**Intervention Mechanism and Effect of Tai Chi on Motor Dysfunction at Different Brunnstrom Stages of Stroke**

**Study protocol for a Randomized Controlled Trial**

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**Abstract**

### Introduction: Tai Chi, a traditional exercise therapy with a long history in China, has been widely used in clinical practice in recent years. However, there is no study on the effect and mechanism of Tai Chi on dyskinesia in different Brunnstrom stages of stroke. This study presents a multicenter, randomized, controlled trial protocol to investigate the dose-response effect and mechanism of Tai Chi in treating stroke-induced motor dysfunction.

**Methods****:** Randomized controlled trials will be conducted in three hospitals in Heilongjiang, Beijing, and Shenzhen. A total of 213 stroke patients at the Brunnstrom [spasm stage](https://xueshu.baidu.com/usercenter/paper/show?paperid=baab92d62602eb6ef8508e05d624b582&site=xueshu_se" \t "https://xueshu.baidu.com/_blank) and 162 at the Brunnstrom[recovery stage](https://xueshu.baidu.com/usercenter/paper/show?paperid=baab92d62602eb6ef8508e05d624b582&site=xueshu_se" \t "https://xueshu.baidu.com/_blank) will be randomly divided into three groups. The two Tai Chi groups will receive the modified Taijiquan intervention at different exercise frequencies, and the control group will receive conventional rehabilitation training. The primary results will be assessed using the Fugl-Meyer Motor Function Scale (FMA). The secondary indicators will include the modified Ashworth scale (MAS), Berg balance scale (BBS), six-minute walking test (6 MWT), modified Barthel Index (MBI), Short Form 36 Health Survey (SF-36), surface electromyography (sEMG) signal analysis, and functional magnetic resonance imaging (fMRI). Patients at Brunnstrom spasm stage will be assessed before treatment and four weeks after the intervention, and patients at the recovery stage will be measured before and 4, 8, and 12 weeks after intervention. Alongside, we will record all adverse events during the trial, including falls, fractures, and increased blood pressure, and evaluate the relevance to the clinical intervention.

**Discussion:** This is the first multicenter randomised controlled trial designed to separately evaluate the effect and mechanism of Tai Chi on dyskinesia in different Brunnstrom stages of stroke. The trial propose an innovative and improved Tai Chi rehabilitation therapy which focused more on patient initiative in training than conventional rehabilitation.

**Trial registration:** Chinese Clinical Trial Registry, ChiCTR2000033417.

**Keywords:** Stroke; Tai Chi; Motor dysfunction; Dose-response; Mechanism

1. **Introduction**

Stroke is a cerebrovascular disease with complex pathogenesis. It is characterized by high morbidity, disability, mortality, and recurrence rates. Additionally, it seriously endangers human life and health and is one of the major causes of death and disability in middle-aged and elderly people.[1]Among them, approximately 70%–80% of stroke patients are accompanied by movement, balance, and cardiopulmonary dysfunction, which seriously affect the work and life of patients.[2,3] Stroke patients with different Brunnstrom stages have distinctive features of motor dysfunction. Lastly, there is a need to address socioeconomic issues, such as long-term medical expenses.[4]

Tai Chi, a traditional exercise therapy with a long history in China, has been effective in the rehabilitation of motor dysfunction after cerebral apoplexy in recent years.[5] Tai Chi emphasizes relaxed movements, slow and continuous movements, and even breathing. It is a kind of physical and mental coordination exercise.[6] Patients concentrate on the changes and convergence of movements, which can possibly improve the balance, gait, and walking ability of stroke patients and reduce the incidence of falls since stroke often show hemiplegia disorder during walking.[7-10] The affected limbs have poor load-bearing capacity and are overly dependent on the healthy limbs. Therefore, some scholars considered Tai Chi as a rehabilitation intervention. Studies applied the modified traditional Taijiquan to the rehabilitation of stroke motor dysfunction and found that the walking and balance abilities of the patients improved.[11] Studies have also found that the mechanism of Tai Chi in promoting the recovery of motor functions such as walking in stroke patients is related to brain plasticity[12]. This is mainly manifested in the improvement of brain structure and function, specifically reflected in increasing brain capacity, and increases the survival of nerve cells, changes the structure of dendritic processes, and enhances the transmission efficiency of synapses.[13,15]

Therefore, this study will use common assessment scales, surface electromyography (sEMG) signals and functional magnetic resonance imaging (fMRI) to evaluate the dose-response efficacy and related mechanisms of Tai Chi in treating stroke patients at different stages of motor dysfunction.

1. **Objectives**

The objective of this study is to clarify the dose-effect efficacy of modified Taijiquan treatment on motor dysfunction in different Brunnstrom stages of stroke. The fMRI technique will be used to partially reveal the central regulatory mechanism of modified Taijiquan treatment in promoting motor function recovery in stroke patients from the perspective of brain functional changes.

1. **Methods**
	1. ***Study design***

This will be a multicenter, randomized controlled study conducted on December 21, 2019 to the solstice on December 20, 2022 at the Second Affiliated Hospital of Heilongjiang University of Chinese Medicine, Xiyuan Hospital of China Academy of Chinese Medicine, and Shenzhen Bao'an District People's Hospital. Patients with motor dysfunction meeting the inclusion criteria in the Brunnstrom spasm stage (BSS) and Brunnstrom recovery stage (BRS) after stroke will be divided into Tai Chi group 1, Tai Chi group 2, and the control group using a central randomized system. The two Tai Chi groups will undergo modified Taijiquan treatment with different exercise frequencies, while the control group will receive routine rehabilitation training. The main results will be obtained using the Fugl-Meyer motor function scale (FMA). Secondary outcome measures include the modified Ashworth scale (MAS), Berg balance scale (BBS), six-minute walking test (6 MWT), modified Barthel Index (MBI), Short Form 36 Health Survey (SF-36), sEMG signal analysis and fMRI. Follow-up measures included FMA and SF-36 health surveys. Patients at Brunnstrom spasm stage will be assessed before treatment and four weeks after intervention, and patients at the recovery stage will be assessed before and 4, 8, and 12 weeks after intervention. fMRI will be performed only in the subject undertaking unit. A total of 165 subjects will undergo pre- and post-treatment fMRI evaluation to analyze the central regulatory mechanisms of motor remodeling in stroke patients treated with modified Tai Chi. **Figure 1** and **Tables 1 and 2** show the flow chart and clinical observation schedule of the trial, respectively.

**Table 1** **Assessment schedule of BBS**

|  |  |  |
| --- | --- | --- |
| **Research stage**  | **Selection** **Period (BSS)** | **Treatment period (BSS)** |
| Evaluation times | First time | Second |
| Evaluation time point | One week before treatment | Four weeks after intervention |
| Inclusion criteria | X |  |
| Exclusion criteria | X |  |
| Informed consent form | X |  |
| Online random grouping | X |  |
| **General assessment** |
| General information | X |  |
| Current medical history / allergic history | X |  |
| Past history / complications | X |  |
| **Evaluation of the curative effect index** |
| Fugl-Meyer motor function scale | X | X |
| modified Ashworth scale | X | X |
| Berg balance scale | X | X |
| six-minute walking test | X | X |
| modified Barthel Index | X | X |
| SF-36 health survey | X | X |
| Surface electromyography signal analysis | X | X |
| functional magnetic resonance imaging  | X | X |
| **Security assessment** |
| Life indication | X | X |
| **Other assessments** |
| Adverse reactions / Events |  | X |
| Treatment compliance |  | X |

**Table 2 Assessment schedule of BRS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Research stage**  | **Selection** **Period (BRS)** | **Treatment period (BRS)** | **Follow-up period (BRS)** |
| Evaluation times | First time | Second | Third time | Fourth |
| Evaluation time point | One week before treatment | Four weeks after intervention | Eight weeks after intervention | Four weeks after the endof the intervention |
| Inclusion criteria | X |  |  |  |
| Exclusion criteria | X |  |  |  |
| Informed consent form | X |  |  |  |
| Online random grouping | X |  |  |  |
| **General assessment** |  |  |
| General information | X |  |  |  |
| Current medical history / allergic history | X |  |  |  |
| Past history / complications | X |  |  |  |
| **Evaluation of the curative effect index** |  |  |
| Fugl-Meyer motor function scale | X | X | X | X |
| Berg balance scale | X | X | X |  |
| six-minute walking test | X | X | X |  |
| modified Barthel Index | X | X | X |  |
| SF-36 health survey | X | X | X | X |
| functional magnetic resonance imaging  | X |  | X |  |
| **Security assessment** |  |  |
| Life indication | X | X | X | X |
| **Other assessments** |  |  |
| Adverse reactions / events |  | X | X | X |
| Treatment compliance |  | X | X | X |

* 1. ***Diagnostic criteria***

The included participants with cerebral infarction/cerebral hemorrhage should meet the following diagnostic criteria: a confirmed diagnosis obtained through brain computed tomography (CT) or MRI, with reference to the Chinese Major Cerebrovascular Disease Diagnosis Points 2019 revised by the Chinese Neurology Society and the Cerebrovascular Group Guidelines Consensus Expert Committee of the Chinese Neurology Society.

* 1. ***Inclusion criteria***

The inclusion criteria will be as follows: clinical diagnosis of first-episode unilateral cerebral hemisphere infarction or cerebral hemorrhage, with confirmation using CT or MRI; age of 45 to 65 years; standing for more than 5 minutes and walking independently for more than 6 meters without any assistance; the Clinical Dementia Rating Scale (CDR) score ≤ 0.5 ; patients in the Brunnstrom spasm stage with an onset of 14 days to 2 months, Brunnstrom stage Ⅳ of upper limb movement and Ⅲ/ Ⅳ of lower limb movement, and grade 1 to 2 in the MAS Scale; patients in the Brunnstrom recovery stage with onset of 14 days to 6 months, Brunnstrom stage Ⅴ, and grade 0 in the MAS Scale; and those who will sign the informed consent.

* 1. ***Exclusion criteria***

The exclusion criteria will be as follows: having acute cerebral thrombosis; having lateral neglect; previous history of dementia or mental illness, visual and hearing impairment, or complicated with serious heart, lung, liver, and kidney diseases; various malignant tumors and other contraindications to sports; having a history of Taijiquan training; motor dysfunction not caused by stroke; failing to detect NMR and sEMG signals due to metal device implantation or other reasons; inability to complete training or poor compliance or cooperation due to other functional disorders; and participation in other studies that could influence the results of this study.

* 1. ***The drop out of cases and disposal***

The criteria for drop-out cases will be as follows: cases of subjects quitting voluntarily, having serious adverse reactions, serious complications, or deteriorating condition during the study and being not eligible to continue the study; poor compliance during the clinical trial and unwillingness to continue to accept the study and propose to withdraw from the study; the evaluation being affected by failure to follow the prescribed treatment or incomplete observation data.

Regarding the disposal of drop-out cases, the researcher will contact the subjects by means of home visits, telephone, and letters. The last treatment time will be recorded and the evaluation items that can be completed will be completed. In addition, the reasons for their withdrawal will be truthfully recorded in the case report form. The observation data of all cases of abscission will be kept and collected and analyzed by the project undertaking unit at the end of the experiment. The researchers should record the shedding information in detail and include the efficacy statistics after more than one course of treatment or more than two weeks of follow-up.

* 1. ***The discontinuity and management of cases***

Patients with serious adverse events, serious complications, or worsening conditions during the trial should be excluded in the clinical trial. In addition, clinical trials should be discontinued based on the judgment of the doctors.

In the case of withdrawal, the doctor should promptly carry out the corresponding clinical treatment. Moreover, the doctor ought to conduct a detailed investigation into the cause and retain the observed data. The final results will be included in the analysis of the efficacy and adverse reactions.

* 1. ***Case exclusion criteria***

Cases that violate the inclusion and/or exclusion criteria, treatment of misgrouped cases, withdrawal from trials, combination of banned drugs or treatments, and incomplete data collection will be excluded.

* 1. ***Recruitment procedure***

The overall clinical trial flow is outlined in Figure 1. Patients referred to the rehabilitation department at one of the three hospitals and complying with the eligibility criteria will be introduced to the RCT study. All eligible patients will be provided detailed information about it and sign the written informed consent form. In order to maximise the recruitment rate, the researchers who participate in the recruitment are specially trained and instructed.

* 1. ***Sample size calculation***

The modified spasticity scale (MMAS) score will be used as the outcome index of the Tai Chi training of BBS patients with motor dysfunction after stroke. According to previous literature, the mean and standard deviation of the treatment group and the control group are 1.67±0.66, and 2.07±0.70,[16] respectively. The Fugl-Meyer motor function score will be used as the main outcome index to evaluate the improvement of Tai Chi in BRS stroke patients with motor dysfunction. Based on the previous research results of a research group, the mean and standard deviation of the treatment group and the control group are 60.50±2.19 and 59.14±1.77,[17] respectively. The level of significance is α=0.05, and the assurance level is 1-β=0.9. At the same time, considering the 15% shedding rate, the minimum required sample size is 71 cases in each group of BSS and 54 cases in each group of BRS. Therefore, the total calculated sample size for BSS is 213, and 162 subjects are expected to be included in the BRS study.

* 1. ***Randomization and allocation concealment***

Using the central random system, the BBS subjects will be randomly divided into three groups: the control group (stretching), Tai Chi group 1, and Tai Chi group 2. The BRS patients will be randomly divided into the control group (exercise re-learning), Tai Chi group 1, and Tai Chi group 2, at a 1:1:1 ratio. To avoid measurement bias as much as possible, the research group secretly divided the evaluators and statisticians into groups because the subjects and researchers could not be blinded in Tai Chi training.

* 1. ***Blinding***

In this study, owing to the particularity of clinical Taijiquan training, it is difficult to implement the blinding method. However, it can be assessed by people who are not involved in the intervention. We plan to use professional doctors from the rehabilitation center as evaluators, and they do not know how the subjects are grouped until the end of the study.

* 1. ***Interventions***
		1. ***Source and distribution of research objects***

A total of 165 cases will be obtained from the Second Affiliated Hospital of Heilongjiang University of Chinese Medicine and Xiyuan Hospital of China Academy of Chinese Medicine, while five patients will be obtained from Shenzhen Bao'an District People's Hospital. Patients with motor dysfunction in the Brunnstrom spasm stage (n=213) and recovery stage (n=162) after stroke will be divided into the Tai Chi group 1, Tai Chi group 2, and control group.

* + 1. ***Treatment***

(1) The Tai Chi group 1 (BSS)

The Tai Chi group 1 (BSS) will undergo BBS modified Taijiquan treatment for a total of 4 weeks of training, with 30 minutes of training each day for five days a week. The specific exercise process is as follows:

*The first form: Tong Li San Jiao*

The left foot is slowly raised from the heel to the tip of the foot. Move to the left with the feet parallel and shoulder width apart. The center of gravity is placed between the legs. Top hip convergence buttocks, Dazhui point to the top, sink shoulder drop elbow, double palm pressure, and maintain three mouth breathing. Return to the Bobath handshake (palms facing each other), lift both arms straight up to the top of the head (pay attention to the affected side of the force), and hold for three breaths. Keep the arms straight down to shoulder level, palms facing outward, and hold for three breaths. Open the arms to sides, keep at shoulder height, palms facing down, and take three breaths. Slowly draw the arms to sides, draw the feet back to a natural standing position, and adjust breathing, deep, even, and slow.

*The second form: Zhan Chi Du Li*

Weight is moved to the right leg, and the left leg is moved to the left, feet parallel, and shoulder-width apart. The Bobath handshake (with the affected thumb on top) is turned down so that the palms face down. Sink shoulders and drop elbows, press palms lower, and keep three breaths. Raise arms, shoulder height, and hold three breaths. The palm turns inward, arms slowly fall, and open to both sides of the body at the same time, fixed at an abduction angle of about 45, palm forward, arms as far back as possible, eyes look at the thumb of the affected hand, and keep three mouth breathing. Arms close to the side of the body and feet back to natural standing. The center of gravity is shifted to the right leg with the Bobath handshake, extend the left leg, and bend the knee to stretch the instep (the patient can point to the tiptoe when the ability is insufficient), maintain six breaths, and withdraw the left leg. The center of gravity is shifted to the left leg, the hip is extended, and the knee of the right leg is bent to stretch the instep (the patient can point to the tiptoe when the ability is insufficient), maintain six breaths, withdraw the right leg, and return the hands to the up position.

*The third form: Zuo You Feng Yuan*

Naturally, with the center of gravity moving to the left leg, position the palms facing each other in front of the stomach. Step with the right foot forward, shift the center of gravity forward, and bring hands to the chest. At the same time, pull the right hand down to the right hip and push the palm forward with the left hand at the eye level. The center of gravity is moved back and brought to the front leg back and arms to sides, and the movement of the left side of the body is the same as above, except for the direction of the different movements.

*The fourth form: Fan Yun Fu Yu*

Move the center of gravity to the left leg and move the right leg to the right and feet shoulder-width apart. Cross arms in front of the abdomen, slightly clench fists, with the eyes of fists toward the abdomen. Place the affected side hand in the hand of the healthy side, the hands slowly outward and upward rotation to open, palm upward pinto, maintain three breathing, turn hands inward and downward, and return to the front of the abdomen. Turn palms and turn hands, palms up, and elbows slightly bend and hands to the waist. Bend the knees slightly and sit behind the hips. The left and right upper limbs alternately rotate out of the palm in the chest and palm forward, alternately three times. Then, rotate back to the waist, palms facing up. Stand naturally with arms at the sides and legs straight.

*The fifth form: Niu Zhuan Qian Kun*

Move the center of gravity to the left leg and move the right leg to the right. The feet should be shoulder-width. Hold the ball in front of the chest with the left hand at shoulder height and the right hand at abdominal height, palms facing each other. Left hand to inward oblique downward arc and right hand to outward oblique upward arc. After the last six cycles, the left elbow is straightened and fall slowly until the shoulder is abducted to 45°. Extend the wrist back, fingertips to the left, and palm with oblique force. Straighten the right elbow and slowly lift until shoulder abduction is 135°. Keep palms to the right, and the heel of the palm pushes to the right, holding for three breaths. Turn the palm of the left hand up and palm down on the right hand. On the chest, hold the ball with the right hand at shoulder height, the left hand at abdominal height, and palms facing each other. The right hand to the inward oblique downward arc and the left hand to the outward oblique upward arc cycle six times. Straighten the right elbow and descend slowly until the shoulder abduction is at 45°. Extend the wrist back, fingertips to the right, and palm heel oblique force. The left elbow is straightened and slowly lifted until shoulder abduction is 135°. Palms to the left. The heel of the palm pushes to the left and hold for three breaths. Slowly bring arms to the sides and feet back to a natural standing position.

*The sixth form: Qing Ting Dian Shui*

Hands akimbo or wall (according to the patient's condition, can choose the affected side of the hand wall). The center of gravity is moved to the left leg, and the right hip joint is rotated externally. According to the patient's situation, they can choose the posture of hip flexion and knee flexion, knee facing outward, and instep hook (shuttlecock kicking posture). The outside of the right foot is placed on the ground in front of the left foot and held for three breaths (Be careful to do this slowly and do not move heels directly into position). Lift the right heel off the ground and bend the hip and knee, turning the knee from facing the outside to facing the inside. Gradually reaching back to the right, jumping on tiptoe, and tiptoe to the ground. Keep the knees straight and keep breathing for three breaths (be careful to make the movement slowly and do not move heels directly to the designated position). Then return to natural standing and repeat the action six times. The movements of the left lower limb are the same as above except in different directions.

(2) The Tai Chi group 2 (BSS)

The group has the same intervention method as that in the Tai Chi group 1 (BSS) with a total of 4 weeks of training, with 30 minutes training twice a day for five days a week.

(3) The control group (BSS)

The control group of BSS will undergo the following rehabilitation methods. Based on conventional treatment, the limbs with spasm will be subjected to stretching training. Muscle drafting technology will be used in passive draft duration generally to 10-15 seconds at a time and can also be up to 30-60 s (close observation of the patient's response to adjust the drafting time), and then repeated 10-20 times. The drawn muscle will be repeatedly extended in length, so that the local tension and pulling will be felt. Each interval will be approximately 30 s, and light massage will be given at the same time to relax. Mechanical draft will be performed for 15-20 min each time. The total time of daily drafting training will be 30 minutes for five days a week, for a total of four weeks.

(4) The Tai Chi group 1 (BRS)

The Tai Chi group 1 (BRS) will undergo the RBS-modified Taijiquan treatment for a total of 8 weeks of training, with 30 minutes of training once a day for 5 days a week. The specific exercise process is as follows:

*The first form: Yi Dong Qian Jun*

Stand still, breathe naturally, eyes straight forward, and chin slightly back. With chest pulled back, the head such as the top, body, and mind are quiet. The center of gravity falls on the right leg, the left heel gently lifts, the left foot moves parallel to the left, and the toe lands first. Move weight between feet and place the left foot with the feet shoulder width. Lift arms flat forward, shoulder-width apart, palms facing down to shoulder height. Position the knee joint of the two legs in a slightly bent squat, loose shoulder sink elbow, and two hands fall to the abdomen before.

*The second form: You Long Ling Bo*

The center of gravity is moved to the right leg and the left foot is brought into the arch of the right foot in the right step. Hold the hands in front of the body as a ball with the left hand at the bottom and right hand at the top. The left hand is in front of the lower abdomen, and the right hand is at shoulder height. Take the left foot out in a left lunge and push the heel back with the right foot on the ball of the foot. Divide the hands in front of the body, pick up the left hand, with fingertips inclined to the top and the same height as the tip of the nose, slide the right hand in an arc, and press fingertips forward on the side of the right hip. The center of gravity moves backward to the right leg, and the left foot turns to 45° to the left in front of the heel as the axis, and the movement of the right side of the body is the same as above, except for the direction of different movements.

*The third form: Huai Bao Tai Chi*

Take the right foot back half step to the body, take the left heel and right forefoot as the axis, turn to the right in turn until the toes of both feet are parallel to move forward. Keep the weight between legs and keep feet solid. The palms should face each other, fingertips up, and bend to the chest. Shift the center of gravity to the left leg, two palms in the chest apart, with shoulder width. Move the center of gravity to the right and close palms together, about the same width as the head. (Note: When switching weight, feet should be shoulder-width apart).

*The fourth form: Peng Zhuan Qian Kun*

The center of gravity is moved to the left leg, right foot closed inside the left foot, and tiptoe into steps. At the same time, the right hand arcs downward to form a ball with the left hand, the left hand is at shoulder height, and the right hand is in front of the lower abdomen. Step forward with your right foot, landing on the heel first in a lunge. The right hand is forward, palm inward with chest height, palm of the left hand downward, fingertips forward, and press to the outside of the left hip joint. Turn body slightly to the right, lift the right hand gently above the right angle, palm of the right hand down, and palm of the left hand up. The center of gravity moves backward, the body turns left, the hands swing downward and backward, the left hand naturally turns back. The left hand finger root presses on the right wrist joint in the chest, and the body turns right. Move weight forward and lunge forward. Keep hands apart, palms shoulder-width down. The center of gravity moves backward, and the right foot tiptoe becomes warped, and the two hands fall to the abdomen as before. Move the center of gravity forward into the right lunge and roll hands forward and up to the chest level. Push them forward and shoulder width apart, looking ahead. The movement of the left side body is the same as above except for the direction of the different movements.

*The fifth form: Bo Yun Jian Ri*

Move the center of gravity back, raise the left toe, and turn the body right on the left heel. At the same time, the left hand swings down and the right hand swings sideways. Turn to the left waist, and the left hand through the front left arc swing. The right hand falls in front of the abdomen with the left waist swing to the left and the right foot moves toward the left foot, the left hand falls, and the right hand is raised. At the same time, the right and left feet are turned, maintaining a distance of 10 cm between the two feet. Turn the left waist, with the belt arm, right hand falls, and left hand arches to the left and right heel steps. Turn the waist to the right, while the left hand falls, the right hand is raised, and the center of gravity moves to the right leg when the left foot starts. Turn left waist, left hand up, right hand down press, and slightly right body to the front. Pick up with the right hand, press down with the left hand, and step on the right heel, shoulder-width apart, with hands naturally falling in front of the abdomen.

*The sixth form: Luan Feng Gui Yuan*

Connect the action, the body turns to the front, two arms naturally relax the fall, two arms to the body two sides level lift, palm down, two legs micro bend down to squat, both hands embrace and before the lower abdomen. Stand up and stretch hands up from both sides of the body as a stand. Put hands together on top of head breathe three times in the same abdominal position while breathing in (stretch hands together once when breathing in and relax when breathing out). Fall with hands clasped on chest, turning fingertips outward, the roots of palms toward the chest, and extending forward with fingertips as guide. Turn the hands into the palm down position, in front of the two arms flat spread, and the shoulder width two arms relaxed and fall on both sides of the body. The center of gravity is shifted to the right leg, with the right leg to support the center of gravity, gently lift the left foot, heel off the ground first, and left foot to the right foot. Both hands in the lower abdomen before the palm (male left hand, female right hand), Lao Gong, and Guan Yuan point relative, harmonize the breathing and the body to relax.

(5) The Tai Chi group 2 (BRS)

This group has the same intervention method as that in the Tai Chi group 1 (BRS) with a total of 8 weeks of training, with 30 minutes training twice a day, 5 days a week.

(6) The control group (BRS)

The control group of the BRS will undergo the rehabilitation methods as follows. Based on conventional treatment, training on the upper limb function and walking ability will be intensified. For patients with weak muscles, electromyographic feedback, electrical stimulation, and simple exercises that induce active movement can be used to improve the ability of weak muscles to contract. Electrical stimulation can be combined with intentionality training. Targeting training for walking ability will be perforemd mainly to correct abnormal gait and strengthen balance control and walking ability. Attention should be paid to increasing the complexity of the actions and providing password guidance. The training will last for 8 weeks, 30 minutes each time for five days a week.

* 1. ***Outcome assessment***

The main outcome indicators will be the FMA, while the secondary outcome assessment will be MAS, BBS, 6 MWT, MBI, SF-36, sEMG, and fMRI. Follow-up evaluation indexes included the FMA scale and the SF-36 health survey. All adverse events during the trial will be record, including falls, fractures, and increased blood pressure and their relevance to the intervention will be evaluated.

Patients at the Brunnstrom spasm stage will be assessed before treatment and 4 weeks after intervention, while patients at the recovery stage will be assessed before and at 4, 8, and 12 weeks after intervention. The follow-up time point for the BRS patients is four weeks after the end of the intervention.

* 1. ***Statistical analysis***

An independent data management unit is responsible for the statistics of data entry and management. After confirming that the established database is correct, the unit will make a statistical analysis plan and determine the statistical software to be used. All statistical calculations will be performed using SPSS24.0, or higher statistical analysis systems. A two-sided test will be used for statistical analysis, and P≤0.05 is considered to be statistically significant. The measurement data will be analyzed using t-test, analysis of variance, and mixed linear model. The chi-square test will be used to compare the counting data between the groups. The Mann-Whitney nonparametric rank sum test will be used to compare the grade data between the groups. All clinical endpoints will be analyzed using intentionality analysis (ITT) and compliance protocol (PP), and safety data sets (SS) will be used for safety analysis.

* 1. ***Ethics***

The project undertaking unit shall formulate a research plan and submit it to the ethics committee of the project undertaking unit for examination and approval. The ethics committee of each participating unit shall be responsible for reviewing the feasibility of the unit on the premise of accepting the ethical review opinions of the unit undertaking the project. Patients will be informed of the study background, purpose, benefits, and risks prior to enrolment. Patients will be enrolled after providing informed consent. If there are problems in the actual implementation of the clinical study and it is necessary to revise the plan, it should be put forward to the sponsor. Participating unit ethics committees have the right to suspend research conducted in their institutions based on concerns regarding subject safety.

* 1. ***Quality control***

This study establishes a three-level quality supervision system. First, each clinical research unit will be assigned an inspector to conduct regular preliminary self-examination of the timeliness and accuracy of CRF tables and other data according to the study protocol. Then, according to the completion of the project and the key points of supervision, the supervisors will regularly inspect the research progress and implementation of the research plan of the participating research institutes. Finally, the third-party monitors will supervise the enrollment progress of each center, investigate and analyze the causes of shedding cases, and provide countermeasure support.

* 1. ***Data management***

All data in this study will be re-entered into the database using a computer software. The data manager will ensure the completeness and accuracy of the data in the clinical data and input the relevant datasets into the computer.The data will be blindly reviewed, and after the review is passed, the data will be locked by primary researchers and statistical analysts. The locked data file cannot be changed.

* 1. ***Dissemination***

The primary RCT results will be communicated to participants, peer-reviewed journals, and presented at international conferences. If the intervention program can effectively treat motor dysfunction after stroke, A key output of this project will be to facilitate the implementation of the application of modified Taijiquan in community and primary care settings.

1. **Discussion**

The treatment of motor dysfunction depends on both pharmacological and non-pharmacological approach. Currently, medication is primarily for symptomatic relief and does not have a satisfactory effect on the symptoms associated with the progression of neurodegenerative diseases. As a result, some health agencies recommend the development of non-pharmacological complementary interventions as a first-line treatment. For example, intensive exercise therapy can improve the motor function.[18] Although many exercises, including standing balance exercises and motor relearning, have been used in patients with acute and subacute strokes, patients with chronic stroke require one-on-one treatment due to limb and sensory impairments.

This is not readily available to many community health center (CHCS) patients and requires supervision by a health care professional.[19] At the same time, different Brunnstrom stages of stroke patients have different characteristics of motor dysfunction; therefore, the modified Taijiquan training can be used as a low-cost, effective, and targeted intervention to treat stroke survivors with motor dysfunction.

The Fugl-Meyer Assessment (FMA) and Modified Ashworth Scale (MAS) are widely used in clinical practice to measure movement disorders and passive movement resistance (spasticity), respectively.[20] The BBS is an effective and appropriate assessment tool for balance in patients with stroke.[21] The 6 MWT has high retest reliability for assessing stroke patients,[22] while the Barthel Index (BI) is a measure of independence for activities of daily living (ADL). In the MBI, the original scoring system of two, three, or four points is replaced by a five-point system.[23] The SF-36 is a short, 36-item questionnaire that measures eight dimensions of health status and is increasingly used and recommended as a suitable measure of subjective health status.[24] The use of three sEMG indicators, namely cluster index (CI), root mean square (RMS), and intermediate frequency (MDF), as a means of examining and monitoring the course of stroke rehabilitation, may be useful in improving the changes in paralyzed muscles. All the complex neuromuscular processes suggested that EMG may be useful for monitoring stroke rehabilitation.[25] The disability and effectiveness of physical therapy after ischemic stroke are highly variable due to the different brain regions affected. Functional magnetic resonance imaging (fMRI) is used to study patients after stroke and after intervention for a period to understand changes in brain function.[26]

At present, many studies have confirmed that Taijiquan has positive significance for the functional rehabilitation training of stroke patients. However, these quantitative studies only focused on the specific impact of Taijiquan exercise intervention on patients, and the mechanism behind its beneficial effect remains to be studied. Moreover, there are a series of problems, such as small sample size, different training routines of Taijiquan, and imperfect evaluation systems, which limit the improvement and development of clinical applications of Taijiquan. Therefore, according to the characteristics of motor dysfunction in stroke patients, it is necessary to improve the traditional taijiquan movements and present the easier Taijiquan exercise for patients to accept. A multicenter, large-sample, randomized controlled clinical study will be carried out to clarify the dose-response effect of the modified Taijiquan treatment on motor dysfunction after stroke. At the same time, from the perspective of brain functional plasticity, the introduction of fMRI technique can systematically explore the rehabilitation effect and mechanism of modified Taijiquan treatment of motor dysfunction after stroke.

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**Conflicts of Interest** The authors have no conflicts of interest to declare.

**Patient consent for publication** Not applicable.

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**References**

**Figure Legends**

**Figure 1** Flow chart of the trial. This figure illustrates the study design (RCT).A total of 375 participants with motor dysfunction after stroke will be randomised to different groups. The primary outcome measure will be the Fugl-Meyer motor function scale (FMA). Secondary outcome measures will be the modified Ashworth scale (MAS), Berg balance scale (BBS), six-minute walking test (6 MWT), modified Barthel Index (MBI), Short Form 36 Health Survey (SF-36), surface electromyography (sEMG) signal analysis, and functional magnetic resonance imaging (fMRI). BSS, Brunnstrom spasm stage. BRS, Brunnstrom recovery stage. RCT, randomised controlled trial.