

Title: Effectiveness of Pelvic Proprioceptive Neuromuscular Facilitation techniques on Balance and Gait parameters in children with Spastic Diplegia: A study protocol for a randomized clinical trial.

ABSTRACT

Background: Cerebral Palsy is a spacious term which highlights an extensive gamut of motor affliction which has a stagnant tendency. The estimated Cerebral Palsy is indeed very prevalent in developed nations 2 out of the next 1000 live births and neonatal survivors. Among several Cerebral Palsy comes in a variety of manifestations. Spastic Diplegia is common in a majority of Preterm babies. Several treatment strategies of Physical therapy are utilized for Spastic Diplegia. This research focusses on assessing the Efficiency of Pelvic Proprioceptive Neuromuscular Facilitation (PNF) techniques over the Dimensions of Balance and Gait in children with Spastic Diplegia.

Objective: To evaluate the Effectiveness and impact of the techniques of Pelvic Proprioceptive Neuromuscular Facilitation (PNF) on Balance, Gait Parameters and Pelvic Asymmetry in children having Spastic Diplegia.

Method: In this Randomized Clinical Trial, subjects (n= 40) having Spastic Diplegia will be selected and segregated in two groups using simple random sampling method with 1:1 allocation ratio. The allocation will be done through sequentially numbered opaque sealed envelope (SNOSE). Subjects in the experimental group will receive Pelvic PNF techniques like Rhythmic initiation and Slow reversal with Task- Oriented training which will contain sit to stand exercises, walking on the ground and reaching tasks for improving the balance and those in the other group will be given only Task- Oriented training for 4 weeks following baseline assessments. Throughout the treatment session and following 4 weeks follow up will be taken by assessing the Balance and Gait parameters of the subjects. The study duration will be of 1 year. Subjects with Spastic Diplegia with an age group of 8 to 12 years who are able to do independent sitting, who are coming under GMFCS level I to III and those who are having pelvic asymmetry will be included in the study while subjects who had any surgery of spine or lower limb in past 6 months, who are having fixed deformities of spine or lower limb or any fracture or dislocation of spine or lower limb will be excluded from the study.

Results: Results will be recorded by using the outcome measures and instruments such as Pediatric Balance Scale, Gait Parameters and Palpation meter device at the end of the intervention and the effects of Pelvic PNF techniques will be compared with the other group which will receive Task oriented training. The statistical analysis will be done by using

paired t test but if the data does not follow a normal distribution then Wilcoxon sign rank test will be used.

Conclusion: The conclusion of this research is to acquire the fruitfulness of Approaches of Pelvic PNF on Balance and Gait Parameters in children having Spastic Diplegia.

Discussion: The intention and motive of the study is to check the Effectiveness of Pelvic Proprioceptive Neuromuscular Facilitation techniques on Balance and Gait Parameters in children with Spastic Diplegia.

Keywords: Pelvic Proprioceptive Neuromuscular Facilitation, Task Oriented training, Spastic diplegia, Pelvic asymmetry.

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INTRODUCTION

The term Cerebral Palsy represents a diverse array continuum of motor dysfunction with a non-progressive nature. Cerebral palsy signifies a division of a continuous motion malleable and demeanour- generating functional restriction disorders that are due to stagnant diseases that have emerged in the evolving foetal or child brain. Motor defects and dysfunctions of the cerebral palsy are also accompanied by visual abnormalities, memory, seizures and secondary musculoskeletal complications. (1)

Pervasiveness of cerebral palsy in developed nations is 2 per 1000 live births and neonatal survivors. According to the population-based research of cerebral palsy males are found to have a greater Pervasiveness of cerebral palsy compared to females, with sex ratios ranging from 1:1:1 to 1.5:1.(2)

Cerebral palsy is classified in different types according to the topography and motor dysfunction. Topographically it is categorized as Monoplegia, Diplegic, Triplegic, Quadriplegic, Hemiplegic and Paraplegic. On the other hand, according to motor deficits it is categorized as Spastic, Athetoid, Ataxic, Flaccid and Mixed. Cerebral palsy can occur either before, during or immediately after the birth of the child therefore the reason why cerebral palsy can be either antenatal, neonatal or postnatal.

According to the abilities of children to execute the Gross Motor activities they are categorized in according to five distinct levels to the Gross motor function classification system.(3)

Spasticity is categorised as an exaggerated resilience to passive muscle or motion which is dependent on the velocity of movement or an inappropriate voluntary muscle task associated with an upper motor neuron paralysis.(4)

Spastic Diplegia is a common variant of Cerebral Palsy in preterm children, particularly in the most unripped preterm children. Majority of children having Spastic Diplegia presents with a healthy tone or even hypotonia, during the period of initial four months. During the first year spasticity have a subtle commencement and a sluggish progression in the legs. (5)

Usual problems resulting from Cerebral Palsy include the contractures of muscles and connective tissues, cognitive and perceptual problems, visual and visuomotor problems, speech and learning impairments, lack of trunk control, asymmetry of the pelvis, abnormalities in gait and balance etc.(6,7)

There are several techniques and interventions which are used for the purpose of treatment in Spastic Diplegia for example Strength training programs, Task oriented training, Sensorimotor training program, Balance training, Neurodevelopmental therapy and Proprioceptive Neuromuscular Facilitation to improve the Gait and Balancing abilities.

PNF is a strategy of therapeutic exercise in which the functionally based diagonal patterns of motion are blended with the strategies of Neuromuscular abetment to endorse the motor feedback and enhance the Neuromuscular control and function. (8) The approach of PNF was discovered during the time period of 1940s and 1950s by Kabat, Knott and Voss. (9) PNF practises are often preceded by verbal/ visual and tactile input to promote and achieve muscle contraction and motor control. PNF stretches are highly effective in improving the strength, flexibility and range of motion but they are complex and involve several movements for an individual stretch.

Task- oriented instruction signifies to the practice of executing important functional activities or works so that a well-organized and effective motor skills can be learned. Task oriented training is based on systems archetype of motor control and existing postulates of motor erudition.

This approach emphasizes on interactions between power components in the sensorimotor system, stamina, range of motion, coordination, sensory perception and postural awareness. It uses the principles of degrees of control and perceptual ability, as well as the philosophy of autonomous movement and legislation. (10)

The study's goal is to draw the Potency of Pelvic PNF Techniques on Balance and Gait parameters in children with Spastic Diplegia.

NEED FOR THE STUDY

Pelvis is a part of the trunk that helps in facilitating the motion of extremities or limbs. Pelvic asymmetry is common in children having Cerebral Palsy. Asymmetry in the pelvis interferes with the effective movement of extremities or limbs. Both the Task-oriented and the PNF have been mentioned to be helpful for the improvement of lower extremity functions. Studies have shown that pelvic PNF has a positive contribution on trunk function. (11) There is a deficiency of literature which emphasizes the role of the pelvic PNF in lower extremity function, Balance and Gait Parameters.

HYPOTHESIS:

Alternative hypothesis: Pelvic PNF will impose a positive impact on Balance, Gait Parameters and Pelvic Asymmetry in children with Spastic Diplegia.

Null hypothesis: Pelvic PNF will have no significant effect on Balance, Gait Parameters and Pelvic Asymmetry in children with Spastic Diplegia.

SCOPE OF THE STUDY:

Pelvic PNF can be an effective technique in Spastic Diplegia to improve the Balance and Gait Parameters by emphasizing on and improving the pelvic control.

IMPLICATION OF THE STUDY:

If the study is proved to be effective then training and enhancing the pelvic control will be an active ingredient in treatment of children with Spastic Diplegia.

METHODOLOGY:

Study Setting:

The research will be executed in the Outpatient wing of AVBR Hospital, Sawangi, Meghe, Wardha after receiving the acceptance from the Institutional Ethical Committee of Datta Meghe Institute of Medical Sciences (Ref.no.DMIMS(DU)/IEC/2021/249).

Study design and Sample size:

In this Randomized Clinical Trial. The number of subjects enrolled in the experimental study will be 40 (n=40)

Study Population: Subjects having Spastic Diplegia

Sample Size Calculation:

For calculation of sample size paired t test will be used with 20 subjects in each group.

: To calculate the sample size, the technique of estimation of sample size for paired t test will be used.

$$n = [(Z_{1-\alpha/2} + Z_{1-\beta})^2 / \sigma^2 + (Z_{1-\alpha/2})^2 / 2]$$

Where α is the level of significance (5%), $1-\beta$ is the power (80%) and σ is the effective size (0.5), lost to follow up (20%) $n = (1.96 + 0.84)^2 / 0.5^2 + (1.96)^2 / 2$ $n = 33$

Sample size is 40 with 20% lost to follow up.

Sample Size: 40

INCLUSION CRITERIA:

Subjects within the age groups of 8 to 12 (as they can understand the commands of the therapist) years of either gender having Spastic Diplegia with Pelvic asymmetry, GMFCS level I to III and MMSE score equal to 22 or more than 22 and children who are able to sit independently.

EXCULSION CRITERIA: Children under botoux medication for a period of more than six weeks, who had any surgery of spine or lower limb in the preceding six months and those who were having any fractures of spine or lower limb in the preceding six months.

PARTICIPANT TIMELINE

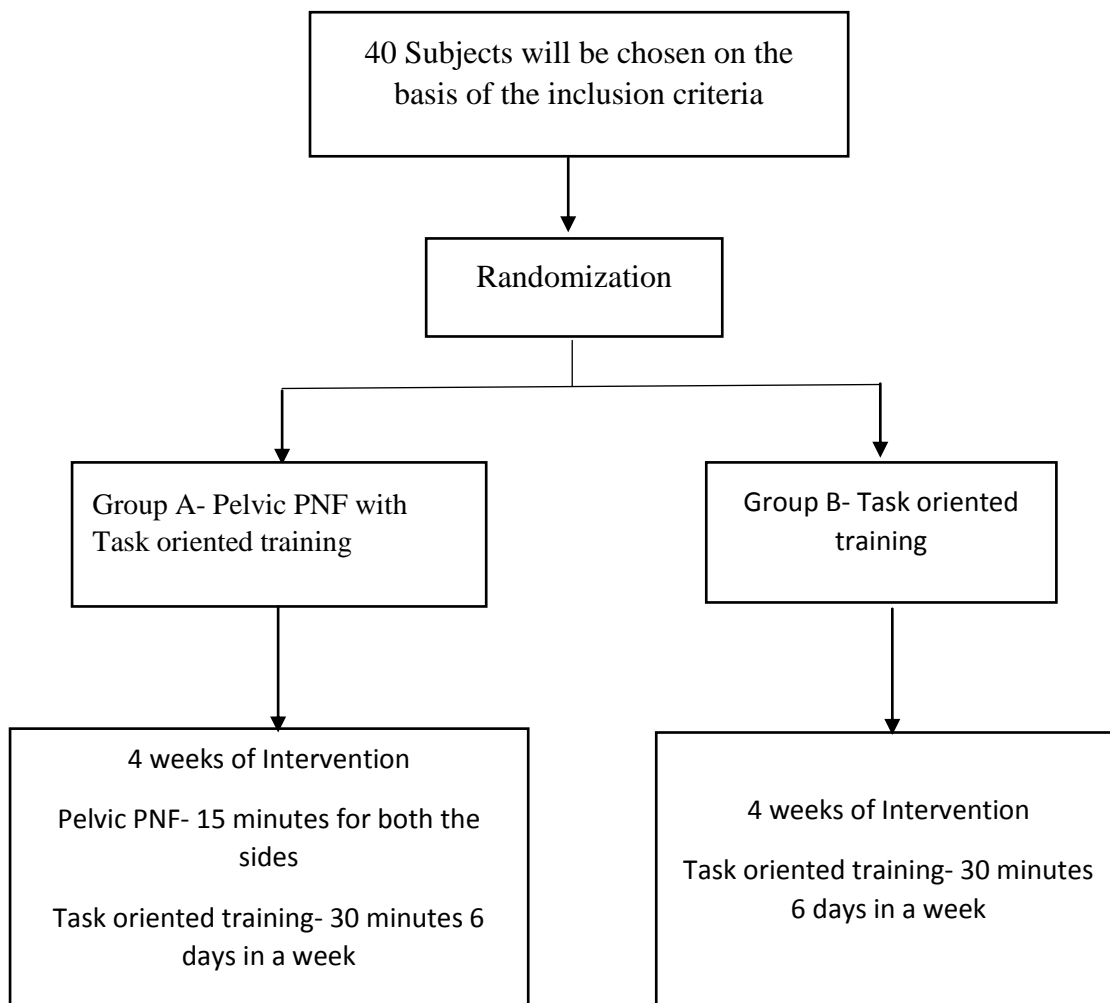
The duration of study is 1 year and that of intervention is 4 weeks so participants will be enrolled during first 11 months of study so 4-week intervention will be completed successfully. Assessment will be taken on 1st day by using PBS, PALM and Gait Parameters.

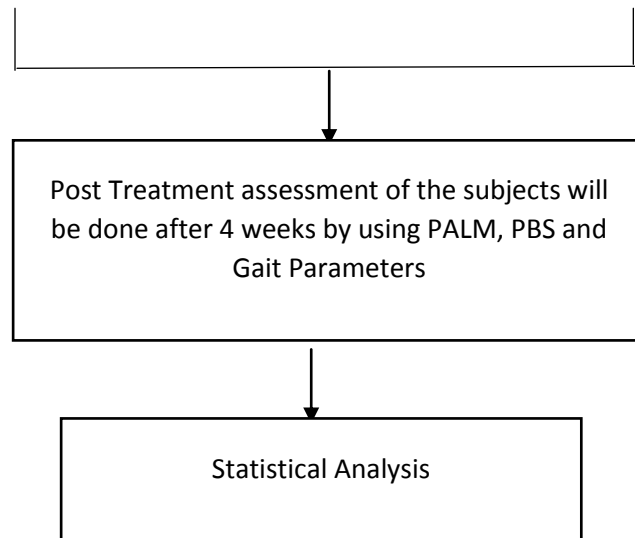
IMPLEMENTATION

Research coordinator and Principal investigator will supervise the process of randomization. Participants will be asked to manually select the envelope, sealed group allocation for the recruitment into either group.

BLINDING

While assigning the subjects to the group the assessor will be blinded. To ensure blinding subjects will be mandated not to reveal any details of their treatment to the assessor.





SAMPLE SIZE CONSIDERATION:

This Randomized Clinical Trial is an experimental two group design which is evaluating the Effectiveness of Pelvic PNF Techniques on Balance and Gait parameters in children with Spastic Diplegia. Total 40 subjects will be taken and then after they will be randomized.

INTERVENTION DESIGN:

40 subjects with Spastic Diplegia and Pelvic asymmetry will be selected from the Physiotherapy OPD of AVBR Hospital and segregated in two different groups

Group A- Intervention group

Group B- Comparator group

Group A: Group A will receive Pelvic Proprioceptive Neuromuscular Facilitation (Pelvic PNF) as well as the Task Oriented Exercises for Lower extremities. **The Pre- treatment assessment of the subjects will be recorded by using the Pediatric Balance Scale (ICC>0.9), Gait Parameters and Palpation meter device (ICC= 0.90).**

Pelvic Proprioceptive Neuromuscular Facilitation techniques will include Rhythmic Initiation technique and Slow reversal technique and the Task- Oriented Exercises will include Sit to Stand Exercises, Walking on the ground and Reaching tasks for improving Balance.

Rhythmic Initiation- In this technique initially the therapist will move the patient through a desired movement by using the Passive range of motion, latter an active- assisted, active- resisted range of motion, and at the end active range of motion.

Slow Reversal- It utilizes an isotonic contraction of the agonist group instantly followed by an isometric contraction, with a hold instruction which is given at the end of every active movement.

The time span of Pelvic Proprioceptive Neuromuscular Facilitation will be 15 minutes for both the sides including Task- oriented tutoring for a period of 30 minutes, 6 days per week for 4 weeks.

Post assessment of the subjects will be recorded by using the same outcome measures (PBS, Gait Parameters and PALM) at the end of the treatment or after the intervention.

Group B: Group B will receive only Task Oriented Exercises for lower extremities which will include sit to stand exercises, walking on the ground and reaching tasks for improving balance.

The baseline assessment of the subjects will be done by using Pediatric Balance Scale (PBS), Gait Parameters (Cadence, Stride length and Gait velocity) and Palpation meter device (PALM) which will measure the asymmetry in the pelvis. The time duration of treatment for group B will be of 30 minutes, 6 days per week for 4 weeks.

Post assessment of the subjects will be done by using PBS, Gait parameters and PALM which are mentioned above in the baseline or Pre assessment of the subjects after the intervention.

OUTCOME MEASURES:

1) Pediatric Balance Scale (PBS):

It is a transformation of the Berg Balance Scale which is used for the purpose to estimate the functional balancing abilities in school aged children. The optimum score of Pediatric Balance Scale is 56 (12)

2) Gait Parameters:

Gait Parameters will be including the following

Cadence

Stride length

Gait Velocity

3) Mini Mental Status Examination (MMSE):

Mini Mental Status Examination Scale is mainly used to check the impairment in the cognitive functions of individuals. It has a maximum score of 30 and the acerbity in the cognitive impairment will depend upon the score of Scale.

4) Gross Motor Function Classification System (GMFCS):

On the basis of Gross Motor Function Classification System (GMFCS) children are classified in five different standards according to their potential to execute the Gross Motor actions (13)

5) Palpation Meter device (PALM):

Palpation meter device is an instrument which is used to measure and check the extent of asymmetry in the pelvic region (14)

DATA COLLECTION AND MANAGEMENT:

The data of the subjects will be collected prior to the treatment (Pre-treatment) and after the intervention or treatment by using Pediatric Balance Scale, Gait Parameters and Palpation Meter device.

STATISTICAL ANALYSIS:

To find out the impact of Pelvic PNF techniques on trunk control in children with Spastic Diplegia paired t test will be used but if the data does not follow a normal distribution then Wilcoxon sign rank test will be used.

ETHICAL APPROVAL AND DISSEMINATION:

The participant individuals of the study and DMIMSU who will fund it will be able to retrieve findings of study. After completion of study and publication of results data will be stored in the DMIMSU data repository.

PATIENT CONSENT AND ACCENT:

Principal Investigator will obtain the written informed consent and accent forms from the participants on a printed form (local language) with signatures and give the proof of confidentiality.

CONFIDENTIALITY:

The study program will be explained to the participant, the Principal Investigator will record the subjective information. The consent form will include the confidentiality statement and signatures of the principal investigator, patient and witnesses. If required to disclose some information for the study, consent will be taken from the patient with complete assurance of his confidentiality.

CONFLICT OF INTEREST:

There is no dispute of fascination among the authors

FUNDING:

Funding will be provided by the Research Cell of Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India.

DISCUSSION:

The purpose of this Randomized Clinical Trial Research study is to evaluate the Potency of Pelvic PNF Techniques on Balance and Gait Parameters in children having Spastic Diplegia. This study will also provide a literature concerning the impact of Pelvic PNF on Pelvic asymmetry in Spastic Diplegic Cerebral Palsy children. Some researches have proved that Pelvic Proprioceptive Neuromuscular Facilitation techniques have a good and positive impact on improving the functions of trunk in Cerebral Palsy as well as in improving the functions of lower extremities.

REFERENCES

1. A report: the definition and classification of cerebral palsy April 2006. *Dev Med Child Neurol.* 2007;49(s109):8-14.
2. Pakula AT, Van Naarden Braun K, Yeargin-Allsopp M. Cerebral palsy: classification and epidemiology. *Phys Med Rehabil Clin N Am.* 2009 Aug;20(3):425–52.
3. Pediatric Physical Therapy |c Jan Stephen Tecklin | download [Internet]. [cited 2021 Mar 6]. Available from: <https://b-ok.asia/book/2492419/f2e82c>
4. Management of spasticity in children with cerebral palsy. [Internet]. [cited 2021 Mar 6]. Available from: <https://www.cabdirect.org/cabdirect/abstract/20143315161>
5. Fenichels Clinical Pediatric Neurology A Signs And Symptoms Approach PDF Book - Online Library [Internet]. [cited 2021 Mar 6]. Available from: <https://glarqual.caringchoices.org.uk/file-ready/fenichels-clinical-pediatric-neurology-a-signs-and-symptoms-approach>
6. ElBasatiny H, Abdelaziem A. Effect of Trunk Exercises on Trunk control, Balance and Mobility Function in Children with Hemiparetic Cerebral Palsy. *Int J Ther Rehabil Res.* 2015;4(5):236.
7. Physiotherapy in Pediatrics : Roberta B. Shepherd : 9780750606202 [Internet]. [cited 2021 Mar 6]. Available from: <https://www.bookdepository.com/Physiotherapy-Pediatrics-Roberta-B-Shepherd/9780750606202>
8. Effectiveness of physical therapy interventions for children with cerebral palsy: a systematic review - PubMed [Internet]. [cited 2021 Mar 6]. Available from: <https://pubmed.ncbi.nlm.nih.gov/18435840/>

9. Joint Structure and Function: A Comprehensive Analysis | Levangie PT DPT DSc FAPTA, Pamela K., Norkin PT EdD, Cynthia C. | download [Internet]. [cited 2021 Mar 6]. Available from: <https://b-ok.asia/book/5264529/c5647f>
10. Kumar C, Ostwal P. Comparison between Task - Oriented Training and Proprioceptive Neuromuscular Facilitation Exercises on Lower Extremity Function in Cerebral Palsy-A Randomized Clinical Trial. 2016 Jan 1;
11. A N, Shanmugam S, P SR. Effectiveness of Pelvic Proprioceptive Neuromuscular Facilitation on Trunk Control in Children with Spastic Diplegia:A Randomized Controlled Trial. Indian J Public Health Res Dev. 2020 Feb 1;11(2):571-576–576.
12. Sook- Hee Yi, Ji Hye Hwang Validity of pediatric balance scale in children with spastic cerebral palsy. Neuropaediatrics. 2012 Dec
- 13 Daniele Piscitelli, Stefano Vercelli Reliability of the gross motor function classification system and manual ability classification system in children with cerebral palsy in Tanzania. Developmental Neurorehabilitation. 2017 June.
14. Matthew R Patrone, Jennifer Guinn The Accuracy of the Palpation Meter for measuring pelvic crest height difference and leg length discrepancy. JOSPT. 2003 June.
15. Agrawal A. The concept of neurosciences in rural practice. J Neurosci Rural Pract. 2010;1(1):1.
16. Agrawal A, Johrapurkar SR, Gharde P. Ischemic stroke in a child mistaken as functional disorder. Clin Neurol Neurosurg. 2007 Dec;109(10):876–9.
17. Agrawal A, Bhake A. Giant testicular tumor with pulmonary metastases: Stroke as the initial manifestation. Indian J Cancer. 2015 Mar;52(1):59–60.
18. Cincu R, Agrawal A, Eiras J. Intracranial arachnoid cysts: Current concepts and treatment alternatives. Clin Neurol Neurosurg. 2007 Dec 1;109(10):837–43.