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Original Research Article

An Intensive Strength Training Intervention to Improve Balance in Post Stroke Hemiplegics - A PROBE Pilot Study

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ABSTRACT

Purpose: Stroke is emerging disease in India and leading cause of disability in elder population. There is lack of evidence in the management of balance with strength training intervention to address the neuro muscular recruitment and post stroke weakness. The purpose this study is to determine the feasibility and sample size for intensive strength training intervention for post stroke population. **Design:** This study is PROBE in design with block randomization. **Methods:** Totally 18 subjects were enrolled and 9 subjects were randomly allotted to each group. The experimental group received intensive strength training program for the period of 2-3 hours per day for 6 days a week for 6 weeks with conventional physiotherapy. The control group received conventional physiotherapy only. The outcome was measured by Berg balance scale (BBS) and the data was collected before the intervention and after 6 weeks of intervention. **Analysis:** The descriptive statistics was done to calculate the mean and SD for both the groups. Based on mean difference and pooled SD, the sample size was calculated. **Result:** The experimental group shown mean improvement of 10.88 $\pm$ 3.78 and control group shown 6.44 $\pm$ 3.97 in BBS and the effect size was 1.15. The sample size estimation was done with assumed statistical power and significance. **Conclusion:** The intensive strength training intervention was a feasible and

effective procedure on balance measures in post stroke hemiplegics. Further studies are needed with intervention and outcome measures on mobility and gait with longer follow up.
Key words: stroke, balance outcome, strength training, physiotherapy.

INTRODUCTION

Stroke is the largest leading single cause of neurological disability, immobility and individuals with post-stroke are the largest consumer of rehabilitation services, [1] of the survivors, about 50% will have a significant long-term disability. [2] Approximately 15% to 30% of stroke survivors are permanently disabled, making stroke a leading cause of serious long-term disability in the entire world. Major impairment causing disability in these patients is motor weakness. Most stroke survivors continue to live with residual physical impairments, which may promote a sedentary lifestyle and resultant secondary complications. [3]

Individuals with mild strokes may have significant impairments in postural control and gait velocity. [3-6] For those who do walk after a stroke, their gait is often slow; they have poor endurance and balance, and have changes in their quality and adaptability of their walking pattern. [7, 8] Although functional ambulation is the primary goal for many individuals after stroke, many never regain this ability. [9] As individuals with chronic stroke continue to ambulate with a degraded pattern of coordination, they are at greater risk of falling, developing a fear of falling, and losing independence and function. [8] Balance impairment is the major cause of locomotor disability in stroke population. [10]

Falls are common in patients with stroke in rehabilitation settings. [11] Fall incidence rates between 23% and 50% have been reported in studies of people with chronic stroke (> 6 months post stroke). [12-15] This rate is much higher than rates reported for older community- dwelling adults without stroke (11%–30%) [16-18] but lower than rates for people with sub acute stroke (1-6 months post stroke-(25%)). [19] Injury is a frequent consequence of falls in people with chronic stroke, with up to 28% reporting an injury. [20]

Balance problems are thought to be common after stroke, and they have been implicated in the poor recovery of activities of daily living and mobility and an increased risk of falls. [13, 21-23] The other consistent finding is a positive relationship between balance disability and other aspects of function, such as mobility, ADL, and falls. [6, 24-34] The major cause of balance disturbances after stroke is the CNS lesion which affects the muscle recruitment and synergies. Following stroke, patients lose functions of the motor, sensory and higher brain cognitive faculties to various degrees which lead to diminished balance. Symmetry of weight bearing is also impaired following stroke; with patients bearing as much as 61% to 80% of their body weight through their nonparetic lower extremity. [35] After a stroke, the recovery of balance is considered to be of crucial importance to achieve autonomy in activities of daily living. [7] Deficits in balance control can make functional activities extremely challenging and result in falls and immobility being considered a leading complication post-stroke.

Exercise programs that are based on knowledge of the pathophysiology of stroke-specific balance and gait deficits can be most successful in preventing falls. Generally, research has suggested that task-specific exercises would be most beneficial for individuals with stroke, because this approach is thought to drive neural plasticity. [36] Therapeutic interventions are

thought to be effective in reducing impairments, improving functional abilities and reducing disability in patients following stroke although scientific evidence is limited. The purpose of our pilot study was to determine the feasibility and to estimate the sample size of intense strength training for individuals with balance disability after stroke.

METHODS

Design:

This pilot study is a Prospective Randomized Open Blind End Point (PROBE) in design with control group.

Study setting:

The study was carried out at department of therapeutic exercise, Krupanidhi physiotherapy center, Krupanidhi college of Physiotherapy. Bangalore.

Subjects:

Totally 18 subjects were enrolled for this study and randomly divided in to two groups with block Randomization method. All subjects have been recruited from the physiotherapy center and from the community. They have been enrolled for this study after screening, based on inclusion criteria: (1) Subjects with first stroke. (2)The stroke must have occurred within the previous 12 months. (3) Subjects with age group between 40 to 70 years. (4) Balance score less than 40 on the Berg Balance Scale. (5) Able to walk independently for 10 meter distance with or without support. (6) Able to understand and follow the verbal commands & has sufficient language ability to follow testing procedures and the exclusion criteria were: (1) Subjects with transitional attack, transient ischemic attack & Hemiparesis. (2) Subjects with double stroke attack and more than one stroke attack. (3) Subjects who are suffering from vestibular and /or visual deficits. (4) Subjects with major cardio vascular problems like mitral valve stenosis, deep vein thrombosis & history of serious cardiac disease & Poor cardio vascular fitness like cardiac insufficiency (like myocardial infarction). (5) Subjects with uncontrolled hypertension (>150/90 mm Hg). (6) Subjects with orthopedic / musculoskeletal problems which could affect balance. (7) Subjects with pain while walking. This study & intervention procedures were approved by the Institutional Review Board and all subjects have been signed the written informed consent.

Intervention

The control group has received the conventional physiotherapy which has standard Physiotherapy intervention and experimental group received the conventional physiotherapy and intensive strength training program for the period of 2-3 hours per day for 6 days a week for 6 weeks. The strength training included the arms, shoulders, chest, abdomen, back, hips, thighs and legs in therapeutic gymnasium. Warm up exercises includes the 25 % of 1 RM [37] for 4 times and followed by 50% to 70% of 1RM [37, 38] for 10-15 [37, 38] repetitions of 3 sets [37, 38] for each muscle groups. Blood pressure and pulse were monitored before, after the intervention and during the intervention if indicated. Intermittent rest was given during strength training not more than 25 minutes in 2 hour session.

Outcome Measures

The berg balance scale is reliable and valid instrument, [39] used to assess the balance before the intervention and after 6 weeks of intervention. The berg balance scale is designed to measure the static & dynamic aspect of the balance and balance

disability [39] in individuals with stroke. The pre intervention data was taken by a principal investigator and post intervention data was collected by another physiotherapist who blinded about the intervention.

Data Analysis

The descriptive statistics (mean, SD) has been done for dependent variable. The power and significance level were determined. The sample size estimation [40, 41] was calculated with pooled standard deviation, mean difference between control and experimental group with assumed statistical power (90%) and significance (0.5). [40, 41] The sample size estimation procedure was recommended by John [40] (2003) & Rohrig [41] et al (2010) for comparison of two group means.

RESULTS

Based on our pilot study findings on primary outcome of BBS, mean and SD difference of pre and posttest in experimental group were 10.88 and 3.78 and the similar values for the control groups were 6.44 and 3.97. The calculated effect size was 1.15 for above mentioned mean and standard deviation. The sample size was calculated with assumed statistical power of 90%, significance level at 0.05 and attrition rate of 10%, the sample size estimated to be 36 (18+18) for the total study with 18 subjects in each group.

DISCUSSION

The purpose of this study was to determine feasibility and to calculate the sample size for an intensive strength training intervention over conventional physiotherapy (experimental & control group) for individuals with stroke. Based on the available mean and SD for control group and experimental group with the 90% statistical power and significant level of 0.05, the estimated sample size was 18 subjects in each group including the attrition rate of 10%.

There is a strong association between balance and falls. The individuals with stroke who has BBS score less than 45/56 is having more risk of falling. In our study, 5 of 9 subjects reached the cut off score (45/56) in experimental group and 2 were reached in control group. While comparing the minimum detectable change of 6 in BBS, the experimental group demonstrated with 7 subjects of minimum detectable change and in control group 4 subjects were demonstrated the change.

The study done by Fritz et al [42] (2007) intervened with intensive mobility therapy for gait, balance and mobility with 3 hours per day for only 10 days with 8 patients without control group. They have enrolled the patients who had a score less than 45 out of 56 in BBS and in our study, we enrolled patients who had BBS score less than 40 out of 56. In our study, we had 2-3 hours of intervention per day for 6 days per week for continuous 6 weeks and had a control group with enrollment of 9 patients in each group.

The study published by Vearrier et al [43] (2005) done intervention with massed practice approach followed by CIMT for 10 patients for 6 hours per day for consecutive 2 weeks and enrolled patients with minimum score of 30/56 in BBS. The result produced significant improvement in reactive postural control and steady state postural control.

In previous studies, Fritz et al enrolled the patients with more than 6 month of stroke duration and Vearrier et al enrolled patients with more than 1 year of post stroke duration comparing to our study enrolled the patients who had less than 1 year of post stroke duration. The present

study intervened with intensive strength training exercises comparing to Fritz et al intervened with intensive mobility therapy and Vearrier et al intervened with intensive massed practice approach. We kept the intervention duration for 2-3 hours per day to avoid the undue fatigue which reduce the capacity for motor learning.

Our study had meaningful pre test to post test improvement in BBS, i.e. 31.2 to 42.1 in experimental group and control group had between 28.7 to 35.2 comparing with study done by Fritz et al was 31 to 43 and study done by Vearrier et al was 31 to 43 in BBS. There was similar mean improvement in our study and Fritz et al study, because both studies had lower functioning subjects and demonstrated more mean improvement in both studies. The study done by Fritz et al and Vearrier et al, did not have a control group and investigators were not blinded. In our study, post test data investigator was blinded about the study and intervention. The follow up might have been done to understand and observe the maintained improvement.

CONCLUSION

The intensive strength training program is a feasible intervention and demonstrated large effect size in balance measures on post stroke hemiplegics. The strength training intervention resulted in a promising effect on balance improvement in post stroke subjects. Further studies are warranted with combination of mobility intervention and task specific activities to address the deficit in gait and functional activities with inclusion of outcome measures on mobility and gait with longer follow up. This may address the overall deficit in functional aspect of improvement in post stroke subjects.

Characteristics of patients in control group

Sl no	Age	Gender	Duration of	Side of	Type of stroke
1	44.00	M	10	Right	ischemic
2	58.00	M	5	Left	ischemic
3	64.00	F	7	Left	ischemic
4	68.00	M	7	Left	Haemorragic
5	62.00	M	6	Left	Haemorragic
6	69.00	M	5	Right	ischemic
7	58.00	M	4	Right	ischemic
8	64.00	M	6	Right	Haemorragic
9	64.00	M	8	Left	ischemic
Mean	58.33	--	6.44	--	--
SD	7.69	--	1.81	--	--

Characteristics of patients in experimental group

Sl no	Age	Gender	Duration of	Side of	Type of stroke
1	63.00	M	8	Right	ischemic
2	62.00	M	11	Right	ischemic
3	50.00	M	10	Right	Haemorragic
4	56.00	M	5	Right	ischemic
5	44.00	M	9	Right	ischemic
6	62.00	M	6	Left	ischemic
7	66.00	M	4	Left	Haemorragic
8	67.00	M	8	Left	Haemorragic
9	55.00	M	5	Right	Haemorragic
Mean	61.22	--	7.33	--	--
SD	7.47	--	2.45	--	--

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