Original Article
The effectiveness of optimal acupuncture prescription for post-stroke motor dysfunction: a study protocol of a randomized controlled trial

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Abstract: Background: Post-stroke motor dysfunction (PSMD) affects the daily activities and social life of patients with PSMD. Acupuncture may be beneficial for patients with PSMD, but no randomized controlled trial has confirmed its effectiveness. We aim to provide study protocol of a randomized controlled trial for assessing the effectiveness of acupuncture in patients with PSMD and the comparative effectiveness of optimal acupuncture versus conventional acupuncture. Methods/design: This is a randomized, open label, parallel-controlled trial. A total of 264 participants with PSMD will be randomly assigned to 3 groups (optimal acupuncture group, conventional acupuncture group, waiting-list group). Participants in the optimal acupuncture group (the acupuncture points will be selected according to a Delphi method) or the conventional acupuncture group (the acupuncture points will be selected according to textbooks) will receive 4-week acupuncture treatment in addition to background treatment. Participants in the waiting-list group receive only the background treatment. The primary outcomes include the Fugl-Meyer assessment (FMA), Modified Ashworth Scale (MAS), and the Berg balance scale (BBS). The secondary outcomes include the Modified Barthel Index (MBI), National Institute of Health Stroke Scale (NIH-SS), and indicators of the blood oxygen level dependent-functional magnetic resonance imaging (BOLD-fMRI). Discussion: The study protocol is approved by the ethics committee in Traditional Chinese Medicine of Fujian University. The result of this study will be published in a peer-reviewed journal. Trial registration: Chinese Clinical Trial Registry: ChiCTR-IOR-15007062. Registration date: 15 September 2015.

Keywords: Stroke, acupuncture, motor dysfunction

Introduction

Stroke is the second most common cause of death, and it is also a major cause of disability worldwide [1, 2]. In China, nearly 80% of stroke patients caused by cerebral ischemia, and has become the main reason of disability [3]. Post-stroke motor dysfunction (PSMD) is the most common sequelae in patients after stroke [4, 5]. PSMD affects patients' daily activities and social life, and it causes heavy economic burden on family and society. Therefore, a reasonable and effective treatment is urgently needed for patients with PSMD.

Currently, many modern rehabilitation technics have been developed to improve the motor function for patients with PSMD, such as task oriented training, transcranial direct current stimulation, robot assisted therapy, and mirror therapy, but their effectiveness is still controversial [6-9]. Acupuncture treatment is an important part of traditional Chinese medicine, which is wildly accepted in the world. In China, acupuncture treatment has been used in the treatment for PSMD [10], and acupuncture improves motor function, sensation, speech, swallowing, cognitive, and other neurological functions in patients with stroke [11, 12].
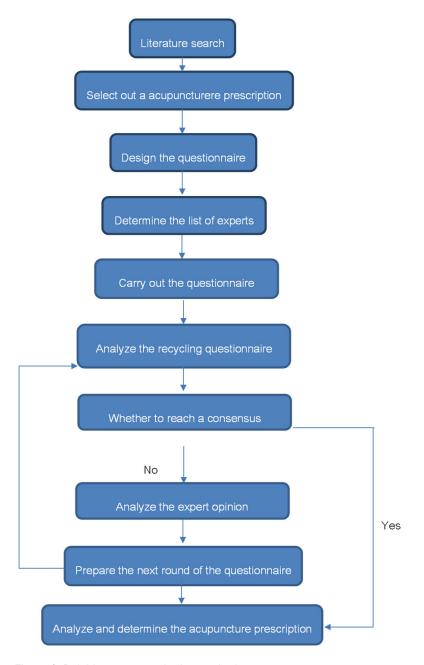
Figure 1. Delphi expert consultation method.

Methods

Overview of trial design

This study is composed of two parts: a literature review to establish an optimal acupuncture protocol and a randomized controlled trial. We will use the Delphi method to develop an optimal acupuncture prescription for the treatment of PSMD on the basis of thorough literature review. **Figure 1** shows the process of developing optimal acupuncture protocol. After the protocol is established, a randomized control trial will be launched.

We will include 264 participants who meet the inclusion criteria and randomly assign them into optimal acupuncture group, conventional acupuncture group, or waiting-list group in a 1:1:1 ratio. Participants in the optimal or conventional acupuncture group will receive 4-week acupuncture treatment in addition to background treatment, while those in the waiting-list group receive only background treatment until the study is finished. The difference between optimal and conventional acupuncture is that the protocol of optimal acupuncture is developed by literature review and Delphi method whereas the conventional acupuncture is developed according to textbooks. Outcomes will be collected at baseline, 4 weeks, 9 weeks after randomization. **Figure 2** shows a flowchart of the trial.

Part One: Establish an optimal acupuncture protocol

A review of ancient literature

Both electronic and manual retrieve will be used to search acupuncture points used to

However, a Cochrane review have demonstrated that there is no clear evidence showing the benefit of acupuncture for PSMD [13]. Conflict findings from randomized trials evaluating the effectiveness of acupuncture may be caused by heterogeneity in selection of acupoints during treatment and outcome measures or underpowered design. Therefore, we design a randomized control trial to investigate the effectiveness of the acupuncture for PSMD, with the used of Delphi method to select an optimal acupuncture prescription.
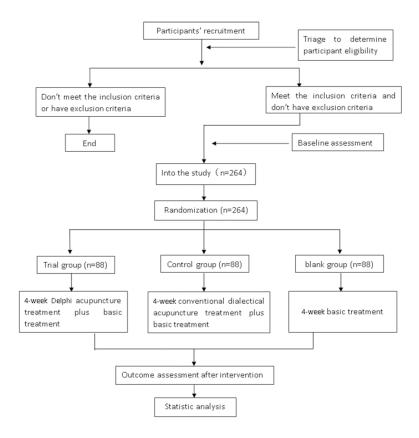
Figure 2. Technology Roadmap.

treat PSMD in the *Canon of Medicine in Chinese* and *Chinese Dictionary of Acupuncture Headquarters,* two books recording most of the ancient Chinese literature about acupuncture treatment. The first 10 acupoints with the highest frequency in acupuncture prescriptions will be sorted out.

The Delphi method

The Delphi method is a method of expert consultation [14, 15], making full use of expert knowledge, experience and wisdom. It has great value in scientific and democratic decision-making. The Delphi method is a structured communication technique or method, which relies on a panel of experts, so the choice of experts is the key to the success of the Delphi method [16]. The experts will be chosen from the mainland of China, and they should have a minimum of 10 years of experience in the acupuncture treatment for stroke.

The process of Delphi method includes several rounds of feedback, and the feedback will be returned anonymously. Experts and the facilitator should communicate through letters. The

way of anonymous enquiry ensures the experts focusing on the value of the opinion itself rather than a person's identity.

We will perform multiple rounds of feedback survey, since the opinion of the experts may be dispersed if we make only a round. Each round of feedback will be collected, analyzed and summarized by the facilitator. Then the summarized result will be distributed to the experts before the next survey. Each expert may draw lessons from the opinions of the others and modify their own opinions. We will repeat the above steps until consensus is reached to determine an optimal protocol of acupuncture.

The questionnaire design

The questionnaire is designed according to the principles of integrity, brief, operability and applicability. We will consult the experts through anonymous letters. Selection of acupoints for PSMD is based on the experts' clinical experience. Two additional columns (the amendments of acupoints and supplementary point) are provided for the experts to fully express their opinions.

Assignment of index

Experts' familiarity with the acupoints will be classified into one of the five grades: 0.1 points indicates unfamiliar; 0.3 points indicates mild familiarity; 0.5 points indicates median familiarity; 0.7 points indicates good familiarity; 0.9 points indicates extremely familiarity.

Part two: Evaluating the effectiveness of the acupuncture for patients with PSMD

Participants and recruitment

A total of 264 subjects will be recruited from the in-patient department of the Rehabilitation Hospital Affiliated to Fujian University of Traditional Chinese Medicine (Fujian province,

Table 1. Trial processes chart

Items	Before enrollment 0 (week)	Intervention period 1-4 (week)	Outcome assessment 9 (week)
Inclusion criteria	×		
Exclusion criteria	×		
Inform consent	×		
Baseline	×		
Randomization	×		
Intervention		×	
FMA	×	×	×
MAS	×	×	×
BBS	×	×	×
MBI	×	×	×
NIH-SS	×	×	×
BLOD-fMRI	×	×	×
Treatment recorded		×	
Adverse events		×	

China). Advertisement will be released on the homepage of the hospital, and leaflets will be disseminated at several locations of the hospital. Individuals who are interested in participation can consult the investigators for details about the trial. A CONSORT diagram of participant recruitment is shown in **Table 1**. Eligible patients will be screened according to the following criteria.

Inclusion criteria

Participants have to fulfill the following criteria: (1) diagnosed with stroke and confirmed by CT or MRI, (2) with motor dysfunction caused by ischemic stroke, (3) with Fugl-Meyer score ranging from 0 to 95, (4) with modified Ashworth score equal to or lower than grade II, (5) aged between 18 to 80 years, (6) with stable vital sign and consciousness, (7) with written inform consent provided.

Exclusion criteria

Patients with any of the following conditions will be excluded: (1) motor dysfunction caused by cerebral trauma, brain tumor, or encephalopathy in the cerebellum or brainstem, (2) Mini-Mental State Examination score <22, (3) bone disease or joint damage that causes limb deformities, (4) serious disease in the heart, liver, kidney, hematopoietic, or endocrine system; (5) being pregnant or breastfeeding; (6) in the pro-

cess of other clinical trials that may affect the results of the trial.

Sample size

The sample size is calculated on the basis of the change in Fugl-Meyer Assessment (FMA) scores from baseline to the end of treatment. Conventional acupuncture can increase the average FMA score by an average of 8.23 points (SD=7.21). According to our preliminary test, the increase in FMA score was estimated to be 5 points, with a standard deviation of 0.84, with a power of at least 80% and an α value of 0.05, β value of 0.10. Sample size is calculated according to the following formula:

$$n = \psi^2 [\sum_{i=1}^{k} s_i^2 / k] / [\sum_{i=1}^{k} (\bar{X}_i - \bar{X})^2 / (k-1)]$$

Considering a 10% dropout rate, 264 participants in total is powered to reject the null hypothesis.

Randomization and concealment

Eligible patients will be randomly assigned to the optimal acupuncture group, conventional acupuncture group, or waiting list group at a ratio of 1:1:1. The randomization sequence will be generated by an independent statistician using SAS9.1. The statistician will not be involved in the process of recruitment and outcome assessment. The allocation of participants will be concealed by using consecutive numbered, sealed and opaque envelopes.

Blinding

This study uses open label design, but outcome assessors, data manager and statistical analyst will be blinded to the group assignment. Blinded implementation process will be monitored by a quality inspector.

Intervention

All participants will receive background treatment delivered by neurologists in the participating hospitals. The background treatment includes conventional medical treatment, health education and rehabilitation program. Participants in the optimal acupuncture group or the conventional acupuncture group will

receive an additional 30-min acupuncture session every day at a frequency of 6 days/week for 4 consecutive weeks.

Optimal acupuncture group

Participants allocated to the optimal acupuncture group will receive 4 weeks of optimal acupuncture treatment in addition to background treatment. The optimal acupuncture will be delivered by experienced acupuncturists with at least five years of experience in acupuncture practice. When receiving optimal acupuncture, participants will take the supine position with the acupoints disinfected. The acupoints in the optimal acupuncture group will be in accordance with the result of the Delphi method. Acupuncturists will needle the acupoints with sterile, disposable needles (0.3 mm in diameter 40 mm in length for body acupoints; 0.25 mm in diameter and 25 mm in length for scalp acupoints). Manual stimulation will be applied to the body acupoints until the patients experience *Deqi*, a sense that is characterized by heaviness, distension, soreness, or numbness [17, 18]. The acupuncturist will retain the needles in situ for 30 minutes and follow the recommendations of a standard acupuncture textbook for the depth and angle of insertion into each acupoint [19].

Conventional acupuncture group

The participants in the conventional acupuncture group will receive 4-week acupuncture on the basis of syndrome differentiation in addition to background treatment. The background treatment will be the same as in the optimal acupuncture group. Acupuncturists will select the acupuncture points according to textbook based on syndrome differentiation, a diagnosis method in traditional Chinese medicine containing an overall assessment of patients' symptoms, signs, tongue and pulse. The parameters for acupuncture are same as in the optimal acupuncture group.

Waiting-list group

Participants in the waiting-list group will not receive any acupuncture treatment until the trial ends. The participants receive background treatment only.

Outcome measurements

The researchers will collect the baseline characteristics of included participants, including age, gender, occupation, and medical and treatment history of ischemic stroke and so on. All outcome measurements will be assessed at baseline, 4-week and 9-week after randomization.

Primary outcomes

Primary outcomes will be motor function assessment, muscle tension evaluation and balance function evaluation. The motor function will be assessed by the Fugl-Meyer Assessment (FMA) scale. The FMA assesses limb function, with a final score ranging from 0 to 100 points (66 points for assessing the upper extremity and 34 points for the lower extremity) [20]. A higher score of FMA indicates the less motor dysfunction. The muscle tension will be evaluated by the Modified Ashworth Scale (MAS). The MAS belongs to one of the skill evaluation method for assessing spasticity, by means of feeling resistance when moving joints passively [21]. The balance function will be evaluated by Berg Balance Scale (BBS). The BBS has been widely applied in the assessment of balance function after stroke [22]. It contains 14 items, including stand up, sit down, stand independently, close eyes to stand, upper arm forward, turn around, alternate tread the stairs, and stand on one leg. It can be finished within 20 minutes. The lowest score of each item is 0 points, and the highest score is 4 points; the total score varies from 0 to 56 points. A score of ≤40 points indicates risk of falls; 0-20 indicates poor balance; 21-40 indicates acceptable balance; and 41-56 indicated good balance [23].

Secondary outcomes

The activities of daily living (ADL) will be assessed by MBI, which is the most widely used assessment method of ADL [24, 25]. It is highly reliable and valid. MBI can be used to assess the functional status before and after treatment and predict the therapeutic effect, hospitalization and prognosis. The MBI includes measurements for fecal or urinary continence, combing, toileting, feeding, transferring, walking, dressing, bathing, and going up and down

stairs. The normal score is 100, and lower scores indicate greater dependency.

The NIH Stroke Scale (NIH-SS) is a standardized stroke severity scale used to describe neurological deficits in stroke patients. It strongly predicts the likelihood of a patient's recovery after stroke. It comprises tests of 11 items (the level of consciousness, selected cranial nerves, motor function, sensory function, cerebellar function, language, and inattention and so forth). The total score of NIH-SS ranges from 0 to 42, with a score ≥25 indicating very severe neurological impairment, 5-24 moderately severe to severe impairment, and ≤5 mild impairment [26, 27].

The Bold-fMRI is a new neuroimaging method, measuring dynamic changes in neuronal activity. The Bold-fMRI has been widely used in basic research, and activation in the brain can be accurately detected. The Bold-fMRI will be observed in order to investigate the relationship between the effect of acupuncture and the activated area in the brain, which may help us to understand the central mechanism of acupuncture.

Date collection and management

Data will be entered into a well-designed electronic case report form (eCRF). A research assistant will independently conduct quality control of data collection process. Besides, an independent Data and Safety Monitoring Board (DSMB) consisting of two senior therapists and a rehabilitation physician who are experienced in treatment of PSMD will be set up to monitor the safety of this trial. The DSMB is an independent board that is responsible for data validity and management and report of adverse events. For safety concerns, the DSMB have the privilege to call termination of the study to a participant when substantial harms are or may be caused by experimental treatments.

Patient safety

Adverse events occur during the intervention period will be recorded, such as dizziness, fainting during acupuncture treatment, bleeding, local hematoma, unbearable prickling, retained needle, and broken needle. They will be handled according to the standard operating procedure.

Statistical analysis

A statistician who is blinded to the allocation of participants will carry out the statistical analysis after the data entry completes. The analysis will be based on intention to treat (ITT) population. The last observation carried forward (LOCF) method will be adopted to deal with missing data. Baseline characteristics will be presented with means, standard deviations or 95% confidence intervals, or with numbers and percentages. The primary outcomes and secondary outcomes are continuous data, so they will be compared between the 3 groups with the analysis of covariance (ANCOVA). Null hypothesis will be that the 3 groups are with the same treatment effect, and a P<0.05 rejects the null hypothesis. *P* values in multiple comparisons between groups will be corrected with Bonferroni method, and baseline characteristics will be included as covariates. The data will be analyzed using the SPSS 18 for Windows, and all of the statistical test indexes will use the bilateral inspection. The *P*≤0.05 will be considered as statistically significant, and the *P*≤0.01 will be considered as significant statistical significance.

Discussion

Acupuncture is widely used in China to treat stroke. World Health Organization points out that stroke is one of the most common indication for acupuncture [28]. However, the result of a Cochrane review has questioned the effectiveness of acupuncture for stroke rehabilitation, which may be owing to small sample size, different acupoints selection and poor methodology.

Besides, the experience of acupuncturists is considered to play an important role in the effect of acupuncture treatment. Thus, in this study, all acupuncturists have more than 5 years of clinical experience in acupuncture treatment.

To set up an optimal acupoint selection for PSMD, on the basis of the literature research, 100 physicians with experience of more than 10 years in in the acupuncture treatment of stroke-related disease will be consulted according to the Delphi expert consultation method. Then a rigorous randomized controlled trial will

be launched to investigate the effectiveness of optimal acupuncture for PSMD.

Disclosure of conflict of interest

None.

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