

# Effectiveness of Liu Zi Jue Qigong versus traditional core stability training for patients with post-stroke complicated with abnormal trunk postural control: a study protocol for a single-center randomized controlled trial

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## Study protocol

**Keywords:** Six character formula, Trunk postural control, Stroke, Core stability, Traditional core stability training, Liuzijue qigong (LQG)

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# Abstract

**Background:** Trunk function in stroke patients with hemiplegia is associated with respiration and core stability, and is also found to be associated with balance and postural control and daily activity of life. Liuzijue Qigong (LQG) is a traditional Chinese method of fitness based on breath pronunciation. The purpose of this study is to compare the clinical efficacy of LQG and traditional core stability training in the treatment of stroke patients with abnormal trunk posture. This protocol is written according to the SPIRT 2013 Statement. **Methods:** This study is a single-center randomized controlled trial in which 160 stroke patients are randomly divided into study group and control group. Patients in the study group will receive LQG combined with conventional rehabilitation therapy, while patients in the control group will receive traditional core stability training combined with conventional rehabilitation therapy. All treatments will be treated 45 minutes a day, 5 times a week for 2 weeks. **Primary outcome** (Trunk impairment scale) and **secondary outcome** (Berg balance scale, Fugl-Meyer assessment, Modified barthel index, Maximum phonation time, Dynamic and Static Balance Testing and The thickness and the Mobile degrees of diaphragm) will be conducted at baseline, 2 weeks at the end of the rehabilitation course. **Discussion:** The aim of this research is to compare the clinical efficacy of LQG and traditional core stability exercise in the treatment of stroke patients with abnormal trunk posture. **Trial registration:** Chinese Trial registration: chinese clinical trial registry : ChiCTR1800014864. Registered on 24 November 2018. **Keywords:** Six character formula, Trunk postural control, Stroke, Core stability, Traditional core stability training, Liuzijue qigong (LQG)

## Background

Several studies have shown that trunk posture control disorder is common in patients with hemiplegia after stroke [1]. Therefore, the problem of trunk control disorder in stroke patients should be paid more attention to in the course of rehabilitation. It is characterized by trunk coordination and sitting balance problems, trunk posture control and trunk muscle strength, as well as trunk position perception [2]. Postural control refers to the ability to keep the body in appropriate space in all during all kinds of physical activities [3]. Correct postural control depends on a valid core stability. The core muscle group is divided into the deep muscle and shallow movement muscle groups, in which the deep muscle group should play the main role for stabilizing the trunk[4]. The deep core muscles, such as the diaphragm, the abdominal transverse muscle and the pelvic floor muscle, are also the main muscles responsible for breathing [5,6]. For example, when we are inhaling, diaphragm centripetal contraction, diaphragmatic roof fall, abdominal and pelvic floor muscles centrifugal contraction, increased intra-abdominal pressure, making core stability enhancement. Obviously, deep core muscles are closely related to posture control and breathing ability [7,8].

At present, Core stability training is often used as a clinical treatment for stroke. However, respiratory training is often neglected in the rehabilitation of stroke. To maintain the core stability of stroke patients with hemiplegia, the chest, pelvis and abdominal cavity are in abnormal positions and the breathing movements of the diaphragm are affected, resulting in over involvement of the auxiliary respiratory

muscles, which exacerbates postural abnormalities. Therefore, it is very important to explore a treatment approach that combines respiration and trunk control to improve a stroke patient's ability to control the trunk.

Inspiration is related to trunk extension and exhaling is related to trunk flexion. Patients with hemiplegia often show abnormal chest uplift, collapsed abdominal muscle force in hemiplegia side and over extension of the trunk. Abnormal trunk posture control with post stroke could lead to abnormal breathing problems. Fugl-Meyer have found that decreased expiratory force is a common feature in stroke patients with hemiplegia[9]. In subsequent studies, it was also found that "abdominal electromyography decreased during forced exhalation" [10]. Patients with cerebral apoplexy generally have abnormal breathing, which is often manifested as decreased exhalation ability [11]. From above all, proper breathing exercises, especially exhalation exercises is necessary to patients with stroke [12].

Liuzijue qigong is a traditional fitness method which focuses on controlling breathing. It is part of a new fitness qigong series launched by the Chinese Health Qigong Association [13]. LQG perform the actions of inhaling and exhaling through different mouth patterns to regulate and control the rise and fall of the breath in the body, and complete the practice of "xu, he, hu, si, cui, xi" with breathing and pronunciation. These exercises significantly enhance the function of the liver, heart, spleen, lungs, kidneys and trifocal organs respectively, and LQG helps to balance the energy and function of the internal organs [14,15]. The method includes breathing in through the nose and exhaling with annunciation of one of the six different voices and breathing sound[16].

Recent studies have shown that the formula can effectively improve lung ventilation function in COPD patients and improve their daily quality of life. It can enhance the cardiopulmonary function of patients with arrhythmia[15,17]. Studies have shown that the LQG improves symptoms, motor function and quality of life in Parkinson's patients[18].

Abnormal breathing patterns are caused by abnormal trunk control. However, abnormal trunk control is not only related to the hemiplegic side trunk but also to the non-hemiplegic trunk muscle weakness. The six character formula improves the diaphragm function through one inhalation and six breaths, strengthens the control of deep core stable muscle group, and increases the control ability of bilateral trunk.

Therefore, the aim of this research is to compare the clinical efficacy of LQG and traditional core stability exercise in the treatment of stroke patients with abnormal trunk posture.

## **Methods/ Design**

### **Trial design**

This study will be a single-center randomized controlled trial in which 160 stroke patients are randomly divided into study and control groups. The study will be conducted at Shanghai Xuhui Central Hospital

between March 1 2018 and March 31 2021. The study will recruit eligible subjects from the inpatient and outpatient departments of rehabilitation medicine of Shanghai Xuhui district central hospital in Shanghai. All patients enrolled in the study group and the control group will be allocated in a 1:1 ratio. LQG combined with conventional rehabilitation will be completed by patients in the study group, while traditional core stability training combined with conventional rehabilitation will be completed by patients in the control group. TIS (Trunk impairment scale) will be used as the main evaluation index. The secondary evaluation index will include the Fugl-Meyer Assessment, Maximum Phonation Time, Dynamic and Static Balance Testing (TecnoBody PK-254, Italy), The thickness of diaphragm, Diaphragm Mobile degrees, Modified Barthel index and Berg Balance Scale. All assessments will be conducted at baseline, 2 weeks at the end of the rehabilitation course. The flow chart of study protocol is shown in Figure 1. The research proposal has been designed according to the recommendation of SPIRIT. (Fig 2 and Additional File 1)

### **Primary and secondary outcomes of the study**

In this study, "Trunk impairment scale" will be selected as the main observation index. At the same time, the clinical effect will be divided into three grades: Complete response (CR), Partial response (PR), No response (NR) to evaluate the curative effect before and after treatment. And this observation index will be defined as ranked data.

The secondary outcome measurements will include other relevant evaluation indicators such as FMA, Berg, ADL, MPT, dynamic and static balance function, the diaphragm thickness and the muscle mobility of the diaphragm. The data obtained from these indicators will be measurement data.

### **Primary outcome measurement procedures**

Experienced physicians will assess the primary measures before and after treatment for 2 weeks. The TIS scale will be used to measure the main results (**Table 1**).

A main investigator will evaluate trunk postural control in the entry and exit stages. Trunk postural control will be conducted according to the Spanish Version of Trunk Impairment Scale 2.0. This scale consists of 3 sub-scales: The subscale of the first item is "static sitting balance" (score range 0-7) to assess the ability of the patient to maintain a sitting balance by landing on their feet and crossing their legs. The patient should cross the leg on the affected side. The second sub-scale will evaluate the dynamic sitting balance (score range 0-10) and assess the lateral flexion of the trunk, starting from the upper and lower trunk. The third sub-scale will evaluate the coordination (score range 0-6) and tests the ability to independently rotate the shoulder girdle and pelvic girdle. The total scores will range from 0 to 23, with a higher score denoting a better performance [19].

We will calculate the evaluation of efficacy before and after the intervention. The criteria will be:

CR: TIS total score increased  $\geq 7$  points after treatment;

PR: 3 points  $\leq$  TIS total score increased  $\leq$  6 points;

NR: the total TIS score after treatment was  $\leq$  2 points or worse.

**Table 1. Specific measurement of trunk posture control levels carried out by TIS**

	Baseline	2 weeks
Trunk posture control measurement		
Evaluation date		
Signature of therapist		

### Secondary outcome measurement procedures

The secondary outcome measurements will include other relevant evaluation indicators such as FMA, Berg, ADL, MPT, dynamic and static balance function, the diaphragm thickness and the muscle mobility of the diaphragm (**Table 2**). Experienced physicians will evaluate the secondary outcomes at baseline and 2 weeks after treatment.

The simplified Fugl-Meyer scale will be used for the assessment of motor function and is often used in clinical rehabilitation, because it is reliable and effective [20,21]. The scale has a total score of 100, which is divided into motor function evaluation of the upper and lower limbs, among which the upper limb score is 56 and the lower limb score is 44. Each item has a 3-point rating, and a higher score indicates better motor function. The classification of its dysfunction is as follows: <50: severe dyskinesia, 50-84: significant dyspraxia, 85-95: moderate dyskinesia, 96-99: mild dyskinesia, 100: normal.

The modified Barthel index (MBI) scale will be used to evaluate the quality of daily life. The scale is divided into 10 items and evaluated on the basis of patients' functional status. The 10 items are bathing, grooming, defecation, eating, entering and leaving the toilet, transferring, walking on flat ground, going up and down stairs, etc. The total score is 100 points. The classification of its dysfunction is as follows: 100 points: self-care, 61-99: mild dysfunction, 41-60: moderate dysfunction,  $\leq$ 40: severe dysfunction. The lower the MBI score, the more independent the patients are and the worse their daily living ability [22].

The Berg Balance Scale (BBS), which is widely regarded as an effective measure of balance in stroke patients and healthy older adults, will be used to evaluate balance function. The BBS scale consists of 14 items, each of which is graded on a scale of 5. The classification of its dysfunction is as follows: 0-20 points, poor balance function, patients need to use a wheelchair; 21-40 points, have a certain balance ability, the patient can walk under the assistance; 41-56 points, with good balance function, the patient can walk independently. A score less than 40 points indicates the risk of falling [23].

Maximum phonation time (MPT) will be used to measure the length of time a simple vowel is emitted after deep breathing. The measurement requirements of MPT are as follows: 1) the longer the

pronunciation time is, the better; 2) breathing evenly; 3) even breathing loudness; and 4) pitch within the correct frequency range. At the same time, the relatively longer MPT value will be taken as the final evaluation result. For instance, According to the reference standard of Chinese MPT [24]: 16-40 males, 95%[24.4,25.2];16-40 females, 95%[16.3,16.9].The assessment results must meet the above requirements, namely the tone and volume of the pronunciation should be kept at a comfortable level [25].

Static stability and dynamic balance testing will be measured by the Prokin proprioception evaluation and training system (PK254P, Tecnobody Srl, Italy). Static stability testing will proceed as follows [26]: Standard seat position; 1) the balance plate is arranged on the platform, the height of the foot platform adjusted, contact with the ground and curtsy subjects sit under 90°-100°; 2) adjustment of the seat of the subject and position the femur large rotor on the balance plate A3-A5 axis; 3) adjustment of the feet-shoulder width of subjects; 4) chest rise, eyes to the front; and 5) subjects arms crossed, elbow, shoulder proneness of 45° hung up. The standard standing position: 1) Symmetrical on the A1-A5 axis and subjects will be close to each other; 2) the medial border of the feet will be 10 cm apart and the highest point of the bilateral arch located on the A3-A5 axis. The static balance test has 6 observation indices as follows: 1) the displacement difference of the x and y axis; 2) the standard deviation of fore and after, left and right directions; 3) the average motion speed before and after, left and right; 4) the motion length; 5) COP area; and 6) the area ratio and length ratio under the test of the motion area and Romberg.

Dynamic balance testing will occur as follows [27]: 1) The two feet standing apart with inclined plates; entry of general data of patients, selection and evaluation module, adjustment of the resistance buffer system as recommended by the "8" (a total of 10 files, if the file number is high the more resistance, set to "8". The tester will be required to wear a chest position sensor, which will be located about the two nipples and connected to the midpoint of the sternum. The dynamic balance test has 4 observational indices thus: 1) Trunk Stability Index (TSI), front and rear, left and right, circumference; 2) Average Trajectory Error (ATE); 3) Test Execution Time (TTE); 4) Average Weight Force Difference (AWFD, kg).

The thickness of the diaphragm will be measured by ultrasound (Tdi): Subjects will take the supine position and breathe autonomously. It is worth noting that in order to avoid measurement error, we uniformly selected the right side of patients for measurement. All phrenic ultrasound examinations in this study were performed by the same doctor with formal ultrasound training. Therefore, A linear high frequency probe will be positioned on the right axillary front and the probe set perpendicular to the chest wall between ribs 8 and 9. If the diaphragm is not visible in this position the probe may be moved up to the 7<sup>th</sup> and 8<sup>th</sup> intercostals. The image of the phrenic junction consists of 3 layers of connective tissue, namely the bilateral hyperechoic area (pleura, peritoneum) and the intermediate mixed type echo area (composed of the anechoic diaphragm tissue and its internal hyperechoic fascia). The 3 layers are parallel during respiration. A moving cursor will be used to measure the thickness of the diaphragm at the end of quiet breathing (functional residual air position, TdiFRC), and the thickness of the diaphragm at the end of maximum inspiration (forced lung capacity, TdiVC), respectively. The values of 3 respiratory cycles will be measured and averaged. The change of diaphragm thickness from the end of quiet exhalation to the end of maximum inspiration will be calculated as:  $TF = (TdiFVC - TdiFRC) / TdiFRC$ [28].

Ultrasonic measurement of phrenic muscle mobility (D/M): degree of diaphragm mobility measurement will be the displacement distance of the diaphragm dome FRC and TLC, with subjects lying at a 45° angle. A convex transducer (3.5 MHz) will be placed in the medial line of the right axilla at the costal margin of the thorax and the fixed finger positioned towards the skull. For each image of the m-mode record, we will determine the vertical distance between the point corresponding to the starting maximum inspiration and the point corresponding to the maximum diaphragm displacement [29].

**Table 2. Comprehensive evaluation of trunk posture control disorders after stroke using FMA, Berg, ADL, MPT, dynamic and static balance function, diaphragm thickness and the muscle mobility of the diaphragm**

	Baseline	2 weeks
Fugl-Meyer assessment		
Berg balance scale		
Barthel index		
Static balance testing		
1) displacement difference of the x and y axes;		
2) standard deviation of fore and after, left and right directions;		
3) average motion speed before and after, left and right;		
4) motion length;		
5) COP area		
6) area ratio and length ratio under the test of the motion area and Romberg.		
Dynamic balance testing		
1) trunk stability index (front and rear, left and right, circumference);		
2) average trajectory error (ATE);		
3) test execution time (TTE);		
4) average weight force difference (kg )		
Maximum phonation time (s)		
Diaphragm thickness		
Muscle mobility of diaphragm		

### Adverse event collection procedure during the trial

Adverse events and procedures during the trial will be reported, processed and recorded in a timely manner. This study will complete a two-week clinical intervention to identify the reasons responsible for adverse events and to ensure that patient safety, health, and their rights are maintained. Serious adverse events will be submitted to the principal investigator within 24 hours. The clinical trial office and ethics committee of Shanghai Xuhui District Central Hospital will jointly put forward reasonable suggestions.

### Trial setting

The rehabilitation department of Shanghai Xuhui District Central Hospital will carry out this study. Physical therapists will provide comprehensive rehabilitation for all patients including exercise therapy, occupational therapy, speech therapy and traditional rehabilitation.

### Inclusion criteria

The criteria for inclusion of subjects in the study will be: (1) met the diagnostic criteria of cerebral infraction or cerebral hemorrhage; (2) with TCM diagnostic criteria of stroke; (3) the first onset of stroke,

with trunk postural control disorder; (4) a trunk impairment scale evaluation score between 6 and 17, and a sitting balance > 2 levels; (5) between 40 and 80 years old; (6) course of disease 2 weeks to 6 months; (7) good physical strength, can withstand 45 minutes of training; (8) at least one side movement function of a normal limb or at least Brunnstrom  $\geq$  4 levels; (10) patients with stable vital signs; (11) agreed to sign an informed consent document.

## **Exclusion criteria**

Exclusion criteria for potential subjects in this study will be: (1) consciousness disorder, severe cognitive dysfunction and hemianopia; (2) at the same time with dysarthria, aphasia; (3) physical training can not be tolerated for 45 minutes; (4) with heart, brain, kidney and other organs in acute diseases; (5) serious mental disorders; (6) modified mini-mental state examination  $\leq$  23.

## **Study population and recruitment**

The study will recruit 160 patients aged 40-80 years who have been diagnosed with cerebral apoplexy in the rehabilitation department ward of Xuhui District Central Hospital in Shanghai from March 2018 to March 2021.

First, Before the start of the study, doctors in the inpatient department of rehabilitation medicine should be informed of the criteria of potential study patients that need to be included in the study, as well as the purpose of the study, and then they should be referred to the researchers of the study. Second, the principal investigator will briefly introduce the inclusion and exclusion criteria for this study and provide the researchers with possible inclusion information, as well as the potential risks and advantages. Third, If the patient are interested in the study, the primary researchers will further provide more detailed information and answer any questions raised. If the patient agrees to participate in the study, the patient or family members will sign the informed consent to guarantee the patient's privacy. Finally, after the patients and their families have signed the informed consent form, the main researchers will include subjects that met the requirements according to the TIS scale.

## **Randomization and Blinding**

### **Randomization**

CW generated the allocation sequence; CW and LY will enroll the participants; YZ will assign participants to the interventions. In this study, a statistician who was not involved in the study used the SPSS 20.0 software to generate a table of random Numbers. patients were randomly divided into two groups at a 1:1 ratio. One group was the study group and the other group was the control group. A table of random Numbers will be placed in a sequentially labeled opaque envelope. The distribution order is then kept by a research assistant who is not involved in recruitment, intervention, outcome evaluation or statistical analysis. After the subjects have met the study criteria, The research assistant will notify the appropriate therapist to intervene and will notify the subject by telephone of the assignment (study group or control group).

## **Blinding**

Patients will be randomly assigned through random coding generated by SPSS to ensure that the evaluator is blind. Only the major researchers will know the order of the random assignments. Outcome assessors will be blinded, that is, the outcome assessors and care providers will be different doctors. The outcome assessors and care providers shall not exchange information in the implementation of the experiments, and the outcome assessors shall not ask the subject for the intervention. In this study, only the assessors will be blinded, so it does not involve unblinding.

## **Intervention**

The LQG (study group) or core stability training (control group) followed by conventional rehabilitation training (30 minutes each) will be completed in 2 weeks 5 times in a quiet room, 10 m<sup>2</sup> room with a background noise of  $\leq 30$  dBA. Experienced physiotherapists will be responsible for completing the training and ensuring that the training process is conducted strictly in accordance with the research program. First, the patient should adjust to a sitting and independent standing position. Then, they should breathe smoothly through their nose, complete the upper body movements, and slowly exhale through the mouth. Meanwhile, it's worth noting that this research will not have a negative effect or side effects on patients, but in the process of study if a patient's condition worsens, the damage caused by treatment or evaluation shall be borne by national health insurance. And all patients will receive comprehensive rehabilitation provided by physiotherapists in the Department of Rehabilitation Medicine, Shanghai Xuhui Central Hospital, including exercise therapy, occupational therapy, daily life ability training, and traditional physical factor therapy. The intensity and frequency of comprehensive rehabilitation programs received by the two groups of patients will be the same.

## **Control group**

Patients in the control group will receive traditional core stability training and conventional rehabilitation therapies. Routine rehabilitation training will include drafting training, passive joint movement, walking between parallel bars, occupational therapy, etc. At the same time, core stability training will include abdominal training in the supine position, double bridge movements, single bridge movements, balance ball half bridge movements and forward and backward movement of the sitting pelvis, The patient will be sat on a Bobath ball and use the Bobath handshake to control the flexion, extension, lateral flexion and rotation of the torso. Before the training begins, the therapist will inform the patient of the brief action instructions. For patients with poor respiratory control, manipulation will be adopted to stimulate their abdominal muscle group contraction, and necessary manipulation should be undertaken according to the different limb functions of the patients. The duration of conventional rehabilitation training will be 5 times a week, 30 minutes per session, lasting for 2 weeks. The traditional core stability training will last for 15 minutes five times a week for 2 weeks. All of the control group interventions for traditional core stabilization training will be performed separately by three experienced therapists (MY, LGL and NWD).

## **Study group**

In addition to receiving conventional rehabilitation training, patients in the study group will be required to complete the LQG treatment. Patients allocated to the study group will be engaged in *LQG* rehabilitation programs in addition to conventional rehabilitation therapies. The sequence will be routine rehabilitation and then core stability training. Each time, the rehabilitation course will be divided into *LQG* for 15 minutes and normal rehabilitation training for 30 minutes. The study group will be completed 5 times per week for 2 weeks in a quiet room. For traditional core stabilization training, all study group interventions will be performed separately by three experienced therapists (YY, WC, FH and WQL).

The key points of *LQG* oral guidance will consist of pronunciation and breathing. For "XU", pronunciation will be assisted by the teeth. Space will be left between the teeth and the tongue, with the upper and lower teeth parallel. Air will be drawn from the space between the teeth, and between the teeth and the tongue, and the corners of the mouth will be pulled back a little. When exhaling and pronouncing, the "HE" will be pronounced with the aid of the tongue. The upper teeth will be tapped with the sides of the tongue and air exhaled between the tongue and the upper jaw. During the exhalation and pronunciation, the "HU" sound will be assisted by the throat. The sides of the tongue will be bent upwards and the lips forward, forming a circular opening through which the patient will exhale. During the exhalation and pronunciation, the "SI" will be pronounced with the assistance of the teeth. There will be a narrow gap between the upper and lower teeth. The patient will lightly touch their lower teeth with the tip of their tongue and exhale air between their teeth. During the exhalation and pronunciation, the "CHUI" will be pronounced with the assistance of the lips. The tongue and the corner of the mouth will be pulled back as will the lips into the stretched position, making the back teeth parallel and thus exhaling air from the throat between the sides of the tongue and the stretched lips. In the exhalation process, the "XI" will be pronounced with the assistance of the teeth. The lower teeth will touch the tip of the tongue, and the corners of the mouth will be slightly tilted back, the posterior teeth gently closed and air exhaled through the space between the posterior teeth[30-32].

Our training is one-on-one intervention by the therapist. Before training, for the elderly, we will tell each patient that the "emphasis" will be on breathing and pronunciation. In order that the patient should learn correct pronunciation and breathing accuracy, the patient will need to learn gradually to 'feel' the key points of strength rather than the absolute power of pronunciation. For example, the patient may complete in a sitting or standing position. Stroke patients should learn to use healthy upper limbs to assist upper limb movement. Or the physiotherapist can stand on the patient's side to assist in the completion of the movement and maintain the normal position of the chest, spine and pelvis, to provide a stable mechanical structure. Meanwhile, Our training is not in the form of group exercises, but in the form of one-on-one therapist intervention.

### ***LQG action points***

Stroke patients with postural dysplasia often show different degrees of hemiplegia and postural abnormalities, resulting in the loss of their ability to sit or stand. It is impossible for these patients to complete the Liuzijue key independently and precisely without assistance. Therefore, the therapist will

properly guide the completion of the movement and adjust the training position according to the patient's functional state. As the improvement of patients' balance ability increase, the training position will gradually transition from the sitting position to an independent standing position. As the patient's limb function improves, the therapist will gradually reduce the amount of assistance. Both active and auxiliary limb movements are based on bilateral limb opposition. The most important goal is to complete an accurate respiratory guidance program.

### **Sample- size calculation**

We will use the Trunk impairment scale as the main therapeutic index to evaluate trunk posture control, The Preliminary experimental findings has showed that the effective rate was 80% in the study group and 50% in the control group. The effective rates of the study group and the control group were set as 80% and 50%, respectively. Based on this, this study conducted sample estimation through G\*power 3.1 software, and adopted rank sum test model to set the rate of 80% in the treatment group and 50% in the control group for bilateral test, and set  $\alpha=0.05$  and power=0.97 (the setting of this value is based on the statistical power after the end of the experiment (power =0.97 after the end of 40 cases). The distribution ratio was matched by 1:1, and the final sample size was 142, with 71 cases in each of the two groups, taking into account the possibility of 12% attrition rate during the test. Therefore, the total number of samples was finally determined to be 160 cases, namely 80 cases in each group.

### **Statistical analysis**

1) In this study, the main indicators were determined according to the change levels before and after treatment of TIS, which were divided into three levels of complete response, partial response and no response, and expressed by rate or percentage. The chi-squared test will be used to compare differences in efficacy between groups. 2) the overall curative effect evaluation and the curative effect evaluation method will be employed. The calculation formula is: Effective = (excellent + effective) / total cases × 100%. 3) Secondary indicators (such as MPT, MBI, Berg, FMA, diaphragm thickness and mobility, static and dynamic balance ability, etc.) were all continuous data, a paired sample *t* test is often used for intra-group comparison, while independent sample *t* test is often used for inter-group comparison of the difference between the two groups after treatment, and a two-sided test will be used and the significance level is set at  $P \leq 0.05$ . 4) to eliminate the influence of the rehabilitation intervention time, stroke type, age and gender on the efficacy and relative size of intervention methods will be considered and the statistical method of stepwise logistic regression model adopted.

ITT is divided into FAS and PP, where FAS refers to the data set obtained after minimal and fair removal of data from all randomized subjects. PP is sometimes referred to as "valid case" and "valid sample" and is a subset of the total analysis set. The subjects had sufficient adherence to the protocol to be able to estimate the effect of the treatment.

The per-protocol (PP) population will include random patients in the intention to treat (ITT) group, but exclude patients who do not meet the inclusion or exclusion criteria. and randomly assigned patients who

do not receive the actual treatment [33].

If the statistical results are the same, ITT (intend to treatment) and PP (per-protocol) are reliable indicators. ITT results will be used if statistical evaluations are different between the two methods. As the final observation result (LOCF), the missing data will be processed. The last observation value of the endpoint will be regarded as the follow-up evaluation point of missing data, and the last observation reaction will be regarded as the endpoint of the study.

### ***Monitoring***

To ensure the quality of RCT, this study will be completed by Shanghai xuhui central hospital. We will upload data through the China clinical trials registry in a timely manner so that the project management team can identify problems, review collected data and control errors. The drug testing center of Shanghai xuhui central hospital will have the opportunity to get the results of the mid-term trial and make a decision on it. A qualified clinical trial specialist will be invited to monitor the RCT.

### ***Trial quality control***

The main researcher, CW and YZ, is responsible for making protocol decisions, while LY is responsible for coordination (e.g., collating/collecting data, analyzing, etc ). JY will be responsible for quality control, YN Z and RW W will be responsible for data development and database management, and YZ will be responsible for setting up a quality control committee.

### ***Researcher training***

All researchers will receive Good Clinical Practice (GCP) training and have clinical expertise, qualifications and appropriate abilities for then study. Prior to the beginning of the project, all subjects enrolled will receive uniform training. Through program training in clinical research, the clinical research of purpose will be fully understood by all researchers including the plan, indicators and CRF documents. Each subject will be issued a "researcher's manual" as a reference guide.

### ***Data management***

This study will be conducted in strict accordance with the phase plan of the trial. After the baseline and 2-week intervention, all data will be recorded into CRF, and then the data in CRF will be uniformly input into Excel by CW and YN Z. We will create a separate folder for storing the data. At the same time, the data will also be transferred to the network disk for backup, so as not to lose data. We also set up a data management team for two people. When there are errors, one person is responsible for finding and correcting the errors, and the other person is responsible for checking the data again.

### ***Ethics***

This study has been approved by the ethics committee of the Shanghai Xuhui District Central Hospital (no. 2017040) and strictly followed the principles of the Helsinki declaration and statement. The trial has

been registered on the Chinese clinical trial website (ChiCTR1800014864). All participants will fully understand the contents of this agreement and sign the informed consent document. To determine whether the members of the committee find it necessary to change the research plan, we will submit a detailed written application to the ethics committee.

## Discussion

Abnormal breathing patterns and trunk posture affect each other in stroke patients [34]. A study has confirmed that breathing training can significantly increase muscle strength and trunk coordination in stroke patients with hemiplegia and also improve respiratory function.[35][36]. It has been reported that respiratory muscle strength training or complex breathing exercises can effectively improve the stability of the trunk posture of stroke patients [37] and it has been proven that resistance training of the thoracic cage can significantly improve respiratory function and the trunk control ability of stroke patients[38]. Nelson proposed that breathing is the foundation of core stability, and core stability is the foundation of movement [39]. Research has shown that abdominal muscle thickness decreases in patients with chronic stroke and that respiratory muscle function is positively correlated with trunk function and balance [40]. Thus, respiratory muscle training should be regarded as part of trunk control training for stroke patients.

LQG is a traditional Chinese breathing training method, with breathing and breathing training at its core. Through 6 words, different mouth types, lips, teeth, throat and tongue force differences can affect different viscera flows [13]. LQG requires the maintenance of an upright posture, relaxation of the neck, and the maintenance of normal positions of the thoracic, spinal and pelvis, which may provide a stable core mechanical environment for stroke patients to exercise correct breathing patterns [41]. Combined with bilateral body and trunk movements, non-invasive opening of the thoracic cavity and increasing the volume of the thorax, may be beneficial to the movement of the diaphragm [15]. Combined with 1 inhalation and 6 exhalations, it guides stable and continuous air flow and controls internal abdominal pressure, which may 'massage' the chest and abdominal viscera, gently activate the weakened core muscle groups, inhibit the over-strained muscle groups, and promote the coordination of trunk core muscles.

We hypothesize that stroke patients with hemiplegia will improve their abnormal trunk posture control through LQG exercises, increase their respiratory control ability and improve their core stability. We hope that stroke patients can gradually learn to transition from single thoracic breathing to abdominal breathing by practicing the combination of LQG motor guidance and mouth type. Only this breathing training method can maximize the coordination of breathing and trunk posture, which is readily accepted by patients. Therefore, the purpose of this study is to compare the effects of LQG with traditional core stability training on trunk posture control after stroke.

A TIS is an evaluation method to test the effects of improvement of main trunk functions through examination of static balance, dynamic balance and dynamic coordination, which is helpful for neurological diagnosis and treatment guidance [42]. Patients with trunk posture control disorder after

stroke will be selected as study subjects through a TIS and other examinations, including Berg, FMA, ADL, MPT and dynamic and static balance function. A comprehensive evaluation of the effectiveness of the training therapy will be achieved by measuring the thickness of the diaphragm and the movement of the diaphragm muscles.

To sum up, the proposed study will focus on patients with abnormal trunk posture control and intends to introduce LQG into the rehabilitation of abnormal trunk posture control post-stroke by ensuring that breathing, speech and movement guidance are trained synchronously.

### **Limitations of the study**

The limitations of the proposed study are as follows: 1) Due to the limited medical resources, patients are hospitalized only for a short period of time, with the intervention period of the study being only 2 weeks; 2) no follow-up investigation will be conducted after the intervention; 3) single or double blind observations will not be achieved; (4) In the study, surface myoelectricity will not be used to test the activity of the trunk muscle group, and abdominal pressure test tools will not be used to reflect changes in abdominal pressure.

### **Current trial status**

The version number of this trial scheme is the first version, December 25, 2017. Patient recruitment began on 1 March 2018 and is expected to continue for 3 years, and patient recruitment will end on March 1, 2021.

## **Abbreviations**

BBS: Berg Balance Scale; MBI: Modified Barthel Index; FMA: Fugl-Meyer Assessment; TIS: Trunk Impairment Scale; MPT: Maximum Phonation Time; TDI: Ultrasound Measurements of the Diaphragm Thickness; D/M: Ultrasonic Measurement of Phrenic Muscle Mobility; DST: Dynamic and Static Testing. CR, Complete response; PR, Partial response; NR, No response.

## **Declaration**

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### **Availability of data and material**

The datasets supporting the conclusions of this article will be included in the published article.

## Authors' contributions

All authors will be responsible for the design of the research program and the analysis of data. In addition, CW, JY and LY will be responsible for data acquisition and statistical analysis. All authors will participate in the writing of manuscripts; CW and YZ will be responsible for revising and annotating the manuscript and approving the final draft. All the authors will read and approve the final manuscript submitted for publication.

## Ethical approval and consent to participate

Our study will be performed in accordance with the Declaration of Helsinki with regard to ethical principles for research involving human subjects. The study protocol will include written informed consent from all the participants and approval by the Shanghai Xuhui Central Hospital Ethics Committee. (Ethical approval number:201740).

## Consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

## Acknowledgements

Not applicable.

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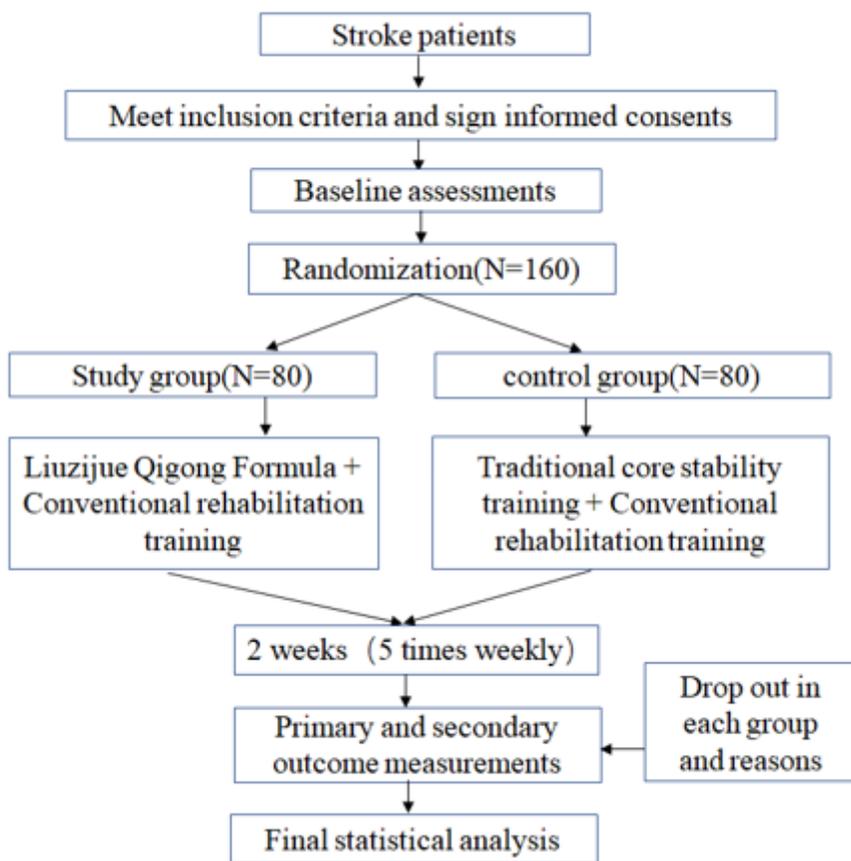
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## Additional File Legend

**Additional file 1:** SPIRIT 2013 Checklist. (DOCX 130kb)

## Figures



**Figure 1**

Flowchart of the study design

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
Timepoint**	wk 0	wk 0	wk 0	wk 2	wk x
<b>ENROLMENT:</b>					
Eligibility Screen	x				
Informed consent	x				
Trunk Impairment Scale, (TIS)	x				
sitting balance	x				
Unilateral upper-limb movement function	x				
Allocation		x			
<b>INTERVENTIONS:</b>					
<i>Six character formula (study group)</i>			x	x	
<i>Traditional core stability training</i>			x	x	
<i>Conventional rehabilitation training (control)</i>	x		x	x	
<b>ASSESSMENTS</b>					
TIS scores in 6-17, and the sitting balance >2 levels					
<b>Primary outcome:</b>					
<i>TIS</i>			x	x	
<b>Secondary outcome</b>					
<i>FMA, MBI, BBS, TDI, MPT, D/M</i>			x	x	
<i>Dynamic and static balance test</i>			x	x	
<i>Adverse event</i>			x	x	

Figure 2

SPRIT figure of the liuzique Qigong study protocol

## Supplementary Files

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