

Study Protocol

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 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 PNF on Balance, Gait Parameters and Pelvic Asymmetry in children having Spastic Diplegia.

Methods: In this Randomized Clinical Trial, subjects (n= 40) having Spastic Diplegia will be selected and segregated in two groups with 1:1 allocation ratio. Subjects in the experimental group will receive Pelvic PNF techniques with Task- Oriented training 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.

Results: Results will be recorded by using 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.

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 demeanor- generating functional restriction disorders that are due to stagnant diseases that have emerged in the evolving fetal 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 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 unripened 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 an 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.

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.

MATERIALS AND METHODOLOGY:

Material Required:

Material which will be required and needed for the study are Plinth, Palpation Meter device, Cushion pad, Data collection sheet, Informed consent and assent forms for the recording of assessment.

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.

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.

Sample Size: 40

INCLUSION CRITERIA:

Subjects within the age groups of 8 to 12 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 botox 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 done 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 (PBS), Gait Parameters and Palpation meter device.

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.

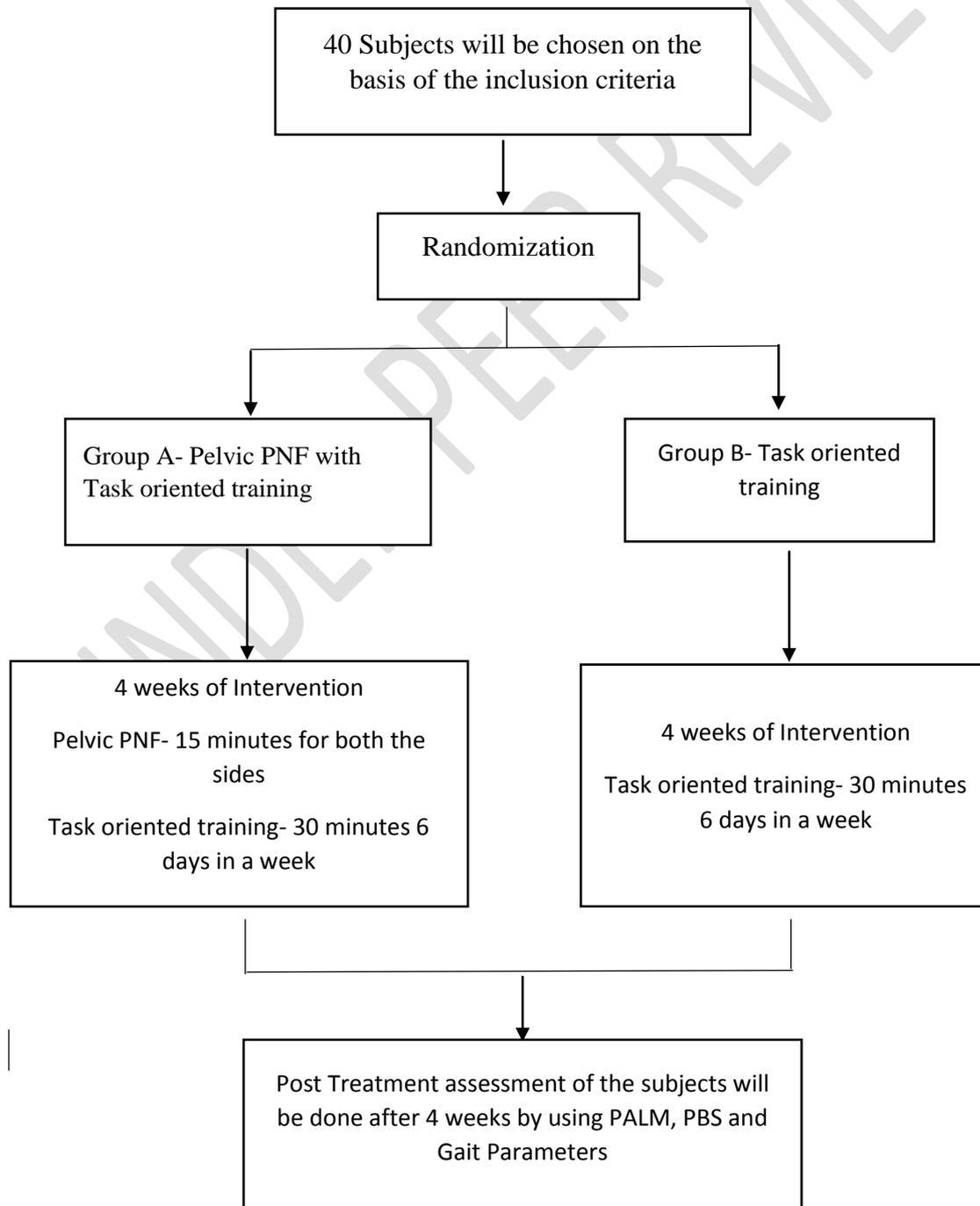
Post assessment of the subjects will be recorded by using the same outcome measures (PBS, Gait Parameters and PALM) at the end of the treatment or after the intervention.

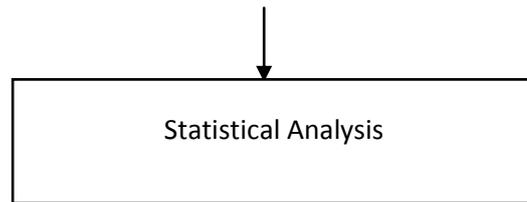
Group B: Group B will receive only Task Oriented Exercises for lower extremities which will include sit to stand exercises, walking on the ground and reaching tasks for improving balance.

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.

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.

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.

CONCLUSION:

At the end of the study, the effectiveness of Pelvic PNF on the patients with spastic diplegia will be drawn. The outcome measures are based on the balance and gait parameters in the affected children. Positive outcomes with this study will open up a new window of treatment approach towards spastic diplegic cerebral palsy children.

UNDER PEER REVIEW

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