

# Acupuncture of fascia points to relieve hand spasm after stroke: a study protocol for a multicenter randomized controlled trial

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## Study protocol

**Keywords:** Fascia points, Acupuncture, Spasm, Stroke

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# Abstract

**Background:** The loss of life ability of patients after stroke is mostly caused by the dysfunction of upper limbs, especially hands. Hand functional exercise is the premise of alleviating hand dysfunction, and the relief of hand spasm is the basis of timely and effective hand functional exercise. Previous clinical observation showed that fascial point needling could effectively alleviate hand spasm immediately after stroke, but further evidence from large sample studies is needed. The overall objective of this trial is to further evaluate the clinical efficacy of fascial point acupuncture on hand spasm after stroke.

**Methods/design:** This multicenter randomized controlled trial will compare the efficacy of fascial point acupuncture versus sham acupuncture and routine rehabilitation therapy in stroke patients with hand spasm. Patients will be randomized to undergo either the fascial point acupuncture or the sham acupuncture or the control (routine rehabilitation therapy). We will recruit 210 stroke inpatients who meet the trial criteria and observe the remission of hand spasm and improvement of limb function after 4 weeks of intervention. The first evaluation indexes are the remission of hand spasm and the duration of spasm remission. The second evaluation indexes are the hand function of affected limbs and the ability of daily living. When the accumulative total number of cases included reaches 120, a mid-term analysis will be conducted to determine any evidence that experimental intervention does have an advantage.

**Discussion:** Our aim is to evaluate the efficacy of fascial point acupuncture in relieving hand spasm after stroke. The results will provide more evidences for the clinical application of this therapy in the future.

**Trial registration:** The trial has been registered at the Chinese Clinical Trial Registry (ChiCTR) on April 9, 2019. Registration number: ChiCTR1900022379

**Keywords:** Fascia points, Acupuncture, Spasm, Stroke

## Background

With the advent of an aging society, the incidence of stroke is increasing year by year<sup>[1]</sup>. In recent years, due to the progress of science and technology and the continuous development of medicine, the survival rate and survival time of stroke patients have been greatly improved and prolonged, but the disability rate is still high<sup>[2]</sup>. The loss of life ability of patients after stroke is mostly caused by upper limb dysfunction, especially hand dysfunction<sup>[3]</sup>. Hand functional exercise is the premise to alleviate hand dysfunction, and the alleviation of hand spasm is the basis for timely and effective hand functional exercise. Therefore, alleviating hand spasm after stroke has far-reaching significance in reducing disability rate and improving daily living ability of patients. At present, the main methods to relieve the increased muscle tension after stroke are drug intervention and non-drug therapy (such as physical factors and kinesiotherapy)<sup>[4, 5]</sup>. Sometimes, traditional Chinese medicine, acupuncture, massage, brace, orthosis and rehabilitation robot are used as adjuvant therapy<sup>[6, 7]</sup>. Each therapy has its own advantages and disadvantages.

Drug intervention mainly includes central antispasmodic drugs and peripheral nerve local blocking antispasmodic drugs. Current clinical applications have also achieved certain results. The use of central antispasmodic drugs is relatively simple and convenient, but long-term use will lead to obvious drug resistance and related adverse reactions, such as muscle weakness, nausea, mental depression, etc. In clinical application, drug replacement and dosage adjustment should be often considered. Botulinum toxin A is the representative of peripheral nerve local blockade antispasmodics. However, botulinum toxin A can only be used as a component of multidisciplinary combination to alleviate the increase of limb muscle tension after stroke. Other therapies are often needed in clinical application. In addition, in view of the technical difficulties and high cost of the clinical implementation of botulinum toxin A, it has not been widely carried out in clinic to alleviate the increase of limb muscle tension after stroke<sup>[8, 9]</sup>. Physical therapy is mainly divided into exercise therapy, manipulation therapy and physical factor therapy. Exercise therapy and manipulation therapy can inhibit and weaken spasticity-inducing factors in patients with post-stroke limb spasm, so that limb movement control and motor function can be significantly strengthened and improved. However, a longer intervening time should be guaranteed in the treatment of post-stroke limb spasticity, and the individual conditions of patients should be taken into account in clinical practice<sup>[10, 11]</sup>. In order to reduce the adverse effects caused by excessive exercise, we should adjust the range, intensity, frequency and course of training. Physical factor therapy includes paraffin therapy, hydrotherapy, repetitive transcranial magnetic stimulation, biofeedback therapy, functional electrical stimulation and shock wave therapy. Physical factor therapy has been widely used in the treatment of limb spasm after stroke, and has achieved a certain effect, but its exact mechanism is still unclear, and lack of evidence-based medical evidence for large sample clinical research. In addition, the implementation of physical factor therapy has not yet been standardized or clinical guidelines, the operation depends on personal preferences and experience, the intensity of stimulation and dose of clinical reports are different<sup>[12-16]</sup>. Orthosis and rehabilitation robots, with their good sustainability and rhythm, can assist in alleviating hand spasm after stroke and reduce the workload of therapists to some extent, but their sensitivity and regulation ability are poor, and their price is expensive. They also require space and related technical personnel, which is not conducive to clinical promotion<sup>[17, 18]</sup>. Although many positive results have been achieved in the study of traditional acupuncture and massage in the treatment of post apoplectic limb spasm, it is often necessary to select multiple acupoints to achieve curative effect. And the acupoints selected by each research group are different, which is not conducive to clinical promotion<sup>[19]</sup>. Moreover, the criteria, principles and operating essentials of massage manipulation need to be unified and standardized, and its mechanism needs to be clarified urgently. All these circumstances encourage us to seek more simple, convenient, effective and inexpensive rehabilitation therapy.

At present, the existence of myofascial trigger point has been widely accepted<sup>[20]</sup>. Myofascial trigger point is a common hand spasm factor in stroke patients. In the long-term rehabilitation clinical practice, the team found that doctors could touch a cord-shaped nodule or the most obvious soreness point of the patient's sensation, i.e. the fascia point to be needled, by pressing between the first and second metacarpal bones on the dorsal palm of the patients with hand spasm after stroke from the far side to the proximal side with thumb pulp. Preliminary clinical observation of 16 patients with hand spasm after

stroke treated by fascial point acupuncture has been completed in our group. The results show that fascial point acupuncture can effectively alleviate hand spasm immediately after stroke, but its cumulative effect, duration of spasm relief and long-term efficacy need further clinical research<sup>[21]</sup>. Therefore, we suggest that this multi-site, prospective clinical trial be carried out to further evaluate the clinical efficacy of fascial point acupuncture in relieving hand spasm after stroke.

## **Trial objectives**

The objectives of this trial are as follows:

1. To verify the efficacy of fascial point acupuncture in relieving hand spasm after stroke, and to improve the limb function and daily living ability of patients.
2. To provide more evidences for the clinical application of this therapy in the future.

## **Methods/design**

### **Trial design**

This is a multi-center, prospective randomized controlled trial supported by Shanghai Science and Technology Commission. The trial will be carried out jointly by the Seventh People's Hospital affiliated to Shanghai University of Traditional Chinese Medicine and two other hospitals in Shanghai. Patients meeting the pre-defined criteria will be randomly divided into three groups: acupuncture group undergoing fascial point acupuncture with routine rehabilitation treatment, sham acupuncture group undergoing sham acupuncture near the fascial point with routine rehabilitation treatment, and control group undergoing routine rehabilitation treatment. The patients will be followed up for half a year to observe the hand spasm and limb function after treatment. The study flow chart is shown in Figure 1. An example template for the content of admission plans, interventions and evaluation recommendations is shown in Figure 2.

### **Ethics**

The ethical committee of the Seventh People's Hospital Affiliated to Shanghai University of Traditional Chinese Medicine approved the ethical approval of this study on June 21, 2018 (reference number 2018-IRBQYYS-012). The research scheme, patient information table and informed consent form were approved by the ethics committee. All participants will receive informed consent. The real names of the participants will not appear in the relevant reports of the trial to protect their privacy.

### **Study setting**

The research objects will be recruited from the Seventh People's Hospital affiliated to Shanghai University of Traditional Chinese Medicine, Shanghai Second Rehabilitation Hospital and Shanghai Hudong Hospital. Interventions for all patients will be conducted in hospitals where participants are recruited. The

Seventh People's Hospital affiliated to Shanghai University of Traditional Chinese Medicine will be responsible for trial coordination and data management.

### **Sample size**

Our study will be designed as a randomized controlled trial, and the main outcome is whether hand spasm after stroke is relieved after treatment. Current experience shows that the previous effective rate of conventional acupuncture treatment is about 50%, and the expected effective rate is 85%. The significance test level is 0.05, and the test power is 0.9. Sample size is calculated by using  $N = \frac{2P_1(1-P_1)U_\alpha^2 + 2P_0(1-P_0)U_\beta^2}{(P_1 - P_0)^2}$ . Among them, N is the required sample size for each treatment group, and the sample size of each group is equal. When  $\alpha$  is 0.05 and  $\beta$  is 0.1, the normal distribution quantile table shows that:  $U_\alpha(0.05) = 1.65$ ,  $U_\beta(0.1) = 1.28$ ;  $P_0$  and  $P_1$  represent the original curative effect and the expected curative effect, 50% and 85% respectively. By substituting the above parameters and values into the formulas, 63 cases will be needed for each group. Accounting for a 10% expulsion rate, the final estimated sample size will be about 70 cases per group (210 in total).

### **Inclusion criteria**

- (1) Cerebral hemorrhage or cerebral infarction confirmed by CT or MRI;
- (2) First onset, unilateral hemiplegia;
- (3) The onset time is more than 2 weeks, and the vital signs are stable;
- (4) Age 30-80 years old;
- (5) The clinical manifestations are spastic paralysis of upper limbs, Brunnstrom stage II-IV of upper limbs and hands with hemiplegia;
- (6) The improved Ashworth score of hemiplegic side hand is 1<sup>+</sup> - 3 grade;
- (7) Stable condition, clear consciousness, no aphasia, no intellectual impairment, can understand the content of the scale and cooperate with the examination and treatment;
- (8) No sedative or muscle relaxant is taken in 2 weeks;
- (9) Patients have signed informed consent forms.

### **Exclusion criteria**

- (1) The condition in critical or acute stage is not stable;
- (2) Those with deafness, aphasia or severe cognitive impairment who are difficult to communicate normally;

- (3) Patients with psychiatric diseases, malignant tumors, severe bleeding tendency and infections of treatment sites;
- (4) Systolic blood pressure is more than 180 mmHg or diastolic blood pressure is more than 110 mmHg;
- (5) Participating in other clinical trials or studies within 3 months and receiving other related treatments in the middle of the study may affect the judgement of the efficacy of this study;
- (6) Dysfunction of muscle tone caused by other causes and previous motor dysfunction;
- (7) Pregnant and lactating women;
- (8) Fear of needling, fainting needles, etc.

### **Elimination criteria**

- (1) Patients who have been mistakenly admitted or misdiagnosed;
- (2) No intervention is given to the patients after admission.

### **Recruitment**

Recruitment of patients began on 1 June 2019 and will be completed in June 2021, or after the required number is obtained, whichever is earlier. We will develop plans and methods for contact with subjects, including preparation of informed consent, necessary data, videos and pictures to help subjects understand the purpose and program of the trial. We will also explain to the subjects the advantages and disadvantages of the treatment and the relevant safety measures taken during the trial. In addition, we will post recruitment posters in and around the hospital, or use the Internet for recruitment. According to the inclusion/exclusion criteria, the research team will preliminarily judge the possibility of subjects' inclusion, and conduct relevant inspection on them after they sign the informed consent, and finally confirm whether the subjects really meet the inclusion/exclusion criteria according to the inspection results.

### **Randomization**

After signing the informed consent, participants will be randomly divided into three groups: acupuncture group, sham acupuncture group and control group. Randomization will be accomplished by qualified researchers using randomization software to generate random number sequences. In the process of randomization, allocation should be kept hidden. All patients will be randomly divided into groups according to the ratio of 1:1:1. The strips revealing treatment allocation will be placed in sealed opaque envelopes with sequential numbers. After obtaining informed consent, the envelopes will be opened in turn. Patients and data analysts are not clear about the randomized grouping.

### **Intervention**

The interventions in the three groups are as follows:

#### Acupuncture group

In addition to routine rehabilitation treatment, fascial point acupuncture will be given 5 times a week for 4 weeks, with 30 minutes each time.

Location of fascial points: the patient will be in a sitting or supine position and the doctor will be placed on the affected side. Firstly, 75% alcohol cotton ball will be used to routinely disinfect the area of the the first web and the finger of the operator. Then, one-way pressure will be applied between the first and second metacarpal bones on the dorsal palm of the patient from the far side to the proximal side with the thumb pulp. At this time, a cord-shaped nodule can be touched. Or the patient feels the most obvious soreness point, which is the fascial point. As shown in Figure 3.

Acupuncture method: routine disinfection will be carried out on the hand of the operator and the fascial spot area of the patient. According to individual differences of patients, different specifications and models of needles will be selected (25mm-40mm). Doctors quickly penetrate the needle tip vertically through the epidermis into the subcutaneous tissues about 1-2.5cm by using single-handed or two-handed needle insertion method, and then through lifting, inserting and twisting to enhance the needling sensation. The doctor will stop manipulating the needle when there is a sense of needle 'stagnation', described as being like 'a fish swallowing a hook'. At the same time, the patient's fascial point area will be sore, numb and painful, accompanied by finger conduction, pain, tremor and twitching. Press the needle hole with dry cotton wool ball after needle removal to prevent bleeding. In the process of needling operation, attention should be paid to the coordinated operation of both hands so as to achieve accurate, rapid, painless or less pain.

#### Sham acupuncture group

In addition to routine rehabilitation treatment, treatment of false acupuncture beside Fascial Points will be given 5 times a week for 4 weeks, with 30 minutes each time.

#### Control group

Routine rehabilitation treatment will be given 5 times a week for 4 weeks. Conventional rehabilitation treatment mainly includes:

- (1) Good limb position: the affected upper limb maintains the position of abduction, external rotation, elbow extension, forearm supination, wrist and finger extension;
- (2) Bobath's handshake exercises: the arm is raised over the head, and the mind is used to force the limbs on both sides 10 times a time for 6 times a day;
- (3) Exercise therapy: Continuous stretching of spastic muscle and joint loosening if necessary. The induced segregation movement and other manipulations are performed after the relaxation of the spastic

muscle, 45 minutes each time for once a day.

## **Uniformity in acupuncture performance**

To ensure the uniformity of fascial point acupuncture, the coordinating centre will designate qualified doctors to train doctors from other participating units and monitor the operation process to ensure the qualified performance before the experiment.

## **Outcome measures**

Therapeutic evaluation will be carried out by the same team member who will be blinded to treatment allocation. The primary evaluation indicators in this study are hand spasm score and duration of spasm relief. The modified Ashworth scale will be used to evaluate the spasm of the hand (mainly including the thumb and the other four fingers) before and after treatment. After the patients are treated with acupuncture and spasticity relieved, the timing will be started to evaluate the duration of spasticity relieved (during this period, the patient should avoid mental tension, so as not to interfere with the test results).

The secondary evaluation indicators included EMG detection of affected limbs, limb function and activity of daily living evaluation. The modified Ashworth scale will be used to evaluate the degree of hand spasm on the affected side at baseline, four weeks after intervention and at 1, 2, 4 and 6 months of follow-up<sup>[22]</sup>. The modified Ashworth scale was divided into 0, 1, 1<sup>+</sup>, 2, 3 and 4 grades, and was quantified as 0, 1, 2, 3, 4 and 5 points respectively (Table 1). Surface electromyography will be used to record the changes of surface electromyography of upper limbs on the affected side at baseline and four weeks after intervention<sup>[23]</sup>. Simplified Fugl-Meyer scale will be used to evaluate the upper limb motor function on the affected side and modified barthel index will be used to evaluate activities of daily living at baseline, four weeks after intervention and at 1, 2, 4 and 6 months of follow-up<sup>[24, 25]</sup>. All measurements will be recorded in the data center.

## **Harms**

In our study an adverse event will be defined as any untoward medical occurrence in a subject without regard to the possibility of a causal relationship. Adverse events will be collected after the subject has provided consent and enrolled in the study. If a subject experiences an adverse event after the informed consent document is signed (entry) but the subject has not started to receive study intervention, the event will be reported as not related to acupuncture. All adverse events occurring after entry into the study and until hospital discharge will be recorded. An adverse event that meets the criteria for a serious adverse event (SAE) between study enrollment and hospital discharge will be reported to the local Institutional Review Board.

## **Data management**

## **Data collection**

All information should be truthfully, accurately and timely recorded in the case report form (CRF). Scale evaluators trained in rehabilitation will be responsible for assessing the simplified Fugl-Meyer scale, Modified Ashworth scale and Modified Barthel index, while other scales and case reports will be recorded by researchers. In the course of the experiment, special personnel will be arranged to manage the relevant data, and the personal information of participants will be kept strictly confidential. All data will be identified using participant numbers, which do not directly display participant's personal information. Data will not be shared without the explicit permission of researchers. At the end of the trial, the research participants should submit the case record form in time and submit the test summary according to the requirements. The research center will appoint a supervisor to check the integrity and accuracy of CRF.

### **Case report form**

In the trial, the content recorded in CRF should be consistent with the original material. CRF must meet the following criteria:

- (1) Fill in data with pen or black signature pen;
- (2) If the participant has received more than two weeks of intervention and evaluation, the data of the volunteer should still be recorded and counted;
- (3) If an error occurs in the record and needs to be corrected, the recorder should draw a horizontal line under the original record, then sign the amendment and indicate the date of correction. Note that you should ensure that the original record is identifiable after modification.

### **Database management and quality control**

The team will take effective measures to control the quality. Data in CRF will be entered into the database uniformly. Data entry personnel carry out manual checks at the first time of data entry, and carry out systematic checks after all data entry is completed. After final confirmation, the database is locked and saved. Any future changes to the database must be agreed in writing by the clinical research director, statistician and data administrator.

### **Data analysis**

#### **Statistical analysis**

Statistical analysis of research data will be performed by health statisticians and major researchers using SPSS or SAS. Pearson's  $\chi^2$  test or Fisher's exact test will be used to analyze classified variables and continuous variables will be evaluated by Student's t-test or an appropriate non-parametric method. All statistical tests will be double-sided. Statistical significance level will be set at 5%. The measured data will be described by mean $\pm$ standard deviation. Before the analysis, the normality test and homogeneity test of variance will be carried out. If the normal distribution is satisfied, t test will be used. LSD or SNK

method will be used for multiple comparisons, and rank sum test will be used for non-normality or non-uniformity of variance.

## **Discussion**

The timely relief of spasticity in stroke patients is particularly important for the rehabilitation of limb function, so it is a key step to apply effective treatment measures to relieve spasticity as much as possible. Preliminary clinical observation of 16 cases of hand spasm after stroke treated by fascial point acupuncture has been completed in our group. The results show that fascial point acupuncture can effectively alleviate hand spasm immediately after stroke. However, its cumulative effect, duration of spasm relief and long-term efficacy need further clinical study. Therefore, we propose a multi-center, prospective and randomized clinical trial to further evaluate the clinical efficacy of fascial point acupuncture in relieving hand spasm after stroke.

In order to eliminate the interference of acupuncture itself on the experimental results, a sham acupuncture group will be established in this study. However, bias exists in all clinical trials. In our trial, the blindness of acupuncturists and patients in designing a randomized controlled trial involving acupuncture manipulation will be the most challenging aspect. Therefore, surface electromyography measurements are also used as part of the outcome assessment in addition to the scales used in previous studies. In recent years, electromyography (EMG) has been widely used in spasticity assessment, especially after stroke<sup>[26]</sup>. The application of electrophysiological measurement can provide quantitative information of spasticity and reduce the interference of subjective factors in scale evaluation. In addition, the multi-center development of the study is also related to biases, mainly including differences in acupuncture techniques. We tried to eliminate these biases according to examining the needling procedures of other participating hospitals and training acupuncturists in all participating centers. We firmly believe that the results of this study will help to lay a foundation for the alleviation of hand spasm after stroke and functional improvement.

## **Trial Status**

The total registration period will last for 2 years and follow-up for 6 months. Recruitment of patients began on June 1, 2019, and trials are currently under way. Protocol version number and date: V1.0 September 26, 2019. Recruitment of patients is expected to be completed in October 2021.

## **Declarations**

### **Acknowledgements**

Thank you to all the participants who contributed to this research.

### **Authors' contributions**

FW conceives and designs this research, and is the person in charge of this research. ZZQ and LKP were the main implementers of the study and drafted manuscripts. HJ, JLM, WW and HXS participated in the design of the study and assisted in drafting the manuscript. All authors know and agree with the final manuscript.

## **Funding**

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## **Availability of data and materials**

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

## **Ethics approval and consent to participate**

The ethical committee of the Seventh People's Hospital Affiliated to Shanghai University of Traditional Chinese Medicine has approved the ethical approval of this study (reference number 2018-IRBQYYS-012). All participants will receive informed consent. The real names of the participants will not appear in the relevant reports of the trial to protect their privacy.

## **Consent for publication**

Not applicable.

## **Competing interests**

The authors declare that they have no competing interests.

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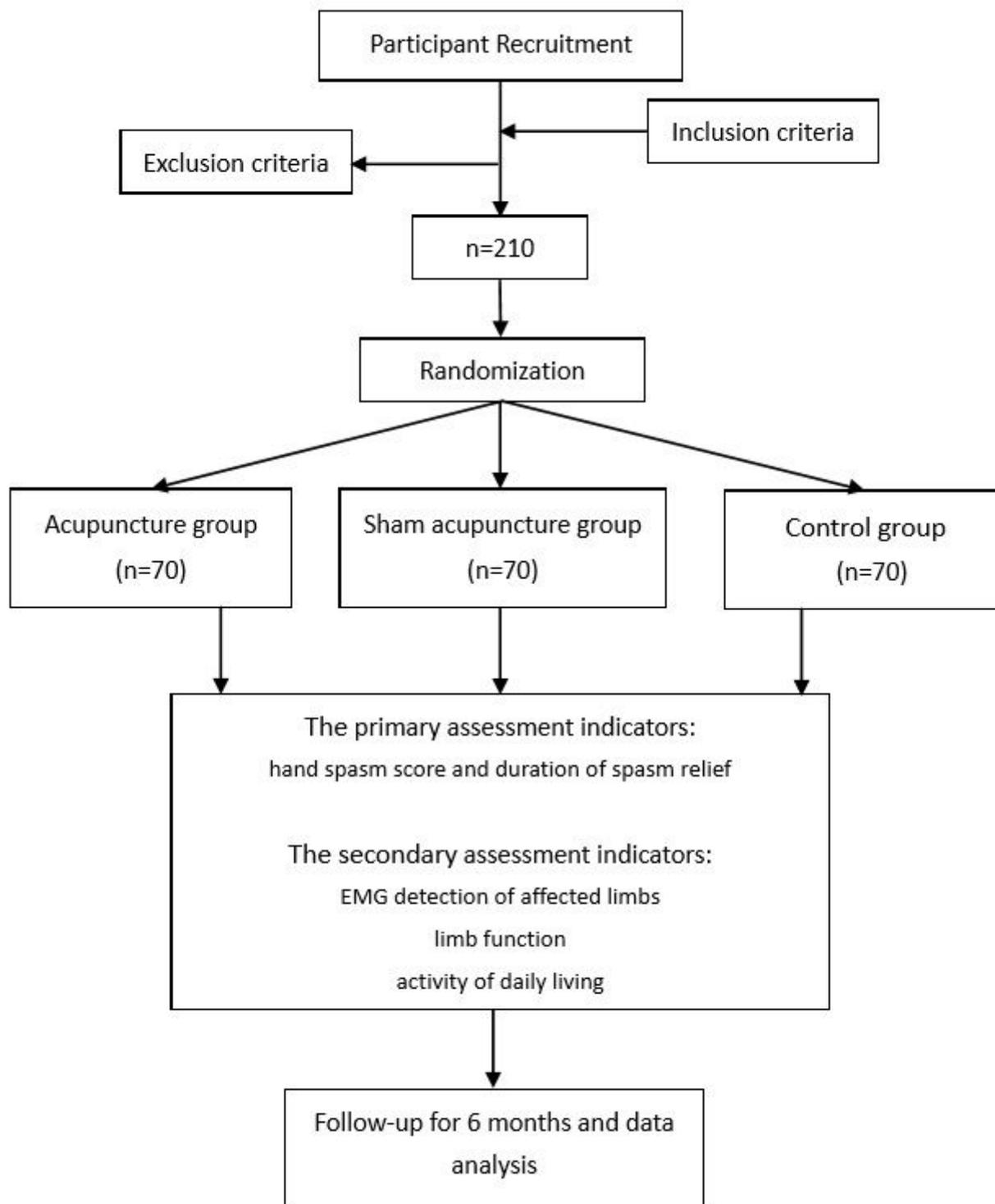
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## Tables

Table 1 Modified Ashworth Scale

Grade	Assessment standard	Score
0	No increase in muscle tension	0
1	Muscle tension increases slightly. When the affected part is passively flexed and stretched, it suddenly gets stuck at the end of joint activity and then presents minimum resistance or release.	1
1 <sup>+</sup>	Muscle tension increased slightly. Sudden stuck in passive flexion and extension occurred within the last 50% range of ROM, and then all showed minimal resistance.	2
2	Muscle tension increased significantly. Muscle tension of affected limbs in passive motion increased significantly in most ROM ranges, but it was still easier to move.	3
3	Muscle tension increased severely. The affected limb of passive movement has resistance in the whole ROM, so it is difficult to move.	4
4	The affected part is rigid and inactive.	5

## Figures



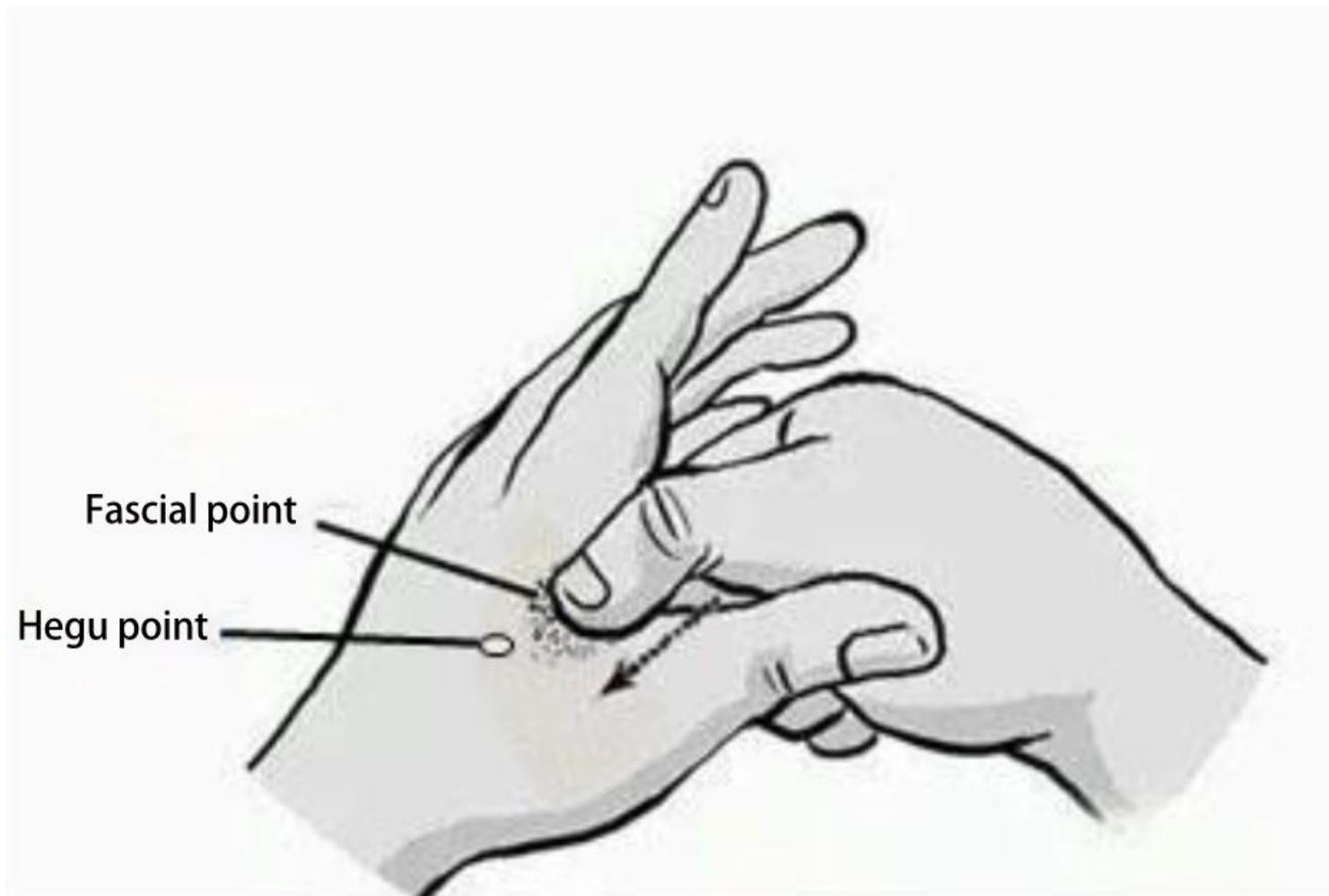
**Figure 1**

Flow chart of the study

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT**	-t 1	Acupuncture	1m	2m	4m	etc.	6 months after acupuncture
<b>ENROLMENT</b>							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
<b>INTERVENTIONS</b>							
Acupuncture group		X					
Sham acupuncture group		X					
Control group							
<b>ASSESSMENTS</b>							
Hand spasm score and duration of spasm relief			X	X	X	etc	X
EMG detection			X	X	X	etc	X
Limb function scale			X	X	X	etc	X
Activity of daily living			X	X	X	etc	X

**Figure 2**

Example template of recommended content for the schedule of enrolment, interventions, and assessments



**Figure 3**

Location of fascial points