Inspiratory muscle training combined with Tai Ji improves balance after stroke:a protocol for a Single-center randomized controlled trial

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Research Article

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Inspiratory muscle training combined with Tai Ji improves balance after stroke:a protocol for a Single-center randomized controlled trial

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Abstract

Background: Balance dysfunction is the main manifestation of patients after stroke in clinic, which leads to unstable gait and seriously affects the prognosis of patients. The first prerequisite to improve the balance dysfunction is to increase the exercise of lower limbs. Previous clinical studies have found that besides Chinese traditional Tai Ji training, inspiratory muscle training can enhance the intra-abdominal pressure, promote the stability of spine and pelvis, and improve the balance function of patients by enhancing their cardiopulmonary function. However, it still needs further proof from large sample research. The overall goal of this experiment is to further evaluate the clinical effect of inspiratory muscle training combined with Tai Ji to further improve the balance function of patients after stroke.

Methods/design: This trial is a randomized controlled trial, which will compare the superiority of Tai Ji training and inspiratory muscle combined with Tai Ji training in improving the balance function of stroke patients. Patients are randomly divided into

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two groups, namely Tai Ji group and inspiratory muscle training group. Recruit 62 inpatients with stroke who meet the test criteria, and observe the improvement of balance function after 4 weeks of intervention. The first evaluation index is American balance manager balance test system. The second evaluation index is diaphragm ultrasound, berg balance scale and trunk injury scale.

Discussion: To evaluate the efficacy of inspiratory muscle training combined with Tai Ji in improving balance function of patients after stroke. The results of this study will provide more evidence for the clinical application of this therapy in the future.

Trail registration: Chinese Clinical Trial Registry (ChiCTR)， ID：ChiCTR2100054576，Registered on 20 December 2021.

Keywords: inspiratory muscle training,Tai Ji, balance,diaphragm

Background:

With the gradual aggravation of the aging population in China, the prevalence rate of stroke has increased significantly in the past 30 years[1]. At present, the number of stroke patients in China ranks first in the world and shows an increasing trend gradually. According to some research, it is estimated that the incidence of stroke in China will increase by 50% in 2030 compared with that in 2010[1]. Stroke has the characteristics of high incidence, high recurrence rate, high disability rate and high mortality rate. Clinically, balance dysfunction is common in stroke patients. Balance dysfunction is one of the important risk factors for stroke patients to fall, and it has seriously affected the quality of life of patients[2]. The balance function of the human body is positively correlated with core stability[3], and the improvement of core stability is mainly

dependent on the relaxation and contraction of the waist and abdominal muscle groups[4]. Based on the physical and economic conditions of clinical patients, in addition to the conventional physical therapy and occupational therapy, Chinese medicine, acupuncture, hyperbaric oxygen, and orthoses are used as auxiliary treatments to improve the balance function of patients with stroke. Each treatment has merits and demerits. From the perspective of traditional Chinese medicine, patients after stroke mainly present with qi deficiency and blood stasis as the main clinical manifestations[5]. Based on this theory, the therapeutic methods of ‘benefiting qi and resolving stasis’[6] and ‘fu zheng bu tu’[7] are proposed. At the same time of dredging meridians and collaterals, they pay attention to the regulation of the yin, yang, and qi and blood in the patients’liver, spleen, kidney. In order to achieve the goal of treating both manifestation and root cause, they are proved to be conducive to improving the symptoms of numbness and sensory deficiency of the lower limbs[7], improving the muscle strength of the lower limbs and enhancing the balance.However, acupuncture manipulation is excessively dependent on professionals' manipulation, and often requires the selection of multiple acupoints to achieve the curative effect. In addition, the selected acupoints of each research group are also different, which is not conducive to clinical promotion[8]. The network structure in the brain stem affects the higher nervous activity of the cerebral hemisphere upward, which is related to the cognition, movement and feeling of the human body, and plays a two-way role of inhibition and excitement. Under the treatment of hyperbaric oxygen[9], the carotid blood flow is decreased, while the vertebral artery blood flow is increased, resulting in an increase in

the partial pressure of oxygen in the brainstem reticular formation system, which is beneficial to ascending activation of the system, promotion of awakening and vital center functional activities, thereby improving the patient's balance function and walking ability. However, hyperbaric oxygen treatment is costly, and long-term application will increase the economic burden on patients' families and society. Although orthoses can improve the gait stability index of patients[10], their effects are bidirectional in patients with mild ankle injury, and their clinical promotion has certain limitation. But our team has found in clinical practices that the above-mentioned methods are excessively dependent on relevant instruments and equipment and therapists' operation, so that patients' active participation and enthusiasm are not so high. Moreover, they will not receive continuous and effective rehabilitation training after being discharged from hospital, making their conditions prone to relapse.

At present, respiratory muscle training is often used to improve the cardiopulmonary function of patients with COPD[11,12], and has achieved good therapeutic effects. In recent years, many people have applied respiratory training to the treatment of patients with stroke[13-15]. It has been proved that respiratory muscle training can effectively improve the trunk control ability, lung function and respiratory muscle movement in the trunk of patients after stroke[16,17].The respiratory muscles are divided into inspiratory and expiratory muscles, and diaphragm, as the inspiratory muscle, is often used for training in clinic. Meanwhile，during the practice of Tai Ji, abdominal breathing is mainly used to increase the diaphragmatic relaxation and contraction force, thus increasing the rise and fall of the diaphragm, making the

abdominal pressure and chest pressure constantly changing, ensuring that respiratory organs receive adequate blood supply, thereby significantly improving lung ventilation function, which is conducive to human blood flow and heart function[18-20]. The elderly who have participated in the Tai Ji exercise for a long time not only receive increased oxygen per second, minute and hour, but also have increased expiration time and vital capacity, thus effectively improving the lung tissue elasticity as well as lung ventilation and air exchange function of the elderly[21]. Abdominal breathing, which is used in the Tai Ji, is also a training method for the inspiratory muscle, thus enhancing the diaphragmatic muscle strength to a certain extent and improving the stability of the trunk. And Tai Ji input a lot of information into the central nervous system[22], increase the activity of cerebral cortex, stimulate the blood circulation of brain, accelerate the establishment of cerebral collateral circulation, increase the excitability of nerve cells that have not yet necrotic in the focus, and reorganize or compensate the surrounding tissues or contralateral brain cells, promote the recovery and compensation of neuron function, make the function be reconstructed to the greatest extent, promote the remodeling of nervous system function, thus forming a new neural pathway [23], and further promote the recovery of balanced function of stroke patients. The long-term training of Tai Ji can stimulate the right brain of human body, thus improving the coordination of human movement[24], and then correcting the posture imbalance of stroke patients. On the basis of this theory and clinical trials of the effectiveness of Tai Ji,we has applied the inspiratory muscle training combined with Tai Ji to patients with balance dysfunction after stroke, and has obtained relatively good improvement results.

However, its cumulative effect, long-term efficacy and the superiority between the two need further clinical research. As a result, we recommend this prospective clinical trial to further evaluate the clinical efficacy of inspiratory muscle training combined with Tai Ji in improving balance dysfunction in patients after stroke.

Trial objectives

The objectives of this trial are as follows:

1. Verify that inspiratory muscle training combined with Tai Ji can further improve the balance function of stroke patients

2. Provide more basis for the clinical application of this therapy in the future.

Methods/design

Trial design

This is a prospective, randomized controlled trial. The trail will be conducted in the Second Rehabilitation Hospital of Shanghai. Patients who met the predetermined criteria will be randomly divided into two groups: the control group receiving Tai Ji training, and the experimental group receiving Tai Ji combined with inspiratory muscle training. The specific treatment plan in the control group is 5 minutes of breathing adjustment, 30 minutes of Tai Ji and 5 minutes of rest adjustment. The specific treatment plan in the experimental group is 30 minutes of Tai Ji and 10 minutes of inspiratory muscle training. The Tai Ji movements in the control group are the same as those in the experimental group, mainly divided into six movements. The six Tai Chi movements are Commencing, Part the Wild Horse’s Mane,Wave Hands Like Clouds, Brush Knee and Twist Step,Reverse Reeling Forearm and Closing derived from the 24

forms of simplified Tai Chi. The main method of inspiratory muscle training is for the patient to use a C-type respiratory trainer, as shown in **Fig** 3. Duration of training was 4 weeks, 5 times per week. The intervention lasted for four weeks, and the study flow chart is shown in **Fig** 1. Details for recruitment plans, interventions and assessment content are shown in **Fig** 2. The setting of this experimental research method follows the SPIRITS principle[25].

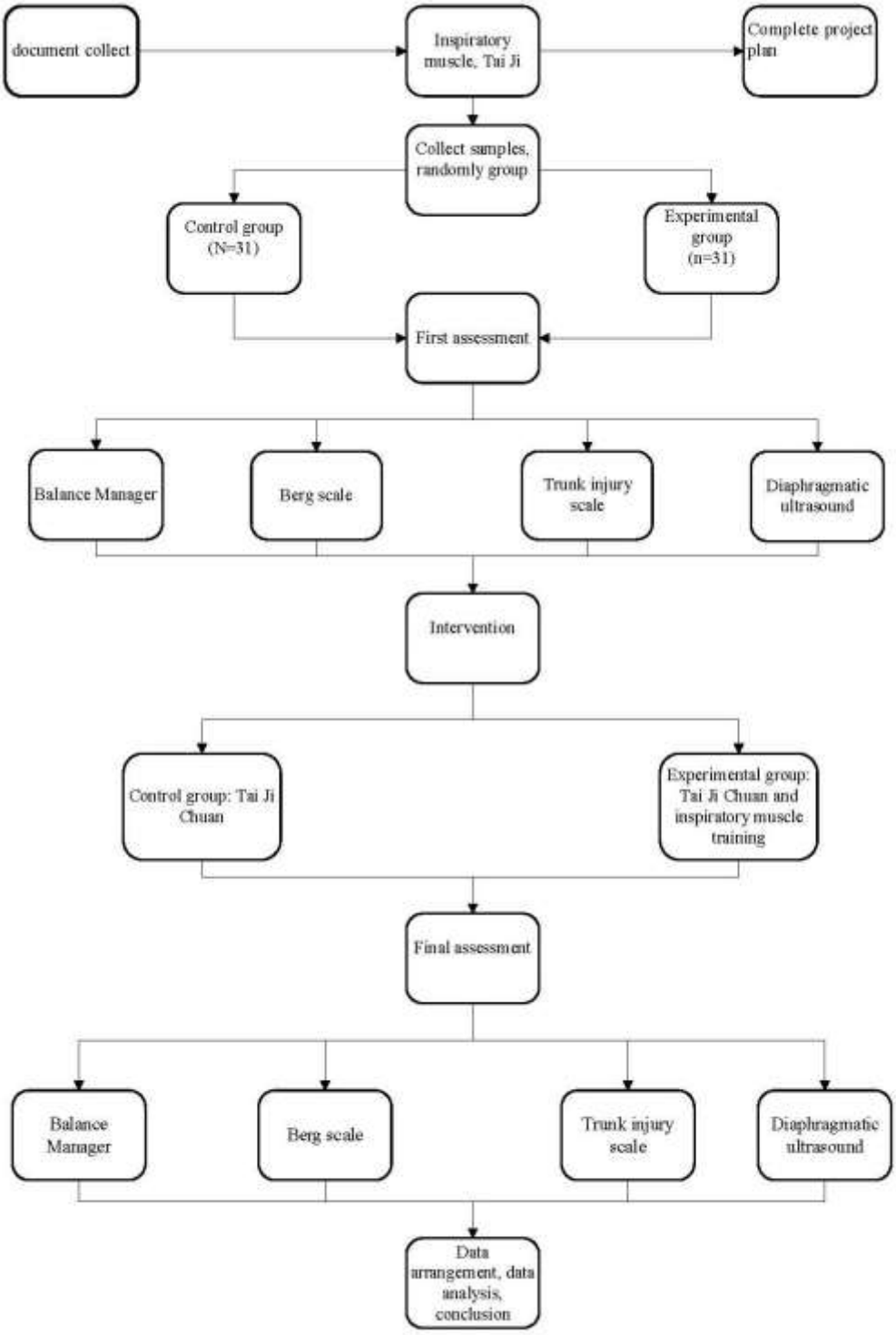

Fig 1 Flow chart of the study

	STUDY PERIOD							
TIMEPOINT	**Enroll-ment**	**Allocation**	**Before-Intervention**	**Intervention**				**Post-Intervention**
				1st	**2ed**	**3rd**	**4th**	
ENROLLMENT								
Demographic information informed	√							
Pulmonary ventilation	√			√	√	√	√	
Informed consent	√							
ALLOCATION		√						
INTERVENTIONS								
Control group				√	√	√	√	
Experimental group				√	√	√	√	
ASSESSMENTS								
Balance manager			√					√
Berg scale			√					√
Trunk injury scale			√					√
Diaphragma-tic ultrasound			√					√

Fig.2 Example template of recommended content of the schedule,interventions,and assessments

Fig 3

Ethics

The ethical approval for this study is granted by the Ethics Committee of Shanghai No.2 Rehabilitation Hospital on December 1, 2021 (referenceNo. 2021-05-01).The protocol, patient information sheet, and informed consent form are approved by the Ethics Committee. Informed consent will be provided by all participants. The participants' real names will not appear in the relevant reports of the trial to protect their privacy.

Study setting

The subjects are inpatients in Shanghai Second Rehabilitation Hospital. Shanghai Second Rehabilitation Hospital will be responsible for trial coordination and data management.

Sample size

Our study will be designed as a randomized controlled trial, the main result of which is whether the balance dysfunction after stroke is relieved after treatment. According to the formula $((z-\alpha+z-\beta)\ 2\ *\ 2\sigma^{2})/\delta^{2}$, $\alpha=0.05$, = 1.96; $\beta=0.9$, = 1.28, according to the literature[26]: $\sigma=0.1149$, $\delta=0.1045$, after calculation, n=26, considering the drop-off rate of 15%, each group included 31 patients.

Inclusion criteria

① Patients who met the diagnostic criteria for ischemic stroke or cerebral hemorrhage, and the transcranial brain CT and/or MRI examinations confirmed that the patients are in the post-stroke recovery period.

② Patients are aged from 45 to 80 years

③ Patients had stable vital signs and physiological stability. There is spontaneous breathing

④ There is no obvious sensory impairment, cognitive impairment and intellectual impairment, and assessment could be well coordinated. Ability to understand and actively cooperate with the development of respiratory muscle training

⑤ Evaluation of voluntary cooperation therapy by family members and patients

⑥ Brunnstrom stage of lower limb reaching stage IV or above; Lower limb muscle strength of 3 or more; Muscular tension of lower limbs shall not exceed grade 1.

⑦ Functional ambulation category scale (FAC) reaches grade 2 or above.

⑧ There is respiratory myotonia.

Exclusion criteria

① Vital signs are unstable, and hemodynamics is unstable.

② Patients with severe heart, liver, kidney, lung and other organ diseases, severe hypertension, diabetes and intestinal diseases.

③ Patients with congenital thoracic deformity and rib fracture or patients with thoracoabdominal combined operation in the past three months

④ Patients with balance dysfunction caused by other nervous system diseases

⑤ Patients with respiratory muscle dysfunction caused by respiratory system diseases and other nervous system diseases

⑥ Patients with tracheostomy and mechanical ventilation without spontaneous breathing

⑦ Patients with severe cognitive impairment or consciousness disorder

⑧ Patients with severe joint lesions, fracture healing stage

⑨ Patients with severe kyphoscoliosis

⑩ Patients with venous thrombosis

Elimination criteria

① Patients who are wrongly admitted or misdiagnosed

② During the trial, the volunteers voluntarily requested to quit or participate in other similar treatments.

Recruitment

Patient recruitment commenced on 1 November 2021 and will be completed in May 2023 or after the required number of patients is obtained, whichever is earlier. We will develop a plan and method of contacting subjects, including preparing an informed consent form and obtaining the necessary data, videos, and images to help subjects

understand the purpose and procedures of the trial. Subjects will also be explained the benefits and disadvantages of treatment and the related safety measures taken during the trial. In addition, we will post recruitment posters inside and outside the hospital, or use the Internet for recruitment. The research group will preliminarily judge the possibility of inclusion of each subject according to the inclusion/exclusion criteria, conduct relevant audit on it after signing the informed consent, and finally confirm whether each subject really meets the inclusion/exclusion criteria according to the audit results.

Randomization

After informed consent is signed, inpatients with stroke meeting the inclusion criteria will be randomly divided into routine training combined with Tai Ji group and inspiratory muscle training combined with Tai Ji group in this study. First, the random number tables generated, and then the random numbers are grouped in a 1: 1 ratio. The random numbers are managed by special personnel. Treatment assignment lists are generated from a set of computer-generated random numbers, and randomization sequences are stratified by assigned personnel. Strips of paper revealing treatment dispensing are placed in sequentially numbered sealed opaque envelopes. With informed consent, the envelopes are opened one after the other.

Intervention

The interventions in the two groups are as follows:

1. Control group

   The starting formula in the 24 type Tai Ji; Left and right wild horse bristle; Roll

back the left and right humerus; Cloud hands; Seabed needles; For example, closing six movements for training, 40 minutes for each training, 5 minutes for respiratory relaxation training, 30 minutes for Tai Ji, and 5 minutes for rest adjustment. The training will be conducted four times a week and lasted for four weeks.

2. Experimental group

   On the basis of the treatment in the control group, threshold load inspiratory muscle training is carried out at the same time, once for 10 minutes, five times a week for 4 weeks.

Uniformity in Tai Ji performance

To ensure consistency in Tai Ji training, qualified physicians will be assigned to train physicians from other participating units, treat patients one-on-one, and monitor procedures to ensure qualified performance prior to the trial.

Outcome measures

Treatment evaluations will be performed by the same team member who will not be aware of treatment assignment.

First evaluation indicator is as follow(**Table** 1)

Balance Manager

1.Limits of Stability

OUTCOME / DIRECTION	RT (sec)		MVL (deg/sec)		EPE (%)		MXE (%)		DCL (%)	
	Start	End	Start	End	Start	End	Start	End	Start	End
Front										
Back										
Affected side										
Normal side										

2.Rhythmic Weight Shift Interpretation

Left/Right		
	On-Axis Velocity	Direction control
Start		
End		
Front/Back		
	On-Axis Velocity	Direction control
Start		
End		

3.Sit to Stand

CONTENT	OUTCOME	
	Start	End
Weight Transfer		
Rising Index		
COG Sway Velocity		
Left/Right Weight Symmetry		

4.Walk Across

CONTENT	OUTCOME	
	Start	End
Step Width		
Step Speed		
Step Length		
Step Symmetry		

Table 1

Stability limit test, walking test, sitting test, and center of gravity transfer test in the balance manager balance test system in the United States. The device is used for

evaluation before and after treatment.

Secondary evaluation indicators are as follows:

(1) diaphragmatic ultrasound(**Table** 2)

① Diaphragmatic thickness(end of expiration)

② Diaphragm thickening fraction [DTF= (Diaphragmatic thickness (end of inspiration)-Diaphragmatic thickness(end of expiration)/ Diaphragmatic thickness(end of expiration)], and the 20% thickening rate is taken as the effective training standard.

③ Diaphragmatic excursion: the average value of the three determinations is taken.

(2) Berg balance scale

Scoring criteria and clinical significance: the maximum score is 56 points, and the minimum score is 0 point. The higher the score is, the stronger the balance ability is. 0–20 points, poor balance, the patient needs to take a wheelchair; 21–40 points, with a certain balance ability, the patient can walk with the help of; 41–56 points, good balance, the patient can walk independently. (A score below 40 indicates the risk of falling)

(3) Trunk injury scale，**Table** 3

Scoring criteria and clinical significance: the scale score range is 0–16 points, the higher the score, the milder the damage of trunk control.

All measurements will be recorded in the data center.

Diaphragmatic ultrasound

NAME: _____ **GENDER:** _____ **AGE:** ____

Inpatient number: _____ **DATE:** _____

NUMBER	CONTENT	OUTCOME
1	diaphragmatic thickness (end of inspiration)	
2	diaphragmatic thickness(end of expiration)	
3	diaphragm thickening fraction	
4	Diaphragm thickness (end of deep inspiration)	
5	Diaphragm thickness (end of deep expiration)	
6	diaphragm thickening fraction(deep breathing)	
7	diaphragmatic excursion	
8	Diaphragmatic contraction time	
9	Diaphragmatic contraction velocity	
10	diaphragmatic excursion(deep breathing)	
11	Diaphragmatic contraction time (deep breath)	
12	Diaphragmatic contraction velocity (deep breath)	

*1. Diaphragm thickness

Under calm breathing, the normal value of diaphragmatic thickness at end expiration was 2.7±0.5mm, which was less than 2.0mm, suggesting diaphragmatic dysfunction.

2.Diaphragmatic excursion (positively correlated with FVC and FEV1 of pulmonary function indicators in subjects):

① Under the condition of calm breathing, the normal values of men and women were 1.8±0.3cm and 1.6±0.3cm respectively. Less than 1.0cm suggests diaphragmatic dysfunction

② Under deep breathing condition, the normal value of men was 4.7cm and that of women was 3.6cm

3. Under calm breathing, the normal value of diaphragmatic thickening rate is 37 9%, which is less than 20%. This indicates diaphragmatic dysfunction

Table 2

Trunk Injury Scale

CONTENT			
Static sitting balance (total 7')			
1	Initial pose	Without arm support, the patient falls or cannot hold the Initial pose10 for 10 seconds.	0'
		The patient can hold the Initial pose10 for 10 seconds(Note: if 0' is obtained, TIS total' is 0')	2'
2	Initial pose	Without arm support, the patient fell or was unable to maintain a sitting position for 10 seconds.	0'
	The therapist placed the unaffected lower limbs crosswise on the affected lower limbs.	The patient can maintain the sitting position for 10 seconds.	2'
3	Initial pose	Patient falls.	0'
	The patient placed the unaffected lower limbs crosswise on the affected lower limbs.	Patients cannot cross legs without arm support on the bed or treatment bed.	1'
		The patient is able to cross the legs, but the trunk will move more than 10 cm backwards, or cross the legs with the aid of a hand.	2'
		The patient is able to cross the legs without torso movement or assistance.	3'
Dynamic sitting balance (total 10')			
1	Initial pose	The patient falls and needs upper limb support or the elbow cannot reach the bed.	0'
	Instruct the patient to touch the bed or cot with the hemiplegic elbow and return to Initial pose.	The patient does not need help to move actively and the elbow can reach the bed (If 0' is obtained, then 0' is obtained for 2 and 3 items.)	1'
2	Repeat item 1	The patient did not exhibit shortening/lengthening of the trunk, or vice versa	0'
		The patient showed proper trunk shortening/lengthening.If you get 0', item 3 gets 0'	1'
3	Repeat item 1	Patient compensation. Possible compensations include (1) using upper limb (2) abduction of contralateral hip (3) hip flexion (4) knee flexion (5) foot sliding.	0'
		There is no compensation when the patient moves the trunk.	1'
4	Initial pose	The patient falls and needs upper limb support	0'

		or the elbow cannot reach the bed.	
	Instruct the patient to touch the level bed with the unaffected elbow and then return to Initial pose.	The patient does not need help to move actively and the elbow can reach the bed.(If 0' is obtained, 0' is obtained for 5 and 6 items.)	1'
5	Repeat item 4	The patient did not exhibit shortening/lengthening of the trunk, or vice versa	0'
		The patient showed proper trunk shortening/lengthening. 0' for item 6 if 0'	1'
6	Repeat item 4	Patient compensation. Possible compensations include (1) using upper limb (2) abduction of contralateral hip (3) hip flexion (4) knee flexion (5) foot sliding.	0'
		There is no compensation when the patient moves the trunk.	1'
7	Initial pose	The patient did not exhibit shortening/lengthening of the trunk, or vice versa	0'
	Instruct the patient to lift the hemiparetic pelvis from the bed and back to Initial pose.	The patient showed proper trunk shortening/lengthening. If you get 0', item 8 gets 0'	1'
8	Repeat item 7	Patient compensation. Possible compensations are as follows: (1) Use upper limb (2) Use ipsilateral foot pedal (heel loses contact with ground)	0'
		The patient can move the pelvis without compensation.	1'
9	Initial pose	The patient did not exhibit shortening/lengthening of the trunk, or vice versa	0'
	Instruct the patient to lift the pelvis of the unaffected side from the bed and back to Initial pose.	The patient showed proper trunk shortening/lengthening. If you get 0', item 10 gets 0'	1'
10	Repeat item 9	Patient compensation. Possible compensations are: (1) using upper limb, (2) using ipsilateral foot pedal (the heel loses contact with the ground).	0'
		The patient can move the pelvis without compensation.	1'

COORDINATION 共 6'			
1	Initial pose	Hemiplegic side did not move 3 times	0'
	Instruct the patient to rotate the upper torso for 6 times (the shoulders on each side should move forward for 3 times), and the first side to move must be the hemiplegic side, and the head should be fixed at the Initial pose.	The rotation is asymmetric.	1'
		The rotation is symmetrical. If you get 0', item 2 gets 0'	2'
2	Repeat item 1 within 6 second.	The rotation is asymmetric.	0'
		The rotation is symmetrical.	1'
3	Initial pose	Hemiplegic side did not move 3 times	0'
	Instruct the patient to rotate the lower torso 6 times (the shoulder on each side should be moved forward 3 times), the first moving side must be hemiplegic side, upper body should be fixed in Initial pose)	The rotation is asymmetric.	1'
		The rotation is symmetrical. If you get 0', item 4 gets 0'	2'
4	Repeat item 3 within 6 second.	The rotation is asymmetric.	0'
		The rotation is symmetrical.	1'

* The starting posture of all events is the same, the patient is sitting at the bedside or the treatment bedside, and the subject's back and arm can't have any support. The thigh is fully in contact with the bed surface or treatment bed, and the distance between the two feet is the same width as the two hips, and is squared on the ground. Bend your knees 90 degrees. Put your arms on your legs. If the patient's tension is too high, the position of hemiplegic arm will be taken as the starting posture. And the head and torso are in the midline position.
If the patient's score in the first item is 0, then the trunk injury scale score is 0. Each test can be conducted for 3 times. Record the highest score. Practice is not allowed. Between each attempt, the patient can be corrected.

Table 3

Harms

In our study, an adverse event will be defined as any adverse medical event in the subject, regardless of the likelihood of causality. Adverse events will be collected after

subject consent and participation in the study. If an adverse event occurred after the subject's informed consent document was signed (entered) but the subject has not yet started study intervention, the event will be reported as unrelated to Tai Ji and inspiratory muscle training. All adverse events that occurred after enrollment into the study and prior to discharge will be recorded. Adverse events that meet the serious adverse events (SAE) criteria between study enrollment and discharge will be reported to the local institutional review committee.

Data management

Data collection

All information should be accurately and promptly recorded on a Case Report Form (CRF). The scale evaluator undergoing rehabilitation training will be responsible for evaluating the berg scale, the trunk injury scale, while other scales and case reports will be recorded by the investigator. During the experiment, special personnel will be required to manage the relevant data, and the personal information of participants will be strictly confidential. All data will be identified using participant numbers that do not directly display the participant's personal information. Data will not be shared without explicit permission from the investigator. At the end of the trial, study participants should submit the CRF in a timely manner and a test summary as required. A supervisor will be assigned by the study center to review the completeness and accuracy of the CRF.

Case report form

In the trial, the content recorded in the CRF should be consistent with the original

material. The CRF must meet the following criteria:

1. Data must be entered with a black pen and signed

2. If the participant has received more than 2 weeks of intervention and evaluation, the data of the volunteer should still be recorded and counted

3. If an error occurs in the record and needs to be corrected, the recorder should draw a horizontal line under the original record, then sign the amendment and indicate the date of correction. Note that it must be ensured that the original

record is identifiable after modification.

Database management and quality control

The team will take effective measures to control quality. Data from the CRF will be entered centrally into the database. Data entry personnel perform manual inspection when data is entered for the first time and perform system inspection after all data entries are completed. After final confirmation, the database is locked and saved. Any future changes to the database must be agreed in writing with the Clinical Study Director, statistician, and data administrator.

Data analysis

Statistical analysis

① The measurement data are all expressed as mean standard deviation ($\bar{x}$s). If the data of the two groups both conformed to the normal distribution and homogeneity of variance, the paired t-test would be applied for intra-group front-to-back comparison, and a difference of statistical significance would be indicated if $P<0.05$. Independent sample t-test is used for comparison between groups, and the

difference is statistically significant with $P<0.05$. If the data did not conform to the normal distribution and homogeneity of variance, Wilcoxon nonparametric rank sum-test is used.

③ The grade data are expressed as average rank, and the difference is statistically significant when $P<0.05$ using Wilcoxon nonparametric rank sum test.

Discussion

The enhancement of balance function in patients with stroke is particularly important for patients to improve their ability to live daily and return to family and society.Therefore, to take effective treatment measures to improve the balance function as efficiently as possible is a very key step.This group has completed the preliminary clinical observation of 62 patients with post-stroke balance dysfunction treated with six moves in Tai Ji and two patients with post-stroke balance dysfunction treated with six moves in Tai Ji combined with inspiratory muscle training.The results showed that the inspiratory muscle training combined with Tai Ji could improve the patient's balance function.However, its cumulative effect, long-term efficacy and the superiority between the two interventions need further clinical research. Therefore, we present a prospective, randomized clinical trial to further evaluate the clinical efficacy of inspiratory muscle training combined with Tai Ji in improving balance dysfunction in patients after stroke.

In order to reduce the interference of subjective factors on scale evaluation, we included diaphragm ultrasound to judge the improvement of patients' balance function. We firmly believe that the results of this study will lay a foundation for the improvement of balance function after stroke.

Trial status

The total registration period is one year. The recruitment of patients began on November 1st, 2021, and the recruitment of patients is expected to be completed in May, 2023.

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Authors’contributions

Wang Xiaolei conceived and designed the study and is responsible for it. Su Jianqing is the main executor of the study and drafted the manuscript. Feng Wei and Zhu Lin participated in the design of the study and helped draft the manuscript. All authors have read and agreed to the final manuscript.

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Availability of data and materials

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

Ethics approval and consent to participate

The Ethics Committee of the Second Rehabilitation Hospital in Shanghai has approved the ethical approval for this study (ReferenceNo. 2021-05-01). Informed consent will be provided by all participants. The participants' real names will not appear in the trial reports to protect their privacy.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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