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Original Article

Conjunct Effects of Supported Standing and Functional Electrical Stimulation on Strength and Functional Mobility in Acute Stroke: A Randomized Clinical Trial

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ABSTRACT

Background: After an acute stroke, many patients face difficulty while performing activities of daily living. Supported standing is used for the early mobilization of patients with stroke. The use of functional electrical stimulation is an adjunct component of rehabilitation to augment the strength of lower limbs resulting in better trunk control during functional mobility. Combined effects of electrical stimulation with early weight-bearing exercises can be an effective treatment as compared to typical conventional post-stroke rehabilitation. **Objective:** To evaluate the conjunct effects of supported standing and functional electrical stimulation on strength and functional mobility in acute stroke. **Methods:** A single-blinded randomized clinical trial was conducted from March to September 2021. Participants aged between 30 to 65 years, both gender, after fulfilling the inclusion criteria were allocated randomly into two groups (32 patients per group). The conventional therapy included positioning, ROM exercises and bed mobility exercises along with supporting standing on tilt tables initially and later on standing frames and walkers for 30 minutes/day five times per week, for almost six weeks while the experimental group received functional electrical stimulation in standing position on the tilt table in addition to conventional therapy. The data was analyzed using SPSS version 24 and for descriptive analysis, mean and standard deviation were used for numerical continuous variables while categorical variables were presented by frequencies and percentages. Independent sample t-test was applied for the comparison between both groups in quantitative

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variables, whereas the chi-square test and Fisher Exact test were used for qualitative variables at baseline. Non-parametric Mann-Whitney U test and Wilcoxon Signed Ranks test was applied to assess **Results:** The findings showed that the score of Berg balance scale, Rivermead mobility index and manual muscle testing were statistically significant for both within and between the groups (p-value<0.001). **Conclusion:** It was concluded that supported standing technique along with functional electrical stimulation and conventional physical therapy was found to be more effective in improving functional mobility, balance and strength among acute stroke patients rather than standard physical therapy alone.

INTRODUCTION

Stroke is a crippling disease rendering thousands paralyzed and leads a huge extent of individuals to death around the world. Pakistan shares a huge weight of this overwhelming disease.[1] Among different causes of mortality and disability, stroke is a major one with only a small extent of patients gaining maximum recovery after the acute phase worldwide.[2] In stroke patients, motor dysfunction is the factor that is restricting one's ability to move and capacity of performing activities of daily living (ADL).[3] In the acute phase of stroke, almost 70 to 80% of individuals have basic mobility issues while ambulating.

One of the common treatment procedures used for the early mobilization of patients in acute stroke is supported standing when the lower limb strength is insufficient and when the patient has poor trunk control.[4] In dealing with patients suffering from stroke, the main physical therapy goal is to enhance the functional recovery of the pelagic side by retraining the patients to regain independence in ADLs.[5] In the last few years, factors that might help to provide recovery from acute stroke are attaining importance.[6] It will bring better results when stroke patients are treated early in the stroke unit. It includes immediate treatment, movements and attentive observation of clinical variables.[7]

Ideal recovery from stroke depends on the examination of factors affecting the functional restoration capability of the patient. These factors include the degree of disablement, different medical conditions, the level of cognitive function, confinement of ADLs, problems in social interaction and incorporation.[8] In an acute stroke, it seems to be difficult for many patients to perform desired movements. Muscle contraction can be produced by functional electrical stimulation (FES) which is known as an effective treatment along with typical conventional post-stroke rehabilitation.

But in most of the studies suggestions are related to the improvement of gait of patients with chronic stroke only when electrical stimulation is applied. While taking into account the significance of quick movement attainment, some investigators study and describe the role of FES in an acute recovery phase.[9] A pilot study was conducted in Korea to evaluate the effects of FES on balance in stroke sufferers in an upright position and concluded that in a standing position, stimulation is more effective and exhibits excellent and more beneficial effects than in a lying position to improve the balance after stroke.[10]

Supported standing strengthens the main antigravity muscles so they can be used to regain trunk muscle control and prepare for standing and walking. In acute treatment, supported standing can be used to enhance respiration, increase alertness and consciousness and treat orthostatic hypotension. It is considered to increase the strength of antigravity muscles, increase and enhance upper body control, increase standing

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capacity and repetitive standing may produce adequate mechanical loads to preserve bone mineral density.[11] Supported standing devices e.g., tilt tables, standing wheelchairs, standers and frames help their users to achieve and maintain upright full or partial weight-bearing standing positions and through the back of the heel, front of knee and back of the hip, with the help of supports and straps, hip, knee and ankle can be stabilized.[12]

Walking is a significant factor in performing many actions of everyday activities. Very few studies were carried out to assess the out measures of early weight-bearing in acute stroke. Similarly, most of the studies evaluated the effects of FES in sitting or lying positions but only a few studies considered FES in standing positions. There is a lack of evidence showing the combined effect of supported standing and FES in acute stroke. Therefore, a study is needed to evaluate the combined effects of supported standing and functional electrical stimulation on strength and functional mobility in acute stroke.

METHODS

A single-blinded, parallel, randomized clinical trial was conducted at Ajaz Ali Physiotherapy Clinic and Wahid Trust Hospital Gujrat, Pakistan from March 2021 to September 2021. The trial was conducted according to the CONSORT Guidelines and registered on 31/01/2021 in the Iranian Registry of Clinical Trials with reference number IRCT20190828044636N1. Participants fulfilling the inclusion criteria were selected consecutively and were then allocated randomly to the experimental group and conventional treatment group. To take readings at pre-treatment and post-treatment levels, outcome assessors were recruited who were blinded to the treatment group. The sample size was calculated by using the Rivermead mobility index (RMI) scale as an outcome measurement tool with $\mu 1-\mu 2$.[4] Using the following formula including 5% drop out, $n = (Z_{\alpha}/2+Z_{\beta})^{2} \times [2(^{\delta})^{2}] / (\mu 1-\mu 2)^{2}$ The total sample size of this study was 58, where n is the sample size required for each group, $\mu 1$ is the mean change in RMI in interventional group A is 12.1, while $\mu 2$ is 10.1. $\mu 1- \mu 2= 2$ which is the clinically significant difference. The standard deviation is 2.7 and $Z_{\alpha}/2$ depends on the power of significance, for 5% that was 1.96. Z_{β} depends on the power of the study, for 80% this is 0.84.[13] The minimal sample size per group was 29 patients per group.[9]

Simple random sampling technique was used to select the participants. Computer generated randomization technique using the online sequence number generator for the random allocation of patients in two groups has been used to collect the data. Participants of 30 to 65 years of age were selected according to the following inclusion criteria; adults with acute stroke, both ischemic and hemorrhagic stroke, patients able to react on verbal command, medically stable patients and those who were able to walk before the stroke.

While the patients with unstable cerebral perfusion, uncontrolled diabetes mellitus, hypertension and associated cardiac problems, having associated problems in the limb e.g., deep vein thrombosis, any orthopedic condition e.g., arthritis and fractures and if the physiological variables (blood pressure, oxygen, heart rate, temperature) go beyond set safety limits and with severe fatigue were excluded from the study.[4] Baseline readings were recorded by an assessor who was a qualified and experienced physiotherapist.

RMI and Berg balance scale (BBS) were used to measure functional mobility while manual muscle testing (MMT) score was used to measure muscle strength. RMI was assessing mobility disability in patients with stroke. The reliability is 0.96. RMI includes 15 items of which 14 are self-reported and 1 is directly observed. Each item is scored “0” for a no response, and "1" for a yes response. A maximum higher score of 15 indicates better mobility execution.[14]

BBS was used to assess balance by performing different functional activities such as reaching, bending, transferring, and standing that incorporates most components of postural control: sitting and transferring safely between chairs; standing with feet apart, feet together, in single-leg stance, and feet in the tandem Romberg position with eyes open or closed; reaching and stooping down to pick something off the floor. Each item is scored along a 5-point scale, ranging from 0 to 4, where zero indicates the lowest level of function and 4 is the highest level of function. The total score ranges from 0 to 56. As the score rises there is less risk of fall. The reliability of BBS is 0.98.[15] MMT is an important tool to assess the strength of the muscles.

It is a six-score scale and as the score increases the muscle is considered to be strengthened.[16] A sample size of 61 was taken with 29 patients in the experimental group and 32 patients in the conventional therapy group. Informed consent was signed by all the participants. The demographic data and pretest measurements were taken with the help of the MMT score of lower extremity antigravity muscles (i.e., Gluteus Maximus, Quadriceps Femoris and Tibialis Anterior), BBS, RMI prior the intervention.

Conventional Treatment Group (CPT):

Patients were randomly allocated through an online sequence number generator. Demographic data was noted and informed written consent was signed by the patient. The conventional treatment included positioning, range of motion and bed mobility exercises along with supported standing using initially a tilt table and later using standing frames and walkers for 30 minutes once a day and five times a week for six weeks. Once the training was over, post-test measurements were taken from both groups by using MMT, BBS and RMI.

The Experimental Group (EXP):

Twenty-nine patients in this group received the same CPT with concurrent application of FES. Stimulation was applied by two-channel comfy stimulators (model EV-806). Stimulation was applied by square surface electrodes of 1"× 1". Electrodes were applied at the points Gluteus Maximus, Quadriceps Femoris and Tibialis Anterior for 10 minutes each. Stimulation was applied at a pulse rate of 40 Hz and pulse width of 180 µs. Posttest measurements were taken from both groups using MMT, BBS and RMI.

Data were entered and analyzed using SPSS version 24. The Shapiro-Wilks test was applied to check the normality distribution. For descriptive analysis, the mean($\bar{x}$) and standard deviation (S.D) were used for numerical continuous variables while categorical variables were presented by frequencies, percentages and median (IQR).

Independent sample t-test was applied for the comparison between both groups in quantitative variables, whereas the chi-square test and Fisher Exact Test were used for qualitative variables at Baseline (Table I). Non-parametric Mann-Whitney U test and Wilcoxon signed-rank test were applied to assess the average difference between and within group comparison at the time of admission (baseline) and after the end of treatment (six weeks) for the BBS, RMI and MMT score of hip extensors, knee extensors and ankle dorsiflexors respectively. Data were analyzed at a 95% confidence level.

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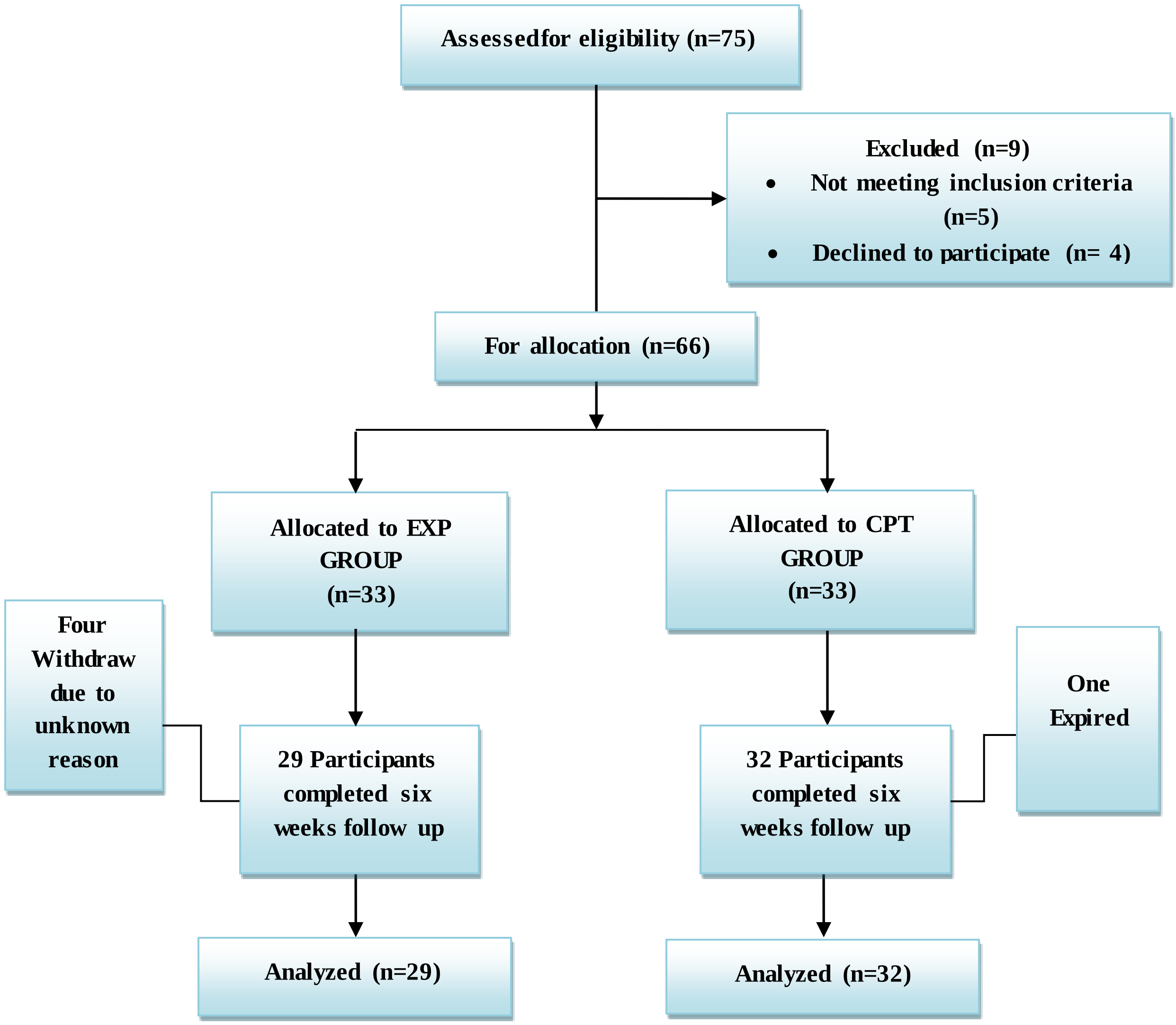
Figure 1: CONSORT Flow Chart Showing Enrollment, Intervention Allocation and Follow-Up



RESULTS

In this trial, 75 patients were assessed with acute stroke and five were excluded due to ineligibility while 4 refused to participate (Figure I). About 66 participants were randomly allocated to two groups and 33 participants were assigned to each group. Table I shows the demographic characteristics of participants. The average age of participants in the experimental and conventional groups was 53.28±7.15 and 56.69±7.28 years respectively while 21(72.40%) and 23(71.90%) participants range in age between 50 to 60 years. Approximately equal distribution of gender, paretic side, type of stroke and stroke duration (days) was recorded in both groups.

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Assessment of outcome measures (BBS, RMI, MMT for hip extensors knee extensors, ankle dorsiflexors) was done at baseline and after six weeks of training. At baseline assessment there were no significant differences between the groups, in contrast, comparing the groups, following 6-week training favored statistically (p<0.001) the experimental group including the respective means rank of outcome measures (BBS 43.47 vs 19.70, RMI 44.17 vs 19.06, MMT for hip extensors 45.07 and 18.25, knee extensors 44.19 and 19.05, ankle dorsiflexors 43.21 and 19.94 were observed as a statistically significant difference with p-value <0.001 as shown in Table II. Within groups comparison at baseline and following training was done by applying the Wilcoxon signed rank test. Results showed that all outcome measures improved significantly (p<0.001) at the end of 6 weeks of training (Table III).

Table I: Baseline Characteristics of participants

Baseline Characteristics		EXP Group	CPT Group	p-value
Age (years)		53.28±7.15	56.69±7.28	0.070+
Stroke duration (days)		4.34±1.23	4.0±1.11	0.254+
Age groups (years)	35-49	7(24.10)	3(9.40)	0.077#
	50-64	21(72.40)	23(71.90)	
	>65	1(3.40)	6(18.80)	
Gender	Male	17(58.60)	18(56.30)	0.852#
	Female	12(41.40)	14(43.80)	
Side affected	Left	18(62.10)	23(71.90)	1.00#
	Right	11(37.90)	9(28.10)	
Type of stroke	Ischemic	26(89.70)	29(90.60)	0.415$
	Hemorrhagic	3(10.30)	3(9.40)	

"+" P-value was calculated by Independent t-test
"#" P-value was calculated by Chi-Square Test
"$" P-value was calculated by Fisher Exact Test

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Table II: Between-group Comparison of Berge Balance Scale, Rivermead Mobility Index, MMT of Hip Extensors, Knee Extensors and Ankle Dorsiflexors

Outcome Measurements	EXP Group	CPT Group	EXP Group	CPT Group	Between-Group Analysis	
	Mean Rank		Median (IQR)		Mann-Whitney U	p-value
Berge balance score (Pre)	32.69	29.47	2(2)	2(1.75)	415.000	0.460
Berge balance score (Post)	43.47	19.70	38(11)	25(9)	102.500	<0.001*
Rivermead mobility index (Pre)	34.79	27.56	1(1.5)	1(0.75)	354.000	0.09
Rivermead mobility index (Post)	44.17	19.06	9(3)	5(1.75)	82.000	<0.001*
MMT hip extensors (Pre)	31.79	30.28	1(2)	1(2)	441.000	0.72
MMT hip extensors (Post)	45.07	18.25	4(1)	2(0)	56.000	<0.001*
MMT knee extensors (Pre)	32.71	29.45	1(1)	0(1)	414.500	0.43
MMT knee extensors (Post)	44.19	19.05	3(0.5)	2(1)	81.500	<0.001*
MMT ankle dorsiflexors (Pre)	29.64	32.23	0(0)	0(0)	424.500	0.39
MMT ankle dorsiflexors (Post)	43.21	19.94	2(1)	1(1)	110.000	<0.001*

Table III: Within-Group Comparison of Berge Balance Scale, River Mead Mobility Index, MMT of Hip Extensors, Knee Extensors and Ankle Dorsiflexors

Outcome Measurements	EXP Group		CPT Group	
	Z	p-value	Z	p-value
Berge balance score (Pre-Post)	-4.70	<0.001	-4.94	<0.001
Rivermead mobility index (Pre-Post)	-4.72	<0.001	-4.98	<0.001
MMT hip extensors (Pre-Post)	-4.75	<0.001	-4.12	<0.001
MMT knee extensors (Pre-Post)	-4.79	<0.001	-4.58	<0.001
MMT ankle dorsiflexors (Pre-Post)	-4.63	<0.001	-3.3	0.002

DISCUSSION

The purpose of the study was to evaluate the conjunct effects of supported standing and functional electrical stimulation on strength and functional mobility in patients with acute stroke. Tiebin Yan, *et al,* reported that after 15 therapeutic sessions, the motor function and mobility of the patient were enhanced by the application of FES. Specifically, they noted improved control of the ankle dorsiflexors as well as shorter hospital stay and early return to their home.[17] Similar to our finding Xiuyuan Zheng *et al,* concluded early application of FES shortly post-acute episode of a stroke could improve functional mobility, balance and ADLs.[18]

The results of this study strengthen the hypothesis that utilizing FES with standardized early training is superior to CPT alone. Shin HE, *et al,* concluded that FES had been shown to improve the strength of lower limb muscles, helped to enhance weight-bearing and upright posture and helped to attain static and dynamic balance in the geriatric population.[19] Similar results were found if applied FES with CPT in early post-stroke, the MMT score of lower limb antigravity muscles and Rivermead mobility score of the FES group exceeded significantly the scores of the CPT group. Dunning *et al* reported a series of cases applying single-channel FES to minimize foot drop in acute stroke.

They concluded that stimulation of the peroneal nerve enhanced walking ability and patient's independence. They suggested that more studies should be conducted to confirm their findings.[20] In contrast, FES was given to three different muscle groups stimulating only 10 min of each group and using different outcome measures. Accordingly, future studies are required to compare different FES training programs. FES combined with different balance exercises improved the strength, balance and mobility in chronic stroke patients reported by Kim *et al,*.[21] Marquez-Chin C *et al,* stated that FES had been providing remarkable assistance to post-stroke patients with mobility impairments for decades and was helping the patients to participate the activities of daily living with a minimum of difficulties.[22] The current study also supported the results of these studies. The BBS, RMI and MMT of the lower limb of FES group participants score higher. Early FES with conventional therapy also improves balance and mobility in acute stroke as well as in chronic stroke.

A study conducted by Hu C *et al,* to find out the outcomes of FES along with cyclic training on post-stroke patients concluded significant effects on muscle activation and tone.[23] According to Ambrosini E *et al,* the loss of strength and motor coordination in the lower extremity in post-stroke patients were the prominent deficits causing long-term functional limitations. Multiple treatments along with different methods of assessment were used to assess the improvement in stroke patients, neuromechanical analysis suggests that functional electrical stimulation along with different treatments like cycles could improve the motor function and walking ability of the sub-acute stroke patient.[24] Post-stroke abnormalities like foot drop and knee hyperextension can cause multiple gait deviation issues.

Santos GF *et al,* suggested that FES improved foot drop and knee issues by stimulating and affecting the tone of muscles. Researchers evaluated the stroke patients with and without FES and suggested that FES had a remarkable effect on the gait and mobility of post-stroke patients.[25] Mitsutake *et al,* concluded in their study that combined FES enhanced the balance and gait of the patient.[26] The current study also supported the results of these studies. Our study also concluded that muscle strength and function increase with FES.

In the current study, it was concluded that in acute stroke FES may have affected muscle activation, augmented contraction in standing position due to antigravity posture and muscle strength enhancement. The results of the study by Noel Rao *et al*, concluded that patients with acute stroke were able to stand and involve in different rehabilitation procedures designed for balance training when they stand with support or partial weight-bearing. Visual feedback plays an important role in this regard.[27]

Mathew J Baltz *et al*, conducted a study on the patients' tolerance of standing on a tilt table in acute stroke and concluded that most of the patients with acute stroke well tolerate the tilt table they also suggested that a tilt table is an effective tool for early upright mobilizations.[28] A pilot study by Rhoda Allison *et al*, conducted to explain the effects of extra upheld position on functional capacity after the cerebrovascular accident was also supported by this study. The results of this study indicated that supported standing improves functional mobility in post-stroke patients.[29] The current study also supported the results of these studies that also concluded that supported standing along with FES had more significant differences in functional mobility, balance and strength among acute stroke.

The current study provided preliminary evidence that the conjunct effects of supported standing and FES training are better than the CPT alone. Small sample size, single-centered study and longer follow-up for better results were considered the expected limitation of this study. Whereas there was a statistically significant improvement in the outcome measures, the magnitude of improvement appears small presumably because of the limited dose of stimulation. Future studies should consider the stimulation dose-response relations. Furthermore, additional interventional studies may explore the effects of early standing and FES training on the other parameters e.g., breathing, bowel and bladder function, arousal and alertness of the patients.

CONCLUSION

Based on the findings, it was concluded that supported standing technique and functional electrical stimulation along with conventional physical therapy were found to be more effective in improving functional mobility, balance and strength among acute stroke patients rather than conventional physical therapy alone.

DECLARATIONS

Consent to participate: Written consent had been taken from patients. All methods were performed following the relevant guidelines and regulations.
Availability of data and materials: Data will be available on request. The corresponding author will submit all dataset files.
Competing interests: None
Funding: No funding source is involved.
Authors' contributions: All authors read and approved the final manuscript.
CONSORT Guidelines: All methods were performed following the relevant guidelines and regulations.
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