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STUDY PROTOCOL

Round-Sharp Needle for Limb Spasms After a Stroke: Study Protocol for a Randomized Controlled Trial

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Objective: Stroke can cause limb spasticity, and numerous clinical studies have demonstrated that acupuncture is an effective treatment for this condition. The round-sharp needle, a type of acupuncture needle, has been reported to shorten treatment durations and reduce the number of clinic visits compared to traditional filiform needles, the conventional acupuncture. However, clinical trial research on its efficacy remains limited. Therefore, this clinical trial is designed to investigate the short-term effects and safety of round-sharp needle therapy in treating post-stroke limb spasticity.

Methods and Analysis: This research protocol outlines a randomized, single-blind, prospective, single-center pilot clinical trial to be conducted at Hubei Provincial Hospital of Traditional Chinese Medicine, scheduled to commence after completion of clinical trial registration. After the recruitment phase, eligible patients meeting the inclusion criteria will be randomly assigned to one of two groups: the round-sharp needle group (3 times per week) or the filiform needle group (5 times per week). The treatment will last for two weeks, with evaluation criteria including surface electromyography (sEMG), the Modified Ashworth Scale (MAS), the Fugl-Meyer Assessment (FMA), the Modified Barthel Index (MBI), and a safety assessment of acupuncture.

Conclusion: This clinical trial investigates the safety and efficacy of using round-sharp needles to treat post-stroke limb spasticity, with the results expected to provide further evidence for the future clinical application of this therapy.

Trial Registration: Chinese Clinical Trial Registry (ChiCTR), ID: ChiCTR2400087907. Registered on 7 August, 2024.

Keywords: acupuncture, randomized controlled trial, round-sharp needle, spasm, stroke, study protocol

Background

The term "stroke" also known as "cerebrovascular accident (CVA)", refers to a neurological disorder caused by the rupture or blockage of blood vessels in the brain, leading to reduced or interrupted blood supply and resulting in brain tissue damage.[1,2] Stroke is classified into two main types: ischemic and hemorrhagic, with ischemic stroke being more common.[3,4] According to the 2024 American Heart Association's statistical report, a global epidemiological analysis shows that, despite a decline in the age-standardized incidence of stroke worldwide, the overall burden continues to rise due to an aging population and increasing risk factors. This trend is especially notable in low-income countries, where stroke incidence and mortality rates have significantly increased.[3]

Patients with stroke often experience various complications during the recovery period, with limb spasticity being the most common,[5] Its primary clinical manifestations include increased muscle tone, impaired mobility, and limitations in daily activities. Spasticity imposes a significant physical, psychological, and financial burden on patients, and may lead to

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a loss of work capacity,[6,7] Therefore, finding effective ways to alleviate spasticity has become an urgent challenge in modern medicine.

The primary treatments for relieving post-stroke muscle spasms currently include pharmacological interventions and physical therapy.[8–10] Pharmacological therapy mainly involves the use of antispasmodics, such as botulinum toxin type A, which, when injected into muscles, blocks neuromuscular transmission and causes temporary localized muscle paralysis.[11] However, studies have shown that its effectiveness is limited[10] and it is associated with numerous side effects and adverse reactions, including arrhythmia and muscle atrophy on the opposite side.[12–14] On the other hand, physical therapy requires active patient participation, which can be challenging for those with severe post-stroke hemiplegia.

Acupuncture is a widely practiced and safe traditional Chinese medical treatment. Ancient Chinese physicians have long used acupuncture to treat limb paralysis following a stroke. The commonly used acupuncture needle is the filiform needle, which has a fine and sharp tip (Figure 1A). Contemporary randomized controlled trials also suggest that acupuncture using filiform needle can help restore physiological function and improve post-stroke spasticity by stimulating nerves through needle insertion at acupoints.[15,16] However, the use of filiform needles to treat post-stroke spasticity also requires the combination of reinforcing and reducing techniques, and the needles need to be retained for a period of time after the manipulation is completed. Therefore, while effective, this approach can be physically demanding for both the practitioner and the patient. The round-sharp needle, with its distinctive design, offers a potential alternative.

The round-sharp needle (Figure 1B), is another type of acupuncture tool, one of the nine needles mentioned alongside the filiform needle in the *Huangdi Neijing* (*Yellow Emperor's Classic of Medicine*). Compared to regular filiform needles, round-tipped sharp needles provide stronger stimulation and do not require retention after insertion. This not only saves patients' time but also enhances the efficiency of acupuncture for practitioners. In recent years, its clinical use has become increasingly widespread,[17,18] the results have been impressive. It features a rounded, waterdrop-shaped tip and a slender body, making it effective for stimulating contracted tendons. The round-sharp needle penetrates with its sharp tip and expands the tendon with its rounded body, alternating tension and relaxation without causing damage. This process not only relieves tendon spasms but also reduces excess stress on associated muscles and joints. According to biomechanical principles, once the spasm is alleviated, abnormal stress on the connected muscles and joints is also

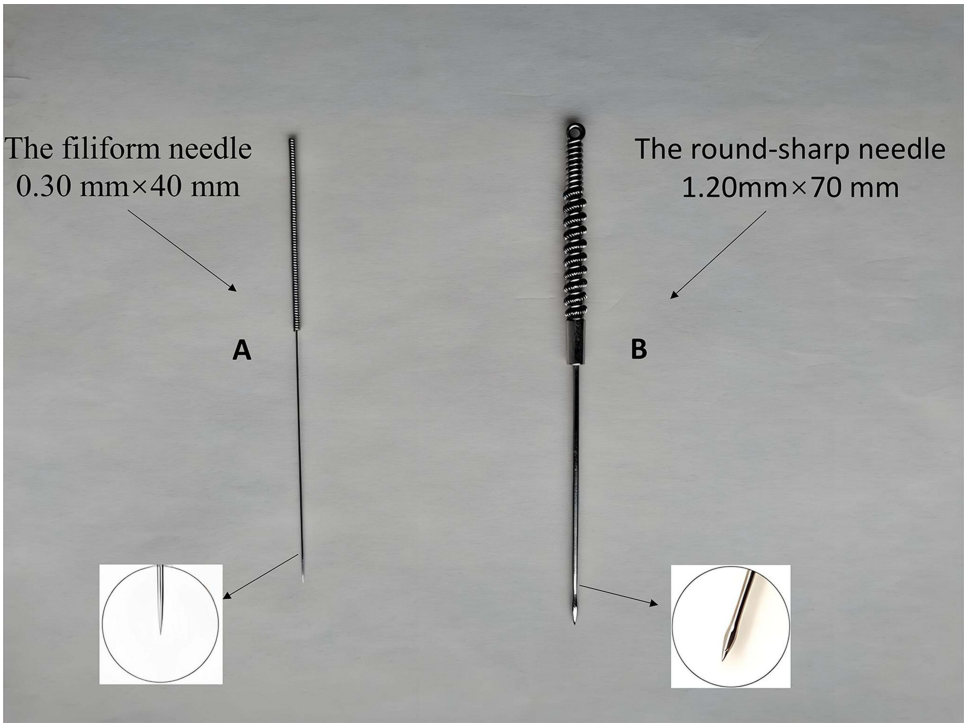

Figure 1 The filiform needle and the round-sharp needle. (**A**) The filiform needle is slender and elongated, firm yet elastic, resembling a pine needle. (**B**) The round-sharp needle is slightly thicker than filiform needle in diameter and has a waterdrop-shaped tip, resembling a drooping ox tail.

released.[19] Therefore, this study aims to investigate the safety and effectiveness of using the round-sharp needle acupuncture to treat limb spasticity in stroke patients.

Study Design and Methods

Study Design

We have designed a prospective, single-center, patient-assessor-blinded, parallel-group randomized controlled trial to evaluate the superiority of the round-sharp needle over the filiform needle in improving muscle tone in post-stroke limb spasticity. It has been designed according to the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) checklist.[20] This article will report based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.[21] The study spans 9 weeks: a 1-week screening period (week −1 to 0), a 2-week intervention period (weeks 0 to 2), and a 6-week follow-up (weeks 3 to 8). Assessments will be conducted at baseline (week 0), week 1, week 2, and week 8. The flowchart and study schedule are shown in Figure 2 and Table 1.

Ethical Considerations and Trial Registration

This study adheres to the principles of the Helsinki Declaration. Written informed consent has been obtained from all participants, and the Ethics Committee of the Acupuncture Research Institute at Hubei Provincial Traditional Chinese Medicine Hospital has approved the study (Approval No.: HBZY2024-C13-02). The trial is registered with the Chinese Clinical Trial Registry (ChiCTR2400087907) (https://www.chictr.org.cn/showproj.html?proj=238364). Participant privacy will be strictly protected, and no real names will appear in any trial-related reports.

Participants

After obtaining ethical approval and registration, patient recruitment will begin after completion of clinical trial registration. Participants will be primarily sourced from the outpatient and inpatient departments of the Acupuncture Department at Hubei Provincial Hospital of Traditional Chinese Medicine. Additional recruitment methods will include posters displayed within and outside the hospital, as well as WeChat and online advertisements. To facilitate participant understanding, we will prepare informed consent forms, along with explanatory materials such as data, videos, and images outlining the trial's purpose and procedures. The benefits and potential risks of the treatment, along with the safety measures in place, will be clearly communicated to all participants.

Sample Size

We conducted a pilot study with 24 participants, following Julious's rule of thumb for sample size estimation.[22] The objective was to estimate the effect size and overall standard deviation for the continuous variable of Integrated Electromyographic (IEMG) values. The pilot results indicated that the average IEMG value was 1.12 in the experimental group (round-sharp needle) and 0.74 in the control group (filiform needle), with an overall standard deviation of 1. Based on these parameters, we recalculated the sample size using PASS 11 software (https://www.ncss.com/software/pass/). To achieve a significance level of $\alpha = 0.05$ and a power of $1 - \beta = 0.9$, approximately 73 participants per group are required. Accounting for a potential 10% attrition rate, we plan to recruit 164 participants, ensuring at least 82 per group. This approach is designed to provide sufficient statistical power and clinical relevance for the study outcomes.

Inclusion, Exclusion Criteria and Elimination Criteria

Inclusion Criteria

(1) Meets the diagnostic criteria for stroke.[23]
(2) Neuroimaging confirms cerebral hemorrhage or cerebral infarction.
(3) Onset within 3–6 months (≥3 month and ≤6 months).
(4) Upper limb flexor spasticity or lower limb extensor spasticity. Modified Ashworth Scale (MAS) score 1-2.
(5) Age: 30–75 years.
(6) Vital signs are generally stable, and the patient is conscious.

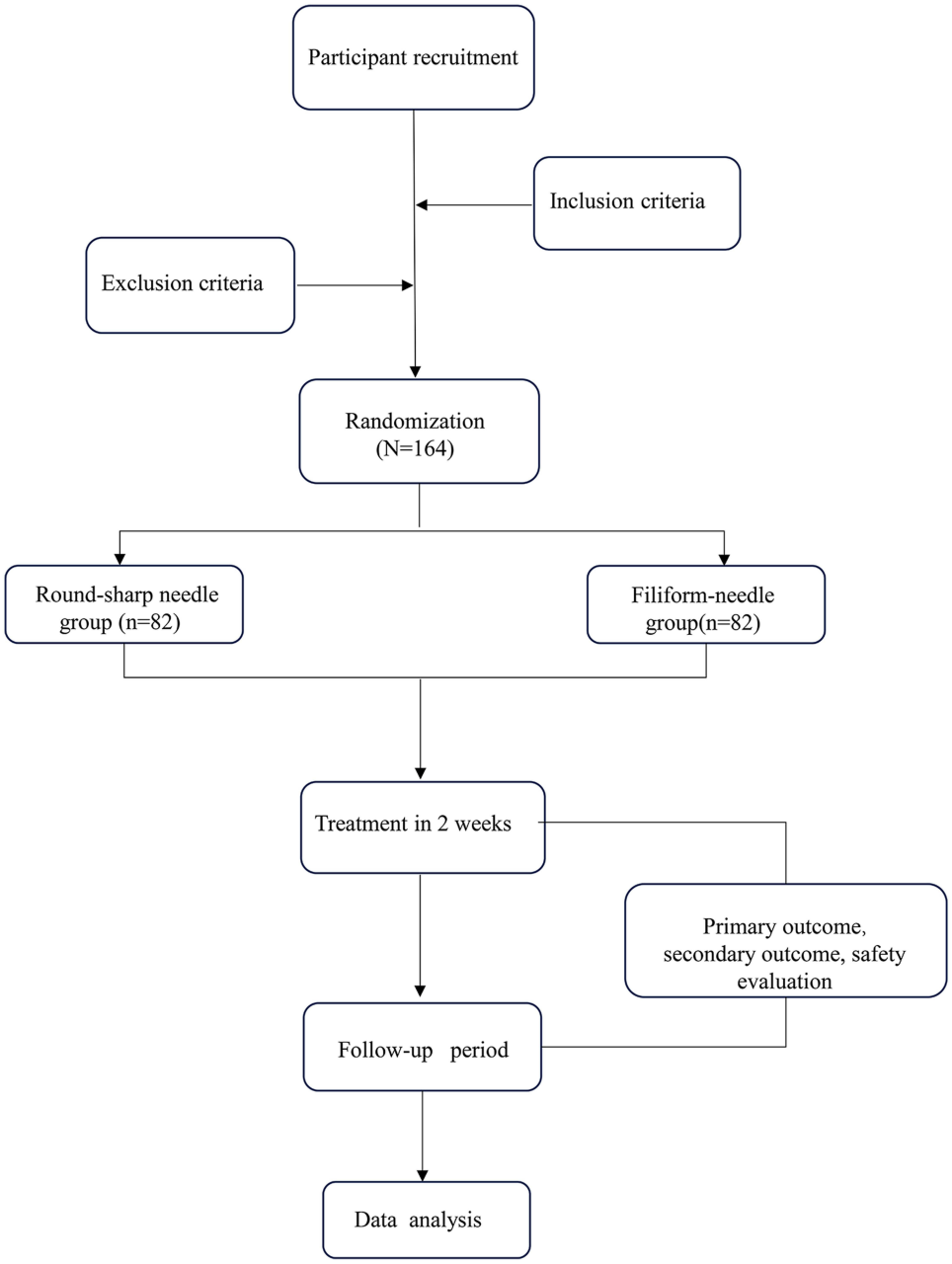

Figure 2 Trial flow chart.

(7) No limb sensory impairment;
(8) No use of other anticonvulsant medications within the past 2 weeks;
(9) Patient agrees to participate in this experiment and signs the informed consent form.

Exclusion Criteria

(1) Use of medications or therapies in the past two months that may affect the results of this experiment. eg: Botulinum Toxin
(2) Suffering from severe underlying diseases such as heart disease or kidney disease;
(3) Patients with psychiatric disorders;
(4) Pregnant or breastfeeding women;
(5) Muscle tension not caused by cerebral ischemia or hemorrhage;
(6) Severe adverse reactions to acupuncture.

Table 1 Study Schedule of Enrolment, Intervention, and Assessments

Study Period	Screening	Intervention		Follow-up
	Before Enrolment (weeks −1 to 0)	1-Week Treatment (Weeks 1)	Week 2 Treatment (Weeks 2)	End of 6 weeks After the End of the Treatment (weeks 8)
Recruitment	X			
Enrolment	X			
Inclusion criteria	X			
Exclusion criteria	X			
Basic characteristic variables	X			
Randomization and allocation concealment	X			
Interventions:				
Round-Sharp Needle group		X	X	
Filliform Needle group		X	X	
Assessments:				
Electromyography	X	X	X	X
The Modified Ashworth Scale (MAS)	X	X	X	X
The Fugl-Meyer Assessment Scale (FMA)	X	X	X	X
The Modified Barthel Index (MBI)	X	X	X	X
Adverse Events(AE)	X	X	X	X
Self-reported drug therapy		X	X	X
Compliance	X	X	X	

Elimination Criteria

(1) Patients who have been mistakenly admitted or misdiagnosed;
(2) Subjects not treated in accordance with the protocol.

Randomization, Blinding and Allocation Concealment

After signing the informed consent form, all patients will be randomly divided into two groups in a 1:1 ratio: the round-sharp needle group and the filliform needle group. Randomization will be carried out by professional researchers by the R. During this process, the random number indicating treatment allocation will be written on a slip of paper and concealed. It will be placed in a sealed, opaque envelope with a serial number. After obtaining informed consent, the sealed envelope containing the patient's random allocation sequence will be opened. Due to the nature of the intervention, neither the acupuncturists nor the participants will be blinded. However, the data analysts and outcome evaluators will remain unaware of the group assignments. The allocation of all participants will be concealed until the completion of the statistical analysis.

Intervention Measures

All patients will receive basic stroke treatment according to guidelines,[24,25] including basic treatment to maintain vital signs, basic rehabilitation care, and other medications or nutritional support.

Round-Sharp Needle Group (See Online Supplemental Video 1)

All patients in this group will undergo round-sharp needle acupuncture therapy. The round-sharp needle acupuncture is guided by the theory of Meridian Sinews (Jingjin), which involves locating the tendon points for treatment. Tendon points include: Tender points on the muscle that are sensitive to pressure; Obvious pain points caused by muscle stretching; The connection points between muscles and skeletal joints. Based on "The study of Chinese Meridian Sinews",[26] in patients with limb spasms after a stroke, the tendon point locations we selected at the following points.

Patients with Upper Limb Spasms After Stroke

(1) Below the spinous process of the seventh cervical vertebra;
(2) The radial and ulnar sides of the biceps tendon at the medial crease of the elbow;
(3) The posterior edge of the fifth metacarpophalangeal joint, at the tendon site.

Patients with Lower Limb Spasms After Stroke

(1) Below the spinous process of the fourth lumbar vertebra;
(2) The area where the tendon of the gluteus maximus deforms, along the line connecting the greater trochanter of the femur and the sacral hiatus;
(3) The tendon attachment site just below the head of the fibula.

The procedure is as follows: After routine disinfection of the acupuncture points, a 1.20mm×70mm round-sharp needle (manufactured by Chongqing Lixin Qizhen Medical Instrument Factory; Figure 1B) will be used. The needle is inserted perpendicularly to the skin, penetrating to deeper layers, then partially withdrawn to the shallower layers. The needle is then manipulated with a "chicken's claw" pattern, consisting of one direct insertion followed by two to three angled insertions, after which the needle is immediately withdrawn. The treatment will be administered three times per week, with a 2-day interval between sessions. Each course consists of three sessions, and two courses will be completed in total.

Filliform Needle Group (See Online Supplemental Video 2)

The patients in this group will receive acupuncture using filiform needles. The selection of acupoints follows the guidelines outlined in the Acupuncture and Moxibustion Therapy.[27] The points selected on the affected side include: Jianyu (LI15), Quchi (LI11), Waiguan (SJ5), Hegu (LI4), Huantiao (GB30), Zusanli (ST36), and Kunlun (BL60). Point localization is based on the Chinese national standard GB/T12346-2006 Names and Locations of Acupuncture Points.

The procedure is as follows: The patient lies in the supine position. Standard local disinfection is performed, and use 0.30 mm × 40 mm Hwatuo brand disposable sterile filiform needles (manufactured by Suzhou Huatuo Medical Instrument Co., Ltd., China; Figure 1A). The needle depths are as follows:

- Jianyu (LI15) and Quchi (LI11): inserted perpendicularly, 25–40 mm;
- Waiguan (SJ5) and Hegu (LI4): inserted perpendicularly, 13–25 mm;
- Huantiao (GB30): inserted perpendicularly, 50–75 mm;
- Zusanli (ST36): inserted perpendicularly, 25–50 mm;
- Kunlun (BL60): inserted perpendicularly, 13–20 mm.

Neutral reinforcing-reducing is applied, with the needles retained for 30 minutes. Treatment is administered once daily, five times per week, with one course consisting of five sessions. A total of two treatment courses will be completed.

Additionally, to improve patient compliance, we will clearly explain to the patients and their families the safety of acupuncture, the mechanism by which acupuncture alleviates post-stroke limb spasm, provide a warm, comfortable, and stress-free treatment environment, and maintain contact whenever they require any medical services.

Outcome Assessment

All participating patients will undergo detailed examinations at baseline, week 1, week 2, and week 8.

Primary Outcome Measures

Electromyography (EMG) is a tool used to evaluate and record the electrical signals generated by muscle activity.[28] Considering the need to safeguard patients' health, we used non-invasive surface electromyography (sEMG) in this trial.[29,30] In this experiment, we plan to use the Bitalino physiological signal acquisition platform from Portugal. The muscles

selected for sEMG signal acquisition include the rectus femoris, biceps femoris, gastrocnemius, tibialis anterior, flexor carpi ulnaris, biceps brachii, triceps brachii, and deltoid. For each muscle, we will use the EMG signal with the largest amplitude and greatest stability, recorded from multiple electrodes, for subsequent analysis. The selected EMG signals will first be processed through a 20–500 hz bandpass filter. The selection criterion for signal segments will be based on the maximum and most stable signal of the primary muscle during each movement. Signal segments of at least 1 second of stable duration will be extracted. Corresponding segments of the other monitored muscles will then be obtained for comparison.

For each muscle, parameters such as the integrated electromyogram (iEMG) and root mean square (RMS) values will be calculated from the selected signal segments. Each movement will be tested three times, and the average of the parameters obtained from these three tests will be used as the final result.

To improve the comparability of our results, we adopted a two-step normalization approach based on previous studies.[31,32] First, we calculated the ratio of task-state to resting-state electromyographic (EMG) signals for each muscle to quantify changes in muscle activity, which we used to define motor overflow. Second, to ensure consistency across different time points, we compared the ratios at each time site with those at baseline, thereby minimizing errors arising from variations in resting-state EMG activity. Furthermore, recognizing the functional differences between upper and lower limb muscles, we separately analyzed and compared their EMG signals.

Secondary Outcome Measures

a. The Modified Ashworth Scale (MAS) is a commonly used clinical scale for assessing the degree of spasticity and is one of the preferred scales for clinical evaluation of spasticity.[33–35] The Modified Ashworth Scale (MAS) is divided into grades 0, 1+, 1, 2, 3, and 4, and these are quantified as 0, 1, 2, 3, 4, and 5 points, respectively. A higher MAS score indicates higher muscle tone (Table 2).

b. The Fugl-Meyer Assessment Scale (FMA) is used to evaluate motor function impairments of the upper limb (UL) and lower limb (LL). The full score for this domain is 100 points, representing normal motor function. Of these, the maximum score for the upper limb is 66 points, while 34 points out of 100 are allocated to the lower limb. The assessment includes measurements of voluntary movement, speed, coordination, and reflex activity, using a graded scale for each item: 0 indicates inability to perform, 1 indicates partial performance, and 2 indicates full performance.

Based on the FMA-UL scores,[36] motor function impairment is classified as severe (less than 32 points), moderate (between 32 and 47 points), or mild (equal to or greater than 48 points).[37] Lower limb motor impairment is also categorized as severe (less than 19 points), moderate (between 20 and 28 points), or mild (equal to or greater than 29 points)[38] (Table 3).

c. The Modified Barthel Index (MBI) is an assessment tool used to measure an individual's independence in Activities of Daily Living (ADLs). It is a revision of the original Barthel Index, designed to improve its sensitivity and accuracy.[39] The MBI includes the assessment of 10 Activities of Daily Living (ADLs), using a scoring system to reflect the patient's level of independence, and the scoring is as follows:[39,40]

- 0 points: Completely dependent on others
- 1–5 points: Partially dependent on others
- 6–10 points: Completely independent

Table 2 Modified Ashworth Scale

Score	Description
0	No increase in muscle tone.
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion (ROM) when the limb is moved in flexion or extension.
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM.
2	More marked increase in muscle tone through most of the ROM, but the affected part is easily moved.
3	Considerable increase in muscle tone, making passive movement difficult.
4	Affected part(s) rigid in flexion or extension.

Table 3 The Fugl-Meyer Assessment Scale

Assessment Domain	Total Score	Assessment Content	Maximum Score	Scoring Criteria	Severity Classification
Motor Function	100				
Upper Limb (UL)	66	Voluntary movement, speed, coordination, reflex activity	66	0: Cannot perform	Severe: < 32
				1: Partially performed	Moderate: 32–47
				2: Performed completely	Mild: ≥ 48
Lower Limb (LL)	34	Voluntary movement, speed, coordination, reflex activity	34	0: Cannot perform	Severe: < 19
				1: Partially performed	Moderate: 20–28
				2: Performed completely	Mild: ≥ 29

Assessment of Safety

The safety assessment will be conducted using an acupuncture adverse reaction observation form developed by our hospital. Adverse events such as pneumothorax, hematoma, allergic reactions, and infections will be carefully documented. The round-sharp needle used in this study has a thicker body compared with the filiform needle, which may result in slightly increased pain during insertion and a more noticeable puncture mark upon withdrawal. However, the discomfort is generally well tolerated by most patients. To reduce the risk of infection associated with minor bleeding, hemostatic adhesive patches were applied after routine compression with a cotton swab. No additional risks beyond these were observed. All procedures were performed by licensed and experienced practitioners. In addition, a contingency protocol was established for any potential severe adverse events, including immediate treatment suspension and access to on-site medical support.

Prior to the trial, participants will be instructed on measures to minimize the risk of negative outcomes. If an adverse event occurs after the participant signs the informed consent but before receiving the study intervention, it will be classified as unrelated to acupuncture. In the event of an adverse reaction during the trial, the project lead will assess whether to suspend treatment based on the specific circumstances. For participants who withdraw due to adverse events, a follow-up investigation will be conducted, and the results will be thoroughly recorded.

Quality Control and Data Management

The Medical Research Ethics Committee considers this study to be a "low-risk" study. Therefore, a Data and Safety Monitoring Board (DSMB) was not recommended during ethical approval. However, the study will be monitored by an independent monitoring committee, which will report to the Medical Research Ethics Committee regarding enrollment rates, adverse events, and study outcomes.

An expert panel will be invited to review and revise the trial protocol, with specialized training provided to all participants. Certified acupuncturists with extensive medical experience will administer the acupuncture treatment. All scales used in this trial will be recorded and evaluated by professional assessors who were blinded to the group allocation. All information must be documented truthfully, accurately, and in a timely manner in the Case Report Form (CRF). The CRF must comply with the following standards:

a. The data must be written in blue ink and signed with the name of the person who recorded it.
b. For critical data, implement a double data entry process to reduce human errors.
c. Data from participants receiving more than 2 weeks of intervention and evaluation should still be recorded and analyzed.
d. In the case of an error, the original entry must be crossed out with a horizontal line, corrected, signed by the recorder, and dated.

All study data will be kept confidential and stored securely in a locked file cabinet. Data will not be shared with individuals outside the trial team without explicit permission from the researchers.

Statistical Analysis

The primary outcome measures will be analyzed using both the intention-to-treat (ITT) and per-protocol (PP) methods. Under the ITT principle, missing data were replaced using the LOCF method and maximum likelihood regression analysis[41]. Secondary outcomes will primarily be analyzed using the PP method. The researchers will use SPSS software to perform statistical analysis on all the research data. If the data follows a normal distribution, it will be described using the mean ± standard deviation; if the data does not follow a normal distribution, it will be described using the median and interquartile range (IQR).

To assess the differences between the two groups: For normally distributed data with equal variances, an independent samples *t*-test will be used. If the assumption of equal variances is not met, as determined by Levene's test for equality of variances, Welch's *t*-test will be applied. For non-normally distributed data, the Mann–Whitney *U*-test (a non-parametric test) will be used to compare the two groups. To assess intra-group differences before and after treatment: If the data for each group follows a normal distribution, a paired *t*-test will be used to compare pre- and post-treatment values within each group. If none of the data follow a normal distribution, the paired Wilcoxon signed-rank test will be used for comparison.

Patient and Public Involvement

Before submitting the protocol to the ethics committee, the researchers collaborated with three stroke patients with post-stroke spasticity to conduct a comprehensive evaluation and improvement of the plan. Necessary corrections were made, and their feedback was carefully incorporated into the current trial design.

Discussion

Spasticity following a stroke presents a significant burden on both patients and their families, making the timely management of spasticity essential for improving limb function. Based on our clinical experience with round-sharp needle acupuncture for treating post-stroke sequelae, this method has shown to be fast-acting, requires fewer treatments, and is associated with minimal side effects. Therefore, it may offer a viable alternative therapy, providing patients with more treatment options. However, there is currently a lack of clinical research in this area. In response, we have carefully designed this protocol to address this gap in evidence.

We selected sEMG, FMA, MAS, and MBI as several indicators to test the validity and safety of the trial results. The Modified Ashworth Scale has a significant response in detecting muscle tone changes in stroke patients and is easy to use.[42] The FMA, as a sensitive assessment tool, not only quantifies patients' motor function but also provides a detailed evaluation of their sensory and balance abilities. The MBI plays an important role in assessing activities of daily living, helping to understand changes in patients' independence after treatment. These three tools are widely used in clinical evaluation.[42–45] The application of surface electromyography (sEMG) can provide quantitative information on spasticity, reducing the interference of subjective factors in scale assessments.[46] Therefore, we also used electromyography as a primary outcome measure for evaluating post-stroke spasticity. In summary, this study aims to explore the multi-dimensional effects of post-stroke limb spasticity by combining sEMG, FMA, MAS, and MBI, providing a more comprehensive evaluation of treatment outcomes. This integrated assessment approach helps offer more informed guidance for clinical practice and lays a foundation for future research.

A limitation of this study is it's a single center trial. Consequently, the sample may not fully represent the broader population, potentially affecting the generalizability of the findings. Nonetheless, we are committed to implementing a rigorous study design, adhering to standardized procedures, and maximizing patient compliance to ensure the highest quality of research.

Data Sharing Statement

The original contributions presented in the study are included in the article, and further inquiries can be directed to the corresponding authors.

Ethics and Dissemination

This study was approved by the Ethics Committee of Hubei Provincial Traditional Chinese Medicine Hospital and registered with the Chinese Clinical Trial Registry. All participants will be fully informed about the study and will sign an informed consent form before enrollment. Patients are allowed to withdraw from the study at any time during the trial without facing discrimination or any form of retaliation. Their medical care and rights will not be affected. The results of this study will be disseminated through peer-reviewed publications and respected academic conferences.

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Disclosure

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as potential conflicts of interest.

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