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A multicentre, double-blind, randomized controlled trial on the effect of functional strength training on gross motor function among children with spastic diplegic cerebral palsy

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Abstract

Introduction. Strength training has shown benefits in rehabilitating children with spastic diplegic cerebral palsy (CP); non-functional activities are less significant in improving gross motor function. There is dearth of evidence concerning the benefits of functional strength training (FST) among children with spastic diplegic CP. Hence, we aimed to compare the benefits of FST and conventional physiotherapy (CPT) in this group.
Methods. Overall, 40 children with spastic diplegic CP with Gross Motor Function Classification System levels I, II, and III were recruited by simple random sampling (Random Number Generator) to participate in this 2-group pretest-posttest, multicentre, double-blind randomized controlled study. The children were randomly divided into 2 groups: FST group and CPT group. Both groups received an active training program of 45–60 minutes for 6 weeks with a 2-month follow-up without intervention. The 88-item Gross Motor Function Measure (GMFM-88) dimensions D, E, and goal total score were recorded at baseline, after the 6-week intervention, and after the 2-month follow-up.
Results. FST group demonstrated significant differences in GMFM-88 dimensions D [7.1 (0.4–13.8); p = 0.038], E [11.8 (3.1–20.4); *p* = 0.009], and goal total score [9.4 (3.3–15.6); *p* = 0.003] when compared with CPT group after the 6-week intervention. Similarly, a significant difference was noted in GMFM-88 goal total score [6.3 (0.1–12.4); *p* = 0.046] after the 2-month follow-up. There were no differences in GMFM-88 dimensions D [3.9 (–2.5 to 10.5); *p* = 0.222] or E [8.6 (–0.3 to 17.4); *p* = 0.059] after the 2-month follow-up.
Conclusions. Six-week FST improved standing, walking, running, and jumping in children with spastic CP. FST had a carry-over effect of strength gained in functional performance.
Key words: cerebral palsy, double-blind method, spastic diplegic, functional strength training, gross motor function

Introduction

The incidence of cerebral palsy (CP) in developed countries is reported to be about 1.5–5 per 1000 live births [1]. CP seems to be the most common cause of lifelong physical disability and has an impact on the child, caregivers, and society [2, 3]; 15–20% of physically disabled children are affected by CP [4, 5]. CP is non-progressive, but often changing, considered as a disorder of movement and posture. Its motor impairment syndromes are secondary to lesions or anomalies of the brain arising in the early stages of its development [6]. CP is the most common motor disability; spastic CP (70–80%) involves such motor impairments as muscular hypertonicity, weakness, and increased deep tendon reflexes [3, 7]. Overall, the symptoms affect the quality of life of children suffering from CP [8, 9]. Among them, the major ones are diplegic (43.5%), followed by quadriplegia (34.3%) [10].

Gross motor functions like sitting, standing, walking, and running are affected badly in children with CP. Children with spastic diplegic CP exhibit increased postural sway when compared with typically developing peers [11] and have poor postural stability [12]. Large muscles of the body are involved in performing gross motor functions. Children with more severe spastic diplegic CP find it difficult to perform gross motor functions [13]. This affects daily functional skills, such as self-care, mobility, and social function [14]. Abnormal muscle tone, contractures, abnormal bone growth, balance deficits, loss of selective motor control [15], and muscle weakness [16] are common neuromuscular and musculoskeletal impairments influencing gross motor functions.

Traditional physiotherapy techniques or approaches, which include stretching exercises [17], range of motion exercises, and strengthening exercises [18, 19], were applied to improve gross motor functions in CP children. In the current era, therapists follow evidence-based approaches, like neurodevelopmental treatment (Bobath) [20–22], Rood approach [23], proprioceptive neuromuscular facilitation, sensory integration [24], constraint-induced movement therapy, and aquatic therapy [25], in treating children with spastic diplegic CP.

Research has shown that muscle strength has greater association with gait and gross motor functions compared with spasticity in spastic diplegic children [26, 27]. Taylor et al. [28] investigated the impact of progressive resisted exercises over general exercise and concluded that it improved gait function with less energy expenditure in adolescents with spastic CP, thus proving that progressive resisted exercises were more effective than other interventions. From previous studies, it is evident that a non-functional activities are less significant in improving gross motor function [29, 30]. Functional strength training (FST) along with plyometric exercises has the potential to enhance muscle strength, power, gait, dynamic balance, and overall gross motor function in

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children with unilateral CP [31]. In a recent systematic review, Fleeton et al. [32] have concluded that there is high quality evidence that resistance training improves muscle strength but only limited evidence regarding functional improvement. Hence, there is a need to find the effect of FST on motor function in children with spastic diplegic CP.

Subjects and methods

Recruitment

By screening 63 children with spastic diplegic CP, 40 participants aged 5–14 years, including both males and females, were recruited for the 2-group pretest-posttest randomized multicentre clinical trial with the simple random sampling technique. The Random Number Generator, an application in the Statistical Package for the Social Sciences (SPSS) was used. *A priori* sample size calculation was not carried out, as recommended by the statistician, because the rule of thumb indicates that $n \geq 30$ is the minimum sample considered as large enough to detect changes between groups. Hence, we recruited $n = 40$ in the convenience sampling.

The study was conducted in a tertiary care teaching hospital and recognized centre for special children. Children with spastic diplegic CP who were able to follow verbal commands and presented level I, II, or III of Gross Motor Function Classification System were included in the study. Those who were uncooperative, had visual or intellectual impairments, received antiepileptic and anti-spasticity medications, with hearing deficits, with any cardiac anomalies affecting exercise tolerance, and those who had undergone orthopaedic surgery or botulinum toxin injections within the previous 4 months were excluded from the study.

Random allocation

Simple randomization was used to allocate the children with spastic diplegic CP into the FST group and conventional physiotherapy (CPT) group. Active training was provided for the period of 6 weeks, followed by a 2-month follow-up without intervention. Before the actual intervention began, anthropometric measures such as age, height, and weight were recorded. Additional information concerning the type of shoes the children with spastic diplegic CP wore and the type of orthosis or walking aid used was also noted. As this was a multicentre clinical trial, 4 qualified physiotherapists with minimum 5 years of clinical experience in treating children with spastic diplegic CP were selected from each centre. The selected 12 therapists were trained for 2 weeks regarding the FST and CPT protocols. The therapists were randomly assigned to either the FST group or the CPT group with the use of sequentially numbered, opaque, sealed envelopes (SNOSE) to minimize bias. The children with spastic diplegic CP and the therapists involved in administering the treatment were blinded to their treatment allocation. Hence, the study was double-blind. The study flowchart in accordance with the Consolidated Standards of Reporting Trials (CONSORT) is presented in Figure 1.

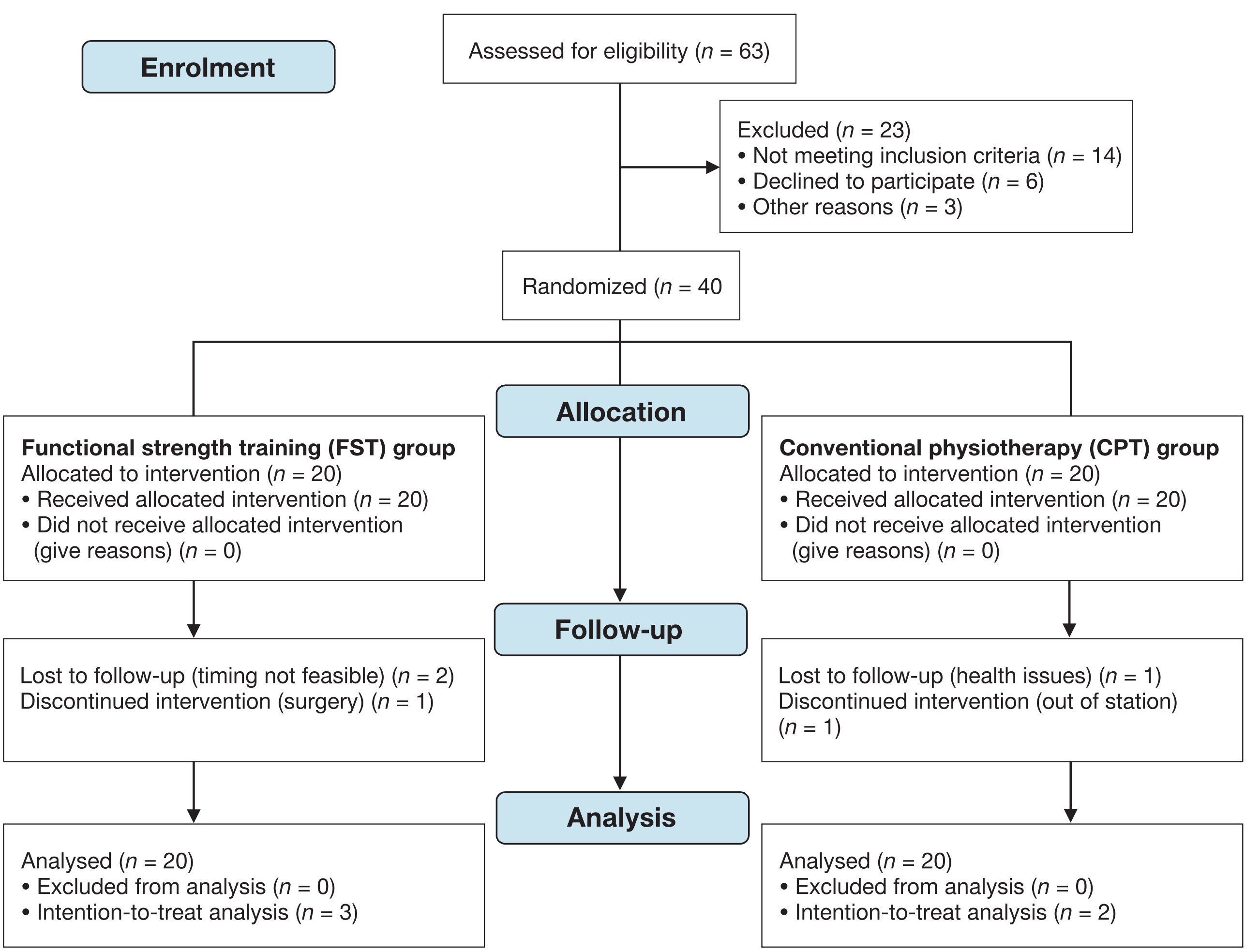

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart of the study

Intervention

Functional strength training group

The FST group followed a 6-week functional progressive resistance exercise strength training program 3 times a week. Each training session lasted for 45–60 minutes. The training sessions were held in small groups with a 5-station circuit and were supervised by an experienced physical therapist for each group. Each training session began with a warm-up of 10 minutes and ended with a cool-down period of 5 minutes, during which muscle stretching exercises and aerobics were performed. The warm-up exercises included low-intensity stretching for hip flexors, adductors, hamstrings, and plantar flexors. Each muscle was held in the stretched position for 15 seconds with a rest period of 5 seconds and this cycle was repeated for 6 times. The duration of the stretching session was 10 minutes. In the main training phase, each child performed 4 different exercises on the 5-station circuit, as described in Table 1. The different stations of the circuit were named as follows: loaded standing on edge of the block, loaded sit-to-stand, loaded game, unloaded game, and relax.

Apart from the relax station, which served as a relax moment, each station had its own training volume (i.e. a combination of load, repetitions, sets, and rest) with which the exercise was performed, as elaborated in Table 2. The choice of the training volume is directly related to the desired goal of muscle training; to provide enhanced muscle strength, the training must be based on a fixed combination of a high load (70–95% repetition maximum [RM]), 8–12 repetitions, 1–3 sets, and sufficient rest to allow muscle recovery. We used the RM method [33] to assign intensity instead of 1RM as this was most feasible; moreover, 1RM estimation is unsafe among children with CP [34]. The protocol was designed in accordance with the recommendations for people with CP provided by Verschuren et al. [34]. The training volumes of progressive resistance exercise in the above mentioned 5 stations and guidelines for predicted load repetitions are displayed in Table 3 and Table 4, respectively. The described FST was continued for the period of 6 weeks of active intervention.

Table 1. Characteristics and training volumes of the 5-station circuit used by children with spastic diplegic cerebral palsy

Station	Load	Trained leg	Exercise	Functional	Supervision	Game	Resistance
1. Loaded standing on edge of the block	High	Bilateral	Standing on edge of the block and reaching up with heel raise	No	Very strict	Yes	Weight vest
2. Loaded sit-to-stand	High	Bilateral	Sit-to-stand	Yes	Very strict	No	Weight vest
3. Loaded game	Low	Unilateral	One leg on the block and reaching sides and forward	Yes	Strict	Yes	Weight vest
4. Unloaded game	No	Contralateral	Quadruped; contralateral rise of hand and leg and reaching	Yes	Strict	Yes	Body weight
5. Relax	NA	NA	NA	NA	None	NA	NA

NA – not applicable

Table 2. Different training volumes, related to the desired goal of muscle training (adapted from [35])

Training goal	Training volume			
	Load (% 1RM)	Repetitions	Sets	Rest between sets
Maximum strength training	95–100	1–3	1–3	2–4 min
(Submaximal) strength training	70–95	8–12	1–3	90–120 s
Strength endurance training	50–70	10–15	1–3	45–90 s
Endurance training	< 50	20–50	3–5	< 45 s
Coordination training	< 30	30–70	4–6	< 45 s

RM – repetition maximum

Table 3. Training volumes of progressive resistance exercise in different stations

Stations	Training volume			
	Maximum load	Repetitions	Sets	Rest
1. Loaded standing on edge of the wooden block	100% 8RM	8	3	90 s
2. Loaded sit-to-stand	75% 8RM	8	3	90 s
3. Loaded game	25% 8RM	8	3	90 s
4. Unloaded game	Body weight	8	3	90 s
5. Relax	NA	NA	NA	NA

RM – repetition maximum, NA – not applicable

Table 4. Guidelines for the predicted 8-repetition maximum

Station	GMFCS level	Predicted 8RM (% of body weight)
1. Loaded standing on edge of the block	I	120
	II	100
	III	80
2. Loaded sit-to-stand	I	35
	II	30
	III	25

GMFCS – Gross Motor Function Classification System
RM – repetition maximum

Conventional physiotherapy group

Children with spastic diplegic CP in the CPT group followed a 6-week routine exercise training program applied 3 times a week. Each training session lasted for 45–60 minutes. Each training session began with a warm-up of 10 minutes and ended with a cool-down period of 5 minutes, during which muscle stretching exercises and aerobics were performed.

The warm-up exercises included low-intensity stretching for hip flexors, adductors, hamstrings, and plantar flexors. Each muscle was held in the stretched position for 15 seconds with a rest period of 5 seconds and this cycle was repeated for 6 times. The duration of the stretching session was 10 minutes. The routine physiotherapy exercises session began with active exercises for lower limbs. Active exercises included: bilateral weight shifts (10 times each side), holding the couch and weight bearing position like quadruped, with half kneeling and kneeling position encouraged. Each position was held for 10 counts, with a rest period of 5 seconds repeated for 10 times. Physio-ball exercises were added, which included: bridging: held for 10 seconds, rest period of 5 seconds and repeated for 10 times in supine position; weight shifts: side to side and anteroposterior weight shifts were encouraged on ball for balance and proprioception in lower extremity, both shifts were applied 10 times with a rest of 5 minutes in between in supine position. These were continued for the period of 6 weeks of active intervention.

Outcome measures

Gross Motor Function Measure (GMFM) is a valid and reliable tool to document physical functional changes following treatment intervention in children with spastic diplegic CP [36]. In this study, the 88-item GMFM (GMFM-88) dimension D (standing) and dimension E (walking, running, and jumping) were selected as goal areas. In accordance with the scoring sheet, the activities were scored as 0, 1, 2, 3, or not tested (NT) by observing the child's performance, with higher ratings representing better performance. During each activity, the level of support, balance reactions, weight transmission, and the type of assistance were noted. GMFM-88 dimensions D, E, and goal total score were recorded at baseline, after the 6-week intervention, and after the 2-month follow-up. All the outcome measures were recorded by a qualified physiotherapist trained in using GMFM and scored by using the Gross Motor Ability Estimator (GMAE-2) scoring software for GMFM.

Data analysis

The collected demographic data and outcome measures were assessed for their normality with the Shapiro-Wilk test. As the demographic data followed normal distribution, all the descriptive statistics were expressed in mean ± standard deviation. An independent test was used to demonstrate significant differences between the groups. The outcome measures of GMFM-88 (domains D, E, and goal total score) followed normal distribution. Hence, they were expressed in mean ± standard deviation. An independent *t*-test was adopted to find out differences between the FST and CPT groups for baseline, post-intervention, and post-follow-up outcome measures. Within-group differences at the 3 time points were analysed by using repeated measures ANOVA. All the data were analysed with the SPSS software, version 20.0 (IBM Corp., Armonk, NY, USA). The value of $p \leq 0.05$ was considered to be statistically significant. *A priori* sample size calculation was not performed; retrospective (post-hoc) statistical power was established with the G*Power 3.1.9.4 analysis software (Franz Faul, Universität Kiel, Germany) with the effect size index to confirm that the power of confidence exceeded 85% (value accepted in clinical outcomes). Hence, type II error would be minimized to 15%.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Fortis Hospital ethics committee, Mohali, India (approval No.: IEC/2018/OAS/11), and by the ethics committee of Chitkara School of Health Sciences, Chitkara University, Rajpura.

Informed consent

Informed consent has been obtained from the parents or legal guardians of all individuals included in this study.

Results

Overall, 40 children with spastic diplegic CP were recruited for the study. Among them, 20 were randomly allocated into the FST group and 20 to the CPT group. The demographic characteristics of the participants are presented in Table 5. There existed no significant differences between the 2 groups. The between-group comparisons at baseline, after the 6-week training intervention, and after the 2-month follow-up for the outcome measure of GMFM-88 domains D, E, and goal total score with mean difference are displayed in Table 6. The within-group analysis revealed significant differences ($p < 0.0001$) at all the 3 time points in both groups. Five drop-

Table 5. Demographic characteristics of the recruited children with spastic diplegic cerebral palsy

Characteristics	FST group (n = 20)	CPT group (n = 20)	p
Age (years)	8.2 ± 2.3	8.75 ± 2.78	0.87
Height (cm)	131.1 ± 14.6	128.1 ± 15.4	0.63
Weight (kg)	32.8 ± 14.5	30.3 ± 11.3	0.09
BMI (kg/m^2)	28.1 ± 4.5	30.3 ± 11.3	0.33

FST – functional strength training
CPT – conventional physiotherapy

Table 6. Comparison of Gross Motor Function Measure domains D, E, and goal total score within and between the conventional physiotherapy and functional strength training groups

GMFM dimensions		FST group (*n* = 20)	CPT group (*n* = 20)	Mean difference (95% CI)	*p*
Dimension D	Baseline	69.1 ± 11.4	70.4 ± 10.6	–1.3 (–8.3 to 5.8)	0.717
	Post-intervention	79.4 ± 10.6	72.3 ± 10.4	7.1 (0.4–13.8)	0.038
	Post-follow-up	75.1 ± 9.7	71.1 ± 10.5	3.9 (–2.5 to 10.5)	0.222
	p	< 0.0001	< 0.0001		
Dimension E	Baseline	59.5 ± 13.9	59.7 ± 13.8	0 (–8.9 to 8.9)	> 0.999
	Post-intervention	73.6 ± 13.3	61.88 ± 13.6	11.8 (3.1–20.4)	0.009
	Post-follow-up	68.9 ± 14.1	60.3 ± 13.7	8.6 (–0.3 to 17.4)	0.059
	p	< 0.0001	< 0.0001		
Goal total score	Baseline	64.3 ± 12.4	64.9 ± 7.3	–0.6 (–7.2 to 5.9)	0.845
	Post-intervention	76.5 ± 11.6	67.1 ± 6.8	9.4 (3.3–15.6)	0.003
	Post-follow-up	71.9 ± 11.6	65.7 ± 7.1	6.3 (0.1–12.4)	0.046
	p	< 0.0001	< 0.0001		

GMFM – Gross Motor Function Measure, FST – functional strength training, CPT – conventional physiotherapy

outs (3 in the FST group and 2 in the CPT group) were analysed by intention-to-treat analysis [37, 38]. The power analysis for baseline and post-6-week intervention scores in GMFM-88 dimensions D, E, and goal total score was performed by using the G*Power 3.1.9.4 software, with the results of 86%, 92%, and 86%, respectively. Thus, type II error was found to be less than 15% and hence the study was sufficiently powered.

Discussion

The objective of this study was to examine the effect of FST on standing, walking, running, and jumping through GMFM-88. Both groups exhibited significant differences in pre- and post-intervention within-group analysis. The experimental group were able to show higher significant results in GMFM-88 domains D, E, and goal total score compared with the control group. The significant improvement in the experimental group may be due to the increase in muscle strength with the resisted exercises provided in functional positions for specific activities. There exists a strong corelation between muscle structure, motor function, and resisted exercises. Lee et al. [30] studied the effects of progressive functional training on lower limb muscle architecture and motor function in children with spastic CP and found improvement in the cross-sectional area and the pennation angle of lower limb muscles, concluding that progressive functional training could improve mobility in spastic CP.

Scholtes et al. [39], in a recent randomized controlled study, investigated the effect of functional progressive exercise strength training on muscle strength and mobility in children with CP and concluded that 12 weeks of functional progressive resisted exercise strength training increased muscle strength by up to 14%; however, the strength gain did not lead to improvement in functions like mobility. The possible factor for this failure in the conversion of functional strength attained to actual functional performance may be that the few positions selected to perform the FST protocol, like child-adapted leg press, half knee raise, or lateral step-up, were relatively non-functional and not children-friendly.

The present study was able to significantly overcome this challenge in connecting the gap in the translations of functional strength to functional performance in daily life. This was possible because the positions selected to implement the FST protocol were typically practised and assumed by the children in their routine activities, which allowed to bring significant improvements in standing, walking, running, and jumping measured through GMFM-88. Hence, the functional training administered to the children with spastic diplegic CP enhanced their functional performance in daily life.

Limitations

The small sample size and multicentred double-blind character are the few limitations affecting the strength of the study. Nevertheless, despite the small sample size, the study was sufficiently powered. We recommend further research on a protocol similar to that used in this study among children with hemiplegic and quadriplegic CP.

Conclusions

The 6-week FST in functional positions improved standing, walking, running, and jumping in children with spastic CP. FST had a carry-over effect of strength gained in functional performance.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

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