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Research Protocol

Physiotherapy Section

Effectiveness of Dynamic Neuromuscular Stabilisation and Neurodevelopmental Therapy on Gross Motor Function and Trunk Control in Children with Spastic Diplegic Cerebral Palsy: A Protocol for a RCT

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ABSTRACT

Introduction: The Dynamic Neuromuscular Stabilisation (DNS) technique uses feed forward feedback to involuntarily activate the diaphragm and deep abdominal muscles prior to purposeful movement in humans. It is an efficient approach for facilitating deep core muscle activation of the underactive muscle chain consisting of the Internal Oblique (IO), transverse abdominals and diaphragm, thereby enhancing age appropriate jumping, walking and standing, in participants with Spastic Diplegic Cerebral Palsy (SDCP), whereas the primary goal of Neurodevelopmental Therapy (NDT) is to facilitate more normal movement patterns for performing performance skills and rectifying abnormal postural tone.

Need of the study: Even though studies have been done in the past, utilising DNS and NDT in children with diplegic CP, for improving core stability, balance, posture and diaphragmatic movement; however, Gross Motor Function (GMF) and trunk control are the aspects that have not been aimed with DNS. There is scarcity in the literature related to impact of DNS on GMF and trunk control in children with diplegic CP. As DNS has specific role on core strength it can be a valuable in the management of trunk control. Because no study comparing the impact of DNS and NDT on trunk control and functions of gross motor in diplegic children has been found; there is a strong need to perform a study to evaluate the same.

Aim: To compare the impact of DNS to NDT on gross motor performance and trunk control in children with SDCP.

Materials and Methods: It will be a Randomised Clinical Trial (RCT) with the assessor blinded, conducted in the Outpatient Department of Physiotherapy, AVBRH Sawangi, Meghe, Wardha, Maharashtra, India, from July 2022 to April 2023. Following the baseline assessments, children with SDCP (n=36) will be enlisted and randomly assigned into two groups, groups A and group B. Group A will be treated using conventional therapy along with NDT; group B will be given conventional therapy as well as DNS. Treatment will be given for four weeks, five days a week. On the first and the last day of the intervention, primary outcome measures Gross Motor Function Measure-88 (GMFM-88), Trunk Impairment Scale (TIS) and secondary outcome measure Modified Ashworth Scale (MAS) will be employed (on the first day and after the completion of four weeks). Mini-mental Scale Examination (MMSE) will be used as inclusion criteria for the children. Statistical analysis will be carried out using Statistical Package for the Social Sciences (SPSS) software version 27.0.

Conclusion: The present study is expected to prove DNS approach to be successful in enhancing the control of the trunk and gross motor abilities in children with SDCP.

Keywords: Modified ashworth scale, Muscle movement, Randomised clinical trial, Trunk impairment scale

INTRODUCTION

The term Cerebral Palsy (CP), refers to a group of ailments of the neurodevelopment system of posture and mobility caused by non progressive lesions in the developing foetus or neonatal brain. The clinical features of this motor condition are neuromuscular dysfunction such as abnormal tone, weakness, and poor trunk control, as well as anomalies involving sensory, perceptual, communication, and cognitive issues [1].

In affluent countries, the condition occurs at an incidence of 2.08% out of every 1000 live births [2]. Males are more likely than females to suffer from CP, with gender ratios ranging from 1.1:1 to 1.5:1. The little club classifies CP as spastic (diplegic, double hemiplegic and hemiplegic), atonic, choreoathetosis, dystonic, ataxic and mixed CP. Spasticity is a clinical sign characterised by increased resistance of a limb to externally imposed joint movement, whereas diplegia is the involvement of both lower extremities [3]. Spastic Diplegic Cerebral Palsy (SDCP) is clinically characterised by varying degrees of spasticity in the lower extremities and pelvis and mild spasticity and/or coordination in the upper extremities [4].

Poor trunk control is one of the most important barriers to the functions of motor system development in children with diplegia. Gross motor skills that are delayed in children with diplegic CP are connected to outcome measures like Activities of Daily Living (ADL). These children usually have poor movement control as well as poor walking ability [5].

The treatment protocol for SDCP includes:

Vojta therapy: Vojta therapy is also known as reflex locomotion and is divided into reflex rolling and reflex crawling [6]. The application of reflex creeping and reflex turning in Vojta therapy enhances the gait function of children with spastic diplegia by improving the body's balanced muscle contractions [7].

Constraint Induced Movement Therapy (CIMT): Its goal is to stimulate the functional use of the affected limb by restraining the unaffected or less affected limb [8].

Neurodevelopmental Therapy (NDT): This is a common treatment method prescribed to children with CP. It trains the brain on how to facilitate functional independence and motor effectiveness by facilitating posturally-controlled motions, to focus on the neuromuscular and central neurological systems [5].

Dynamic Neuromuscular Stabilisation (DNS): DNS because of its effectiveness is now widely used in clinical practice. It provides subcortical core stabilisation through simultaneously activating the Transverse Abdominis (TrA), diaphragm, IO, and in coordination of the pelvic floor with IAP, multifidus, and superficial abdominal muscles. DNS utilises unique stimulation zones to rebuild the sensory circuits mediating dynamic stability of the neuromuscular system, culminating in automatic core stabilisation [9].

The therapeutic benefits of the DNS technique for the control of the trunk and gross motor skills in SDCP are unknown. The focus of this research is to look at how DNS and NDT affect Gross Motor Functions (GMF) and trunk control in children who have diplegia. Even though studies have been done in the past, utilising DNS and NDT in children with spastic CP, for improving their core stability, balance, posture diaphragmatic movement and gait [9,10]. However, GMF and trunk control are the aspects that have not been aimed with DNS. No study comparing the impact of DNS and NDT on functions of gross motor and trunk control in diplegic children has been found. The aim of the present study is to compare the impact of DNS to NDT on trunk control and gross motor performance in children with SDCP.

MATERIALS AND METHODS

The study is a RCT and will be conducted in the Outpatient department of Neurophysiotherapy, AVBRH, Sawangi, Meghe, Wardha, Datta Meghe Institute Of Medical Sciences, Sawangi, Meghe, Wardha, India; from July 2022-April 2023, on children diagnosed with SDCP. Ethical approval was obtained from the Institutional Ethical Committee (No. DMIMS(DU)/IEC/2022/894). Written consent will be obtained from the patient's parents before including them as a sample for the study.

Inclusion criteria: Children of either gender from 8-12 years diagnosed with SDCP and who can follow commands {paediatric Mini-mental Scale Examination (MMSE) score more than or equal to 23}, will be included in the study.

Exclusion criteria: Children who have received botulinum medication in the last six months, who have undergone any surgical intervention involving the spine and lower limb in the past six months, children with uncontrolled seizures for the past six months, who have taken antispastic drugs in the last six months, with injuries or fractures to the trunk and extremities in the past six months will be excluded from the study.

Sample size calculation: The sample size was calculated using the Daniel formula, 18 children in group A and 18 children in group B.

Daniel formula [11]:

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

Where,

$Z_{\alpha/2}$ is the level of significance at 5% i.e., 95% confidence interval=1.96

P=Prevalence of CP=2.08%=0.0208 [2]

D=Desired error of margin=5%=0.05

$$n=\frac{1.96^2\times0.0208\times(1-0.0208)}{0.05^2}$$

n=31.29

n=36.

The report will be delivered to one of the children's relatives and the primary researcher will collect the private data. The confidentiality statement will be included in the consent form, as well as the signatures of the lead researcher, the patient's family members and two witnesses. If the patient's consent is required to reveal any information for the report, it will be obtained with confidence, knowing that participant's confidentiality will be respected.

Study Procedure

Participants timeline: The study will last for nearly one year, and the intervention will last four weeks, as four weeks of DNS training improves balance and gait performance in people with spastic CP [10]. Participants will be enlisted for one year so that the four week intervention can be completed successfully. The assessment will take place on the first day of the visit and the last day of the intervention.

Implementation: The children will be randomly distributed in a 1:1 fashion using computer-based randomisation, and they will be assigned into two groups using the Sequentially Numbered Opaque Sealed Envelope (SNOSE) method.

Blinding: The research will be a RCT with assessor and participant blinding and two parallel groups for children with SDCP.

The participants will be divided into two groups of 18 children each as [Table/Fig-1]:

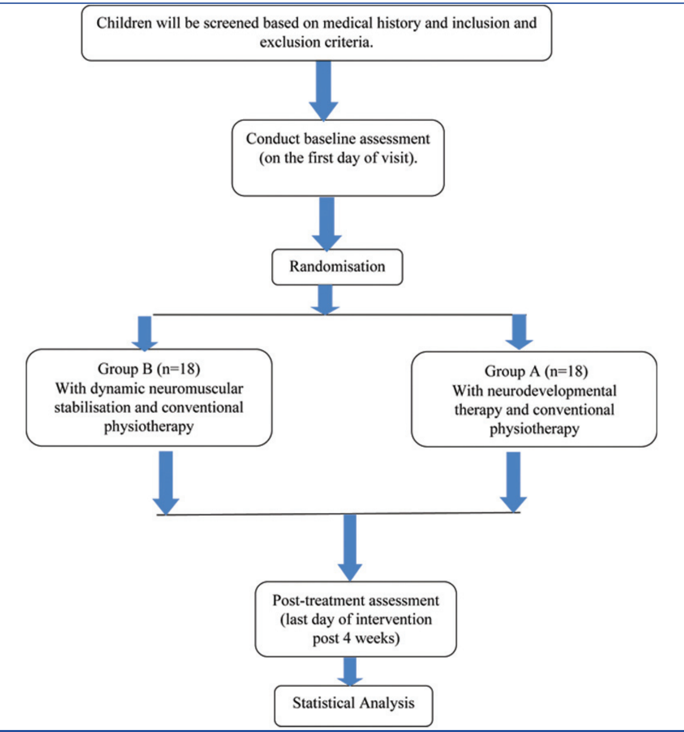
Group A: Children in this group will be receiving NDT for 30 minutes per day, five times a week for four weeks. This group includes exercises such as activation of the trunk in the transverse, frontal and sagittal plane while the child is sitting or standing, weight shifts and trunk elongation in sitting and standing positions, reaching out for and popping the soap bubble in all planes, reach out for the ball and moving the plastic rings from one end of the table to another. Standing will necessitate attempting to put the ball in the basket in all three planes, trunk activities in the sagittal plane while sitting (stability) (mobility), providing ideal pelvic alignment for weight transfers at the hips, and trunk elongation toward the reaching side of the task. Standing while attempting to reach an object in the transverse plane, to reach the target object [5].

Group B: This group will receive DNS for 30 minutes per day, five times per week for four weeks. This group includes exercises such as diaphragmatic breathing, certain postural exercises using developmental kinesiology (the positions attained by an infant are used) such as stabilisation exercise in a three month infant supine position, stabilisation exercise in a three-month-old infant prone position, side-lying five-month-old infant position, side-sitting position with forearm support corresponding to a seven-month-old developmental age, eight month, all fours (quadruped) position [12].

Conventional Physiotherapy (CPT): For four weeks, both groups will receive CPT therapy for 30 minutes each day, five days per week. The treatment will include passive stretching for the calf muscles, hamstring, quadriceps and adductors in both lower extremities (three repetitions with a 10-second hold) as well as active/active assisted/ passive ROM exercises for both the limbs in supine and sitting postures. The children will be instructed to remove and replace the pegs on the pegboard. They will be expected to stand on the board which is used for balancing and engage in fun tasks such as ball tossing into a basket ring set-up in front of them. The children will be required to balance on the board for balancing [5].

Primary Outcomes

Trunk Impairment Scale (TIS): The TIS is an instrument that can assess coordination, dynamic balance, and static balance in sitting position as well as measure trunk control ability in CP. TIS can evaluate children with motor impairment ranging in age from 5-19 years, fast and effectively, which makes it beneficial in clinical care [13].



[Table/Fig-1]: Flow diagram of randomisation.

Gross Motor Function Measure (GMFM)-88: The GMFM is the most well-known and widely used instrument in the world for evaluating gross motor development in children who have CP. The GMFM-88, the original version of the GMFM, consists of 88 items classified into five dimensions of GMF: lying and rolling; sitting; crawling and kneeling; standing; and walking, running, and jumping. It enables quantitative assessment of motor function in order to determine the effectiveness of interventions in children with CP [14].

Secondary Outcomes

Mini-Mental Scale Examination (MMSE): The MMSE, is a standardised tool to assess the mental status which covers five areas of cognitive functions *i.e.*, orientation, attention-concentration, registration, recall and language in a single set of questions for use in children aged between 3-14 years [15].

Modified Ashworth Scale (MAS): MAS measures spasticity and are applied manually to determine the resistance of muscle to passive stretching, the tool is very common to clinical practice and is frequently used [16].

STATISTICAL ANALYSIS

For the statistical analysis, Statistical Package for the Social Sciences (SPSS) version 27.0 will be used. The paired t-test will be used to compare differences within groups if the data distribution is normal, while the unpaired t-test is used to make comparisons differences between groups, if the data is not normally distributed. If the data will not be distributed normally, the Wilcoxon signed-rank test will be used to compare the differences between the groups, while the Mann-Whitney U test will be used to estimate differences between groups.

DISCUSSION

The protocol will be followed for a RCT to assess the impact of NDT and DNS in SDCP. DNS is an effective intervention for improving age appropriate standing, walking, and jumping in participants with SDCP by facilitating deep core muscle activation of the underactive muscle chain comprised of the diaphragm, Internal Oblique (IO) and transverse abdominals [9]. Whereas, NDT focuses on the central nervous and neuromuscular systems, teaching the brain to improve motor efficiency and functional independence by facilitating typical postural controlled movements [5].

Sah AK et al., conducted a study in 2019 to investigate the effects of task-oriented activities based on NDT principles on trunk control, balance, and GMF in children with SDCP, which demonstrated that NDT principles were effective in improving all of the aforementioned parameters in diplegic CP [5]. Labaf S et al., investigated the effects of NDT on GMF in children with CP and concluded that NDT improved GMF in four dimensions: laying, rolling, sitting, crawling, kneeling, and standing [17].

Son MS et al., conducted a study to see the impact of DNS on diaphragm movement, posture control, balance, and gait performance in CP, and the results showed that DNS core stabilisation exercise was effective for activating the underutilised or underactive deep transverse abdominal and IO core muscles and diaphragm movement, as well as associated balance and gait performance in the GMFM measure [9].

In 2017 Kim DH et al., conducted research on the effect of four weeks of DNS training on an adolescent with spastic hemiparetic CP on balance ability. The subject underwent four weeks of DNS training, demonstrating that four weeks of training is effective in improving balance and gait performance in spastic hemiparetic CP [10]. The above-mentioned studies prove that both NDT and DNS are beneficial approaches for children with SDCP.

CONCLUSION(S)

The present study on DNS over NDT in SDCP could provide healthcare providers with an important therapeutic approach that could be a turning point in the treatment protocol for children with SDCP since this approach directly focuses on the strengthening of our axial skeleton and core muscles which might improve GMF and trunk control in the children. To avoid any disparities in the recovery period between the two groups, the total recovery time for both groups will be the same. The findings of the study would help children with SDCP by providing a more advanced and efficient recovery technique. Furthermore, this research could aid in the rehabilitation of spastic diplegic children, improving their functional independence and, as a result, their quality of life.

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