EFFECTS OF LOWER LIMB INTENSIVE FUNCTIONAL TRAINING ON GAIT AND BALANCE IN SPASTIC DIPLEGIC CEREBRAL PALSY CHILDREN

NCT NO: None

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Study Protocol:

Objective:

1. To compare outcomes of lower limb intensive functional training (LIFT) with conventional physical therapy on gait and balance in spastic diplegic cerebral palsy children.
2. To access if changes in motor capacity can further improve their motor performance level.

Study Design:

Randomized Controlled Trial

Study Method:

Settings

Children with Spastic diplegic from Physiotherapy Department of 2 different centers from Lahore.

Duration of Study

Duration of study was 9 months after approval of synopsis.

Sample Size

The calculated sample size using 30-sec chair test as outcome measure is 35 in each group after adding 20% dropout the sample size will be 35+7=42 in each group.

$$n = \frac{2\sigma^2(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

$Z_{1-\alpha/2}$ Level of significance=95%

μ_1 Expected mean change in 30 sec chair rise test in Control group= 17.25

μ_2 Expected mean change in in 30 sec chair rise test in Experimental group= 13.25

δ_1 Expected standard deviation in Control group = 6.25

δ_2 Expected standard deviation in Experimental group = $5.12Z_{1-\beta}$

power of the study= 80%

n Expected sample size in a group= 35

After adding 20% drop out 35+7=42 in each group.

Sampling Technique

Non-probability Purposive sampling technique was used.

Statistical Procedure:

SPSS version 21 was used for data entry and analysis. Quantitative variables presented with mean±SD and qualitative variables presented with frequency and percentage. Normality of the data was assessed with Shapiro-Wilk test. The data not fulfilled the assumption of normality. So, non-parametric test Friedman and Mann Whitney U test were applied. The p-value <0.05 was considered statistically significant

Consent Form

You are invited to participate in a research study conducted by Husna Albab. The purpose of this research is to evaluate the 'Effects of Lower limb intensive functional training ongait and balance in Spastic Diplegic Cerebral Palsy children'

Risks and Discomforts

There will be no known risks associated with this research.

Potential Benefits

Participant will get effective treatment.

Protection of Confidentiality

We will do everything we can to protect your privacy. Your identity will not be revealed in any publication resulting from this study.

Voluntary Participation

Your Child participation in this research study is voluntary. You may choose not to participate her/him and you may withdraw your consent to participate any time. You will not be penalized in any way should you decide not you participate or to withdraw from this study.

CONSENT

I have read this consent form and have been given the opportunity to ask questions. I give consent for the participation of my child in this study.

Participant's Parent Signature_____Date: _____

Group A: The Control group received conventional physical therapy (Stretching followed by Strengthening program and traditional gait training) at clinical setting. Stretching muscles were hip flexors, hip adductors, hamstrings and calf and stretching applied for 30 sec with 30 sec rest for 3 -5 times for each muscle group with in pain limit followed by strengthening exercise for week muscle which includes the strengthening of anti-gravity muscles of lower limb they are: Quadriceps, Gluteus maximus and soleus performed in 3 groups. Each group contain 10 rep for each week muscle group. Conventional Physical therapy applied 5 days/week for consecutive 20 weeks. They were also guided to perform activities at home but they're unbound to do the designed activities freely.

Group B: The experimental group will receive Lower extremity functional training (LIFT) at home environment and routine physical therapy at clinical setting. LIFT will be provided at home environment for 3 hours/day, 5days/week for 5 months. A log book will be maintained and the goals and strategies will be guided to child's parents. 3 hours' treatment will be performed in intervals at different time of the day. LIFT will help the child in motor learning, skill progression and resistance training to target the strength, proprioception and coordination impairments of the lower extremities. Motor learning will be based on Strength domain (Cycling) and progression from smooth to rough surface. Balance and Coordination domain involves activities such as (ball kicking with alternate legs and Static standing) and progression will be done by increasing accuracy and complexity. Proprioception domain (Vertical jumping, sit to stand and cursing) while applying knee-immobilizers if needed and progression number of repetitions and sets will be increased over time. Skill progression will be used to challenge the LIFT and make it intensive enough to obtain changes in motor skills and function. AFO's will be required during therapy session if needed.

Caregiver will be provided proper guidelines before implementing the treatment at home. 3 training sessions will be given prior to treatment. A log book will also be provided to get the structured record of the treatment. Further videos and mode of tele-rehabilitation will be used for supervision and guidance throughout the study. Therapist will closely monitor the activities by checking daily logs.

Data Analysis Procedure

Data will be analyzed using IBM SPSS version 21. The quantitative variables like age will be presented in the form of mean ±SD and qualitative variables like gender will be presented in the form of frequency and percentage. After checking normality of data if parametric tests will be required the independent sample t-test will be used to determine mean difference of GMFM-88 for motor capacity and 6-min walk test, Timed Up and Go test and 30 sec chair raise test for motor performance. Further, mixed model will be used to compare the outcome variables at follow-ups on the other side if data will not be normally distributed then Friedman test will be used. P-value ≤ 0.05 will be considered as significant.