Title: Baduanjin qigong improves balance, leg strength and mobility in individuals with chronic stroke: a randomized controlled study

Authors:

Mandy Yuen,[1,2](DHSc), H.X. Ouyang[2] (MPhil), Tiev, Miller[2] (MSc), Marco Y. C. Pang[2] (PhD)

Affiliations:

1. Physiotherapy Department, Queen Elizabeth Hospital, Kowloon, Hong Kong
2. Department of Rehabilitation Sciences, Hong Kong Polytechnic University, Hong Kong

Corresponding author:

Marco Y. C. Pang, Department of Rehabilitation Sciences, Hong Kong Polytechnic University, Kowloon, Hong Kong.

Email: Marco.Pang@polyu.edu.hk Phone: (852) 27667156, Fax: (852) 23308656

Word count: 4690; Number of tables: 4; Number of figures: 2

Baduanjin Qigong Improves Balance, Leg Strength and Mobility in Individuals with Chronic Stroke: A Randomized Controlled Study

Abstract

Background. Balance deficits after stroke are common. Effective and sustainable exercise training methods for improving balance post-stroke are needed. ***Objective*****:** To evaluate the effect of Baduanjin for improving balance among people with stroke. ***Methods***: This was a single-blinded randomized controlled study in which only the assessor was blinded. Fifty-eight people with chronic stroke (mean age: 62.5±11.8 years) were randomly assigned to the experimental or control group. The experimental group (n=29) underwent 8 weeks of supervised Baduanjin training (3 sessions per week), which consisted of 8 different balance exercises. This was followed by home-based practice of the same exercises 3 days a week for another 8 weeks. The control group (n=29) underwent 2 sessions of supervised conventional fitness training in the first week, followed by home-based exercise practice 3 days a week until the end of week 16. All outcomes were measured at baseline, week 8, and week 16. ***Results***: Significant time × group interaction was found on the Mini-Balance Evaluation Systems Test (Mini-BESTest) (p<0.001), composite equilibrium score (Sensory Organization Test) (p<0.001), five-times-sit-to-stand (p<0.001), and timed-up-and-go test (p=0.001). Significant improvements in these outcomes among the experimental group were detected at week 8 (p<0.017). Further improvement in the Mini-BESTest was observed from week 8 to week 16 (p<0.001). Other outcomes (Limit of Stability, Fall-Efficacy Scale, Modified Barthel Index, Stoke-specific Quality of Life) showed no significant results. ***Conclusion***: Baduanjin is effective in improving balance, leg strength and mobility, and is a safe and sustainable form of home-based exercise for people with chronic stroke.

Trial registry name: Effect of qigong on balance, fall efficacy, wellbeing of people with stroke in Hong Kong (ClincalTrials.gov, NCT02999464).

Key words: balance, stroke, Baduanjin, qigong, rehabilitation, randomized controlled trial

Abbreviations

BBS: Berg balance scale

FTSTT: Five-times-sit-to-stand-test

Mini-BESTest: Mini-Balance Evaluation Systems Test

TUG: Timed-up-and-go test

Introduction

Balance dysfunction is common after stroke[1,2,3,4] and is an important factor that contributes to decreased ambulatory ability and increased fall rate.[1,5] Various exercise therapies have been used to manage balance dysfunctions in individuals with stroke.[6-8] Some common challenges are related to sustainability and adherence to exercise upon returning to community living. Many of the existing training methods involve complex instructions and movements. These require extensive resources, such as supervision of healthcare professionals and expensive and space-occupying devices (e.g., robotics, virtual reality, etc.).[6-8] As stroke is a chronic condition, a simple, easy-to-learn exercise program that can be conducted at home or in community-based settings is necessary to enhance or maintain balance ability post-stroke in a sustainable manner.

Baduanjin Qigong is a traditional Chinese exercise and is as popular as Tai Chi within the Chinese community.[9] It is rooted in the concept of "qi", which is an energy that flows through the meridian system in the body.[10] According to traditional Chinese medicine philosophies, the uninterrupted flow of qi is essential to health and wellbeing. It is believed that qigong facilitates the movement of qi throughout the body, thereby improving health.[10] Similar to Tai Chi, Baduanjin Qigong is characterized by slow and fluid movements, mental focus and breathing control.[9] The movements involved in Baduanjin require the individual to reach beyond the base of support, change the base of support between bilateral and unilateral stance, and perform movements in a sustained squatting posture.[9] These maneuvers challenge one's balance and demand leg strength for their successful execution, thus making Baduanjin a potentially useful method to improve balance performance and leg strength. This may in turn confer benefits on other related functions such as mobility and activities of daily living.

While Tai Chi and Baduanjin share some similarities, there are also some distinct differences.

Tai Chi is a form of Chinese martial art characterized by its attack and defense principles. It contains numerous and complex movement patterns. It often takes several months or even a year to master the skills. For example, the Ng style, one of the most popular Tai Chi styles, has 108 forms.[11] Baduanjin Qigong, on the other hand, involves only eight forms of movements, which require less cognitive and physical demand for acquiring the skills. Baduanjin Qigong may be more appropriate for people with motor or cognitive deficits.[9] Assistive equipment is also not necessary during Baduanjin exercise. These advantages make Baduanjin a potentially suitable form of exercise training for individuals with stroke in home-based and community-based settings.

To date, the scientific evidence regarding the Baduanjin Qigong in stroke rehabilitation is scarce. Systematic reviews by Chen et al.[12] (9 studies) and Lyu et al.[13] (21 studies) showed that traditional Chinese exercises (Tai Chi, Baduanjin, and others) improved balance in people with stroke. However, the quality of overall evidence was considered very low, and the results were not specific to Baduanjin. Only two of the reviewed studies were Baduanjin exercise trials. A systematic review by Zou et al.[9] specifically addressed the effects of Baduanjin training post-stroke. Although their meta-analysis found that Baduanjin induced significant improvement in balance, the assessor was not blinded and the overall risk of bias was rated as high in all of the 6 randomized trials (8 articles) included in the review. Only one or two outcome measures were used in all of these trials so that a comprehensive evaluation of the effects of Baduanjin on different aspects of physical functioning was not achieved. In addition, only one of the reviewed studies (2 articles) involved chronic stroke patients. However, balance and mobility were not measured. [14,15] The efficacy of unsupervised, home-based Baduanjin programs is unknown.

To address the knowledge gaps and some of the limitations of previous Baduanjin studies in stroke, an assessor-blinded randomized controlled study was undertaken to investigate the effects of a 16-week Baduanjin Qigong practice program on balance, mobility, leg strength, fall-efficacy, activities of daily living, and quality of life among people with chronic stroke. It was hypothesized that 8 weeks of supervised Baduanjin training would lead to significantly improve the aforementioned outcomes among people with chronic stroke compared to conventional exercise training. It was also hypothesized that the treatment effect induced by Baduanjin training in the first 8-week period would be sustained after another 8 weeks of unsupervised home-based practice.

Methods

Study design

This was an assessor-blinded randomized controlled trial with two treatment arms (Baduanjin vs conventional exercise training). This study was registered at ClinicalTrials.gov (NCT02999464). Ethical approval was granted by the Institutional Review Board of the clinical institution (approval number: KC/KE-16-0063/ER-2) in which the study was conducted, and the Human Research Ethics Subcommittee of the university with which the Principal Investigator was affiliated (approval number: HSEARS20151013001).

Participants and sample size

Adults with chronic stroke were recruited from a local hospital outpatient center using convenience sampling by a researcher who was not involved with group allocation, intervention, outcome assessment. The inclusion criteria were: (1) a diagnosis of stroke >3 months, (2) stable medical condition, (3) able to stand for more than 15 minutes, (4) able to take anteroposterior and lateral steps without assistance or walking aid, (5) able to follow simple verbal commands. The exclusion criteria were: (1) other neurological disorders, (2) experience in qigong practice, (3) cognitive impairment as indicated by Abbreviated Mental Test score <7[16], and (4) other severe illnesses (e.g., cancer). All participants gave written informed consent before participation in the study. The participants in this study were enrolled between December 2016 and February 2018.

The sample size estimation was performed using G Power 3.1 software (Universitat Dusseldorf, Germany). None of the previous Baduanjin studies used the Mini-Balance Evaluation System Test (Mini-BESTest) as an outcome (the primary outcome of this study).[9] Therefore, previous results on the Berg Balance Scale (BBS, also a balance measure) and Timed Up and Go test (TUG, one of the outcomes of this study) were used to estimate the sample size. Most studies showed that traditional Chinese exercises induced a significant effect on BBS (Hedges' g: 0.56-6.34) and TUG (Hedges' g: 0.73-2.22), with medium to very large effect sizes.[9,13] A more conservative approach was used, in which the smallest value identified within the effect size ranges previously stated was assumed for this study (Hedges' g=0.56, equivalent to f=0.28 for ANOVA analysis). Based on a 2 × 3 two-way repeated measures analysis of variance (ANOVA), with an alpha value of 0.05, power of 80%, and an attrition rate of 15%, the minimum sample size required to detect a significant group × time interaction effect would be 56 participants (28 in each group).

Randomization

The eligible participants were randomized into the Baduanjin group or the control group using sequentially numbered sealed opaque envelopes. All randomization procedures were performed by a researcher who was not involved in the recruitment of participants, exercise training, or outcome evaluation. Given that the participants were recruited continuously as the trial progressed rather than a single point in time, a permuted-block randomization method was used to ensure equal sample sizes between groups over time.[17,18] Whenever 4 individuals were successfully recruited, the randomization procedure was conducted (i.e., block size: 4), with an allocation ratio of 1:1 (i.e., 2 assigned to experimental group, 2 to control group).[17,18] As we were able to recruit 6 participants for the last block, these participants were randomized to the two groups as one block (block size 6; 3 assigned to experimental, 3 assigned to control).

Intervention

The experimental group engaged in 8 weeks (3 days per week) of Baduanjin training in an outpatient physiotherapy department. All Baduanjin training was provided by a physiotherapist who was also a Baduanjin instructor. Each session was approximately 50 minutes in duration, which consisted of 10 minutes of warm-up exercise, 30 minutes of Baduanjin Qigong practice and 10 minutes of cool-down exercise. The Baduanjin program involved 8 exercises (forms) (Figure 1). After the 8-week supervised training period, the participants practiced the same exercises unsupervised in their own homes 3 days a week for another 8 weeks. Thus, the total exercise duration was 150 minutes per week. This protocol was chosen because most previous Tai Chi or Baduanjin trials that reported benefits in persons with stroke had a program duration of 6-24 weeks, with a total exercise time of 120-300 minutes per week.[9,12,13]

Participants in the control group were taught upper and lower limb stretching, strengthening, weight shifting and breathing exercises. All the control participants received two sessions of supervised training within the first week that was conducted by a physiotherapist. The duration of each session was the same as the Baduanjin group (50 minutes). The participants were instructed to do the same exercises at home at a session frequency of 3 days a week until the end of week 16.

To facilitate home-based practice, leaflets with clear illustrations of the respective exercises were provided to the participants in both groups. In addition, a weekly phone call was made by the investigators to check the physical health status of the participants in both groups, to confirm whether they were following the exercise protocol, and also address any concerns regarding the exercises.

For both groups, attendance of the supervised sessions was recorded. To measure the adherence to the home exercise component, an exercise diary was given to each participant to record whether they performed the prescribed exercises as scheduled.

Outcome assessment

Demographic data were obtained from medical records and interviewing the participants in the baseline assessment session. The Modified Rankin Scale was used to indicate the level of stroke severity at baseline.[19] (e.g., 1- No significant disability despite symptoms; able to carry out all usual duties and activities; 2-Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance; 3-Moderate disability; requiring some help, but able to walk without assistance.) The following outcomes were assessed at three time points (baseline, week 8 and week 16) by a physiotherapist who had more than 5 years of clinical experience and was blinded to group allocation. All outcome assessments were administered in an assessment room of an outpatient physiotherapy unit.

Primary outcome

Mini-Balance Evaluation Systems Test (Mini-BESTest): This14-item test is a reliable and valid tool for assessing the dynamic balance of people with chronic stroke (score range: 0-28).[20,21] A higher score denoted better balance ability.

Secondary outcomes

Limit of Stability test: It is a valid and reliable measure of dynamic postural stability.[22] It measures the farthest distance an individual can move away from the vertical position without altering the base of support, inducing a fall, or taking a step.[23] Participants were asked to remove footwear, socks, and ankle-foot orthosis (if any) and stand barefoot on the Smart Balance Master System with an upright posture (NeuroCom System Version 7.0.6, NeuroCom International Inc., Clackamas, OR, USA). Each participant was protected by a harness, with their arms placed alongside their body and their feet on a pre-designated position on the force platform of the device. Participants were requested to lean their body towards a target displayed on a computer screen by shifting their center of gravity within their original base of support as far, precisely, and rapidly as possible for a duration of 8 seconds. The reaction time is the time in seconds from the appearance of the cue and the onset of the center of gravity movement towards the target position. The end-point excursion is the extent of the center of gravity movement and is calculated as a percentage of the built-in norm of the device. The reaction time and end-point excursion of the eight targets spaced at 45° apart around the center of gravity were registered and averaged by the system. The mean reaction time and end-point excursion values were used for data analysis. Shorter composite reaction time and larger composite end-point excursion indicated better dynamic postural stability.

Sensory Organization Test: It is a reliable and valid measurement used to evaluate the sensory organization of balance control.[24] The starting position was the same as the Limit of Stability Test (NeuroCom System Version 7.0.6, NeuroCom International Inc., Clackamas, OR, USA). In each 20-second trial, participants were asked to maintain the upright standing posture as best as possible. The system detected the path of the center of gravity. After a practical trial, the participants underwent three trials in each of the six sensory conditions (eyes open, eyes closed; eyes open with sway-referenced surround, eyes open with sway-referenced support surface, eyes closed with sway-referenced support surface, eyes open with sway-referenced surround and support surface). An equilibrium score was generated for each sensory condition.[25] The composite equilibrium score is the average score of the six sensory conditions with a possible range from 0 to 100 (“0” indicates sway beyond the Limit of Stability and “100” indicates no sway).

Five-times-sit-to-stand (FTSTT): It is a measure of functional muscle strength and balance.[26,27] Its reliability and validity in stroke has been established.[27] Participants were asked to stand up and sit down five times as rapidly as possible with their arms folded and their back against the back of a standard armchair. A practice trial was given before actual data collection. Less time taken to complete the test was indicative of better performance.

Timed-up-and-go test (TUG): It is a reliable and valid timed walking test used to assess functional mobility.[28] Participants were asked to "rise and stand from a standard armchair, walk a distance of 3 meters, turn around, walk back to the chair, and sit down".[28] The time taken to complete the test was documented. Less time taken to complete the test was indicative of better functional mobility.

Fall-Efficacy Scale International: The validated Chinese version was used to assess fear of falling (score range: 16-64).[29] A higher score indicated a greater degree of fear of falling.

Modified Barthel Index: It was used to assess independence in performing activities of daily living (score range: 0-100).[30] A higher score indicated greater independence.

Stroke-Specific Quality of Life: It is a valid and reliable patient-reported outcome assessing the health-related quality of life specific to people with stroke (score range: 49-245).[31] Higher scores denoted better quality of life after stroke.

Statistical analysis

All data was analyzed with SPSS 24.0 (IBM, Armonk, NY, USA) for windows. The baseline differences in demographic characteristics and outcome measures between the experimental and control groups were compared using independent t-tests, Mann-Whitney U tests, or Chi-square tests, depending on whether the criteria for parametric statistics were met. For each of the outcome measures, two-way repeated measures ANOVA [mixed design; within-subject factor: time (3 levels), between-subject factor: group (2 levels)] was used to determine whether the experimental treatment had any significantly different effects compared with the control treatment. Any particular baseline characteristics that showed a significant between-group difference would be treated as covariates in the analysis (i.e., analysis of covariance or ANCOVA). Post-hoc analyses were performed if a significant group × time interaction effect was found. Post-hoc within-group differences at various time points were analyzed using paired t-tests, whereas the between-group comparisons of change scores were made using independent t-tests. Statistical significance was defined as a two-sided p-value of <0.05. The significance level of the post-hoc analyses was adjusted to 0.017 (i.e., 0.05/3) (Bonferroni correction) due to multiple comparisons.

The adherence to each exercise program during the first 8-week period, and week 9-16, and the entire 16-week study period was compared between the two groups using Mann-Whitney U tests. The change in exercise adherence rate within each group between week 1-8 and week 9-16 was assessed using Wilcoxon tests.

An intention-to-treat approach with the last-observation-carried-forward method was first used for data analysis. Any missing observations were substituted by the last available data. This was followed by a per-protocol analysis, in which only those participants who completed all assessments were included in the analysis.

Results

The first study participant was enrolled on December 2016. A total of 58 participants met the inclusion criteria and were randomly assigned to the experimental group (n=29) or the control group (n=29). Two participants in the experimental group and five individuals in the control group dropped out for different reasons (Figure 2). Moreover, another participant in the control group was found to be participating in another study after baseline assessment and was thus excluded.

There was no significant difference in the attrition rate (Chi-square=2.320, p=0.128). The remaining 50 (experimental: control = 27:23) participants completed all outcome assessments. The last participant completed the outcome assessments in June 2018.

Table 1 describes the demographic characteristics of the participants. There were no significant between-group differences in key demographic characteristics including age, sex, time since stroke onset, and Modified Rankin Scale scores (p>0.05). Additionally, the majority of the outcome measures did not significantly differ between the two groups at baseline (p>0.05), except that the control group had a slightly higher Mini-BESTest score by an average of 2 points (p=0.040) and took a shorter time to complete the FTSTT by an average of 3.6 seconds (p=0.028) (Table 2). These variables were thus entered as covariates in our ANOVA model when analyzing the treatment effect. The baseline comparisons between the two groups generated similar results after excluding the drop-outs.

We were able to obtain the exercise logs from all participants except the drop-outs (experimental: n=27; control: n=23). For these participants in the experimental group, the attendance rate of the supervised sessions during week 1-8, 9-16 and the entire 16-week study period was high (>90%) (Table 3). There was no significant between-group difference in exercise adherence rate for any of the periods (p>0.05). Also, none of the groups demonstrated any significant change in exercise adherence between week 1-8 and 9-16 (p>0.05). None of the participants, regardless of group assignment, reported adverse effects.

Intention-to-treat analysis revealed a significant time × group interaction (F=29.59, p<0.001) on the Mini-BESTest (Table 3), composite equilibrium score (F=15.38, p<0.001), FTSTT (p<0.001), and TUG (p<0.001). Post-hoc analysis indicated that these outcomes improved significantly in the experimental group (p≤0.001) between the baseline and week 8. The Mini-

BESTest scores even continued to improve from week 8 to week 16 in the experimental group (p<0 .001). The composite equilibrium score (p<0.001), FTSTT (p<0.001) and TUG (p<0.001) did not significantly improve during the home-based practice period but were significantly better compared with baseline scores. In contrast, the control group showed no significant change in these variables over time. The only exception was the composite equilibrium score, which showed a significant decrease at week 8 (p=0.006), but returned to baseline values at week 16 (p=0.372). Regarding the post-hoc comparisons of change scores between the two groups, the experimental group demonstrated significantly greater improvement in the Mini-BESTest (p<0.001), composite equilibrium score (p=0.001), FTSTT (p<0.001) and TUG (p=0.005) at week 8, which was also maintained at week 16 (p<0.001) (Table 4). Neither the time × group interaction nor the time effect was significant for the rest of the outcomes (Table 3).

The above analyses of the treatment outcomes were repeated after excluding the drop-outs (i.e., per-protocol analysis). The results (experimental group: n=27; control group: n=23), were similar to those generated by the intention-to-treat analyses. (Supplementary tables)

Discussion

The results indicated that the Baduanjin group showed a significant improvement in the Mini-BESTest score, composite equilibrium score, FTSTT and TUG in comparison to the control group after the 8-week training period. These outcomes remained better than the control group after another 8 weeks of home-based Baduanjin practice.

Improvement in balance function

The Mini-BESTest score improved significantly after 8 weeks of Baduanjin training. The Mini-BESTest score continued to improve between week 8 and 16, suggesting that the home-based practice improved balance ability. In this study, the mean improvement in the Mini-BESTest score for the experimental group was 5.6 points more than the control group after 16 weeks of Baduanjin training (Table 4). The minimal clinically important difference value of the Mini-BESTest was found to be 4 points for balance disorders.[32] Our results indicate that our Baduanjin training induced a clinically meaningful change in the Mini-BESTest score. The dynamic nature of the Baduanjin exercises may partially explain why the experimental group had a clinically meaningful improvement in the Mini-BESTest, which is a measure of dynamic balance.

The experimental group also had greater improvement in the composite equilibrium score derived from the Sensory Organization Test at week 8 and at 16-week follow-up, suggesting that the sensory organization component of balance was enhanced after Baduanjin training. After 16 weeks of Baduanjin practice, the improvement in the composite equilibrium score was 9.1% higher in the experimental group than the control group (Table 4), which exceeded the minimal detectable change value found in patients with vestibular disorders (8%).[33] Effective balance control involves organization and integration of sensory information. During Baduanjin practice, different senses are required to engage in different forms of Qigong movements (Figure 1). For instance, in practicing the forms of 'Two Hands Held up the Heavens,' 'The Wise Owl Gazes Backward,' and 'Clench the Fists and Glare Fiercely', a wide field of view is required for looking at the hands, looking backwards, and looking at the fist, respectively. The vestibular system is also involved when performing the head and neck movements in 'The Wise Owl Gazes Backward' and 'Sway the Head & Shake the Tail'. Engaging in repetitive Baduanjin exercises may have enhanced the balance ability of our participants through improving the integration of sensory information required for effective balance control.

Four previous Baduanjin studies in stroke have incorporated balance as an outcome measure. These studies reported a significant improvement in BBS scores after 6-12 weeks of Baduanjin practice in persons with subacute stroke, with an overall standardized mean difference of 2.39.[9,34-37] The standardized mean differences obtained in our study at week 16 were still considered large (1.62 and 1.06 for the Mini-BESTest and composite equilibrium score respectively), although they were smaller than those reported in subacute stroke trials. The differences in participant characteristics (e.g., chronicity) and balance outcome measures used may have contributed to the different effect sizes reported. Nevertheless, our results in persons with chronic stroke are largely in line with these studies demonstrating that Baduanjin training was effective in improving balance function post-stroke.

Improvement in leg strength and mobility

The FTSTT performance improved significantly in the experimental group after 8 weeks of training, and was well maintained at the 16-week follow-up point. At the end of the 16-week study period, the improvement in FTSTT gained by the experimental group was 5.4 seconds more than the control group, which exceeded the minimal clinically important difference value of 2.3 seconds established in people with vestibular disorders (Table 4).[38] The results thus suggested that the Baduanjin training induced clinically meaningful changes in leg strength and balance.

Many exercises involved in Baduanjin practice require the individual to move to and away from the semi-squatting posture with good concentric and eccentric muscle control around the knee joints. It is known that the combination of concentric and eccentric contraction during training is more effective in muscle strengthening than concentric training alone.[39] Such movements during Baduanjin practice resemble the movements required in many daily activities (sit-to-stand, transfers, picking up objects from floor, managing stairs, etc.), which may account for the better performance in FTSTT in the experimental group.

The TUG performance also improved significantly in the experimental group relative to the control group at week 8 and week 16. The improvement in balance ability (Mini-BESTest, composite equilibrium score) and leg muscle strength (FTSTT) may partly explain the observed gain in functional mobility (TUG) because these factors are highly correlated with mobility and function.[28,40] The improvement of performance in TUG observed in the experimental group was on average 3.5 seconds more than the control group at week 16. This is comparable to the minimal detectable change of the TUG (2.9 seconds) in persons with chronic stroke.[41] In Tai Chi studies, a meta-analysis (based on 4 studies) showed that Tai Chi was effective in improving TUG performance in persons with stroke, with a standardized mean difference of 2.59, although the quality of evidence was considered very low.[13] None of the previous Baduanjin trials measured leg strength or mobility.[9] Thus, our study was the first to demonstrate the Baduanjin training was beneficial in improving leg strength and mobility post-stroke.

Other outcomes

No significant between-group difference was detected in other secondary outcomes (e.g. Modified Barthel Index, Stroke-Specific Quality of Life, etc.). A previous study reported that 12 weeks of Baduanjin training improved the Barthel Index scores in persons with chronic stroke.[15] Two previous studies also reported better quality of life (as measured by Health Organization Quality of Life and SF-36 respectively) after 6-12 weeks of Baduanjin training.[14,42] The discordance in results may be explained by several reasons. First, the experimental group had more treatment time in previous studies. The Badjuanin training was added to usual care (e.g., education, other exercises) whereas the control group received usual care only. In our study, each of the two treatment arms had different types of exercise training, but the prescribed exercise frequency and duration were the same. Second, the lack of treatment effect on Modified Barthel Index may be due to a ceiling effect, as the mean Modified Barthel Index score of both groups were >90/100 at different time points, indicating that the participants in this study were quite independent in their daily activities. Finally, only balance and mobility outcomes were used to estimate the sample size of this study. This study may be underpowered to detect significant treatment effects in some of the secondary outcomes. A multi-centered study with a larger sample size is warranted to further examine the therapeutic effects of Baduanjin on these outcomes in people with stroke

Supervised training versus unsupervised home–based practice

Whether the benefits gained from supervised Baduanjin training can be enhanced or maintained by home-based practice is an important question. This is an essential aspect of chronic disease self-management and living a healthy lifestyle. Only the Mini-BESTest scores showed significant improvement during the home-based exercise period in the experimental group. The degree of improvement was also less in the home-based practice period than the first 8-week supervised training period (Table 4). While the composite equilibrium scores, TUG and FTSTT showed significant improvement in the first 8 weeks, the degree of improvement in the subsequent home-based practice period did not reach statistical significance. One possible explanation of the lesser effect during the home-based practice period was that the participants' functional status was approaching or had already reached a plateau at week 8. Further practice may not induce the same degree of improvement. Another explanation was the placebo effect related to the attention from and/or interaction with the Baduanjin instructor. Finally, it cannot be completely ruled out that the exercise adherence during the home-based practice period might be lower than reported. As the data on exercise adherence during the home-based practice period were based on self-report, it may be subject to over-reporting because of the desirability bias. Nevertheless, the results on these outcomes measured at week 16 remained significantly better in the experimental group than the control group, indicating that the benefits gained from the initial 8-week training period can be sustained for another 8 weeks with continued home-based practice.

Attrition, exercise compliance and safety

The overall attrition rate of the study was 13.7%, which was considered acceptable according to the criterion stated in the PEDro scale, a common tool to assess methodological quality.[43] The control group had a higher attrition rate than the experimental group, although it was not statistically significant. The possible reasons may be a lack of motivation, less interaction with the Baduanjin instructor and limited perceived benefits from the exercises. However, the confounding effect of attrition should be minimal. The dropouts did not have any important impact on the balance of baseline demographic and clinical characteristics between the two groups. In our analysis of the treatment effect, the results generated from the intention-to-treat analysis were similar to those obtained from the per-protocol analysis.

The exercise adherence rate of this study was high in both groups throughout the study period, which was comparable to previous reports (85-100%).[44-46] The high exercise compliance observed in this study might be due to the impact of weekly telephone calls intended to reinforce the importance of regular exercise. No adverse events were reported throughout the study period, indicating that Baduanjin is a safe exercise intervention for individuals with chronic stroke.

Limitations

This study has several limitations. First, a convenience sampling method was adopted and all participants were recruited from the same hospital, which may have decreased the representativeness of the sample. The results can only be generalized to those who have similar demographic and clinical characteristics as our study participants. Second, blinding of the participants was not feasible in this study because of the differences in the nature of the two training programs. Third, the amount of supervision received by the experimental group participants was more than the control group. Baduanjin was a novel exercise for the participants. Therefore, more time was required for the participants to learn and master the techniques in the initial stage. This factor may have had a confounding influence on the results. Despite the random allocation to groups, significant differences were detected in the Mini-BESTest and FTSTT scores at baseline, which may also be confounding factors. However, we attempted to address this problem by using the baseline values of these variables as covariates. In addition, the mean between-group differences in these outcomes were relatively small. For example, the 2-point difference in the Mini-BESTest scores between the two groups was below the minimal detectable change value previously established in the chronic stroke population.[20] This study was not designed to address the question of whether the supervised Baduanjin training had a carry-over effect after a period of no or less intervention (e.g., no home-based practice). However, we felt that the implementation of home exercise practice after training under supervision was a better reflection of current clinical practice in stroke rehabilitation.

Conclusion

This study demonstrated that Baduanjin training was effective in improving balance, leg muscle strength and mobility among people with stroke relative to traditional fitness training. Baduanjin Qigong can be considered a safe and sustainable form of exercise that can be incorporated in stroke rehabilitation programs.

Acknowledgements

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. The authors declare that there is no conflict of interest.

References

1. Tyson SF, Hanley M, Chillala J, Selley A, Tallis RC. Balance disability after stroke. Phys Ther. 2006; 86:30-38. doi: 10.1093/ptj/86.1.30
2. Dean CM, Richards CL, Malouin F. Task-related circuit training improves performance of locomotor tasks in chronic stroke: a randomized, controlled pilot trial. Arch Phys Med Rehabil. 2000;81: 409-417. doi: 10.1053/mr.2000.3839
3. Marigold DS, Eng JJ, Tokuno CD, Donnelly CA. Contribution of muscle strength and integration of afferent input to postural instability in persons with stroke. Neurorehab Neural Repair. 2004;18:222-229. doi: 10.1177/1545968304271171
4. Ikai T, Kamikubo T, Takehara I, Nishi M, Miyano S. Dynamic postural control in patients with hemiparesis. Am J Phys Med Rehabil. 2003;82:463-484.
5. Harris JE, Eng JJ, Marigold DS, Tokuno CD, Louis CL. Relationship of balance and mobility to fall incidence in people with chronic stroke. Phys Ther. 2005;85:150-158.
6. van Duijnhoven HJ, Heeren A, Peters MA, et al. Effects of exercise therapy on balance capacity in chronic stroke: systematic review and meta-analysis. Stroke. 2016;47:2603-2610. doi:10.1161/STROKEAHA.116.013839
7. Weber LM, Stein J. The use of robots in stroke rehabilitation: A narrative review. NeuroRehabilitation. 2018;43:99-110. doi: 10.3233/NRE-172408
8. Laver KE, George S, Thomas S, Deutsch JE, Crotty M. Virtual reality for stroke

rehabilitation. Cochrane Database Syst Rev. 2015;2015:CD008349. Published 2017 Nov 20. doi:10.1002/14651858.CD008349.pub4

9. Zou L, Wang C, Chen X, Wang H. Baduanjin exercise for stroke rehabilitation: a systematic review with meta-analysis of randomized controlled trials. Int J Environ Res Public Health. 2018;15:600. Published 2018 Mar 27. doi:10.3390/ijerph15040600
10. Kemp CA. Qigong as a therapeutic intervention with older adults. J Holist Nurs 2004;22:351-373. doi: 10.1177/0898010104269313
11. Tsang WW, Hui-Chan CW. Effect of 4- and 8-wk intensive Tai Chi Training on balance control in the elderly. Med Sci Sports Exerc. 2004;36:648-657. doi: 10.1249/01.mss.0000121941.57669.bf
12. Chen BL, Guo JB, Liu MS, et al. Effect of traditional chinese exercise on gait and balance for stroke: a systematic review and meta-analysis. PLoS One. 2015;10:e0135932. Published 2015 Aug 20. doi:10.1371/journal.pone.0135932
13. Lyu D, Lyu X, Zhang Y, et al. Tai Chi for stroke rehabilitation: a systematic review and meta-analysis of randomized controlled trials. Front Physiol. 2018;9:983. Published 2018 Jul 25. doi:10.3389/fphys.2018.00983
14. Cai W. Influence of sitting Baduanjin on quality of life of cerebral apoplexy patients with sequela in community. J Nurs. 2010;24:2667–2668. Published 2018 Mar 27. doi: 10.3390/ijerph15040600
15. Cai W, Liang C. Effects of sitting Baduanjin on the ability of activities daily living of patients with stroke sequelae in community. J Nurs Adm. 2011;11:810–811.
16. Chu LW, Pei CKW, Ho MH, Chan PT. Validation of the Abbreviated Mental Test (Hong Kong version) in the elderly medical patient. Hong Kong Med J. 1995;1:207-211.

17. Broglio K. Randomization in clinical trials: permuted blocks and stratification. JAMA. 2018;319:2223–2224. doi:10.1001/jama.2018.6360

18. Suresh K. An overview of randomization techniques: An unbiased assessment of outcome in clinical research. J Hum Reprod Sci. 2011;4:8-11. doi: 10.4103/0974-1208.82352

19. Bonita R, Beaglehole R. Modification of Rankin Scale: Recovery of motor function after stroke. Stroke. 1988;19:1497-1500. doi:10.1161/01.str.19.12.1497

20. Tsang CSL, Liao LR, Chung RCK and Pang MYC. Psychometric properties of the Mini-Balance Evaluation Systems Test (Mini-BESTest) in community-dwelling individuals with chronic stroke. Phys Ther. 2013;93:1102-1115. doi: 10.2522/ptj.20120454

21. Di Carlo S, Bravini E, Vercelli S, Massazza G, Ferriero G. The Mini-BESTest: a review of psychometric properties. Int J Rehabil Res. 2016;39:97-105. doi: 10.1097/MRR.0000000000000153

22. Clark S, Rose DJ. Evaluation of dynamic balance among community-dwelling older adult fallers: a generalizability study of the limits of stability test. Arch Phys Med Rehabil. 2001;82:468-474. doi: 10.1053/apmr.2001.21859

23. Shumway-Cook A, Woollacott MH. Motor Control: Theory and Practical Applications. 2nd ed. Lippincott Williams & Wilkins; 2001.

24. Ford-Smith ACD, Wyman JF, Elswick RK, Fernandez T, Newton RA. Test-Retest Reliability of The Sensory Organization Test in Noninstitutionalized Older. Arch Phys Med Rehabil. 1995;76:77-81. doi: 10.1016/s0003-9993(95)80047-6

25. Nashner LM. Computerized dynamic posturography. In: Jacobson GP, Newman CW and Kartush JM. Handbook of balance function and testing. Mosby Yearbook Inc; 1997:280-307.

26. Whitney SL, Wrisley DM, Marchetti GF, Gee MA, Redfern MS, Furman JM. Clinical measurement of sit-to-stand performance in people with balance disorders: validity of data for the Five-Times-Sit-to-Stand Test. Phys Ther. 2005;85:1034-1045.

27. Mong Y, Teo TW, Ng SS. 5-repetition sit-to-stand test in subjects with chronic stroke: reliability and validity. Arch Phys Med Rehabil. 2010;91:407-413. doi: 10.1016/j.apmr.2009.10.030

28. Ng SS, Hui-Chan CW. The timed up & go test: its reliability and association with lower-limb impairments and locomotor capacities in people with chronic stroke. Arch Phys Med Rehabil. 2005;86:1641-1647. doi: 10.1016/j.apmr.2005.01.011

29. Kwan MM, Tsang WW, Close JC, Lord SR. Development and validation of a Chinese version of the Falls Efficacy Scale International. Arch Gerontol Geriatr. 2013;56:169-174. doi: 10.1016/j.archger.2012.10.007

30. Leung SO, Chan CC, Shah S. Development of a Chinese version of the Modified Barthel Index-validity and reliability. Clin Rehabil. 2007;21:912-922. doi: 10.1177/0269215507077286

31. Williams LS, Redmon G, Saul DC, Weinberger M. Reliability and telephone validity of the Stroke-specific Quality of Life (SS-QOL) scale. Stroke. 2000;32:339.

32. Godi M, Franchignoni F, Caligari M, Giordano A, Turcato AM, Nardone A. Comparison of reliability, validity, and responsiveness of the Mini-BESTest and Berg Balance Scale in patients with balance disorders. Phys Ther. 2013;93: 158-167. doi: 10.2522/ptj.20120171

33. Wrisley DM, Stephens MJ, Mosley S, Wojnowski A, Duffy J, Burkard R. Learning effects of repetitive administrations of the sensory organization test in healthy young adults. Arch Phys Med Rehabil. 2007;88:1049-1054. doi: 10.1016/j.apmr.2007.05.003

34. Bai Y, Mao H, Guo J, Zhang M. Research on Baduanjin combined with function training in improving balance function of stroke patients. Chin J Chin Med. 2011;26:1231–1232.

35. Tian H. Effect of Baduanjin on balance function in post-stroke patients. World Newest Med. Inf. Dig. 2017;17:251–252.

36. Zhang M, Guo J, Bai Y, Feng X. Effect of Baduanjin on balance function among survivors of stroke. Lishizhen Med. Mater. Med. Res. 2013;24:2938–2939.

37. Zhang Y, Li L. Effect of a combined intervention (Baduanjin and balance training) on balance and sensorimotor function in post-stroke patients. Shangdong J Chin Med. 2016;35:716–718.

38. Meretta BM, Whitney SL, Marchetti GF, Sparto PJ, Muirhead RJ. The five times sit to stand test: responsiveness to change and concurrent validity in adults undergoing vestibular rehabilitation. J Vestib Res. 2006;16: 233-243.

39. Lacerte M, deLateur BJ, Alquist AD, Questad KA. Concentric versus combined concentric-eccentric isokinetic training programs: effect on peak torque of human quadriceps femoris muscle. Arch Phys Med Rehabil. 1992;73:1059-1062.

40. Knorr S1, Brouwer B, Garland SJ. Validity of the Community Balance and Mobility Scale in community-dwelling persons after stroke. Arch Phys Med Rehabil. 2010;91:890-896. doi: 10.1016/j.apmr.2010.02.010

41. Flansbjer UB1, Holmbäck AM, Downham D, Patten C, Lexell J. Reliability of gait performance tests in men and women with hemiparesis after stroke. J Rehabil Med. 2005;37:75-82. doi: 10.1080/16501970410017215

42. Chen Y, Li L, Wang M, Zhang Y, Chen Q. Clinical study on Post stroke depression treated with music therapy of five elements combine with Baduanjin. Shangdong J Chin Med.

2017;36:23–25.

43. Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro scale for rating quality of randomized controlled trials. Phys Ther. 2003;83:713-721.

44. Au-Yeung SS, Hui-Chan CW, Tang JC. Short-form Tai Chi improves standing balance of people with chronic stroke. Neurorehabil Neural Repair. 2009; 23:515-522. doi: 10.1177/1545968308326425

45. Taylor-Piliae RE, Coull BM. Community-based Yang-style Tai Chi is safe and feasible in chronic stroke: a pilot study. Clin Rehabil. 2012;26:121-131. doi: 10.1177/0269215511419381

46. Taylor-Piliae RE, Hoke TM, Hepworth JT, Latt LD, Najafi B, Coull BM. Effect of Tai Chi on physical function, fall rates and quality of life among older stroke survivors. Arch Phys Med Rehabil .2014;95:816-824. doi: 10.1016/j.apmr.2014.01.001

Figure captions

Figure 1. Eight forms of Baduanjin

The Baduanjin exercises are characterized by frequent weight-shifting to one's limit of stability, reaching beyond the base of support, changing the base of support, sustained squatting motions, and heel raises. The 8 forms are linked together with smooth transitions from one form to the next. For forms 1-7, participants were required to repeat 6 times of each form before transition to next. After form 8 was repeated 7 times, the whole set of Baduanjin exercises was completed.

Figure 2. CONSORT flowchart diagram

Figure 1. Eight forms of Baduanjin

Form 1. Two Hands Hold up the Heaven

Form 2. Drawing the Bow to Shoot the Eagle

Form 3. Separate Heaven and Earth

Form 4. Wise Owl Gazes Backwards

Form 5. Sway the Head and Shake the Tail

Form 6. Two Hands Hold the Feet

Form 7. Clench the Fists and Glare Fiercely

Form 8. Bouncing on the Toes

Figure 2. CONSORT flow diagram

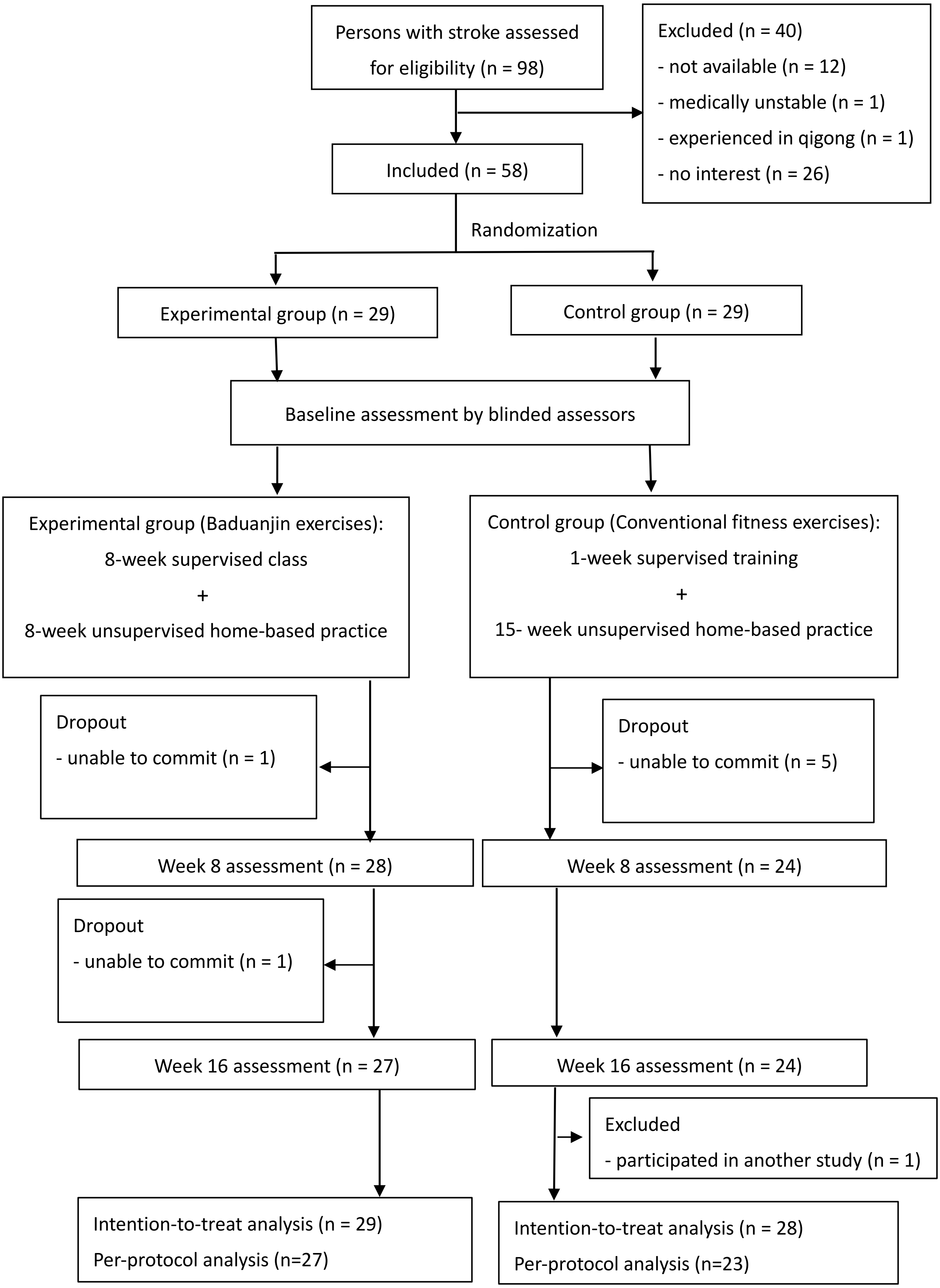

Table 1. Demographic and clinical characteristics of participants

	Experimental (n = 29)	Control (n = 29)	Total (n = 58)	*p*
Age in years (mean±SD)	63.1±10.6	62.0±13.1	62.5±11.8	0.733
Sex				0.793
Men (n, %)	15(51.7%)	14(48.3%)	29	
Women (n, %)	14(48.3%)	15(51.7%)	29	
Education				0.423
Illiterate (n)	1	0	1	
Primary (n)	7	12	19	
Secondary (n)	14	12	26	
University (n)	7	5	13	
Marital status				0.717
Single (n,%)	4(13.8%)	5(17.2%)	9	
Married (n,%)	25(86.2%)	24(82.8%)	49	
Employment				0.877
Unemployed (n)	8	6	14	
Working (n)	9	9	18	
Retired (n)	8	8	16	
Housewife (n)	4	6	10	
Stroke types				0.279
Ischemic (n,%)	16(55.2%)	20(69.0%)	36	
Hemorrhagic (n,%)	13(44.8%)	9(31.0%)	22	
Affected side				0.593
Left (n)	17	17	34	
Right (n)	12	11	23	
Bilateral (n)	0	1	1	
Time since stroke in months (mean±SD)	23.1±21.5	25.3±21.6	24.2±21.4	0.698
Use of ankle-foot-orthosis (n)	3	0	3	0.237
Modified Rankin Scale (median, interquartile range)	2 (1, 2)	2 (1, 2.5)	2 (1, 2)	0.887

Abbreviations: n=number of participants
*****significant between-group difference ($p < 0.05$)

Table 2. Intention-to-treat analysis (n=57): time × group interaction and time effect

Outcome	Experimental Group (n = 29) Mean±SD			Control Group (n = 28) Mean±SD			Time × Group Interaction		Time Effect	
	Baseline	Week 8	Week 16	Baseline	Week 8	Week 16	*F*	*p*	*F*	*p*
Mini-BESTest	17.1±3.3	**20.6±3.8***	**22.0±3.7***	19.1±4.2	18.3±5.1	18.4±5.0	29.59	**< 0.001**^[a]	14.85	**< 0.001**^[a]
LOS										
RT	1.1±0.3	1.1±0.3	1.0±0.3	1.0±0.3	1.0±0.3	1.0±0.3	0.61	0.537	0.75	0.475
EPE	45.4±12.0	**50.4±12.5***	**52.1±14.0***	48.8±13.9	51.6±15.02	51.9±14.6	1.03	0.349	8.18	**0.001**[a]
SOT										
Composite ES	71.2±10.3	**76.7±5.9***	**79.1±5.7***	74.9±6.1	**71.5±8.0***	73.7±8.6	15.38	**< 0.001** [a]	6.79	**0.004** [a]
FTSTT	16.8±7.1	**13.8±6.3***	**12.6±5.3***	13.2±4.7	14.3±5.9	14.4±7.1	20.12	**< 0.001**^[a]	5.61	**0.007**^ [a]
TUG	18.7±9.7	**16.6±9.4***	**15.3±7.7***	16.6±11.8	16.6±11.1	16.7±11.2	8.79	**0.001**[a]	8.20	**0.002** [a]
FES-I	33.9±12.2	33.9±12.8	35.9±13.2	31.7±14.1	30.6±12.8	34.6±15.1	0.19	0.829	2.07	0.132
MBI	94.5±10.9	95.3±9.5	96.2±7.3	95.5±8.3	97.0±5.7	96.4±6.1	0.54	0.552	2.21	0.125
SS-QOL	198.8±25.5	201.8±27.1	204.7±35.4	201.2±27.2	200.3±25.2	201.5±26.2	0.49	0.549	0.61	0.489

Abbreviations: Mean±SD=mean±standard deviation; n=number of participants; Mini-BESTest=mini balance evaluation systems test; LOS=limits of stability; RT=reaction time; EPE=end-point excursion; SOT=sensory organization test; ES=equilibrium score; FTSTT=five-times-sit-to-stand test; TUG=timed-up-and-go test; FES-I=fall efficacy scale-international; MBI=modified Barthel index; SS-QOL=stroke-specific quality of life scale

*****significant difference compared with baseline (paired t-test, $p< 0.017$)

^analysis with baseline values as covariates

[a] significant difference (ANOVA, $p< 0.05$)

Table 3. Exercise adherence rate

Time period	**Experimental (n=27)**	**Control (n=23)**	***P* (between-group comparison)**
Week 1-8	95±13%	95±11%	0.979
Week 9-16	93±15%	95±11%	0.646
Overall (Week 1-16)	94±14%	95±11%	0.925

Table 4. Change scores and effect sizes

Outcome	Experimental Group (n = 29) Change Score Mean (95% confidence interval)			Control Group (n = 28) Change Score Mean (95% confidence interval)			Standardized mean difference		
	Wk 8 - baseline	Wk 16 - Wk 8	Wk 16 - baseline	Wk 8 - baseline	Wk 16 - Wk 8	Wk 16 - baseline	Wk 8 - baseline	Wk 16 - Wk 8	Wk 16 - baseline
Mini-BESTest	**3.5 (2.4, 4.6)***	**1.3 (0.7, 2.0)***	**4.8 (3.7, 6.0)***	-0.8 (-2.2, 0.6)	0.1 (-0.5, 0.6)	-0.8 (-2.2, 0.7)	**1.30 (0.45, 2,15)**	**0.76 (0.35, 1.16)**	**1.62 (0.73, 2.50)**
LOS									
RT	0.0 (-0.1, 0.2)	-0.1 (-0.2, 0.1)	-0.1 (-0.2, 0.0)	-0.1 (-0.2, 0.1)	0.0 (-0.1, 0.1)	-0.0 (-0.1, 0.1)	0.28 (0.19, 0.37)	-0.28 (-0.37, -0.19)	-0.33 (-0.41, -0.25)
EPE	4.9 (1.4, 8.5)	1.7 (-1.3, 4.7)	6.7 (2.6, 10.7)	2.8 (-1.4, 7.0)	0.3 (-2.3, 2.8)	3.0 (-1.3, 7.4)	0.21 (-2.42, 2.83)	0.19 (-1.68, 2.06)	0.33 (-2.52, 3.19)
SOT Composite ES	**5.5 (2.6, 8.4)***	2.4 (0.1, 4.7)	**7.9 (4.2, 11.6)***	-3.3 (-5.6, -1.1)	2.1 (0.3, 4.0)	-1.2 (-3.8, 1.5)	**1.28 (-0.48, 3.04)**	0.05 (-1.36, 1.47)	**1.06 (-1.15, 3.26)**
FTSTT	**-2.9 (-4.1, -1.8)***	-1.2 (-2.2, -0.2)	**-4.2 (-5.6, -2.7)***	1.2 (0.0, 2.3)	0.1 (-1.2, 1.4)	1.2 (0.4, 2.8)	**-1.34 (-2.13, -0.57)**	-0.43 (-1.20, 0.36)	**-1.37 (-2.37, -0.35)**
TUG	**-2.0 (-3.0, -1.1)***	-1.4 (-2.4, -0.4)	**-3.4 (-4.9, -1.9)***	-0.1 (-1.0, 0.9)	0.2 (-1.0, 1.3)	0.1 (-1.4, 1.6)	**-0.75 (-1.39, -0.10)**	-0.54 (-1.30, 0.21)	**-1.06 (-1.91, -0.22)**
FES-I	-0.0 (-4.6, 4.6)	2.0 (-2.8, 6.8)	2.0 (-3.1, 7.1)	-1.0 (-4.0, 2.0)	4.0 (-0.4, 8.3)	2.9 (-2.2, 8.0)	0.10 (-2.55, 2.75)	-0.17 (-3.25, 2.92)	-0.07 (-3.53, 3.40)
MBI	0.9 (-1.0, 2.8)	0.9 (-0.8, 2.6)	1.7 (-0.9, 4.3)	1.4 (-0.7, 3.6)	-0.5 (-1.8, 0.7)	0.9 (-1.0, 2.8)	-0.09 (-1.47, 1.28)	0.36 (-0.65, 1.36)	0.13 (-1.43, 1.69)
SS-QOL	3.0 (-2.7, 8.7)	2.9 (-6.6, 12.4)	5.9 (-4.4, 16.2)	-0.9 (-5.5, 3.7)	1.3 (-6.9, 9.4)	0.4 (-9.9, 10.6)	0.29 (-3.22, 3.79)	0.07 (-5.93, 6.07)	0.20 (-6.76, 7.16)

Abbreviations: n=number of participants; Mean±SD=mean±standard deviation; vs=versus; Mini-BESTest=mini balance evaluation systems test; LOS=limits of stability; RT=reaction time; EPE=end-point excursion; SOT=sensory organization test; ES=equilibrium score; FTSTT=five-times-sit-to-stand test; TUG=timed-up-and-go test; FES-I=fall efficacy score-international; MBI=modified Barthel index; SS-QOL=stroke-specific quality of life scale

*****significant difference compared to control group (independent t-test, $p < 0.017$)