Study Protocol

EFFICACY OF BILATERAL LOWER LIMB TRAINING OVER UNILATERAL TO RE-EDUCATE BALANCE AND WALKING IN POST-STROKE SURVIVORS: A PROTOCOL FOR RANDOMIZED CLINICALTRIAL

ABSTRACT:

Background: One of the majorcauses of morbidity worldwide and a significant contributor to disability is Stroke. As said by the National Stroke Association, 9 post-stroke survivors out of 10 experience somedegree of weaknesspost-stroke. The hemiplegic patients with sub-acute stroke, who will undergo training to both the lower limb overtraining to only involved side will have an improvement in balance and walking.The goal of this study is to see how much trainingto both the lower limb improves functional recovery in patients who have had a subacute stroke compared to unilateral lower limb training.

Objective: The goal of this study was to see howtraining to both the lower limb overtraining to the hemiparetic lower limb on balance and walking in subacute stroke patients.

Methods:A randomized clinical study with assessor blinding will be conducted with participants with subacute stroke (n=40). Participants will be randomized to one of two groups after performing baseline assessments: Group A or Group B.1st group will receive training only to the hemiparetic side i.e., MRP and PNF and 2nd group participants will receive bilateral training i.e., Strengthening to the unaffected side along with MRP and PNF to the affected side. During the therapy period, we will assess lower limb function through static and dynamic balance, walking, as well as gait measures.

Results: The purpose of the research is to look into the effect of training to both the lower limb overtraining to the hemiparetic lower limb on balance and walking in subacute stroke patients.The results of this study will be based on the outcome measures that are static and dynamic balance in the stroke patients along with walking.

Conclusion: The study's findings will shed more light on the benefits of training to both the lower limb over training to only involved side in patient'spost-stroke. If this trial proves to be successful, it will help post-stroke patients improve their balance and walking.

Keywords: Bilateral training, Unilateral training, Lower Limb, Balance, Walking, Stroke, Rehabilitation.

TRIAL REGISTRATION:

CTRI number: CTRI/2021/05/03361

INTRODUCTION

Background

Stroke is defined as "rapidly developing clinical evidence of focal (or global) cerebral dysfunction, with symptoms lasting 24 hours or more or leading to death, with no evident cause other than the vascular origin," according to the World Health Organization[1].The prevalence rates range from 84 to 262 strokes peopleper 100,000 inhabitants in rural areas [2]. There is a reduction in the motor function with limitation in performing activities of daily living along with impairments in 80 to 90 percent of stroke survivors due to impaired muscle strength[3]. Hemiplegia or hemiparesis on the opposite side of the lesion indicates a motor function deficit. Furthermore, there is evidence of considerable weakening on the less affected side of the lesion [4,5]. This could be since only 75-90 percent of corticospinal fibers pass to the opposite side in the medulla. The remaining fibres are transferred ipsilaterally to the spinal cord in the anterior corticospinal tract. The cause of bilateral paralysis is that fewfibersdo not cross in the spinal cord[6]. The degree of weakness thatone experiences vary, based on his or her amount of inactivity leading to disuse atrophy[7].

Ample evidence is there that a stroke survivor's motor functioning on the unaffected side has been damaged, as demonstrated by weakness in the muscle, atrophy, or disuse [8,9]. Task-oriented training to both sides may be more beneficial than task-oriented training only to involves the side in improving upper limb functions in post-stroke survivors with paresis [10]. In post-stroke patients, training to both arms combined with simultaneous auditory cues improves the functioning and motor performance of the involved extremity [11]. Lower limb strength training may increase theability to perform all the ADLs independentlylike getting up from a chair[12], walking, and step climbing[13].The purpose of

this research is to determine if bilateral lower limb training is more helpful in retrainingbalance along with walking in stroke patientsthan unilateral lower limb training[14]. The task-oriented method is used in bilateral training patients, with MRP and PNF for the involved side and strength training for the less involved side.

Using the Motor Relearning Program, “rehabilitation of the involved side entails relearning of real-life activities.” “The movements to be mastered are performed in a proper situation, with movements targeted directly at the muscles and muscle synergies required to complete the task.” The missing component is discovered, and that component is exercised, resulting in re-learning of the movement. Task-specific training is incorporated into treatment sessions since functional recovery is the preliminary requirement of rehabilitation. As most therapeutic efforts are directed toward the injured side, it appears that the less-involved d side also needs attention to develop greater balance and restore equilibrium.

During planning any rehabilitation protocol and application of it, what we consider during stroke is the affected or the hemiparetic side, leaving them less affected side unaddressed making it lose its competencies.Once the patient obeys the spoken command, there is a window of opportunity for training to both the lower limb to replace unilateral training to improve motor function, speed up recovery, and aid in subsequent rehabilitation. This provides a way for the development of a specialized methodology that quantifies the demand to restore control in motor function in the damaged side while maintaining the unaffected side's integrity.

MATERIAL AND METHODOLOGY:

Material Required:

The material will be used are Plinth, Stool, TheraBand, Weight cuffs.

For the assessment, a pen and paper are required.

Study Design: Interventional study

Study Population: Post-stroke survivors

Sample Size Calculation:

G* power analysis was used to determine the sample size, that is 20 samples in each group.

Sample Size: 40

Study Setting:

The research will be carried out in OPD and IPD of RNPC and AVBRH, Wardha. Research Protocol was approved by the Institutional ethical committee. We have also registered with the Clinical trial Registry of India (CTRI) with registration no, **CTRI number: CTRI/2021/05/03361.**

Participants:

Eligibility Criteria:

The inclusion criteria for the participants are as under:

- Either gender between 40 and 65 years of age.
- Stroke patients who are in the subacute stage of the disease.
- Patients diagnosed with hemiparesis or hemiplegia after a single stroke history.
- Patients havingthe ability to understand and follow instructions.
- Patients who wish to participate in the research.

The exclusion criteria for the participants are as under:

- Patients who are less than 40 years and more than 65 years of age.
- Patients diagnosed with Brainstem stroke and MCA stroke.
- Patients whohad a transient ischemic attack (TIA)
- Patientshaving any joint or muscle problem that is not related to a stroke.
- Patients with any unstable cardiovascular condition, as determined by the physician.
- Patients diagnosed with the failure of vital organs, such as lung, heart and kidney.
- Patients registered in another clinical trial.

Procedure:

Participant timeline:

All the participants will complete a rehabilitation program for 6 weeks after enrolment in the study. The evaluations will be performed at baseline and before their last session. As shown inTable 1.

	STUDY PERIOD			
	ENROLMENT	**ALLOCATION**	**POST-ALLOCATION**	
TIMEPOINT	**$-t_1$**	**0**	**Intervention(t_{1-6})**	**Post-test(t_6**
ENROLLMENT:				
ELIGIBILITY SCREEN	x			
INFORMED CONSENT	x			
ALLOCATION		x		
INTERVENTIONS:				
[Conventional to affected lower-limb]			x	
[Bilateral lower limb training]			x	
ASSESMENTS:				
BBS	x			x
GAIT PARAMETERS	x			x
DGI	x			x
FRT	x			x
OLST	x			x
FMA-LE	x			x

Table 1: The evaluations will be performed at baseline and before their last session

Implementation:

The participants will be randomized in a 1:1 manner using computer-based randomization and allocation will be done using SNOSE (Sequentially numbered opaque sealed envelope)method into a unilateral training program (group A) and a bilateral training group(group B).

Blinding:

The study will be an assessor and patient blinded randomized clinical trial with two parallel groups for individuals diagnosed with stroke in the sub-acute stage.

Study Procedure:

The subjects will be divided into two different groups, each group will be consisting of 20 subjects and their demographic data will be collected.

Group A: The participants in this group will undergo 20 min of lower limb training to the affected side only daily, 5 days per week for 6 weeks. It will be performed by a physiotherapist. It will comprise the Motor Relearning Programme and PNF, which includes task-specific training and multiplanar movements of the affected lower extremity and upper extremity.

Group B: The participants in this group will receive bilateral lower limb training which would include the MRP and PNF for the involved side and strengthening[15,16] of the less affected side. The participants in this group will undergo 20 min of lower limb training and upper limb to affected side only and 20 min of strength training to the less affected side for 5 days per week for 6 weeks provided by a physiotherapist. The study procedure is shown in Figure 1.

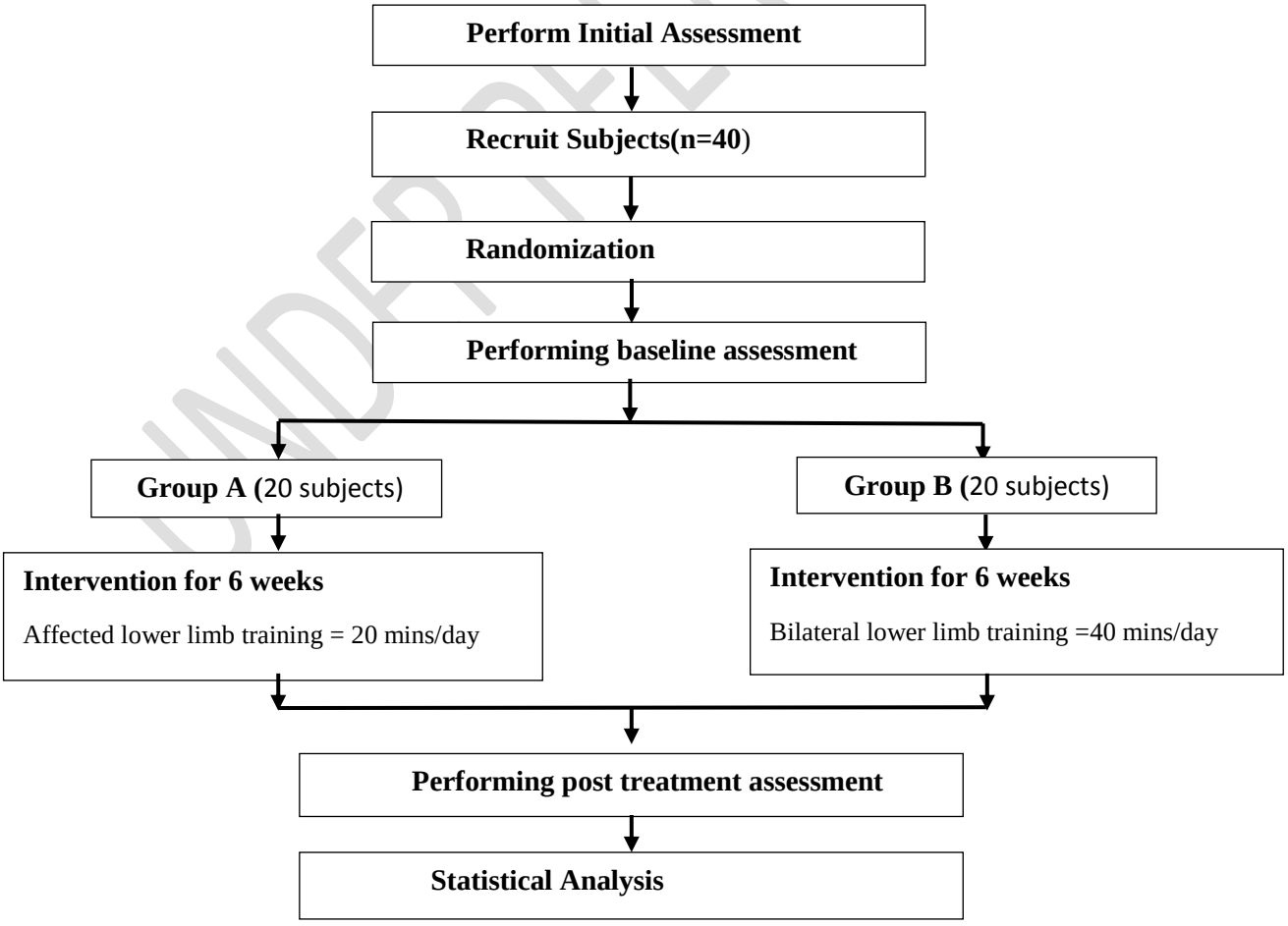

Fig.1: Procedure Flowchart

Outcome measure:

Primary outcome measures:

• **Berg Balance Scale (BBS**) is a clinical measure that is commonly used for checking the static and dynamic equilibrium of a person. For practical balance tests, the BBS is commonly known as the gold standard tool. This test lasts 15-20 minutes and consists of 14 basic balancing tasks that range from standing to standing on one foot from a sitting position.

• **Gait Parameters (Stride length, Cadence, and Gait velocity by 10-meter walk test)-** The distance between two consecutive placements of the same foot, which are made up of two-step lengths, is known as stride length. The total number of steps taken in a certain amount of duration is referred to as cadence. The 10 Metre Walk Test is an indicator that tests walking velocity in meters per second over a given short distance.

• **Dynamic Gait Index (DGI**) is a scientifically validated approach for evaluating gait, balance, and fall risk. This involves both frequent steady-state walking and walking during more strenuous tasks.

• **Functional Reach Test (FRT**) is a single-task clinical outcome test for assessing complex equilibrium. The FRT assesses a patient's stability by determining the maximum forward reach a person can make while standing in a fixed position.

• **One-Legged Stance Test (OLST) or Single Leg Stance Test** is used to assess static posture and balance control. A client who can't stand for more than 5 seconds is more likely to fall and get an injury.

Secondary Outcome measures

• **Fugl Mayer Assessment Lower Extremity (FMA-LE)** is a performance-based, stroke-specific index of disability. It is designed to assess motor coordination, balance, sensation, and joint function in patients who have undergone hemiplegia following a stroke.

Data collection and management:

Under the supervision of the chief investigators, data will be collected and reported. Documentation for the analysis will be carefully scrutinized for accuracy. The Excel spreadsheet will be issued to an allocation blinded statistician at the end of the study to perform the required analysis, after which the groups will be unblinded. The trial's data will be stored in a safe, locked storage area with restricted access for later analysis by a biostatistician and the lead researcher.

Statistical analysis:

The SPSS latest version will be used to perform statistical analyses.The group impact will be compared using an analysis of variance (ANOVA). Individual studies will be checked for homogeneity of the two study groups using the student's t examinationBoth statistical tests should be conducted with a 95% confidence interval to assess the effect of two measures (p-value 0.05).

Discussion:

The protocol will be conducted for a Randomized Clinical trial to test incorporation of lower limb training to less involved side with the hemiparetic one in post-stroke survivors. In an RCT conducted by Jeon and Hwang in 2018 to see how bilateral training has an impact on balance and walking in stroke patients and found out that BTG achieved dramatically betterFunctional Reach and Berg Balancescores relative to UTG[17]. A systemic review on the similar type of studies done on the upper limb by Wu et.al in 2020 stated the effect oftraining to both the arms may be more effective than involvedone in accelerating recovery of upper limb function post-stroke[18]. Our study could aid healthcare providers in predicting patient functional status at discharge and predicted motor function status in post-stroke survivors.To prevent any differences in recovery time between the two groups, the overall rehabilitation time for both groups would be the same. The findings of the study will benefit post-stroke survivors by offering a more sophisticated and effective recovery technique.Furthermore, this study

could be useful in the care of post-stroke survivors to aid their early recovery and increase their degree of independence.

Conclusion:

After the completion of the study, the conclusion will be drawn which treatment protocol is better, bilateral training or unilateral for rehabilitation of patient's post-stroke. The study's findings will shed more light on the benefits of training to both the lower limb over training to only involved side in patient's post-stroke. If this trial proves to be successful, it will help post-stroke patients improve their balance and walking.

ETHICS AND DISSEMINATION

Research ethics approval:

The trial will follow the guidelines laid out in the Helsinki Declaration.

Patient Consent:

Principal Investigators will obtain written consent on a printed form with signatures from the patient and one of his or her family, as well as evidence of confidentiality.

Confidentiality:

The participant and one of his or her relatives will be informed about the report, and the principal investigator will collect personal information. The confidentiality statement, as well as the signatures of the principal investigator, patient, and two witnesses, will be included on the consent form.If the patient's consent is needed to reveal any details for the report, the patient's consent will be obtained with full assurance of his confidentiality.

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