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Effect of Baduanjin exercise on cognitive function in patients with post-stroke cognitive impairment: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Poststroke cognitive impairment is one of the most common complications in stroke survivors, and >65% of these patients suffer from cognitive impairment at 12 months following onset, which strongly affects the rehabilitation of their motor function and quality of life. Therefore, it is important to improve the cognitive ability of stroke survivors. As an important component of traditional Chinese Qigong exercises, characterised by the coordination of mind and body with a low exercise intensity, Baduanjin has the potential benefit of improving cognitive ability for patients who had a stroke with cognitive impairment. The primary purpose of this study is to investigate the effectiveness and safety of Baduanjin training on the cognitive function of stroke survivors.

Method and analysis This study is designed as a randomised, two-arm parallel controlled trial with allocation concealment and assessors blinding. A total of 48 participants will be recruited and randomly allocated into the Baduanjin exercise intervention or control group. Baduanjin intervention will last 24 weeks with a frequency of 3 days a week and 40 min a day. Global cognitive function and the specific domains of cognition (ie, memory, processing speed, execution, attention and visuospatial ability) will be measured at baseline, 8, 16 and, 24 weeks after intervention and after an additional 4-week follow-up period, while the motor function and quality of life will be measured at baseline, 24 weeks after intervention and after an additional 4-week follow-up period.

Ethics and dissemination Ethics approval was obtained from the Ethics Committee of Fujian University of Traditional Chinese Medicine Subsidiary Rehabilitation Hospital (approval number: 2016KY-022–01). The findings will be disseminated through peer-reviewed publications and at scientific conferences.

Trial registration number ChiCTR-INR-16009364; Pre-results.

Strengths and limitations of this study

- This protocol presents a rigorous design of a randomised parallel controlled trial that aims to evaluate the effectiveness of Baduanjin exercise on the cognitive function, motor function and quality of life in patients who had a stroke with cognitive impairment.
- A broad measurement tool and multiple measurement time points will be used to judge the effects of Baduanjin exercise on cognitive ability in patients who had a stroke .
- If the result we will reach is positive, then that will provide a powerful evidence of Baduanjin exercise on improve cognitive function, motor function and quality of life in stroke survivors with cognitive impairment.
- The efficacy of a 24-week Baduanjin exercise intervention in patients who had a stroke with cognitive impairment remains to be determined.

INTRODUCTION

Stroke affects 15 million people annually and is a leading cause of death and disability worldwide.[1] In China, there are 6 million patients suffering from stroke, and this number increases at an annual rate of 9%. Stroke is associated with many long-term complications, such as motor dysfunction, language dysfunction and cognitive impairment. Post-stroke cognitive impairment is one of most common complications. Approximately 65% of stroke survivors suffer from some extent to cognitive impairment at 5 years poststroke, and up to a quarter of those stroke survivors with cognitive impairment are more likely to transition to dementia,[2] which is associated with increased disability and a poor quality of life.[3] As a consequence, it is significant to improve the cognitive function as soon as possible to promote functional recovery and improve quality of life in stroke survivors.[4]

Theoretically, pharmacological therapy for cognition function may lead to improved recovery. Current data also indicate that a

number of drugs may have short-term benefits,[5–7] but no drug treatment to date has shown convincing clinical evidence on preventing further cognitive decline or restoring cognitive function for stroke survivors.[8] Thus, increasing attention has been paid to non-drug treatments. Aerobic exercises have been widely recognised because of their obvious effect of improving cognitive ability in stroke survivors.[9–11] However, most stroke patients do not have sufficient compliance to achieve sufficient improvements in aerobic exercise protocols due to an important concern of safety. Therefore, future stoke studies involving aerobic exercise training should determine optimal protocols for individuals with physical limitations.[12] As a mind–body aerobic exercise with mild to moderate intensity, Baduanjin exercise has an emphasis on a combination of symmetrical physical postures, meditative mind and breathing techniques in a harmonious manner, and is one of the most common forms of Qigong that has been practised in China for >1000 years.[13] Compared with complex and lengthy exercise form such as Tai Chi, Baduanjin exercise only consists of eight separate and smooth movements which is less physically and cognitively demanding, and is easier to learn and practice with less limitation.[13 14] Therefore, this exercise is more suitable for older adults, especially patients who had a stroke. Increasing studies have demonstrated that regular practice of Baduanjin exercise was beneficial to improve the physical and psychological outcomes in older people, such as improving blood lipid metabolism and sleep quality, lowering blood pressure, reducing depression and anxiety, and improving physical flexibility.[15–19] Currently, several studies also show that regular Baduanjin exercise could slow normal age-related decline in the memory domain and delay ageing of intelligence in older adults.[20 21] Consequently, the primary aim of this study is to conduct a randomised controlled trial to evaluate systematically the effect of Baduanjin exercise on the cognitive function in patients who had a stroke with cognitive impairment.

METHOD/DESIGN

This report describes a two-arm, randomised, parallel controlled trial with allocation concealment and assessor blinding. The primary purpose is to evaluate the effect of Baduanjin on cognitive functions, including global cognitive ability, and primary cognitive domains, such as memory, attention and visuospatial ability, in patients who had a stroke with cognitive impairment.

This study will be conducted at the Wufeng Community Centre in the Gulou District and the Cangxia Community Centre in the Taijiang District, Fuzhou City, Fujian, China, which are counterpart support communities of the Affiliated Rehabilitation Hospital of Fujian University of Traditional Chinese Medicine. A total of 48 eligible participants will be randomly allocated to either the intervention group (the Baduanjin exercise group) or the control group (the health education group) in a 1:1 ratio. The participants in the intervention group will accept Baduanjin exercise training intervention three times a week and the routine health education once every 4 weeks for 24 weeks, while those allocated to the control group will only receive the routine health education once every 4 weeks for 24 weeks. Primary and secondary outcomes will be measured at baseline, 8, 16 and 24 weeks after intervention and after an additional 4-week follow-up period. A flow diagram of the study design is shown in figure 1. The study protocol is reported according to Standard Protocol Items: Recommendations for Intervention Trials 2013 (SPIRIT). A SPIRIT Checklist and the schedule of enrolment, interventions and assessments are provided in the online supplementary additional file 1 and figure 2.

Patient and public involvement

This trial is currently in the recruitment phase. No patients and/or public has been involved in the trial.

Sample size

Sample size was calculated on the basis of the changes in global cognitive ability after 24 weeks of intervention between comparison groups with a significance level of 5% and a two-tailed critical region. The means and their SDs (mean ±SD) of global cognitive ability in the control and aerobic exercise intervention group were 75.93±4.9 and 81.07±6.16, respectively, at postintervention according to the published literature.[22] A sample size of 40 participants was calculated to ensure the same effect size with 80% power by Gpower V.3.1.9.2 software. Considering a 20% attrition rate, a total of 48 participants is necessary, with 24 participants being assigned to each group.

Study population

The study population is patients who had a stroke with a diagnosis of cognitive impairment living in Fuzhou City. The inclusion and exclusion criteria for the study sample are as follows.

Inclusion criteria

The eligible participants should meet all of the following criteria:

1. Clinical diagnosis of stroke according to the Fourth National Academic Conference on Cerebrovascular Diseases Diagnostic Criteria for All Kinds of Cerebrovascular Disease[23] and confirmed by CT or MRI.
2. Have cognitive impairment diagnosed by Diagnostic and Statistical Manual Disorders (DSM-V).
3. First ever stroke over 3 months.
4. Aged between 45 and 75 years.
5. Be conscious, with stable vital signs.
6. Ability to walk at least 10 m without external force and auxiliary equipment.
7. Written informed consent.

Exclusion criteria

Criteria for exclusion are the following:

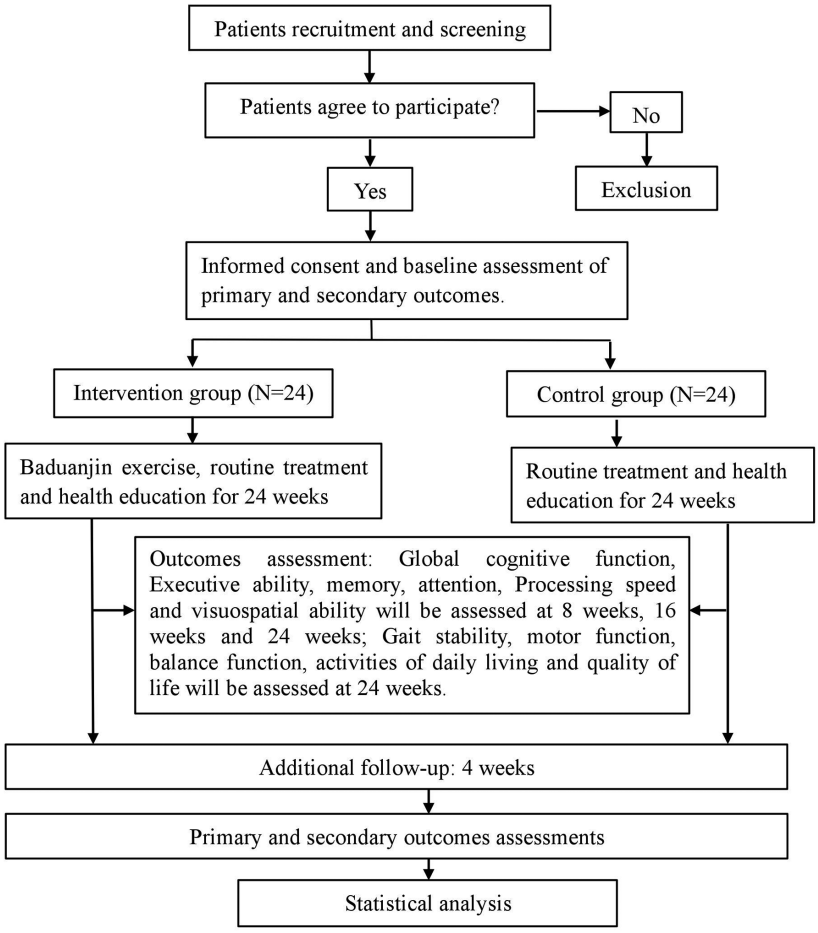

Figure 1 Study design.

1. Have been suffering from brain tumour, brain trauma, brain parasite disease or other diseases that could cause cognitive impairment.
2. Severe language, vision and/or auditory impairment or a neuropsychiatric disorder precluding cognitive examination.
3. Have been suffering from diseases related to cognitive impairment confirmed by anamnesis, doctors or families or with a history of cognitive drug use before stroke.
4. Beck Depression Scale-II score >13.
5. Patients with alcohol or drug abuse.
6. Have been suffering from a severe medical condition, such as heart, liver, kidney and endocrine diseases and haematopoietic system disease.
7. Participating in another clinical trial that would affect the evaluation results of this study.

Withdrawal or dropout criteria

Participants in neither the intervention nor control group will be terminated to continue this trial according to the following criteria:

1. Unwilling to continue this trial.
2. Suffering from the deterioration of stroke disease or other serious organic diseases during the study period.
3. Do not complete the training scheme for 4 weeks during the study period.
4. Those who reject to be measured or followed up.
5. Suffering from the serious adverse event (AE) related to the research.

Recruitment and screening

The recruitment of eligible participants will be conducted by posting up posters on the community publicity column, sending leaflets and setting up a recruiting station at the Wufeng Community Centre in the Gulou District and the Cangxia Community Centre in the Taijiang District, Fuzhou City. The potentially eligible individuals will first complete a screening to determine their eligibility according to the inclusion and exclusion criteria. Eligible individuals will receive the information about this trial and have an informed discussion with two trained research assistants regarding the information provided. Those who are interested in this study will sign the written informed consent, and the baseline assessment will subsequently be arranged.

Randomisation and allocation concealment

After baseline assessment, the eligible participants will be randomly assigned to either the intervention group or the control group with equal rate. The random allocation

STUDY PERIOD						
	Enrolment	Allocation	Intervention			Follow-up
TIMEPOINT*	$-t_1$	0	t_1	t_2	t_3	t_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
ALLOCATION		X				
INTERVENTIONS:						
Intervention group (Baduanjin exercise training+health education)			←	—	→	
Control group (Health education)			←	—	→	
ASSESSMENTS:						
Basic characteristics	X					
Global cognitive function	X		X	X	X	X
Executive ability	X		X	X	X	X
Memory	X		X	X	X	X
Attention	X		X	X	X	X
Processing speed	X		X	X	X	X
Visuospatial ability	X		X	X	X	X
Gait stability	X				X	X
Motor Function	X				X	X
Balance Function	X				X	X
Activities of Daily Living	X				X	X
Quality of Life	X				X	X
Adverse events			X	X	X	

Figure 2 Schedule of enrolment, interventions and assessments. t_1=−2(−1) weeks, 0=baseline, t_1=week B, t_2=week 16, t_3=end of treatment week 24, t_4=follow-up week 28.

sequence will be generated using the PLAN procedure of the statistical software SAS V.9.0 and be managed by an independent research assistant who is not involved in recruitment, evaluation and intervention of the participants. The eligible participants will be informed of their allocation result by the independent research assistant via telephone.

Blinding

In this trial, it is impossible to blind the participants and exercise coaches because this trial investigates a non-pharmacological intervention, but two types of blind codes will be used to blind the outcome assessors and data statisticians. We will assign an independent research manager to be in charge of the random allocation sequence and the blind codes. The participants' allocation result (the intervention group or the control group) will be replaced using alphabet 'A' or 'B' in the first blind code, and the real meaning of 'A' or 'B' will be marked in the second blind code. When the database is locked, the independent research assistant will deliver the group code 'A' or 'B' of participants to the statistician and the real meaning of group 'A' or 'B' will be declared after analysis of all data is completed.

Intervention

All participants will continue routine medical or rehabilitative treatment and maintain usual visits with their primary care physicians throughout the study if necessary. Meanwhile, all of the participants will also receive the same health education programme during the intervention period. The Baduanjin exercise will be applied to the participants in the intervention group, while participants in the control group will be informed to maintain their usual lifestyle.

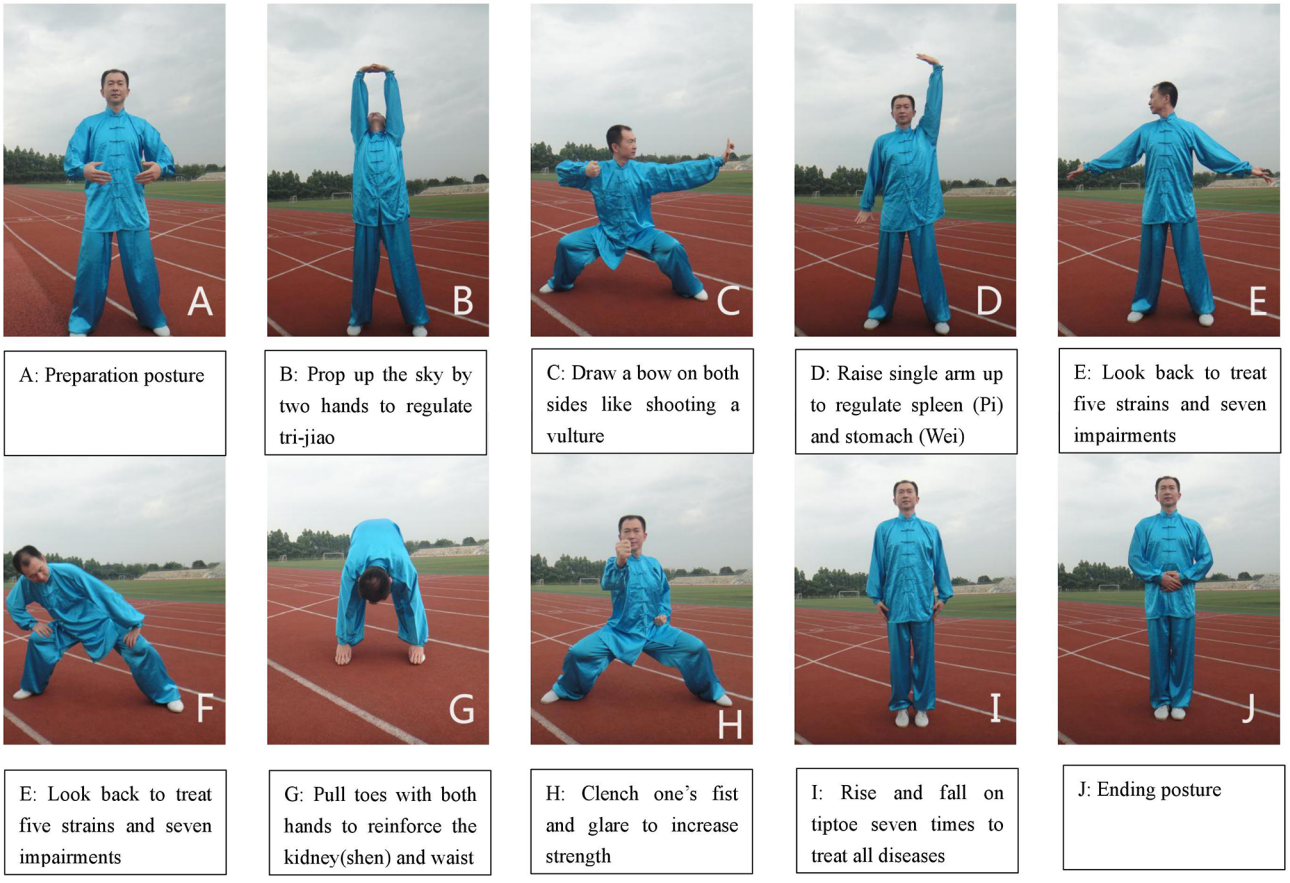

Figure 3 Ten postures of Baduanjin.

The routine medical or rehabilitative treatment will be in accordance with the Chinese Medical Association's Guidelines for the Prevention and Treatment of Cerebrovascular Disease in China (2010).[24] The detailed treatment schedule will be conducted by their primary care physicians and recorded by the research assistants. The health education is conducted by the professional neurologists with a frequency of once a month and 40 min each time. The content of health education primarily involves the knowledge of the prevention and rehabilitation of stroke according to 'Out of the Misunderstanding of Stroke Patients' Rehabilitation' (a bestseller book for health education after stroke from the Chinese Association of Traditional Chinese Medicine).[25]

Intervention group

Participants in the intervention group will receive a 24-week Baduanjin exercise training, at the same time, they also receive routine medical or rehabilitative treatment and health education. The Baduanjin exercise training will last for 24 weeks with a frequency of 3 days a week and 40 min a day. The training scheme of Baduanjin exercise originates from the 'Health Qigong Baduanjin Standard' enacted by the State Sports General Administration in 2003.[26] The whole set of Baduanjin exercise consists of 10 postures (including the preparation and ending posture) (figure 3). The participants will be gathered together to train when there are more than five participants recruited in the same community. Qualified Baduanjin exercise coaches from the Fujian University of Traditional Chinese Medicine with >5 years of teaching experience will be employed to guide participants' training.

Control group

The participants in the control group will not receive any specific exercise training from the study scheme. These participants will be requested to maintain their original habit of lifestyle.

In order to exclude bias from the exceed activity of participants, all participants in both intervention and control group will be required to record an activity log in the intervention period, in which the duration and intensity of their activity in a whole day will be classified into three sections including the duration of low-intensity, moderate-intensity or high-intensity activities.

Follow-up

After the 24-week intervention period, all participants will enter an additional 4-week follow-up period. The participants will resume their original lifestyle during the follow-up period. Telephone follow-up or home visiting will be performed once a week by the research assistants. The information on participants' subjective feeling, medications and daily activities will be recorded. The primary and secondary outcomes will be evaluated at end of follow-up period.

Participant retention and adherence

The success of the intervention is strongly dependent on participants' active participation. To motivate participants' active participation, the staff will use several strategies to improve adherence to the intervention programme: (1) researchers will explain in detail the benefit of practising Baduanjin exercise after participants are randomly allocated into the intervention group; (2) coaches will motivate participants' interest for the Baduanjin exercise training when they instruct participants practising the Baduanjin exercise; and (3) the research assistants will remind participants to practice the Baduanjin exercise according to the study scheme by the WeChat group. In addition, participant who complete the programme successfully will be rewarded with 100 RMB incentive money no matter which group they belongs to. Attendance of the Baduanjin exercise training will be recorded and assessed through records of the proportion of training days. Participants will be marked as absent when they do not attend the training session.

To improve participant retention, once a subject is randomised, the research assistants will make every reasonable effort to ensure the subjects stays for the entire study period. In detail, study assistants will (1) maintain participants' interests by interview and phone calls; (2) provide periodic communications via materials and talks to inform the participants of our acknowledgement of their support; and (3) be as flexible as possible with the study schedule in resolving time conflicts with participants' life.

OUTCOME ASSESSMENT

Primary outcome

Global cognitive function will be measured using the Montreal Cognitive Assessment scale (MoCA). The MoCA scale is a brief test to evaluate the global cognitive ability by testing attention, naming, visuospatial/executive function, memory, language, visual structure skills, abstraction, calculation, and orientation with a total score of 0–30 (a higher score equals better function). The Chinese vision of the MoCA (Beijing version) was revised and is widely used in China with good validity and reliability.[27] Primary outcome will be assessed at baseline, 8, 16 and 24 weeks after intervention and after an additional 4-week follow-up period by the neurologists at the Affiliated Rehabilitation Hospital of FJTCM, who will be blinded to the allocation results of participants.

Secondary outcomes

Secondary outcomes involving the specific cognitive domains (ie, execution, memory, attention, processing speed and visuospatial skill), gait, motor ability, balance ability, activities of daily living (ADL) and quality of life. Executive ability, memory, attention, Processing speed and visuospatial ability will be measured at baseline, 8, 16 and 24 weeks after intervention and after an additional 4-week follow-up period. Gait stability, motor Function, balance function, ADL and quality of life will be assessed at baseline, 24 weeks of intervention and after an additional 4-week follow-up period. All outcome assessments will be measured by the blinded medical staff.

- Executive ability will be assessed using the Trail Making Test (TMT). The TMT consists of two parts, TMT-A and TMT-B: TMT-A requires the participants to sequentially connect 25 encircled numbers on a sheet of paper, while TMT-B requires participants to draw a line alternating between numbers and letters in ascending order between the number and the letter, and the TMT-B/TMT-A is considered as a valid index of executive ability.[28]
- Memory will be measured using the Chinese vision of the Auditory Verbal Learning Test (AVLT).[29] AVLT includes three subtests of immediate recall, short-term-delayed recall and long-term delayed recognition. In the immediate recall test, subject will be requested to repeat immediately a list of 15 unrelated words said by the assessor three times; after 15 min, subject will be asked to recall the 15 words and the correct rate is the score of short-term-delayed recall. In the long-term delayed recognition test, a subject is given another list of 15 unrelated words and must recognise the original list of 15 words.[30] The Chinese version of the AVLT has been reported reliable with split-half reliability, internal consistency and structure validity.[29]
- Attention will be measured using the Test of Attention Performance (TAP, V.2.3), which is based on computer-aided neuropsychological tests for assessing the attentional performance.[31] Four of this test's subtests, including alertness for reaction, general attention, Go/No Go and divided selective attention, will be chosen for this trial.
- Processing speed will be measured by the Digit Symbol Coding (DSC), which is a subtest of the Wechsler Adult Intelligence Scale-Revised China (WAIS-RC) with nine numbers from 1 to 9 and nine corresponding symbols.[32] A subject will be asked to draw each symbol under its corresponding number within a 90 s time limit, and the number of correct answers is its scores.
- Visuospatial ability will be assessed by the Clock Drawing Task (CDT), which is a vision-dependent task.[33] The participants will be asked to draw a clock reading a specific time (generally 11:10). The correctness in clock drawing will be classified according to four categories.[34]
- Gait stability and the interactions between cognitive tasks and gait will be measured by gait analysis.[35] Participants were instructed to walk in two assigned conditions: free walking as usual and walking as usual with executing a calculation task. The gait parameters in two conditions will be measured with the America Motion Analysis gait analysis system, and the numbers of completion and error rates in calculation tasks will be recorded. Those gait parameters mainly comprise step length (cm), stride length (cm), forward velocity

(cm/s), cadence (steps/min), total support time (%), swing time (%), double support time (%), single support time (%) and step width (cm). All these parameters include the affected and unaffected side.

- Motor function will be evaluated using the Fugl-Meyer Assessment scale (FMA), which is known for its good validity and reliability in evaluating upper and lower limb function after stroke.[36] The FMA consists of 50 items based on a six-stage recovery process of Brunnstrom's hemiplegia classification, and 66 points of a possible 100 total score apply to the upper limbs and the other 34 points are applied to the lower limbs.[37]
- Balance function will be measured by the Berg Balance Scale (BBS), which consists of a set of 14 tasks to quantitatively assess the static and dynamic balance abilities.[38] The BBS is not only one of the most important measurement scales to evaluate the balance function of patients after stroke but can also be used as the risk predictor of accidental fall in patients who had a stroke.[39]
- ADL will be assessed using the Modified Barthel Index (MBI), which is a widely used standard scale for assessing functional disability in basic ADL. The MBI contains 10 projects with a total of 100 points, and the higher the score means the better the daily life self-care ability.[40]
- Quality of life will be measured by the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), which is currently the most commonly used in clinical evaluation of quality of life in the general population and patients. The SF-36 consists of 36 items to assess eight health concepts and each of them is evaluated separately by the normalised scores from 0 to 100, with the higher score corresponding to better health status.[41] The Chinese SF-36 has been demonstrated to have high reliability and validity in the Chinese population.[42]

Safety evaluation

Although no AEs are reported currently regarding Baduanjin exercise, any unexpected AEs during the intervention period will be reported to the research assistants, and causality in relation to the Baduanjin exercise training and the severity of AEs will be evaluated. Serious AEs will be reported to the ethics committee immediately.

Data management and monitoring

Data will be collected by the outcomes assessors using the print-based case report forms (p-CRFs), and the p-CRFs will later be inputted into the web-based case report forms (w-CRFs) in an electronic data capture (EDC) system by research assistants. The research assistants are also responsible for the integrity and accuracy of data when data are inputted into w-CRFs by means of checking on value ranges or logical checks. The EDC system and web servers will be provided to the data management centre of FJTCM (http://210.34.74.191/srtp/users/loginlangth.action) and meet the available standards for security (the data management centre, which belongs to the Science and Technology Department of FJTCM, is in charge of the monitoring and auditing of all research data in FJTCM). Participants' data in w-CRFs will be stored in the EDC system in a separate password-protected location. All documents will be retained securely for 5 years after completion of the study.

Statistical analysis

Statistical analysis will be performed using SPSS V.22.0 software package by an independent statistician who is not involved in the outcome assessment, with a two-sided p value <0.05 being considered to be statistically significant. Continuous variables will be expressed using mean and its SE for normal distributions or median and its IQR for non-normal distributions. Categorical variables will be described as frequencies or percentages.

Baseline characteristics between comparison groups will be compared using a t-test or Mann-Whitney U test for continuous variables and Pearson χ^2 or Fisher's exact test for categorical variables.

The analysis of primary or secondary outcomes will be based on an intention to treat (ITT) principle, and the missing data will be imputed using a multiple imputation method. The group difference between intervention and control group at each time point (8, 16 and 24 weeks after intervention or 4-week follow-up period) will be analysed using Student's t-test or Mann-Whitney U-test. Linear models or linear regression will be applied to adjust analysis if incomparability of baseline characteristics between groups appears. The linear mixed model with restricted maximum likelihood will be used to analyse the interaction effect of group×time.

AEs will be analysed using a X^2 test or Fisher's exact test. If the formal statistical analyses between-groups cannot be performed due to the lack of power, AEs will be tabulated and summarised using descriptive statistics.

Ethics

This study protocol conformed to the Declaration of Helsinki. Ethics approval of this study protocol and consent forms were obtained from the Ethics Committee of Fujian University of Traditional Chinese Medicine Subsidiary Rehabilitation Hospital (approval number: 2016KY-022–01). The study background and main objective as well as potential benefits and risks will be fully explained to the participants and their families. Before participating in the study, participants will sign the informed consent document prior to participation.

Dissemination

The study protocol has been registered and is available on the Chinese Clinical Trial Registry website (http://www.chictr.org.cn with the identifier number ChiCTR-INR-16009364). Study results will be first informed to each participant and later disseminated to researchers, healthcare providers, healthcare professionals and the

general public through courses, presentations and the internet, regardless of the magnitude or direction of effect. The results will also be documented in a published peer-reviewed academic journal.

DISCUSSION

As one of the most common forms of Chinese traditional exercises, Baduanjin exercise consists of eight separate movements, each of which focuses on a different physical area of the body.[13] Compared with other aerobic exercises, Baduanjin exercise is not only easy to learn but also is less physical and cognitive demanding.[43] Therefore, Baduanjin has become a popular and safe community exercise to promote health in the community of the older population of China. Furthermore, different from other types of aerobic exercise, Baduanjin is also a mind–body exercise combined with the holistic view and the theory of traditional Chinese medicine in that practitioners are required to reach coordination between mind and body.[14] Several studies have reported that regular Baduanjin training has a positive effect in slowing normal age-related memory decline.[20 21] Zhu *et al* even reported that Baduanjin exercise can delay the cognitive impairment progression for the elderly patients with diabetes with mild cognitive impairment.[44] Therefore, it is reasonable to assume that regular Baduanjin training could be beneficial to cognitive function in patients who had a stroke. This proposed study aims to investigate the effect of Baduanjin exercise on cognitive function, as well as observing the effect on motor function and quality of life in the patients who had a stroke with cognitive impairment. This study will employ rigorousness to control bias, such as randomisation, parallel control and blinding of the outcome assessors and statistician. To ensure participants master standard Baduanjin movements, we will also employ qualified physical exercise teachers to serve as the Baduanjin exercise coaches. However, a potential limitation of this study is that participants and coaches cannot be blinded because it is impossible to make them blinded in non-pharmacological trials.[45] Therefore, performance bias may be inevitable, but the exercise coaches will be not involved in the recruitment, outcome assessment or data analysis of this study. Another challenge that we may encounter for the study is the difficulty in recruiting the eligible patients who had a stroke. Those patients who had a stroke or their families may worry about the exercise risk and prefer to stay in their home and maintain a fairly static life. In addition, a higher dropout rate may also be expected due to the above concerns. To address these problems, we will encourage participants to practise the Baduanjin training at their home after they master this exercise. We also accounted for the higher dropout rate in the sample size estimation to ensure the sufficient statistical power for the study.

In summary, this report describes the first randomised controlled trial to evaluate systematically the rehabilitative effect of Baduanjin exercise on cognitive ability and motor function in stroke patients who had a stroke. This study will determine if Baduanjin training is likely to be effective in improving cognitive function, including global cognitive function and specific cognitive domains, in patients who had a stroke with cognitive impairment. This study will also investigate if Baduanjin training can improve the motor function and quality of life for patients who had a stroke with cognitive impairment and determine if this exercise is acceptable to them. If this trial is successfully conducted and demonstrates a significant result, that intervention would provide an effective rehabilitation approach for patients who had a stroke and adequate supporting evidence for the application of regular Baduanjin exercise in patients with poststroke cognitive impairment. Conversely, if this exercise training is not effective, the study will identify the factors that contributed to the negative outcome.

Trial status

This trial is currently in the recruitment phase.

Contributors LC and GZ: conceived and designed of the study protocol and contributed to drafting the manuscript. YZ and ZX: wrote the manuscript and participated in the coordination and implementation of the study. GZ: revised the study protocol and wrote several sections of the manuscript. BY and JT: helped develop the study measures and data collection. All authors contributed to drafting the manuscript and have read and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval The Ethics Committee of Fujian University of Traditional Chinese Medicine Subsidiary Rehabilitation Hospital.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Data will be collected by the outcomes assessors using the print-based case report forms (p-CRFs), and the p-CRFs will later be inputted into the web-based case report forms (w-CRFs) in an electronic data capture system (EDC) by research assistants. The research assistants are also responsible for the integrity and accuracy of data when data are inputted into w-CRFs by means of checking on value ranges or logical checks. The EDC system and web servers will be provided to the data management centre of FJTCM (http://210.34.74.191/srtp/users/loginlangth.action) and meet the available standards for security (the data management centre, which belongs to the Science and Technology Department of FJTCM, is in charge of the monitoring and auditing of all research data in FJTCM). Participants' data in w-CRFs will be stored in the EDC system in a separate password-protected location. All documents will be retained securely for 5 years after completion of the study.

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