinding, participants in Groups A (real acupuncture) and B (sham acupuncture) were blinded, whereas Group C (no stimulation) remained unblinded due to the nature of the control condition. Because the acupuncture intervention requires practitioner involvement, acupuncturists could not be blinded; however, outcome assessors, data collectors, and statisticians were all blinded to group allocation to minimize bias.

Both Groups A and B received stimulation at identical acupoints using the Park Sham Acupuncture Device (PSD). Group B received sham stimulation via non-penetrating blunt needles, which mimic the sensation of skin contact and manual stimulation without breaking the skin. Participants were not informed about the concept or expected sensations of Deqi, thus minimizing expectancy effects. They were only told that individual perceptions of stimulation may vary, reducing potential psychological bias. To further ensure blinding effectiveness and prevent communication between participants, all treatments were conducted in separate individual rooms, minimizing potential contamination of group allocation awareness. After the intervention, participants in Groups A and B were asked to guess whether they had received real or sham acupuncture, in order to assess the success of the blinding procedure.

Table 2 Location of Acupoints

Acupoints	Location
Qiuxu (GB40)	On the anterolateral aspect of the ankle, in the depression lateral to the extensor digitorum longus tendon, anterior and distal to the lateral malleolus.
Zulinqi (GB41)	On the dorsum of the foot, distal to the junction of the bases ofthe fourth and fifth metatarsal bones, in the depression lateral to the fifth extensor digitorum longus tendon.

Interventions

The intervention measures will adhere to the Uniform Standard for Trial Reporting and the Standard for Reporting Interventions in Clinical Trials of Acupuncture.[26,27] Based on the primary distribution of pain along the gallbladder meridian and the fact that ALAS typically occur on one side, the study select Zulinqi (GB41) and Qiuxu (GB40) acupoints on the unaffected side for acupuncture treatment. These acupoints will be positioned based on the WHO Standard Acupuncture Point Locations 2010 (ISBN: 9787117123327). The locations of the acupoints are shown in Table 2 and Figure 2. All acupuncture operations will be performed by acupuncturists with at least 5 years of clinical experience.

Appliance Selection

Park Sham Acupuncture Device (PSD) (Figure 3): The device consists of a transparent catheter (Φ 4 × 20 mm), double-sided tape (Φ 1 × 15 mm) and an opaque plastic base (Φ 4 × 15 mm). It was manufactured by Suzhou Medical Devices Co., Ltd. in China and has the batch number 210401.

Acupuncture needles: Huatuo disposable acupuncture needles manufactured by Suzhou Medical Devices Factory in China. Manufacturer license number: Su Food and Drug Administration Production License 20010020; registration certificate number: 201622770970. Acupuncture needles are 0.25 × 40 mm in size.

Blunt needle: 0.25 × 40 mm retractable stainless steel blunt needle produced by Suzhou Medical Supplies Co., Ltd. in China, batch number: 200304.

Protractor: A stainless steel protractor with dimensions of 90 × 155 mm is used. It was manufactured in Huzhou, Zhejiang, China, and has the batch number LJQ915D.

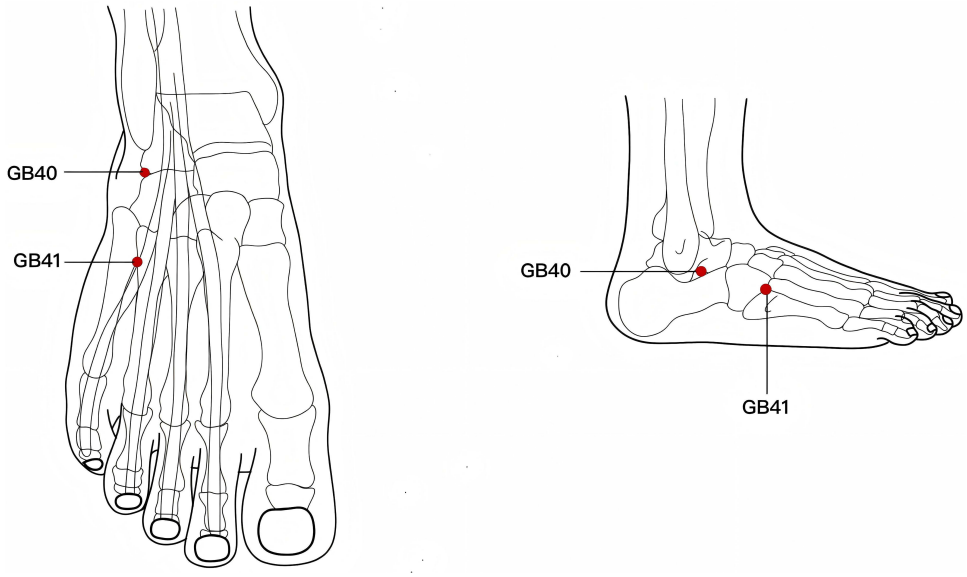

Figure 2 Location of acupoint.

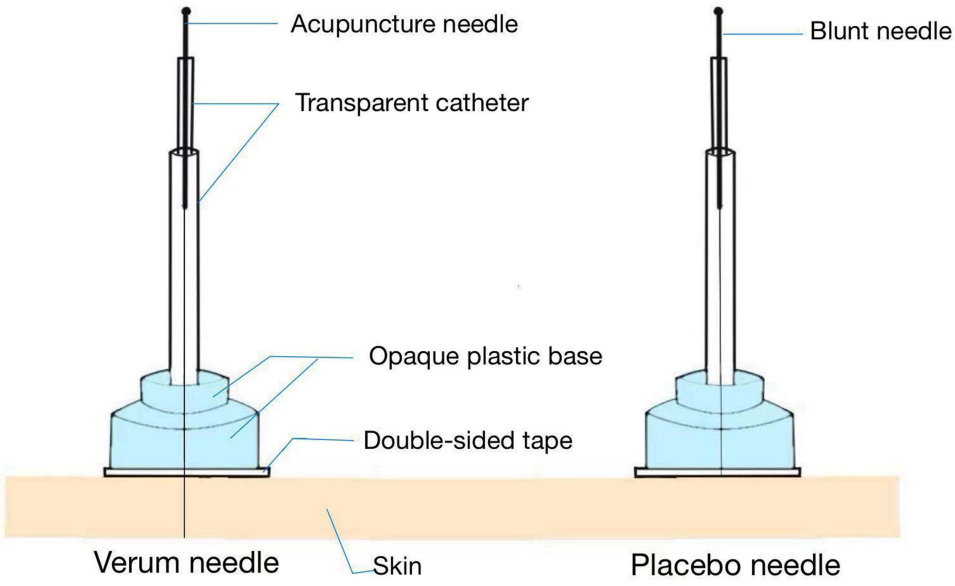

Figure 3 Park Sham Acupuncture Device.

Procedures

Before treatment, the patient lies in a supine position with the ankle joint fully exposed. The acupuncturist uses 75% medical alcohol to sterilise the skin around the points.

Group A

Group A will use the PSD and acupuncture needles. First, remove the tape on the skin side of the PSD, insert the needle into the PSD so that the tip is exposed, and then stab it straight into and fix it on the GB41 and GB40 acupuncture points, with a depth of 0.3–0.8 cun. At 0, 1, 3, and 10 minutes, perform lifting, inserting, twisting, and rotating movements on the acupuncture points to elicit the "Deqi" sensation.[28] At the same time, the practitioner repeatedly guides the patient to slowly and steadily perform plantar flexion, dorsiflexion, inversion, and eversion movements of the ankle joint until the patient reaches their maximum tolerance level.[29,30] At the end of each range of motion, perform a slight rotation, then relax and return to the starting position. After 10 minutes, remove the needle device and press the needle puncture site with a sterile dry cotton ball.

Group B

Group B will use the PSD and Blunt needles. First, remove the tape from the skin side of the PSD and insert the blunt needles into the PSD, gently stimulate on the GB41 and GB40 points on the healthy side to simulate the needling process. When the needle tip touches the skin, the blunt needle will not pierce the skin, but will create the illusion of insertion. To maintain this illusion, the PSD will also be fixed in place to simulate the presence of the needle. Acupuncturists will mimic the same techniques at the same time, such as lifting, inserting, and rotating movements, and guide patients to perform active ankle movements. This is done to maintain consistency with the patient's experience and expectations.

Group C

Group C will only receive active ankle joint movement guidance, with the same movement methods as Groups A and B.

Outcomes

Primary Outcome

The primary outcome is the change in pain intensity 10 minutes after treatment compared to before treatment, measured using the VAS scale.

Secondary Outcomes

(1) Pain intensity changes at 1 and 3 minutes of treatment, measured using the VAS scale.

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(2) Changes in range of motion (ROM) at 1, 3, 10 minutes of treatment.
(3) IRT: IRT temperature of the affected side before treatment and the healthy side, and IRT temperature changes of the affected side after treatment (1, 3, 10 minutes).

Other outcomes include the blinded assessment, the treatment expectation scale, and rescue analgesia rates.

Measurement Methods

(1) VAS is a widely used tool for predicting pain severity and judging pain relief. It usually consists of a 10cm long continuous line anchored by two verbal descriptors ("no pain" and "worst imagined pain"). The health-care professional asks the patient to choose a point between the two ends to express the intensity of the pain he/she perceives. It is also very sensitive in detecting the effectiveness of treatment[31] (Supplementary Material 4).
(2) ROM is one of the indicators for assessing the mobility of the ankle joint. A goniometer will be used to measure the range of motion of the ankle joint during the treatment process at intervals during the plantar flexion, dorsiflexion, inversion, and eversion movements (Supplementary Material 5).
(3) Infrared Thermography Assessment:
    1. Research Instrument: FOTRIC 348L-L25 thermal imaging camera (Figure 4) from Shanghai Thermal Imaging Co., Ltd. equipped with a high resolution detector of 640 × 480 pixels, high thermal sensitivity, temperature recognition error less than 30mK (0.03°C), minimum imaging distance of 0.25 m, with autofocus and auto-recognition functions.
    2. Test requirements: The collection room is a separate room with a relatively stable environment, with a temperature of 20–24°C and a humidity of 50–60%. Air circulates naturally, without interference from drafts or bright light, and the heat and cold sources in the test chamber are kept away from the subject. The patient should lie on their back and wait for 10–15 minutes before the test. During the waiting period, the patient should take off their shoes and socks, expose the ankle joint, refrain from pressing or scratching the lower extremities, relax the whole body, and rest quietly to adapt to the ambient temperature.
    3. Testing process: The researcher adjusted the infrared thermal imager for filming (fixed shooting distance (1m) and angle (facing the measured plane ±15°)), and the imaging work was completed by professionally trained personnel. Before treatment, infrared thermal imaging will be performed on the corresponding areas of both ankle joints, and the temperatures will be recorded. During treatment, infrared thermal imaging will be performed on the affected ankle joint at 1, 3, and 10 minutes, and the temperature changes will be recorded.

Figure 4 Infrared thermography device.

The rectangular averaging method will be used to collect temperature data to ensure spatial consistency of the ROI region at multiple time points. The anatomic center landmark point to be measured, the tip of the outer malleolus, will be first identified, and then a square with sides of about 1 cm will be drawn around this center point. Finally, the average temperature within the square will be calculated. During the initial screening, images that can be recognised as abnormal by the naked eye are discarded. Thermogram files that meet the criteria and have no obvious problems will be saved with a name in the format of "group-number-time-node" and transferred to a computer for further processing.

(4) The Efficacy Expectancy Scale: Including four options: ineffective, mildly effective, moderately effective, and completely effective. This will be assessed before the intervention.
(5) The success of blinding will be assessed using a blind assessment at the end of the treatment. When recruiting and screening eligible participants, patients will be informed that they will have an equal opportunity to receive traditional acupuncture, acupuncture-like stimulation treatment, or no acupuncture treatment. After treatment, patients in the real acupuncture group or the sham acupuncture group will be asked whether they had received real acupuncture treatment to test the blinding effect.
(6) The percentage of patients requiring additional analgesic medication will be calculated at the end of treatment.

Adverse Events Reporting and Safety Monitoring

The researcher will monitor adverse events (AEs) information related to the intervention in real time, including infections, bleeding, local hematomas, broken needles, paleness, sweating, palpitations, fainting, headaches, etc, as well as participants worsening of existing symptoms. Regardless of whether these AEs are directly related to the intervention in this study and regardless of their severity, they will be recorded in the case report form CRFs and dealt with promptly. Serious AEs will be reported to the Ethics Committee promptly, with a detailed report provided within 48 hours or within 24 hours if life-threatening.

Data Collection Methods and Study Monitoring

Data will be collected and recorded in CRFs by a dedicated researcher and subsequently entered into a computer and carefully checked by two research assistants who are not involved in the trial. For all participants who withdraw or discontinue the trial, we will complete the final data collection as much as possible. The reason for withdrawal and the corresponding treatment will be recorded in CRFs. The research assistant will verify the accuracy of the data, check for any missing information, and ensure data consistency to avoid bias in the results. To protect the privacy and rights of patients, all patient data involved in the study will be anonymized. The study director will strictly monitor the quality and progress of the research data and regularly report the progress of the trial to the Ethics Committee of the Second Affiliated Hospital of Yunnan University of Traditional Chinese Medicine. The ethics committee will be responsible for monitoring the collection, distribution and confidentiality of data and has the power to modify or terminate the trial. The sponsor is independent of the ethics committee and there is no conflict of interest.

Sample Size

To our knowledge, there are no experimental studies directly comparing the efficacy of acupuncture and sham acupuncture for the treatment of ALAS. Therefore, we referenced a previous study on the efficacy of acupuncture for acute pain and used our own clinical experience to estimate the sample size for this study.[32] We assume that the changes in VAS scores after 10 minutes of treatment in the Group A, Group B, and Group C are 4.6 ± 1.0, 2.7 ± 1.0, and 1.3 ± 1.0, respectively, $\alpha = 0.025$ (one-sided), $\beta = 0.1$, $\Delta = 1.3$,[33] and $K = 1$. The required sample size for each group is calculated according to the following formula:

$$n_C = \frac{\left(Z_{1-\alpha} + Z_{1-\beta}\right)^2 \sigma^2 \left(1 + \frac{1}{K}\right)}{\left(\mu_T - \mu_C - \Delta\right)^2}$$

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It is calculated that a minimum of 59 patients are required per group. Since the study is an immediate efficacy observation and only one treatment is required, patient dropouts do not need to be considered. A total of 177 participants need to be recruited.

Statistical Analysis

All data will be analyzed using SPSS 28.0. The statistical analysis will be conducted by an independent statistician to ensure the objectivity of the results. Continuous variables will be described as mean ± SD (standard deviation) with a 95% CI in a normal distribution and median (range) in abnormal distribution, while categorical variables will be represented by numbers (percentages). The level of significance will be established at 0.05 in a two-sided test.

Data analysis will be based on the intention-to-treat (ITT) principle, which is defined as all participants who have been randomized and have complete baseline data. All missing data will be handled using the multiple imputation method.

The primary outcomes will be compared using analysis of covariance (ANCOVA). If potential covariates are identified, ANCOVA will be adjusted according to patient characteristics and baseline outcomes. If significant differences are found in the overall test between the three groups, pairwise comparisons will be performed using the least significant difference test in post hoc analyses. This study has multiple visit time points, therefore, repeated measures ANCOVA will be conducted to detect differences between visit time point groups, as well as interactions between groups and time points. Secondary outcomes will be analysed in the same ANCOVA model. Categorical variables will be compared using χ^2-tests or Fisher's exact tests. Paired *t*-tests or Wilcoxon signed-rank tests will be used to compare within-group differences. In addition, Spearman or Pearson correlation analysis will be used to explore the correlation between pain VAS scores and IRT data, as well as efficacy expectation scores.

Quality Control

Before the trial, the researchers will receive comprehensive training on the entire trial process, inclusion criteria, exclusion criteria, precise acupoint locations, appropriate needle insertion depths, and exercise guidance methods to ensure the quality of the trial and consistency of the research. Acupuncturists must have at least 5 years of clinical experience in acupuncture. Outcome assessments will be performed independently by personnel not involved in the conduct of the study.

Confidentiality

In accordance with the stipulated protocol, all patient data collected during the study will be anonymised and kept strictly confidential. No data will be disclosed to any person or organisation without permission, in order to protect the privacy and safety of the participants. All researchers and data processors are required to sign a confidentiality agreement and strictly comply with data security and privacy protection regulations.

Discussion

ALAS is a prevalent clinical sports injury disease characterised by pain, swelling and dysfunction caused by ligament tears and soft tissue damage. Rapid relief of symptoms and return to normal functional activity are urgent needs of ALAS patients. This study uses acupuncture treatment for 10 minutes to observe the immediate efficacy of acupuncture on pain relief and functional recovery in ALAS.

Modern medicine believes that ankle sprains are mostly caused by external forces, resulting in damage to the soft tissues of the ankle and subcutaneous blood vessels, nerves, ligaments, impaired local motor function, swelling, pain, subcutaneous bleeding and a series of inflammatory reactions. Several studies have demonstrated the clear efficacy of acupuncture in improving acute ankle sprains.[34–36] A review reported that acupuncture may relieve pain by activating acupuncture points and transmitting signals related to the regulation of inflammatory factors to the spinal cord and brain.[37] Chen et al[38] found that acupuncture may alleviate inflammatory symptoms in the ankle joint by lowering serum TNF-α and anti-cyclic citrullinated peptide antibody levels. Therefore, acupuncture is chosen as the intervention in this study.

In addition, as ALAS mostly occur unilaterally, followed by very severe local swelling, pain, bruising and petechiae, acupuncture on the affected area will further exacerbate the patient's local pain and discomfort. Therefore, we choose

stimulating specific acupuncture points on the healthy side to treat the affected side, this method is now widely used in various studies of acute unilateral pain and shows clear advantages. Modern research has further confirmed that contralateral acupuncture therapy can effectively avoid local inflammation interfering with treatment by regulating bilateral sensorimotor function and through spinal segmental reflexes.

The primary distribution area of ALAS is closely associated with the gallbladder meridian. Based on acupuncture theory, we select the acupoints GB41 and GB40 for this study. In previous studies on acupuncture treatment for acute pain, the treatment duration is typically set at 30 minutes or longer.[9,39] However, recent studies have shown that acupuncture can effectively alleviate acute pain in a relatively short time and achieve good results.[40,41] Given the severe acute pain experienced by ALAS patients and the need to alleviate symptoms within a short timeframe, this study set the treatment observation time at 10 minutes. In terms of efficacy assessment, this study uses VAS, ROM and IRT as evaluation indexes, aiming to evaluate the efficacy more objectively, comprehensively and quickly, and to ensure its correlation with clinical symptoms and the reliability of the results.

This study adopt a three-arm randomized controlled trial design, methodological advantages are provided for stripping acupuncture-specific efficacy. By applying movement therapy as a standardised basic intervention uniformly to the real/sham acupuncture groups, the interference of movement programme variability in the results is effectively controlled, allowing between-group comparisons to focus on the incremental benefits of acupuncture. The use of non-penetrating blunt needles (producing only superficial tactile stimulation) as a sham acupuncture intervention can minimise physiological responses.[42] This design enhances the intrinsic validity of the results, confirming that the pain reduction and improved ankle mobility stemmed from the inherent biomechanical and neuromodulatory effects of acupuncture, rather than from exercise alone or placebo-expected effects.

However, there are certain limitations to this study. Due to the specific nature of the intervention, the acupuncturist cannot be blinded to group allocation, so the results may be influenced by the acupuncturist's subjective awareness. To minimize this bias, the acupuncturist will not be involved in data analysis or data management. Second, this is a single-center study with a relatively small sample size, which may limit the generalizability of the findings. Third, the study focuses on the short-term, immediate effects of treatment, and no follow-up was conducted. These issues will be addressed and improved in future, more comprehensive studies.

Conclusions

The results of this study may provide evidence-based medical evidence for the treatment of ALAS with acupuncture, and it is expected that the findings of this study will provide a simple, rapid, safe and effective treatment option for patients with ALAS.

Data Sharing Statement

The data generated during this study is available from the corresponding author, Taipin Guo, upon reasonable request.

Ethics Approval and Consent to Participate

The trial follows the principles of the Declaration of Helsinki. The study has been approved by the Ethics Committee of the Second Affiliated Hospital of Yunnan University of Traditional Chinese Medicine, Ethics Committee Approval Number: 2025-002. The researchers will follow the principles of GCP and the approved protocol to conduct the clinical research and protect the health and rights of each patient. All participants will sign an informed consent form before the study begins.

Acknowledgments

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Author Contributions

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

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Disclosure

The authors report no conflicts of interest in this work.

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