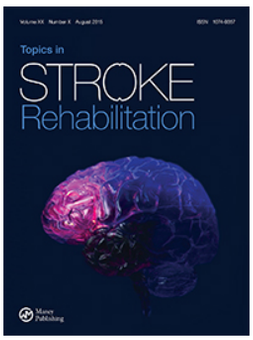

Topics in Stroke Rehabilitation

ISSN: 1074-9357 (Print) 1945-5119 (Online) Journal homepage: https://www.tandfonline.com/loi/ytsr20

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To cite this article: Padukka Vidanalage Hasitha Madhuranga, Yasith Mathangasinghe & Dimonge Joseph Anthony (2019): Improving balance with wobble board exercises in stroke patients: single-blind, randomized clinical trial, Topics in Stroke Rehabilitation, DOI: 10.1080/10749357.2019.1645439

To link to this article: https://doi.org/10.1080/10749357.2019.1645439

TOPICS IN STROKE REHABILITATION
https://doi.org/10.1080/10749357.2019.1645439

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ARTICLE

Improving balance with wobble board exercises in stroke patients: single-blind, randomized clinical trial

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ABSTRACT

Background: A primary objective in stroke rehabilitation is to restore functional balance, in order to reduce falls.

Objectives: To identify the efficacy and safety of wobble board exercises when combined with conventional physiotherapy, in improving balance in hemiplegic patients following ischemic strokes.

Methods: A block-randomized, controlled, observer blinded, superiority trial was conducted on ambulatory hemiplegic patients following ischemic strokes of middle cerebral artery territory. Subjects in the control group received a conventional physiotherapy regime. Subjects in the intervention group received training on a wobble board combined with conventional physiotherapy. Main Outcome measures were the improvement of Four-Square Step Test (FSST) and the Berg Balance Scale (BBS), both of which assess functional balance at the end of 6 weeks.

Results: Thirty patients were randomly assigned for intervention (n = 15) and control (n = 15) groups. One patient dropped out from the study, leaving 29 eligible for the analysis. Intervention and control groups were comparable in sociodemographic characteristics and pre-test scores of balance. A repeated-measures MANOVA showed a significant difference in improvement of balance between the two study groups after 6 weeks [$F(1,28) = 32.6, p = .000$; Wilk's lambda = .46]. The improvement of mean score of balance in interventional group was greater than in the control group [BBS:9.5 (intervention group),5.5 (control group); FSST:3.9 (intervention group),1.7 (control group)]. There were no injuries in both groups.

Conclusions: Wobble board exercises, when combined with the conventional physiotherapy, are safe and effective in restoring functional balance in patients with hemiplegia following ischemic strokes.

ARTICLE HISTORY
Received 26 April 2019
Accepted 13 July 2019

KEYWORDS
Stroke; Berg Balance Scale; Four Square Step Test; rehabilitation; physical therapy modalities; balance board

Introduction

The Global Burden of Disease study concluded that ischemic strokes account for 2 690 200 deaths worldwide in 2016.[1] The incidence of stroke in Asia is 116 to 483 per 100 000 per year[2] and this incidence remains static.[3] However, the mortality due to stroke is reducing globally[4–6] as well as in Asia.[3] With the aging population and rapidly rising prevalence of strokes in this region[2,7], it will be one of the leading causes of healthcare burden in developing countries like Sri Lanka in near future.[8]

Postural balance is often affected by strokes. Balance is a complex function with dynamic and static components.[9] It is a major determinant of community ambulation[10,11] and gait performance[12] following strokes. Falls in post-stroke patients commonly occur due to impairment of balance.[13,14] Hence, one of the primary objectives in stroke rehabilitation is to restore functional balance, which is a combination of dynamic, static and reactive balance.[15,16] Improved functional balance enables the individual to be more independent and it minimizes falls. Complex integration of cortical functions is necessary to maintain balance in post-stroke patients.[17] Modulation of neuronal plasticity, the cornerstone of neurorehabilitation in stroke, is achieved by means of physiotherapy.[18,19] Complex approaches such as aquatic therapy[20,21], virtual reality simulators[22–26], robot-assisted gait rehabilitation therapy[27,28], computer-assisted visual feedback therapy[29,30], artificial-intelligence-based vibrotactile feedback system[31] and electromechanical gait orthoses[32,33] have shown promising results in restoring balance in post-stroke patients. These high-tech physical treatment modalities require expensive instruments and technical expertise, therefore may not be affordable for developing countries like Sri Lanka. Current choice of physiotherapy in Sri Lanka is a set of conventional exercises including standing up on a flat surface, sitting down, walking, climbing up and down a staircase, cycling and hand cycling. Efficacy trials on these locally utilized methods for rehabilitation of post-stroke patients are sparse. Hence, there is a strong need of cost-effective and safe techniques of physical therapy to enhance recovery from stroke.

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Supplemental data for this article can be accessed here.

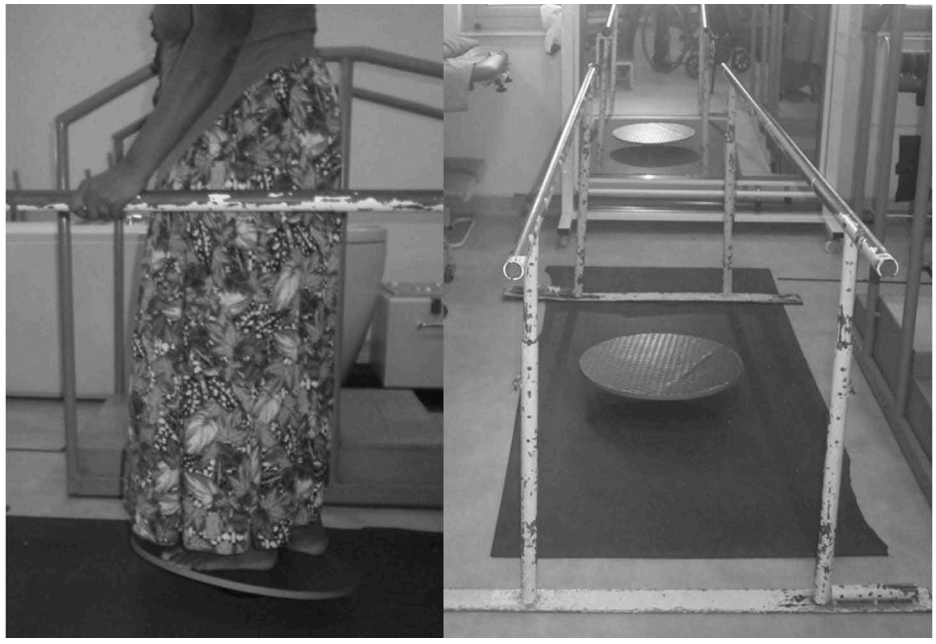

Figure 1. (a) A post-stroke hemiplegic patient performing wobble board exercises; (b) Wobble board and the frame used for stroke rehabilitation.

Wobble board is a low-tech instrument with an unstable surface, on which a person is able to stand up (Figure 1(a,b)). It has proven effects in improving counter-movement strategies to maintain balance in healthy subjects.[34] Moreover, wobble board is used to enhance dynamic balance in athletes[35,36], to restore balance in geriatric populations[37], to manage complex regional pain syndromes[38] and to rehabilitate patients with ligament sprains of ankle joint.[39,40]

A Nigerian study by Onigbinde and colleagues found that wobble board exercises were effective in increasing dynamic and static balance in stroke survivors.[41] To our knowledge, this is the only study which assessed the efficacy of wobble board exercises in rehabilitation of patients with stroke. Genetics[42,43], anthropometry[44–46], body composition[45] and geographical location[47] are major determining factors of balance. Sri Lanka is an Asian country which houses more than 20 million people from diverse ethnicities.[48] Hence, the aim of this study was to compare the findings of the above Nigerian study with our population. The current trial was designed to test the hypothesis, whether combining wobble board exercises to the existing physiotherapy program would increase the rate of recovery of the functional balance in ambulatory hemiplegic stroke patients.

Materials and methods

This study was approved by the Ethics Review Committee, Faculty of Medicine, University of Colombo, Sri Lanka (UCP/LE/13/287), and the National Hospital of Sri Lanka (AAJ/ETH/COM/2018). The study protocol conformed to the guidelines set forth by the Declaration of Helsinki.[49] Consolidated Standards of Reporting Trials (CONSORT) guidelines were used to report data.[50]

This trial was a block-randomized, controlled, observer blinded, single center superiority trial conducted in the stroke rehabilitation unit of the National Hospital of Sri Lanka from June to August 2018. The National Hospital of Sri Lanka is the premier tertiary care hospital and ultimate referral center in Sri Lanka with the largest stroke unit in the country. Eligible subjects were all adults aged 18 years or above with hemiplegia following middle cerebral artery ischemic (both acute and chronic) strokes and those who could ambulate without assistance (a score of 21 to 40 in the BERG balance scale (BBS).[51] Non-ambulatory patients, having multiple strokes, arthritis, extremity fractures, other neurological disorders affecting motor systems such as Parkinson disease and sensory systems with loss of toe or ankle proprioception of the stroke-unaffected lower limb and peripheral neuropathy were considered as exclusion criteria. Patients who could not perform a three-stage command test[52] were also excluded, as poor comprehension of the commands by the patient is a confounding factor of the BBS score. Therefore, cognitive functions and attention of those who passed the test were considered adequate to carry out the experiment. Patients in the stroke unit of the National Hospital of Sri Lanka were referred to the Department of Physiotherapy for rehabilitation by Consultant Neurologists. The primary outcome measures were the change in functional balance as measured by BBS and Four-Square Step Test (FSST) during the 6 weeks of the study. There were no secondary outcome measures. BBS and FSST are described in detail elsewhere.[51,53] BBS was calculated based on how precisely a patient could perform 14 different activities such as sitting, standing and transferring. In FSST, patient was asked to step over horizontally placed sticks in a predetermined sequence, and the best time of two consecutive tests was recorded. Patients were neither given assistance by the bystanders nor supporting devices during these tests. Both BBS[54,55] and FSST[56–58] have been recommended and validated for elderly populations with impaired balance due to strokes.

The sample size was calculated according to the method

described by Charan and colleagues.[59] A sample of 15 patients per group was necessary at 5% significant level, 80% power and 10% dropout rate based on a study by Onigbinde et al.[41] There were no changes to the trial design after the commencement.

An incomplete factorial design with two arms, each having a 1:1 allocation ratio was employed to randomize participants. A computer-generated list of random numbers with random block sizes of 4, 6 and 8 was generated by YM to allocate the participants into two groups. The neurologists, physiotherapists and the observer who measured the outcome were blinded to the allocation sequence and block sizes. Initially, 30 min of the baseline exercise program was conducted for the intervention group by a physiotherapist. The baseline exercise program included standing up on a flat surface, sitting down, walking, climbing up and down a staircase, cycling and hand cycling (supplementary file 1). Soon after baseline exercises, the wobble board exercises (Figure 1 and Table 1) were conducted by PV under the supervision of another physiotherapist for 20 min (supplementary file 2). A locally manufactured wobble board was used for this experiment. The same baseline exercise program was conducted by the same physiotherapist for 30 min for the control group. Following that the same exercise program was continued by YY for another 20 min. All three physiotherapists were trained under an expert physiotherapist and were continuously supervised during the experiment by the said person to minimize potential bias. Two assistants were kept on either side of the patient throughout the exercise program to ensure safety of the patient. The exercise program was closely monitored by a medical doctor from the neurology unit. This program was conducted twice a week for a total of 6 weeks. Before the commencement of the program and at the end, the functional balance was assessed by an independent blinded observer using FSST and BBS. All the measurements were obtained by a single observer to avoid inter-observer bias. The instructions given to the patients were culturally pre-validated and were read out by a single person during the assessment. A random sequence was generated by YM to determine the order of the assessment of participants in intervention and control groups.

Table 1. Comparison of baseline demographic and anthropometric characteristics of the participants in intervention and control groups. All the continuous data are presented as mean ± standard deviation, and categorical data are presented as number (percentage). The fourth column indicates the *p* value of the independent sample *t*-tests (#) and Pearson's Chi-square tests (§) comparing the intervention and control groups.

	Intervention group	Control group	*P*-value
Age (years)	54.93 ± 6.07	55.93 ± 5.92	.815#
Gender	9 (60%)	8 (57.1%)	.713§
Male	6 (40%)	6 (42.9%)	
Female			
Stroke characteristics			.573§
Right-sided MCA	8 (53.3%)	7 (50.0%)	
Left-sided MCA	7 (46.7%)	7 (50.0%)	
FSST pre-test score(seconds)	26.92 ± 6.68	25.14 ± 5.74	.402#
BBS pre-test score	31.33 ± 4.04	31.80 ± 4.17	.277#
Height (cm)	157.06 ± 4.99	158.80 ± 7.25	.381#
Weight (kg)	58.40 ± 7.96	57.43 ± 9.76	.477#

Abbreviations: BBS – Berg Balance Scale test; FSST – Four Square Step Test.

Statistical methods

A repeated measure multivariate analysis of variance (MANOVA) was performed to compare the effect of wobble board exercises and conventional physiotherapy in improving balance among hemiplegic patients following stroke. The dependent variables were functional balance scores as measured by the FSST scale and the BBS score. The independent variable was the study group, i.e. the intervention group or the control group. Subgroup analyses or interim analyses were not performed.

Results

Initially, 50 patients were screened for the eligibility. Of them five had peripheral neuropathy, three had multiple strokes, three could not follow three-staged command test, two had rheumatoid arthritis and one had Parkinson disease. One patient had both peripheral neuropathy and rheumatoid arthritis. Of 35 eligible patients, consent for the study was not given by five. Hence, 30 patients were randomly assigned in 1:1 allocation ratio to intervention and control groups. Subsequently, in four weeks, one patient dropped out from the intervention group as she changed her residency and defaulted follow up at our clinic. All 12 practice sessions were completed by the rest of the participants. Thus, at the end of the study 29 subjects were eligible for the analysis. Participation flow is summarized in Figure 2.

The baseline characteristics of sociodemographic variables were comparable in the two groups (Table 1). According to an independent sample *t*-test, there was no significant difference for FSST pre-test scores ($p = .441$) or BBS pre-test scores ($p = .758$) between the two groups (Table 1).

After 6 weeks of intervention, the mean FSST post-test score of the interventional group was 23.03 ($SD = 8.97$) and the mean of BBS post-test score was 40.80 ($SD = 4.81$). The mean FSST post-test score for the control group was 23.45 ($SD = 6.72$) and the mean of BBS post-test score was 37.26 ($SD = 3.76$). Apparent improvement in both groups was shown in the descriptive statistics (Table 2). Improvement of functional balance score, i.e. reduction of the elapsed time to complete the test task of the FSST and improvement of the BSS Scores in the two groups are shown in Figures 3 and 4 respectively. A Paired sample *t*-test was conducted between pre-test and post-test scores of FSST and BBS. There were no statistically significant differences in those scores (Table 2).

There were no violations of the assumptions of normality, linearity, univariate and multivariate outliers, homogeneity of variance-covariance matrices, and multicollinearity. A statistically significant difference in improvement of balance between the two study groups, $F(1,28) = 32.6$, $p = .000$; Wilk's lambda = .46 was found in a repeated measure multivariate analysis of variance

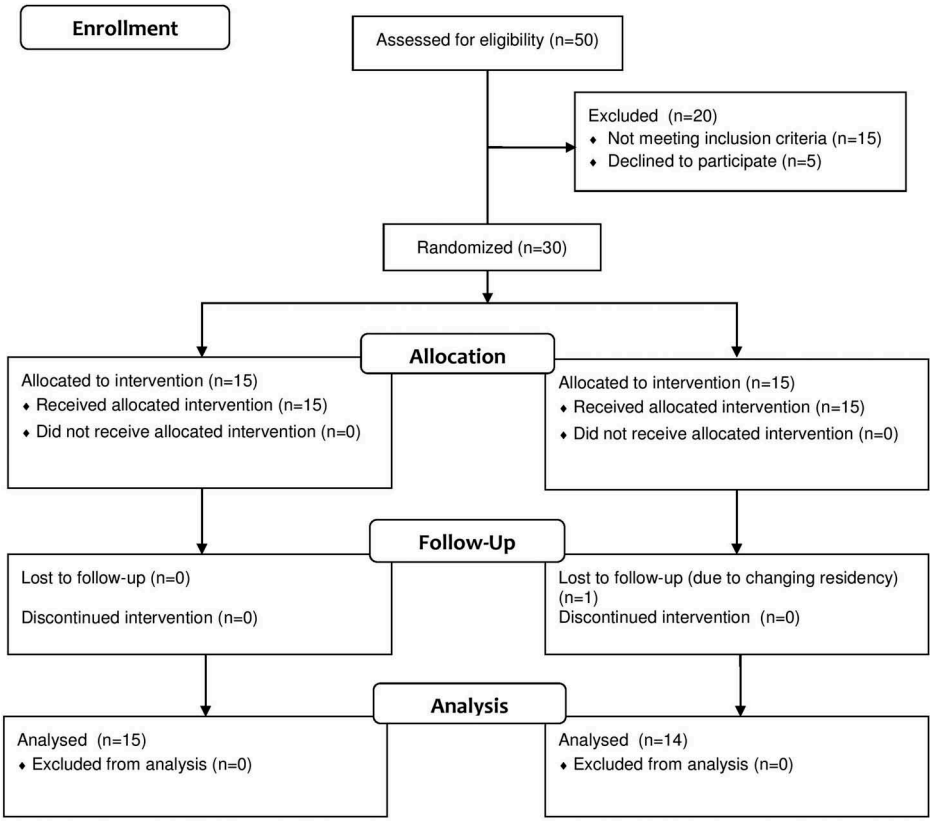

Figure 2. A summary of the participation flow in the study.

Table 2. Comparison of test scores before and after the intervention. All the continuous data are presented as mean ± standard deviation. The last column gives the *p*-value of paired sample *t*-test of pre- and post-test scores.

		Mean pre-test score	Mean post-test score	*P*-value
Interventional group	FSST	26.92 (± 6.68)	23.03 (± 8.97)	.001
	BBS	31.33 (± 4.04)	40.80 (± 4.81)	.000
Control group	FSST	25.14 (± 5.74)	23.45 (± 6.72)	.007
	BBS	31.80± (4.17)	37.26 (± 3.76)	.000

Abbreviations`BS – Berg Balance Scale test; FSST – Four Square Step Test.

(MANOVA) test. Improvement of the mean BBS score was 9.5 in the intervention group and 5.5 in the control group. Similarly, improvement of the mean FSST score was 3.9 in the intervention group compared to an increase of 1.7 in the control group. This indicated that the increment of functional balance was best achieved in the intervention arm.

There were no accidental falls or injuries to any of the participants during the trial.

Discussion

The results of this randomized controlled trial suggested that the combination of wobble board exercises with the conventional physiotherapy regime improved functional balance in patients with ischemic stroke. Since this technique does not utilize sophisticated instruments and expertise, it can be adopted in both specialized and non-specialized settings. Therefore, it can be conveniently used in resource-poor clinics in developing countries worldwide.

The efficacy of wobble board exercises to improve balance in post-stroke hemiplegic patients was initially assessed by Onigbinde and colleagues in 2009.[41] After a six-week program, there was a significant improvement in dynamic and static balance in the group who did wobble board exercises compared to the conventional exercises group.[41] However, there were certain limitations in this study. The total sample size of the study was 17; therefore, the experiment and control groups had only 10 and 7 patients, respectively. Whether the experimental group received extra time for wobble board exercises in addition to baseline therapy was not specified by the authors. Similarly, the process of blinding of the investigators who assessed the dynamic and static balance of the patients, and the subgroup analysis methodology were unclear. In addition to dynamic balance, the static balance was assessed by Onigbinde using a modified timed balance test. The BBS was used by us to assess the functional balance which is more important to perform activities of daily living.

Strengths and limitations

This clinical trial was intended to validate the use of a low-cost intervention in stroke rehabilitation, where the vast majority of clinicians of the developing countries do not have access to high-tech interventions. However, the present trial had certain limitations. There was an overrepresentation of males (n = 17, 58.6%) in the study. Only short-term outcomes of wobble board therapy were investigated; thus, the sustainability of achieved balance needs to be investigated in the long-term follow-up. This study

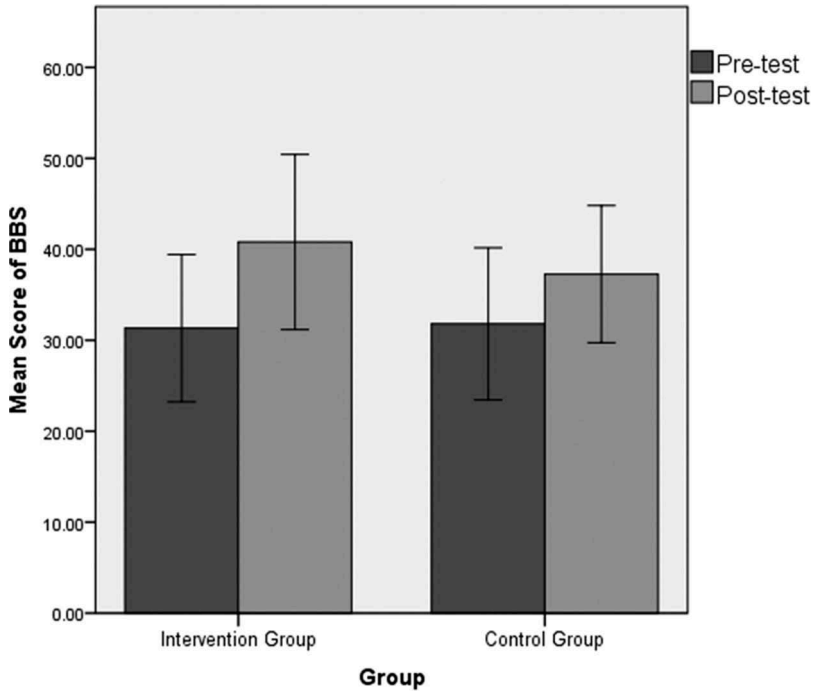

Figure 3. A column graph showing the pre- and post-means of Four Square Step Test score in the intervention and the control groups with vertical error bars for two-times the standard deviations.

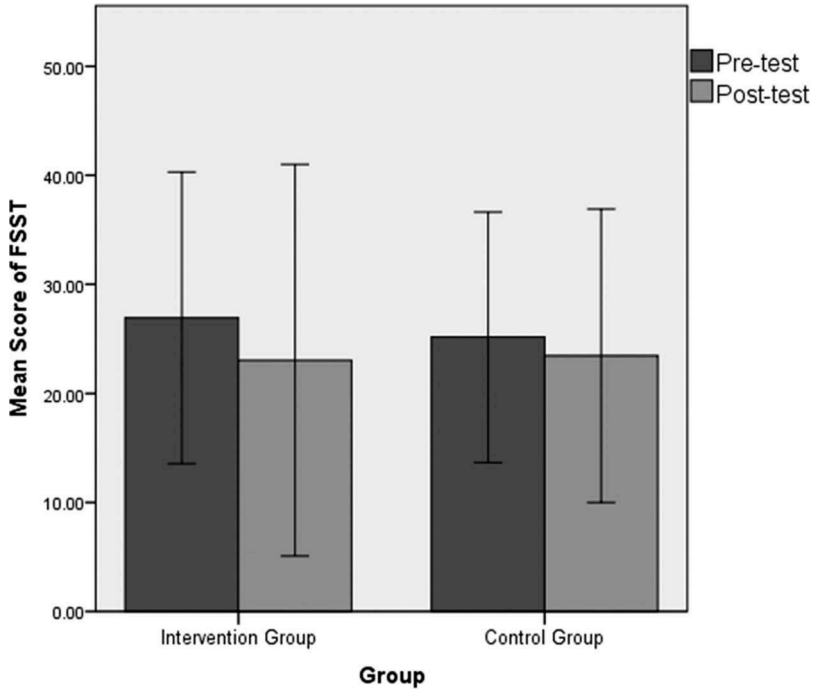

Figure 4. A column graph showing the pre- and post-means of BERG balance scale test score in the intervention and the control groups with vertical error bars for two-times the standard deviations.

replicates and extends the evidence by Onigbinde who concluded that the wobble board exercises were effective in restoring balance in hemiplegic patients following strokes. However, meticulous techniques were employed by us as per the CONSORT guidelines to conduct a single-blinded randomized controlled trial.[50] This was a single-center trial in a small sample. Nevertheless, 29 patients were studied based on a sample size calculation to achieve a power of 0.80, in contrast to the study by Onigbinde where they studied only 17 patients. An "only wobble board" treatment arm was not employed due to ethical issues since there was no good quality evidence to suggest the efficacy and safety of wobble board exercises in hemiplegic patients following strokes. Two persons were kept on either side of the patients as safety precautions during the exercises; nevertheless, there were no injuries during

the trial. Therefore, we believe that a single therapist could conduct these interventions independently. Therefore, providing safety precautions will not be a limitation to practice this technique in the general physiotherapy clinics.

Generalizability

Trial was conducted in both sexes at different levels of BSS. Post-stroke patients in both acute and chronic stages were enrolled in the study. Thus, the results of this trial are generalizable to the rehabilitation care in a wide range of patients with ischemic strokes.

Conclusions

Wobble board exercises, when combined with the conventional physiotherapy, are safe and effective in restoring functional balance in patients with hemiplegia following ischemic strokes. Multicentric large scale randomized controlled trials are necessary to establish the safety and efficacy of this novel therapy. It will enable the physiotherapists to amalgamate this technique in the rehabilitation guidelines of ischemic stroke. Furthermore, the effect of intense gait training could be compared with the wobble board treatment for stroke rehabilitation.

Acknowledgments

The authors wish to thank the patients and their family members who participated in the study. We also thank the physiotherapy staff who were involved in the trial.

Contributors

PV and DJA made substantial contribution to the conception and study design. PV was the main contributor in data collection. PV, DJA, and YM were involved in refining the study design, statistical analysis and drafting the manuscript. All authors read and approved the final manuscript.

Data sharing statement

The data are available from the corresponding author upon reasonable request.

Ethics approval

Ethics Review Committee, Faculty of Medicine, University of Colombo, Sri Lanka (UCP/LE/13/287), and the National Hospital of Sri Lanka (AAJ/ETH/COM/2018).

Funding

This research received no specific grants from any funding agency in the public, commercial or not-for-profit sector.

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