Study Protocol

Research protocol of NDT- Bobath and Proprioceptive Neuromuscular Facilitation Vs Proprioceptive Neuromuscular Facilitation alone, to Improve Trunk Control, Balance, and Gait Parameters in Post-Stroke Patients – A Randomized Clinical Trial

ABSTRACT

Background: The majority of stroke survivors suffer from a lifelong disability. Spasticity on the affected side and loss of balance are the common deficits mainly responsible for the impaired postural alignment, trunk control, and gait in stroke patients. Earlier studies have proven that Proprioceptive Neuromuscular Facilitation (PNF) is not much effective than Neurodevelopmental Therapy (NDT)- Bobath and Bobath is not effective alone to provide impressive results in stroke patients. Hence, the purpose of this study is to demonstrate the combined impact of both techniques and compare them to PNF alone in trunk control, balance, and gait parameters in stroke survivors.

Methods: Total 30 stroke patients will be recruited by the study by considering the inclusion criteria and They will be split into two equal groups, A and B. Group A will receive the combined therapy of PNF and NDT-Bobath and group B will be treated with the PNF alone. The study will be carried out for 6 months. Outcome measures that are The Berg Balance scale(BBS), Trunk impairment scale(TIS), Dynamic Gait Index(DGI), Gait parameters will be utilised to evaluate stroke patients before and after the study.

Result: The expected result will show whether the combined therapy of NDT-Bobath and PNF can help you improve trunk control, balance, and gait in patients with stroke and will it be better than the PNF therapy alone.

Conclusion: If the study proves that NDT—Bobath and PNF is effective in enhancing trunk control, balance and gait parameters, it will be a valuable insight into the available literature and thus helps physiotherapists to choose the combined approach in future. If PNF alone proves to be effective then it will save the time and helps the physiotherapist to frame goals according to PNF alone.

Keywords: NDT-Bobath, proprioceptive neuromuscular facilitation, stroke, trunk control, balance, gait.

INTRODUCTION:

Cerebrovascular injuries (stroke) are the 2nd major cause of death and the third major cause of disability worldwide(1). The WHO defines stroke as a rapid developing symptoms suggestive of localised (or widespread) impairment of brain activity that lasts more than 1 day or results in death, with really no apparent cause besides the vascular origin(2). Ischemic and haemorrhagic strokes are the two most prevalent forms of recognised strokes, defined according to their pathology.

Stroke is more prevalent in low- and middle-income nations such as India(1); current population-based research show that the incidence rate in India is 119-145/100,000 individuals. Stroke is more prevalent in an urban population ranging from 334-424 out of 100000 due to Risks of lifestyle factors like smoking, low physical activity levels, unhealthy diet as compared to rural population which ranges from 84-262 out of 100000(2).

The majority of stroke survivors suffer from lifelong disability(3). Spasticity, fatigue, and loss of balance and equilibrium at any one side of the body are all common deficits in stroke, resulting in altered postural alignment and gait(4,5). Balance is a dynamic mechanism that includes the reception and processing of sensory input as well as the strategy and implementation of movement to attain a goal that requires erect posture(6). The torso is thought to be a major key point in the body's ability to maintain an erect posture and modify weight shifting during static and dynamic postural alterations.

Following a stroke, extremities of only one side are affected, whereas core muscles of both the sides are involved as a result of which there is limited trunk movement, difficulty maintaining balance, and gait deficits(7,8). Stroke patients' centre of gravity also tend to move to the non-affected lower extremity, as a result of which the posture is asymmetric, impaired body control, and diminished capacity to adjust their weight(9).People with stroke

have trouble producing, pacing, and evaluating muscle contraction, as well as hypertonicity and physical changes in soft tissues(10,11).The main aim of stroke patient's functional recovery is improving balance and gait by achieving effective trunk control.

For decades, many conventional therapies have been shown to enhance trunk balance and control in stroke survivors. The PNF technique (Proprioceptive Neuromuscular Facilitation) and NDT-Bobath method (Neurodevelopmental Treatment) are the most extensively utilised approaches today, both of which provide a thorough treatment approach. Pelvic PNF improves pelvic function by stimulating muscle and joints, which is essential for retaining balance, trunk control, gait(12). According to the IBITA(13), The Bobath definition attempts to improve a person's function following a stroke by promoting postural stability and facilitating specific activities, focusing them as much as possible towards tasks of daily life or specialised tasks(7).

The studies conducted by Kılınç et.al ,2016, and Lennon 2001 demonstrated that the individually developed bobath therapy exercise program improves trunk performance, balance, walking ability, more regular motor patterns and functional capabilities in stroke patients(10,14,15).

But few current systematic review studies performed by Díaz-Arribas et.al 2020, and Gray and Ford 2018concludes that Bobath therapy alone is not more efficient than any other post-stroke treatment(7,16). Also, Scrivener et.al, 2020in their systematic study concluded that Bobath therapy is ineffective in comparison to other therapeutic modalities including strength training and combined interventions in adults with stroke(17). Hence there was a need to combine it with some other intervention methods to gain impressive results in stroke survivors.

Sharma and Kaur (2017) studied the effect of core strengthening coupled with pelvic PNF on balancing, trunk impairment, gait, and functional capacity in 23 chronic stroke survivors and discovered that the cumulative impact of trunk stabilisation and pelvic PNF was considerably more beneficial(6). Seo and Kim (2015) investigated the effect of ramp gait training combined with lower limb proprioceptive neuromuscular facilitation (PNF) on the dynamic balancing capacity of post-stroke patients and validated the improvement(9). Kim et.al 2011 found that after conducting the therapeutic exercise programme, which included trunk stability exercises utilising the PNF there was a substantial improvement(18).

Pelvic proprioceptive neuromuscular facilitation (PNF) was found to be beneficial in improving balance, trunk impairments, and gait in all three investigations.(6,9,18). However, they also concluded that PNF alone is not effective enough to provide the impressive results in the stroke rehabilitation. It needs to be combined with some other therapy like they combined it with either core strengthening or ramp gait training. In this study we are trying to combine it with NDT-Bobath therapy as a few studies like Scrivener et.al, 2020's systematic study and the randomised controlled experiment conducted by Krukowska et al in 2016 revealed that the PNF approach is not as successful in improving balance as the NDT-Bobath approach in stroke rehabilitation(17,19).

Hence both the approaches alone were not comprehensive enough to provide impressive results in stroke patients. There was a need for an effective treatment approach which may be seen by combining the effects of these two treatment approaches. Hence through this study, we are trying to demonstrate the combined effects of the PNF and NDT-Bobath approach and compare their combined effect with PNF alone in balance, trunk control and Gait Parameters in stroke survivors.

Objectives:

- To investigate the cumulative impact of NDT-Bobath and PNF on post-stroke patients' trunk control, balance, and gait.
- To compare the effects of combined therapy of NDT-Bobath to the PNF alone in post-stroke patients.

METHODOLOGY-

STUDY SETTING AND ELIGIBILITY CRITERIA:

The study will be conducted in Neuro-Physiotherapy OPD of our hospital and college. The participants will be recruited on the basis of the inclusion criteria of having at least single stroke history; should be in the sub-acute phase of stroke (stroke episode occurred within 6 months before treatment); either gender is accepted but the age should be in between 35-60 years; should be able to comprehend, communicate, and follow directions; should be willing to participate and their Modified Ashworth Scale Score ≤ 2. The participants will be excluded if they do not fit in the age group; not willing to participate; having history of

transient ischemic attack, any other neurological disorders, visual or hearing deficits; those who have registered in another clinical trial.

INTERVENTION:

Group A: Intervention will be NDT-Bobath as well as PNF

Group B: Intervention will be PNF only

Group A: Participants in this group will undergo combined therapy of bobath as well as PNF. NDT-Bobath technique will use the trunk control and lower extremity training through facilitation of movements and activating the base of support through specific key points of control. The therapy exercises will be planned and modified according to the individual participant's capabilities and daily routine activities. The PNF therapy will include the trunk and pelvis training focusing on the affected side. Rhythmic initiation and slow reversal techniques will be used. Pelvic movement patterns which will be used during these techniques will be posterior elevation- anterior depression and anterior elevation - posterior depression of the affected side. Each pattern will be repeated ten times before moving on to the next pattern. Throughout the therapy sessions, the therapist will ensure adequate alignment, manual contact, resistance, and vocal directions. Participants in this group will do 40 minutes of trunk and pelvis PNF exercises on the affected side, followed by 20 minutes of bobath therapy concentrating on lower extremity function and trunk control and 10 minutes of relaxation period in between for five days a week, for four weeks.

Group B: This group's participants will undergo PNF therapy only. The technique of therapy will be the same as of group A. Participants would do 40 minutes of the trunk and pelvic training on the affected side along with the interval periods. The daily therapy session could lengthen for 1 hour. The therapy session will be carried out five days a week for four weeks. It will be carried out by a physiotherapist.

OUTCOMES:

Primary outcome indicators

- **Berg Balance Scale (BBS)** is a clinically accepted measure of a person's static and dynamic equilibrium. The BBS is widely regarded as the gold standard for realistic balance studies. The test lasts approximately 15-20 minutes and consists of 14 simple balancing

tasks ranging from standing to standing on one foot from a seated position. The level of success in completing each task is assigned a score ranging from zero (unable) to four (independent), and the final measure is the sum of all the scores.

- **Trunk impairment scale (TIS)-** This scale is designed to assess the trunk in patients with stroke. In a sitting posture, the TIS assesses dynamic and static sitting balance, along with core coordination. Total score spans from 0 to 16 points.
- **Dynamic Gait Index (DGI)-** This test is a scientifically proven method for evaluating gait, balance, and fall risk. This includes both frequent steady-state walking and walking while performing more intensive activities. This test assesses people's ability to walk while maintaining balance in the face of external challenges. A four-point ordinal scale with a range of 0-3, and total score of 24, where less than 19 is predictive of falls in elderly.

- **Gait Parameters (Stride length, Cadence and Gait velocity by 10-meter walk test)**

The distance between the two successive foot placements that are made up of two step lengths is defined as stride length. Cadence is defined as the number of steps taken in one minute of time. The 10 Metre Walk Test is a performance indicator that measures walking velocity over a short distance in metres per second. All the three parameters are well effective in indicating the improvement in gait.

Secondary outcome indicators

- **Modified Ashworth Scale**: It is used to evaluate spasticity in people suffering from neurological diseases such as stroke or spinal cord injury. It contains 6 grades ranging from 0,1,1+,2,3,4 that help to identify spasticity at different ranges of motion and so aids in the formulation of treatment plans. Scale validity and reliability are both excellent, and it is commonly used to calculate spasticity.

PARTICIPANT TIMELINE:

Each patient will have to go through 4 weeks of rehabilitation after enrolment in the study. The duration of study is going to be 6 months. So, the patients will be recruited till the first 5 months of the study. The evaluations will be carried out at the beginning and end of each session. For treatment, the participant will need to come in 5 days a week for 4 weeks.

	STUDY PERIOD							
	Enrolment	**Allocation**	**Post-allocation (4 weeks intervention period)**					**Follow up test**
TIMEPOINT**	$-t_1$	**0**	t_1	t_2	t_3	t_4	**Post -test** t_5	t_x
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
[NDT-Bobath+PNF]			X	X	X	X		
[PNF]			X	X	X	X		
ASSESSMENTS:								
baseline variables (MAS)	X	X						
outcome variables (BBS, TIS, DGI, GP)		X					X	X

Fig. 1 Enrolment, assessment, and intervention schedule

STUDY DESIGN: Randomised clinical trial, an experimental comparative study.

SAMPLE SIZE-This study protocol will be an independent two-group study investigating the impact of NDT- bobath, pelvic and lower limb PNF Vs PNF technique alone over trunk control, balance and gait parameters. G. Power 3.15 software is used to assess the number of patients who will participate in the study using data from Banerjee TK and Das SK (2016) on the prevalence of stroke in India. 30 patients will be enrolled in the study (15 each in both Group A and Group B). In the event of a dropout or an issue with data collection, four additional participants will be recruited to preserve the sample size. We assume 44 subjects will complete the study as a conservative estimate (dropout rate = 25%).

$$n = \frac{Z\alpha/2^2.P.(1-P)}{d^2}$$

Where,

Z α /2 is the level of significance at 5% i.e., 95 %.

Confidence interval = 1.96

P = Prevalence of Stroke= 0.84% =0.0084

d = Denied error of margin =5% =0.05

$$n = \frac{1.96^2 \times 0.0084 \times (1-0.0084)}{0.05^2}$$

=12.79

= 15 patients needed in each group.

RECRUITMENT:

Neurologists and other health care practitioners affiliated with DMIMSU will be requested to recommend potential patients to our In-patient department (IPD) and Out-patient department (OPD). Patients with stroke who are already getting rehabilitation at our IPD will be carefully examined for study eligibility based on eligibility criteria. Following participation in the study, participants will be randomly assigned to two groups: A or B, and will subsequently participate in a 6-week rehabilitation programme with intermediate assessments.

ALLOCATION AND IMPLEMENTATION:

The principle investigator and research coordinator will supervise the randomization. The allocation sequence will be through Computer generated random number table. The participants diagnosed as Subacute Stroke will be randomised through Simple Random sampling and the Sequentially numbered opaque sealed envelope (SNOSE) method will be used to divide the population into 2 groups, A and B.

BLINDING: The assessor, who has similar experience as the primary investigator and has taken outcome measures before, will take pre and post outcome measures and will be blinded.

DATA COLLECTION AND MANAGEMENT

The chief investigators will be in charge of data collecting and reporting. The trial's data will be kept in a safe, locked storing area with limited accessibility for subsequent evaluation by a biostatistician and the main researcher. The documentation for the report will be thoroughly reviewed for accuracy. At the end of the report, the Excel spreadsheet will be given to an allocation blinded statistician to conduct the required analysis, after which the groups will be unblinded. Checklists are used to prevent data loss due to insufficient personnel procedures.

STATISTICAL ANALYSIS:

In persons who have had a subacute stroke, the paired t test is used to assess the effects of Bobath + PNF with PNF alone on trunk control, balance, and gait measures. The Wilcoxon sign rank test will be applied if the data does not include a standard deviation. Statistical significance is defined as a p value less than 0.05. The outcome measures will be evaluated using SPSS software version 20.

BIAS:

Measures will be taken to reduce attrition bias by sending out reminder calls before to each intervention and offering travel help to those who require it. As a result, we anticipate a low percentage of dropouts.

RESULT:

The successful completion of this research study will provide evidence on the optimal treatment strategy for stroke patients to enhance their trunk control, balance and gait, whether it is individual PNF or PNF combined with NDT-Bobath, and the findings of this investigation will provide a better insight of both treatments. The paired t-test will be used to analyse the data after the study's results are finalised, which will then be provided in the form of a research report.

DISCUSSION:

Stroke is a cerebrovascular incident that leaves the patient with several impairments among which Spasticity, loss of strength and balance on the hemiplegic side greatly affects the patient's postural alignment and locomotion which indirectly affects the quality of life. We are attempting to combine the individual effects of two different therapies, NDT-Bobath and proprioceptive neuromuscular facilitation (PNF), and correlate them to the effects of a single PNF therapy in order to provide an effective treatment mode for stroke rehabilitation that yields more impressive results in improving trunk control, balance, and gait. We will induce irradiation by permitting the neuromuscular process with stretch, particular movement patterns, and maximum resistance using trunk and pelvic PNF approaches(20). Pelvic PNF improves pelvic function, which is essential for retaining balance, trunk control, and gait, by stimulating muscle and joints in hemiplegic patients(12). According to the IBITA(13), The Bobath definition attempts to improve a person's functions following a stroke by promoting postural stability and facilitating specific activities, focusing them as much as possible towards tasks of daily life or specialised tasks(7). As per the Kılınç et.al, individually developed bobath therapy exercise program improves trunk performance, balance, walking ability, functional ability and more normal movement patterns in stroke patients(14). Finally, the goal of this study is to look at the cumulative impact of PNF and NDT-Bobath in stroke survivors. The study's findings will aid patients' recuperation and improve their quality of life. The main outcome measures of this study are trunk impairment scale (TIS), berg balance scale (BBS), Dynamic gait index (DGI), and gait parameters (Stride length, Cadence and Gait velocity by 10-meter walk test). These scales help to measure the improvement in balance, trunk control, and gait respectively.

ETHICAL APPROVAL AND DISSEMINATION

The Ethical approval is obtained from Institutional Ethical committee. The DMIMS, which will fund the research, as well as the subjects who will take part in the study, will have access to the research's key findings. Data is kept securely for a minimum of five years for the enrolled subjects. Following the completion of data collection and statistical analysis, a completion report will be created and sent for publication after being reviewed by the institutional research cell.

PATIENT CONSENT

The informed consent form will be signed by the patient and one of the patient's family members, which the Principal Investigator will collect and present as the evidence of confidentiality.

CONFIDENTIALITY

The study protocol will be explained to the participant and one of his/her relatives, and personal information will be collected as part of the protocol. The confidentiality declaration and signatures of the lead investigator, patient, and two witnesses will be included on the consent form. If the patient is asked to provide certain information for the study, consent will be acquired with complete assurance of his/her anonymity.

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