

Study Protocol

Effect of Neuro Developmental Treatment versus Passive Stretching Exercises on Spastic Diplegic Cerebral Palsy for Improving Posture: A Research Protocol.

ABSTRACT:

Background:

Cerebral Palsy can be defined as a cluster of disorders acting on a person's movement, posture and balance. Cerebral Palsy, which affects 2 to 3 out of every 1000 live births, is caused by a variety of factors, including brain injury which can affect the movement, posture, and balance. It's linked to the perinatal period in about 92% of cases. Premature birth, perinatal infections, intrauterine growth restrictions, multiple gestations, and other risk factors are all factors to consider. This disorder prevents normal motor function Development. This protocol was developed to describe the design of an interventional study for the evaluation of the effect of Neuro Developmental Treatment with conventional therapy and Passive Stretching with conventional therapy on improving posture in diplegic spastic Cerebral Palsy patients. **Methods:** Participants (n=70) with spastic diplegic Cerebral Palsy who meet the included criteria will be hired for the study. Patients in group A will receive Neuro Developmental Treatment and conventional therapy, while patients in group B will receive Passive Stretching with conventional therapy. The Treatment protocol will last 6 weeks. Regular evaluations will take place. The Modified Ashworth Scale and the Gross Motor Function Classification System is

going to be used to assess our progress. **Discussion:** The intervention's efficacy will be assessed by analysing gross motor functions with the help of Gross Motor Function Classification System and spasticity level using Modified Ashworth Scale. Study and analysis will significantly support the use of Neuro Developmental Treatment with conventional therapy and Passive Stretching in conjunction with conventional therapy in Cerebral Palsy patients.

Keywords: Cerebral Palsy, spasticity, Neuro developmental Treatment, Passive Stretching, conventional therapy, physiotherapy.

INTRODUCTION:

Cerebral Palsy is collection of unchanging, but frequently fluctuating, motor dysfunction disorders caused by injuries or anomalies in the developing brain. Secondary alterations in the musculoskeletal system can occur as a result of this Neurological condition, including decreased muscular strength, tightness or contractures around joints and abnormalities in both bone structures and gait.(1) More than 15 million people are thought to be affected with Cerebral Palsy around the world. According to WHO statistics Cerebral Palsy is identified in 1-2 instances out of every 1000 live new-born children. The prevalence of Cerebral Palsy varies by country, ranging from 1.5 to 2.5 instances per 1000 infants. (2) It has a diverse set of clinical characteristics. Posture, muscular tone, and mobility problems are all prevalent symptoms.(2)

The spine's posturing made it difficult for carers to maintain hygiene during feeding, dressing, and other procedures.(3) One of the most prevalent usual kind of Cerebral Palsy is spastic Cerebral Palsy, that is considered as 70-80% of all identified cases. It is the most prevalent form of impairment in children, restricting movement and causing social dysfunction. As a result, decreasing spasticity is one of the most challenging aspects of treating such

children.(4) Spasticity is specified by a rise depending on the velocity in tonic stretch reflexes as a result of stretch reflex hyper excitability.(5)When compared to typical children, children having spastic CerebralPalsy have stiffer ankle joints and a smaller range of motion.(6) It is referred to as a global epidemic because it is considered as one amongst the most usualsources of disability and mortality.(7)

Children having Cerebral Palsy often benefit from stretching therapy as a non-intrusive regimen. The premise in therapeutic way is that thecontinuous bouts of stretching can lengthen muscles and hence reduce muscle rigidity, delaying emergence of muscle tensions.(8)Stretching helps relieve discomfort and restore range of motion.(7)

One of the most prevalent modern therapeutics is Neuro Developmental Treatment, which aims to optimize the potential for the betterment of motor function in children having Cerebral Palsy. Controlled sensory-motor experiences, that are meant to suppress unusual motions and permit postural modifications to assist functional movements, are used in Neuro Developmental Treatment to elicit and create normal patterns of movement.(9)

Rational:

Based on previous studies the problems described in adult patients of Cerebral Palsy disclosed that 77% of Cerebral Palsy children were facing problems due to spasticity, 80% had tensions and 18% experienced pain every day. The rise in muscle tone is accountable for respective failure of muscle growth and may produce functional problems. Calf muscle is relatively weaker in spastic diplegic children than in normal children. As there are very limited studies done on Neuro Developmental Treatment (NDT) and Passive Stretching. Thus, requirement of the analysis is to collate the effect of both techniques on calf muscle spasticity.

AIM:

To study the effect of NeuroDevelopmental Treatment versus Passive Stretching in calf muscle of spastic diplegic Cerebral Palsy children.

METHODOLOGY:**Study setting –**

This study is going to be accomplished in Neuro-Physiotherapy OPD of Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha after getting approved by the Institutional Ethical Committee of Datta Meghe Institute of Medical Sciences, Deemed to be university.

Study design and sample size:

This study is an interventional study with a total of 70 participants. Participants in this study are going to be randomly assigned to two groups: one will get Neuro Developmental Treatment with conventional therapy (Group A) and the other will receive Passive Stretching with conventional therapy (Group B) for 6 weeks. Before being included in the study, the patient's parents or relatives will be educated about the study's goals and approaches, and they will sign written informed permission forms.

PARTICIPANTS:

The inclusion criteria of participants are under –

1. Spastic diplegic type of Cerebral Palsy subjects

2. Age group - 4-9 yrs. of age
3. Both the genders
4. Modified Ashworth Scale 2.
5. Capable to participate in the tasks and carry out simple commands
6. Patients with a low intelligence quotient.

Exclusion criteria for participants are under-

1. Subjects who has sustained primary orthopaedic surgery
2. Subjects who had been given botulinum toxin injection in the past 6 months
3. Patients having contractures
4. Patients having acute restrictions in passive range of motion at lower extremities.
5. Known case of seizures and on anti - epileptic drugs.

PARTICIPANT TIMELINE:

As study duration is of 6 months and intervention duration is 6 weeks so participant will be enrolled mostly during first 4 months of study so 6-week intervention will be completed successfully. Assessment will be done on first day of visit then in third week and last on sixth week of intervention. Participant will have to visit 4-5 days a week for 6 weeks for Treatment.

RECRUITMENT:

The Neurologists and health care practitioners of DMIMSU are requested to refer the potential patients to our In-patient department (IPD) and Out-patient department (OPD). The patients preceding receiving recuperation in our IPD and are recognised with spastic Cerebral Palsy (Diplegic) going to be methodically examined in order to the suitability in the study according to the inclusion and exclusion criteria. Following the enrolment in the analysis participants will be randomized in one of the group A or B and accordingly will undergo the rehabilitation program for 6 weeks with intermediate assessments. Advised patient approval will be taken ahead to the allocation and given the explanation of the motive of the study, process, expected gains and after effects of intercession.

IMPLEMENTATION:

Randomizing will be directed according to the research coordinator and principal investigators.

BLINDING:

Tester(s) are going to be blinded for appointing subjects to the group. For assuring blinding, subjects are going to be instructed not to disclose any specifics of their Treatment to the tester.

STUDY PROCEDURE:

The patients are going to be split up in two batches.

Group A – NeuroDevelopmental Treatment with conventional Treatment

Group B - Passive Stretching with conventional Treatment

Group A- NDT (Neuro Developmental Treatment) therapeutic exercises that focuses reviving normal movement and obstruct unusual muscle tone.

The therapy will be given on the basis of 35 minutes /day and 4-5 times / week. Participants will be assessed twice (before and after the NDT programs) and acquired details will be stored.

NDT programs will be organized specifically for every one of the patients according to the requirement.

Conventional Treatment will be given for 30 min per session. Total duration of Treatment will be one hour and 5 min in one session.

Researchers in the study will supervise and encourage all participants to fully participate in the training to guarantee the quality of the training.

Group B - In Group B, Passive Stretching with conventional Treatment will be given to the spastic diplegic Cerebral Palsy.

Passive Stretching will be given to a particular muscle (calf muscle).

Dorsiflex the ankle to stretch the calf with proper positioning and then hold the position for 30 seconds and then repeat it two times.

OUTCOMES:

Pre and post intervention measures

1. Modified Ashworth Scale
2. GMFCS scale (Gross Motor Function Classification System)

DATA COLLECTION AND MANAGEMENT:

Data collection

The evaluation data is going to be obtained out of prearranged spreadsheet having varying output features. Research data is going to be placed in a safe record. Non-electronic records, including hard copies of assessment forms, signed informed consent, etc., is going to be gathered safely in the study program.

DATA MANAGEMENT:

Data collecting and reporting will be governed by principal investigators. The research report must be carefully checked for veracity. The excel spreadsheet is going to be published at the conclusion of the study and given for statistical analysis. Checklist can be used to avoid lost data due to incorrect staff procedures.

STATISTICAL ANALYSIS PLAN:

The data obtained would be written down and then organised in a tabular format. It will be examined using the SPSS variant.

BIAS:

Precautions will be considered to avert this from happening attrition bias by giving reminder calls prior to every intercession and by providing travel assistance to whoever need it. So, we expect a less dropout percentage.

DISCUSSION:

Cerebral Palsy is a diverse motor condition which impacts babies of various gestational ages, but is more severe in preterm neonates.⁽¹⁰⁾ Muscle weakness, stiffness, reduced range of motion, and fall in particular motor function are all common motor deficits in children having Cerebral Palsy.⁽¹⁰⁾ As a result of the occurrence of greater tone, gradual growth and progression

of the brain, the pattern of clinical manifestations in Cerebral Palsy might show transition.(12) The goal of this analysis is to see whether Neuro Developmental Treatment versus Passive Stretching, when used in conjunction with traditional therapy, improves posture and functional recovery in Cerebral Palsy patients. NeuroDevelopmental Treatment is a set of procedures aimed at improving muscle tone, postural alignment, and the control of aberrant reflexes by sensory input in order to facilitate a child's active engagement in the Development and practice of functional abilities. (13)According to a study conducted by Fatih Tekin, the bobath concept is particularly successful in normalizing muscle tone, which improves postural control and independence in daily life tasks.(14)Passive Stretching is a manual approach that improves a child's motor capabilities by maintaining or expanding range of motion.(15) According to a study conducted by Katrin-Mattern-Baxter, Passive Stretching is useful in lowering spasticity and increasing range of motion, hence boosting functional recovery. (16)

CONCLUSION:

The goal of this study is to see how Neuro Developmental Treatment and Passive Stretching affect patients having spastic Cerebral Palsy. The findings of the analysis will aid patients in recovering faster and improving their abilities. Modified Ashworth Scale and gross motor functions classification system are the study's main outcome measures. Spasticity and gross motor functions will be assessed using these scales.

RESULT:

The successful completion of this study will provide evidence on the best Treatment strategy for Cerebral Palsy patients to improve their posture, combining Neuro Developmental Treatment with conventional therapy and Passive Stretching with conventional therapy, and the findings of

this analysis will provide a clearinsight of both Treatments.Later, the data will be examined and a study paper will be submitted.

ETHICAL APPROVAL AND DISSEMINATION:

Ethical approval is going to be givenby the institutional ethical committee. The DMIMS who will fund for research and the subjects who will be participating in the study will be able to access the main analysis of research. Data held safely for the enlisted subjects for at least five years. After completion of data collection, statistical analysis a completion report will be formed and after review by institutional research cell will be send for publication.

PATIENT CONSENT:

Principal investigator is going to acquire the informed consent from the patient's parents and any relative on a printed form having signature and given proof of confidentiality.

CONFIDENTIALITY:

The study routine is going to be elaborated to patient's parents or relatives, and principal investigator will take personal information as a part of procedure. The consent form will have the confidentiality statement and signature of the principal investigator, and patient' parents. If needed to disclose details for the study, consent will be obtained from the patient's parents including total surety about the confidential details.

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