

Is Swiss-ball-based exercise superior to plinth-based exercise in improving trunk motor control and balance in subjects with sub-acute stroke?

A pilot randomized control trial

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Yagna Khurana, Manju Devi, Anujot Kaur, Thiagarajan Subramanian, Suresh Mani 

Department of Physiotherapy, School of Allied Medical Sciences, Lovely Professional University, Phagwara, India

Abstract

Introduction. Stroke is the most common cause of neurological dysfunction, associated with high mortality and morbidity. Early stroke rehabilitation is essential for optional functional recovery, particularly motor control of the trunk muscles and balance. The study investigated the effects of Swiss-ball-based and plinth-based trunk exercises for improving trunk control and functional balance in subjects with sub-acute stroke.

Methods. Overall, 20 sub-acute stroke patients aged 40–60 years were recruited and divided into the experimental group (Swiss ball exercise) and the control group (plinth exercise). Upper and lower trunk exercises were performed by the patients sitting on a Swiss ball or a plinth. The 45-minute sessions were applied for 5 days a week for a total of 4 weeks. Trunk Impairment Scale, Modified Functional Reach Test, and Functional Balance Scale evaluations were performed at baseline and at the end of the 4 weeks.

Results. The differences between the baseline characteristics of participants in both groups were not significant. After the intervention, there were significant ($p > 0.01$) changes in the Trunk Impairment Scale total, static, dynamic, and coordination scores, mental status, Modified Functional Reach Test results, and functional balance scores, with high effect sizes in the Swiss ball exercise group.

Conclusions. In patients with sub-acute stroke, trunk exercises performed on a Swiss ball were found to be more effective than those performed on a plinth to improve trunk control, forward and lateral reach, and functional balance.

Key words: trunk control, Swiss ball, plinth exercise, sitting balance, sub-acute stroke

Introduction

Stroke is the most common cause of neurological dysfunction, affecting 15 million people globally every year, and is associated with high mortality and morbidity [1]. Stroke ranked second and fifth in causing death in patients aged over 60 years and 15–59 years, respectively [2]. Among these deaths, 85% occur in developing countries alone [3]. Moreover, stroke can cause permanent disability in 5 million people each year and therefore impose a substantial burden on individuals, families, society, and government. The estimated loss of disability-adjusted life years (DALY) was 5.3% in the world, whereas 13.3% of DALY are lost in India [4]. Stroke survivors exhibit various types of disabilities: altered sensorimotor and coordination functions, cognitive and language dysfunction, and emotional disturbance [5]. One-third of stroke survivors present poor functional recovery at the end of 5 years. Hence, it is imperative to initiate stroke rehabilitation at the early phase of recovery for optimizing functional outcomes. Particularly, early recovery of trunk control and balance has been considered as a predictor for functional recovery and duration of hospital stay [6]. Therefore, the therapist should administer an early and effective exercise program aimed to improve the motor control and balance of the trunk.

Trunk muscles play an important role in supporting the human body in anti-gravity postures and providing a stable base for static and dynamic movements of daily living activities [1]. They are responsible for the dynamic stability of the spine and pelvis, which enables adequate weight shifts during

lower limb and trunk movement against gravity [7]. Subjects with stroke exhibit functional trunk and pelvic asymmetries as compared with healthy individuals of the same age and gender [8]. Trunk muscles are weakened on both the ipsilateral and contralateral side of the body to that of the brain lesion [1]; this leads to sitting balance difficulties and low sitting capacity, which are considered significant clinical problems after stroke. In regular clinical practice, trunk training exercises are applied such as reaching [2, 9–11], perturbation [12], core stability [13], and proprioceptive neuromuscular facilitation exercises [14, 15], with and without electromechanical devices providing electrical stimulation or vibration, as well as virtual and augmented reality games. However, trunk and balance recovery is the most neglected area of stroke rehabilitation, in contrast with limb rehabilitation [1]. A recent systematic review concluded that trunk muscle exercises on an unstable or stable surface could improve the trunk control and balance in both sub-acute and chronic phases of stroke [5].

Several publications demonstrated the efficacy of Swiss-ball-based exercise in stroke rehabilitation [2, 7, 10, 11, 16] but there is a scarcity of literature reporting on the effectiveness of Swiss ball training for sub-acute stroke patients; specifically, the studies describe the efficacy of trunk training for improving motor control and sitting balance. Significantly, alongside the focus of medical and physiotherapy management in the form exercise, additional neuromuscular or sensorimotor training using Swiss balls has emerged in the recent past. The research questions of this study were: Do

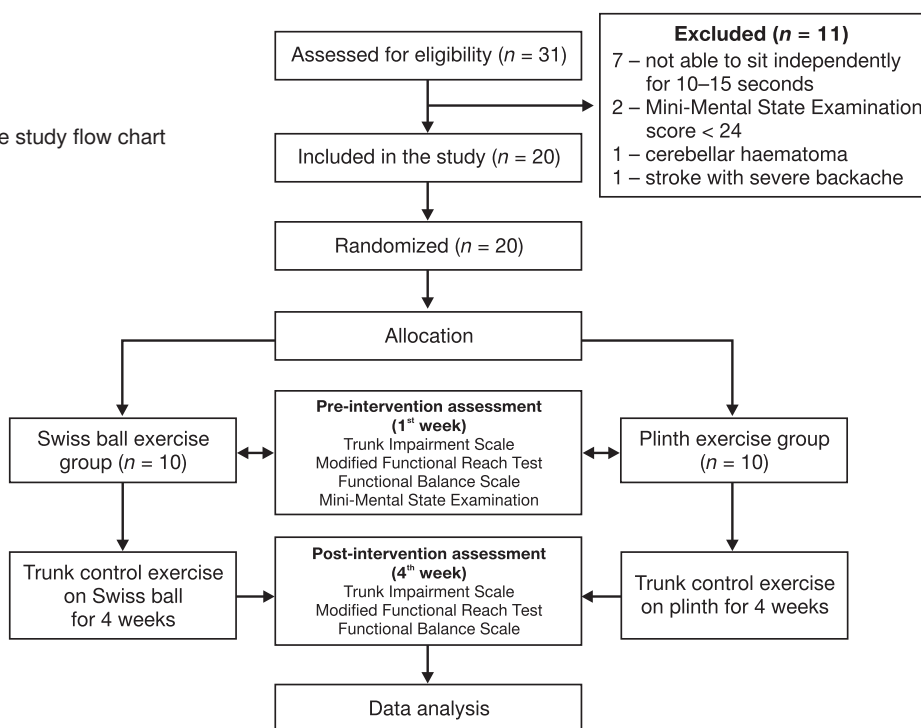
Correspondence address: Suresh Mani, Department of Physiotherapy, School of Allied Medical Sciences, Lovely Professional University, Jalandhar-Delhi, Grand Trunk Rd, Phagwara, Punjab 144001, India, e-mail: suresh.22315@lpu.co.in

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Figure 1. The study flow chart



neuromuscular exercises of trunk muscles on a Swiss ball or plinth surfaces effectively augment the motor control and balance in sitting? Is the efficacy of Swiss-ball-based exercise training different than that of plinth-based exercise training for improving trunk impairment, forward and lateral reach, as well as functional balance in sitting? This study hypothesized that there would be a statistically significant difference in sitting trunk control in sub-acute stroke patients after Swiss-ball-based and plinth-based exercise training. Therefore, the study aimed to determine the comparative efficacy of Swiss-ball-based and plinth-based exercises for improving trunk control and equilibrium in a sitting position.

Subjects and methods

Study design

This was a single-blinded pilot randomized control trial in which the study participants were blinded. The study involved pre- and post-intervention trunk control and balance data analysis in post-stroke patients. It was conducted in the in-patient departments of 3 multi-specialty hospitals between November 2019 and February 2020.

Participants and sample collection

A total of 31 hemiparetic stroke subjects were assessed for eligibility. The inclusion criteria for the study were as follows: sub-acute stroke (30–60 days after stroke), age of 40–60 years, Mini-Mental State Examination (MMSE) score of > 24, middle cerebral artery involvement as confirmed by computed tomography or magnetic resonance imaging, Brunnstrom stage I or II, ability to keep a steady sitting posture with postural sway and eyes open for 10–15 seconds, and low trunk performance (Trunk Impairment Scale score < 21). The subjects were excluded if they had any history of vertigo, faints, or other condition that might impair balance and postural control, visual deficits (visual anosia), unilateral neglect, cerebellar disease, musculoskeletal conditions like lower back pain, arthritis, or lower extremity degenerative diseases affecting motor execution. After excluding 11 patients,

20 individuals were involved. There were no dropouts in the study (Figure 1).

Outcome measures

The trunk balance, forward and lateral reach, and sitting balance were evaluated by using the Trunk Impairment Scale (TIS), Modified Functional Reach Test (mFRT), and Functional Balance Scale (FBS), respectively. TIS is a reliable ($r = 0.96$ for test-retest reliability and $r = 0.99$ inter-rater reliability) and valid tool, with good internal consistency, that has been employed in both clinical and research settings [17]. The mFRT is a modified version of the Functional Reach Test [18] and it has been utilized to evaluate the limits of stability by calculating the maximum distance that a person can travel forwards and laterally while sitting in a fixed position. The test-retest reliability of mFRT was excellent (intraclass correlation coefficient: 0.90–0.95) [19]. FBS evaluates the degree and direction of sway during quiet sitting. The available movement strategies to avoid destabilization were investigated and reported during disturbed/perturbed sitting. For seated trunk control, it was determined whether the movement techniques were (1) present and normal; (2) present but restricted or delayed; (3) present but inadequate for the specific context or circumstance; (4) abnormal; or (5) absent. MMSE was used to assess the cognitive function. It is a screening method to quantitatively evaluate cognitive mental status. It comprises questions on 11 items. Higher scores indicate better function (score range: 0–30) [20].

Procedure

A total of 20 sub-acute stroke subjects aged 40–60 years were selected on the basis of the eligibility criteria. With simple random sampling, they were divided into 2 groups: experimental (Swiss ball exercise group, SEG) and control (plinth exercise group, PEG), each consisting of 10 subjects. The participants were given a short description of the objectives and procedures of the study. Then, the baseline evaluations of trunk control (by using TIS), forward and lateral reach (by using mFRT), and sitting balance (with FBS) were taken.

Table 1. Exercises applied in the study

Exercises	Description
Active sitting [9]	The patients were asked to sit on the surface with erect back, hands on the sides, and the hip joint and knee joint bent at 90°. Both feet flat on the ground for 10 seconds
Forward, posterior, lateral bending and hip hiking activities [21]	Forward and posterior bending with hip hiking activities: the patients were told to move the trunk forward and backward while sitting on the surface with hands on the sides
	Lateral bending – upper trunk lateral flexion: the patients were asked to begin the shoulder girdle movement to put the elbow towards the ball
	Lower trunk lateral flexion: this was done by initiating the pelvic girdle movement to take the pelvic off the surface and bring it towards the ribcage
Graded weight shifting activities: anterior, posterior, and diagonal [10]	The patients were asked to sit with feet flat on the floor and move weight in anterior direction, posterior direction, and diagonally without directly bending the trunk. They were only asked to tilt the pelvis gradually, anteriorly and posteriorly eventually without losing balance
Trunk rotations to the left and right side [9]	Upper trunk rotations: these exercises were carried out with the patient sitting on the surface, arms flexed forward, and hands clasped together. Then the patient turned their arms to the left and then to the right
	Lower trunk rotations: the patients were asked to perform lower trunk rotations by moving each knee forwards and then backwards
Reaching activities in all directions [10]	Forward reach: the patients were asked to touch the target in the forward direction at shoulder height in a sitting position
	Lateral reach: this was achieved by asking the patients to reach laterally at a set point at shoulder height in order to lengthen the trunk on the weight-bearing side and shorten the non-weight-bearing side of the trunk
Proprioceptive neuromuscular facilitation technique with lift and chop [22]	Chopping: the patients were asked to sit on the surface; the therapist supported the patient, then the left arm of the participant went into the extension-abduction-internal rotation pattern, with the right arm doing the extension-adduction-internal rotation. The patient's head and neck moved into flexion to the left. The right hand grasped the left wrist and slowly moved in modified flexion-abduction-external rotation with the right arm. The patient looked to the left hand and brought the neck to the right in modified extension
	Lifting: the left arm moved into the pattern of flexion-abduction-external rotation, with the right arm holding the left arm in flexion-adduction-external rotation. The patient's neck and head stretched and moved into extension to the left. At the same time, the upper trunk of the participant started to stretch with rotation and lateral bending towards the left. The goal was to lengthen the trunk. Then, the patient brought back the arms in the opposite side
Reciprocal marching with hand raises [22]	The subjects were told to sit with erect spine, with hands on the sides or on the hips. They were then asked to start slow march, raising alternative feet off the ground, handling with comfortable pace and balance. The patients were also asked to lift alternative arms in order to increase the intensity of the exercise

Afterwards, 4 weeks of treatment were administered in both groups. Table 1 describes the applied trunk control exercises. The post-intervention assessment was conducted at the end of the fourth week, by using the same outcome measures as in the baseline assessment. No harmful or adverse event was observed during the study.

Intervention

Both SEG and PEG received the intervention for 4 weeks. The total duration of the active session was 45 minutes for 5 days a week. Each session comprised warm-up, trunk control exercise, and cool-down phases. The subjects performed stretching exercises for the hamstring, gluteus maximus, quadriceps femoris, gastrocnemius, soleus, trapezius (lower and middle fibres), biceps brachii, latissimus dorsi, and paraspinal muscles with 10-second holds for 5 repetitions lasting for 5–10 minutes [2]. SEG received trunk control exercises on a Swiss ball and PEG received the same exercises on a plinth. Depending on the patient's needs, a 5–7-minute rest was given during each exercise session. The individuals did all the exercises in a sitting position. Each exercise was performed for 4 minutes (10 repetitions, 3 sets of each seg-

ment). Implementing one or more of the following changes enhanced the intensity of the exercises: (1) decreasing the base of support; (2) trying to raise the lever arm; (3) progressing the balance limits; (4) raising the hold time (Table 1).

Data analysis

The Statistical Package for the Social Sciences (SPSS, IBM, version 18) was used for the statistical analysis. The baseline and demographic data, such as age, gender, body mass index, hypertension, diabetes, MMSE, length of post-stroke period, affected side, and type of stroke, were analysed with descriptive statistics. A descriptive analysis was performed for both groups. A paired *t*-test served to analyse changes in the dependent variables between the pre- and post-treatment status within each group. An unpaired *t*-test was used to compare the dependent variables between the groups. The ordinal data were analysed with the Wilcoxon signed-rank test and the Mann-Whitney test for comparing within and between SEG and PEG, respectively. The effect size index (*d*) was calculated as the standardized mean difference between the 2 independently observed groups. The effect size was interpreted in accordance with Cohen's clas-

sification as small ($d = 0.20$), medium ($d = 0.50$), or large ($d = 0.80$) [23].

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Lovely Professional University Ethics Committee (reference No.: LPU/IEC/2019/03/07).

Informed consent

Informed consent has been obtained from all individuals included in this study.

Results

Figure 1 shows the total number of patients recruited and the treatment allocation. Out of the 31 screened subjects, 20 patients (10 males and 10 females) were included in the study, with the mean age of 56.10 years. The general characteristics of the participants in SEG and PEG are presented in Table 2. There were no significant differences in the baseline parameters between the 2 groups.

Table 3 depicts the pre- and post-intervention values of the mental status, trunk impairment, and balance within SEG and PEG. There was a significant improvement in the total TIS ($t(9) = -7.51, p < 0.01$) and its static ($t(9) = -7.68, p <$

Table 2. Demographic and baseline characteristics of the investigated groups

Variables	Swiss ball exercise group (n = 10)	Plinth exercise group (n = 10)	p
Age (years)	56.10 ± 8.07	56.10 ± 7.534	1.000
Gender	Male	5 (50%)	
	Female	5 (50%)	
Side affected	Right	1 (10%)	
	Left	9 (90%)	
Body mass index	24.58 ± 3.84	23.66 ± 3.82	0.598
MMSE	25.70 ± 1.42	25.20 ± 1.40	0.438
TIS: total (0–23)	9.60 ± 2.22	6.90 ± 5.07	0.140
mFRT: forward lean	15.20 ± 8.83	15.93 ± 10.29	0.866
mFRT: affected side	6.59 ± 2.678	5.48 ± 2.64	0.363
mFRT: unaffected side	8.45 ± 4.29	8.01 ± 3.973	0.813
FBS	Normal	0 (0%)	
	Good	2 (20%)	
	Fair	7 (70%)	
	Poor	1 (10%)	

MMSE – Mini-Mental Status Examination, TIS – Trunk Impairment Scale, mFRT – Modified Functional Reach Test, FBS – Functional Balance Scale

Table 3. Within-group changes in the mental status, trunk impairment, and forward reach

Variables	Swiss ball exercise group (n = 10)					Plinth exercise group (n = 10)				
	Mean difference	Standard deviation	95% confidence interval	t	Cohen's d	Mean difference	Standard deviation	95% confidence interval	t	Cohen's d
MMSE	-0.60	0.82	-0.98 to -0.22	-3.27*	0.77	-0.2	0.422	-0.50 to 0.10	-1.50	0.15
TIS: total	-5.25	3.13	-6.71 to -3.79	-7.51*	3.68	-2.6	1.776	-3.87 to -1.33	-4.63*	0.54
TIS: static	-1.75	1.02	-2.23 to -1.27	-7.68*	1.84	-2.1	1.197	-2.96 to -1.24	-5.55*	1.30
TIS: dynamic	-2.10	2.27	-3.16 to -1.04	-4.14*	2.80	-0.2	1.398	-1.2 to 0.8	-0.45	0.08
TIS: coordination	-1.40	1.39	-2.05 to -0.75	-4.50*	3.48	-0.3	0.675	-0.78 to 0.18	-1.41	0.23
mFRT: forward lean	-8.55	6.02	-11.37 to -5.73	-6.35*	1.89	-4	2.449	-5.75 to -2.25	-5.16*	0.42
mFRT: affected side	-3.30	2.08	-4.27 to -2.33	-7.10*	2.02	-0.2	0.422	-1.97 to -2.25	-9.80*	0.60
mFRT: unaffected side	-7.60	3.57	-10.15 to -5.05	-6.74*	0.59	-2.20	0.92	-2.86 to -1.54	-7.57*	0.59
	Mean difference			Z		Mean difference			Z	
FBS	-1.89			-2.6656*		-0.2			-2.0226*	

MMSE– Mini-Mental Status Examination, TIS –Trunk Impairment Scale, mFRT – Modified Functional Reach Test, FBS – Functional Balance Scale
* p < 0.01

Table 4. Between-group comparison of the mental status, trunk impairment, and forward reach

Variables	F	Mean difference	Standard error	95% confidence interval	t	Cohen's d
MMSE	0.04	1.30	0.54	0.16 to -2.44	2.40*	1.13
TIS: total	8.80	8.00	1.57	4.71 to -11.29	5.11**	2.41
TIS: static	3.31	1.50	0.43	0.6 to -2.4	3.50**	1.65
TIS: dynamic	11.24	4.30	0.92	2.38 to -6.22	4.70**	2.22
TIS: coordination	2.37	2.20	0.51	1.12 to -3.28	4.28**	2.02
mFRT: forward lean	6.16	8.30	3.05	1.90 to -14.70	2.72**	1.28
mFRT: affected side	0.06	4.70	1.13	2.33 to -7.11	4.17**	1.97
mFRT: unaffected side	5.80	6.10	1.19	3.61 to -8.60	5.15**	2.43
	Mean rank (Swiss ball)	Mean rank (plinth)	Z			
FBS	14.5	6.4	3.06**			

MMSE– Mini-Mental State Examination, TIS –Trunk Impairment Scale, mFRT – Modified Functional Reach Test, FBS – Functional Balance Scale
 * $p < 0.05$, ** $p < 0.01$

0.01), dynamic ($t(9) = -4.14, p < 0.01$), and coordination ($t(9) = -4.50, p < 0.01$) scores, MMSE ($t(9) = -3.27, p < 0.01$), mFRT ($t(9) = -6.35, p < 0.01$), and functional balance ($Z = -2.02, p < 0.01$) in SEG, with high effect sizes. Similar significant changes were noticed in PEG, with moderate effect sizes, except for the dynamic ($t(9) = -0.45, p > 0.01$) and coordination ($t(9) = -1.41, p > 0.01$) scores of TIS and MMSE ($t(9) = -1.50, p > 0.01$).

Table 4 describes the differences in the mental status, trunk impairment, and dynamic balance between SEG and PEG. There was a significant improvement in the total TIS ($t(18) = 5.11, p > 0.01$) and its static ($t(18) = 3.50, p > 0.01$), dynamic ($t(18) = 4.70, p > 0.01$), and coordination ($t(18) = 4.28, p > 0.01$) scores, mental status ($t(18) = 2.40, p > 0.05$), mFRT ($t(18) = 2.72, p > 0.01$), and functional balance ($Z = 3.06, p < 0.01$), with high effect sizes, in SEG. This indicates that the Swiss-ball-based exercise management was superior to plinth-based exercises for improving the mental status, trunk impairment, as well as dynamic and functional balance among the stroke subjects. It is worthwhile to note that the dynamic balance on the paretic side improved significantly ($t(18) = 4.17, p > 0.01$) in SEG as compared with PEG.

Discussion

This randomized control trial aimed to determine the effect of exercises administered under a stable (plinth) and unstable (Swiss ball) surface in improving static and dynamic trunk control of post-stroke subjects. The results of the study clearly show that both SEG and PEG exhibited significant improvements in TIS, mFRT, and FBS. However, SEG obtained much greater effect sizes and significant results for trunk lateral flexion and rotation as measured by dynamic balance and coordination subscales of TIS, respectively. A significant improvement in the cognitive function in SEG as compared with PEG was observed. Similarly, both the dynamic balance and functional balance as determined by mFRT and FBS, respectively, showed improvements in both groups. Even though the same sets of an exercise-based intervention targeting trunk control muscles were applied in both groups, the post-stroke subjects in SEG demonstrated a superior benefit than those in PEG in trunk control and static and dynamic control.

Stroke survivors often experience functional, as well as cognitive impairments, which hamper their personal and social lives. It is said that about 69% of stroke survivors suffer from post-stroke cognitive impairments [24]. In the present study, an effort was made to determine exercise intervention effects on the changes in the mental status of stroke patients. Mental status plays a very important role in rehabilitation as it helps the patient to learn and understand the emotional, social, and intellectual skills needed to live, learn and work in the community with the least amount of professional and family support. The MMSE scale evaluating the cognitive mental status [25] showed an improvement in the cognitive function among subjects in SEG. The post-intervention values for MMSE in SEG reflected significant improvements as compared with PEG. These changes in cognitive function may be due to the fact that SEG faced more challenges on the unstable surface of a Swiss ball, which demands more focus from the patients and requires a considerable amount of therapist supervision.

The regular tasks in the sitting position demand a good trunk control to create a static and dynamic base for maintaining postural control and equilibrium [5, 26]. Higher trunk control and sitting balance improve the functional recovery and reduce the duration of hospital stay in patients with stroke [6]. Impairments in balance and mobility are early predictors of post-stroke recovery [2]. In this study, although the total and static components of TIS improved significantly in both SEG and PEG, the dynamic and coordination TIS scores significantly improved in SEG alone, with high effect sizes. A Swiss ball offers the most unstable base for exercising, which augments the dynamic balance and coordination. It was reported that when trunk training exercises were administered in conjunction with physiotherapy, the recovery period of stroke subjects enhanced and greater recovery of trunk strength and dynamic sitting balance was observed [5]. On the other hand, the study revealed that the sitting balance training on a Swiss ball was superior to the plinth-based exercise training in improving balance. This result is strongly supported by earlier studies [5, 6, 10, 16, 21] which concluded that the dynamic and coordination subscales of TIS improved much after trunk control exercises among stroke patients. This is because postural characteristics of the trunk, as well as the dynamic sitting posture of hemiparetic patients im-

proved after TIS-measured trunk exercises [27]. Therefore, truncal exercises on an unstable base such as a Swiss ball should be recommended and administered during the early phase of stroke recovery when the tone initiates to optimize the good functional outcomes.

A possible reason for improved trunk control in SEG could be that the motion of the Swiss ball underneath the patient causes postural instability in a gravitational pull, to which the trunk muscles respond reactively to maintain the postural stability needed. Swiss ball rocking and rolling movements improve alertness by linking the vestibular system to the reticular formation [28]. Exercises performed on a Swiss ball, therefore, enhance the role of movement and balance, and promote patient engagement, facilitating the use of affected muscles. In addition, the trunk function was enhanced in our study owing to improved trunk proprioception. The practice of movements such as trunk lateral flexion and rotation may improve the sensory-motor perception, postural alignment of the trunk, and equilibrium reactions in post-stroke patients via indirect cortical links to the extrapyramidal network [7].

In this study, both SEG and PEG displayed significant changes in dynamic forward and lateral reach and static and dynamic sitting balance, measured with mFRT and FBS, respectively. The trunk exercises increased the average distance of forward reach and lateral reach toward the *hemiparetic* side while securing a stable base of support. However, the changes in forward reach were bigger in SEG as compared with PEG. Similarly, the lateral reach for the affected side had a very high effect size in SEG as compared with PEG. Administering balance and trunk control exercise on a Swiss ball results in a substantial increase in maximum distance in all 3 planes of movement (forward, ipsilateral, and across) without compromising balance [5]. Yu et al. [29] reported the post-intervention distance of forward reach among the study group that performed balance training on a Swiss ball as 35.8 ± 5 cm, with the baseline assessment of 32.1 ± 4.9 cm. Summing up, Swiss-ball-based trunk control and balance training may improve the forward reach and dynamic balance in patients with stroke [29].

Limitations and future research

There are a few limitations to this study. Firstly, it was performed among individuals aged 40–60 years. Future research should focus on patients older than 60 years with stroke. Secondly, the majority of the subjects had stroke lesions on the right side. So, future studies should include left-sided lesions as the dominance of the affected side plays a major role in rehabilitation and functional recovery. In this study, only 20 sub-acute stroke patients were investigated; hence, it is difficult to extrapolate the application to all elderly population. Further research should thus involve a wide variety of stroke populations in a multi-centre setup with a larger sample size. As there was also no follow-up after the intervention, the study cannot indicate the carry-over effects for the patients. Therefore, in the future, it would be useful to determine the duration of the progress by including a delayed post-intervention test or a follow-up. This therapy may be extended to other forms of neurological impairments, e.g. spinal cord injury, multiple sclerosis, and cerebral palsy. Furthermore, future studies may apply more objective outcome measures for muscle tone assessment, such as electromyography, and evaluate quantitative changes in the balance reaction by using the Balance Master or force platforms.

Conclusions

In conclusion, trunk exercises performed on an unstable support surface improved the trunk muscle adjustment, hence affecting the mobility of distal lower limbs. Therefore, an unstable support surface provides a superior environment for training trunk muscles in the sub-acute phase of stroke. This indicates the importance of trunk exercises in the rehabilitation of stroke patients. Swiss ball exercises more effectively improve the trunk control and sitting balance in sub-acute stroke patients as compared with plinth-based exercises.

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Disclosure statement

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Conflict of interest

The authors state no conflict of interest.

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