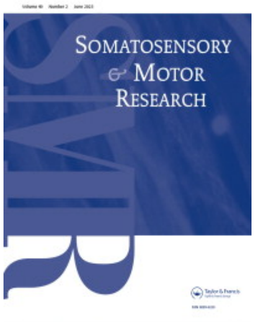

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ARTICLE

The effects of functional electrical stimulation cycling on gait parameters in diplegic cerebral palsy: a single-blind randomized controlled trial

Duygu Türker[a], Yavuz Yakut[b], Evren Yaşar[c], Mintaze Kerem Günel[d], Bilge Yılmaz[c,e,f] and Arif Kenan Tan[c,e,f]

[a]Faculty of Gülhane Physiotherapy and Rehabilitation, Department of Pediatric Rehabilitation, University of Health Sciences, Ankara, Turkey; [b]Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Hasan Kalyoncu University, Gaziantep, Turkey; [c]Department of Physical Medicine and Rehabilitation, Gulhane School of Medicine, University of Health Sciences, Ankara City Hospital, Physical Therapy and Rehabilitation Hospital, Ankara, Turkey; [d]Faculty of Physical Therapy Rehabilitation, Hacettepe University, Ankara, Turkey; [e]Department of Physical Medicine and Rehabilitation, Gulhane School of Medicine, University of Health Sciences, Gaziler Training and Research Hospital, Ankara, Turkey; [f]Department of Physical Medicine and Rehabilitation, Gulhane School of Medicine, University of Health Sciences, Gaziler Training and Research Hospital

ABSTRACT

Purpose: To investigate the effects of functional electrical stimulation cycling (FES-C) training in addition to conventional physical therapy on gait, muscle strength, gross motor function, and energy expenditure in ambulatory children with spastic diplegic cerebral palsy.

Materials and methods: Twenty children with diplegic cerebral palsy were randomly assigned to FES-C group ($n = 10$) or control group ($n = 10$). Subjects trained 3 days/week for 8 weeks. Control group received conventional physical therapy. The FES-C group additionally received FES-C training. The functional muscle test was used for muscle strength assessment. Vicon-3D system was used for gait analysis. Gross Motor Function Measure (GMFM-88) was used for motor function assessment and calorimeter was used for energy expenditure. Measurements were performed at the baseline, at the eight week and at the sixteenth week.

Results: Functional muscle strength, gross motor function, and energy expenditure improved more in the FES-C group after training and follow up ($p < 0.05$). There was no significant difference found between the changes in gait parameters of the two groups after treatment and follow up ($p > 0.05$). Pelvic tilt while walking decreased after training in the FES-C group ($p < 0.05$).

Conclusions: FES-C applied in addition to conventional physical therapy in children with diplegic cerebral palsy is more effective than conventional physical therapy for increasing functional muscle strength, improving gross motor function functions, and reducing energy expenditure.

HIGHLIGHTS

1. FES-C improves lower extremity functional muscle strength, gross motor function, and energy expenditure in ambulatory children with spastic dCP.
2. The use of FES-C in combination with conventional physiotherapy methods may be beneficial in outpatients with spastic dCP.

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KEYWORDS
Cerebral palsy; gait analysis; electric stimulation therapy; resistance training; oxygen expenditure

Introduction

Gait capacity limitations, one of the most frequent and disabling problems in children with spastic diplegic Cerebral Palsy (dCP), affects their ability to participate in social activities by reducing their daily life activities and independent mobility (Taylor et al. 2013; Van Vulpen et al. 2017). Additionally, it increases the rate of energy expenditure required for walking, thus, the children often complain of fatigue (Balemans et al. 2015). For these reasons, improving gait ability and capacity is the one of the main therapeutic goals for many children with dCP. A key element in the decreased gait capacity in these children is the lower extremity muscle weakness (Van Vulpen et al. 2017; Pouliot-Laforte et al. 2020). Various approaches have been used to improve the muscle strength, endurance, and gait capacity of children with dCP including task-oriented gait training, robotic or treadmill-based gait training, assisted functional electrical stimulation, or standard stationary cycling (Franki et al. 2012).

Cycling is a dynamic approach that can be used to improve lower extremity muscle strength, endurance, and it supports the motor development of individuals with CP (Harrington et al. 2012). The kinematic pattern of cycling is similar to gait (Damiano et al. 2017). Since most of the children with CP have different joint kinematics and muscle activity compared to their healthy peers, their pedalling strategies differ. They experience difficulties in the motor

CONTACT Duygu Türker duygu.turker@sbu.edu.tr Faculty of Gülhane Physiotherapy and Rehabilitaion, Department of Pediatric Rehabilitation, University of Health Sciences, Etlik, Ankara 06018, Turkey

performance of the bicycle because they apply asymmetric and irregular force resulting from uncoordinated pushing and pulling of the pedals instead of rotating the bicycle symmetrically and reciprocally (Harrington et al. 2012). Researchers have emphasized that threshold heart rate should be reached in individuals with CP to achieve more symmetrical cardiorespiratory exercise effects and musculoskeletal changes. Methods to increase the duration of the positive force that enables the children with CP to pedal strongly and support pedalling at appropriate rates should be used in order to reach this threshold rate. For these purposes, they proposed functional electrical stimulation cycling (FES-C) as a possible application that can be applied to improve cycling performance. FES-C may be a viable option to properly activate/deactivate muscles and maintain stronger muscle contraction (Johnston and Wainwright 2011; Trevisi et al. 2012).

FES-C is used in individuals with spinal cord injury and a stroke in order to facilitate cycling and has been shown to have obvious benefits in muscle strength, cardiovascular endurance, oxygen expenditure, motor control, and walking ability (Janssen et al. 2008; Johnston et al. 2008; Yaşar et al. 2015). These benefits suggest that the administration of this technique may be effective in children, as the central nervous system is more plastic and flexible (McRae et al. 2009; Trevisi et al. 2012). The only randomized controlled trial (RCT) (Armstrong et al. 2020) determining the effectiveness of FES-C in children with CP focussed on functionality and case series have shown the beneficial effects in children with CP (Johnston and Wainwright 2011; Trevisi et al. 2012). However, until today, no RCT has investigated the efficacy of FES-C or its combination with another exercise training aimed to improve gait in ambulatory children with dCP.

The aim of this RCT was to determine the efficacy of an 8-week programme of FES-C applied to the lower extremity in addition to conventional physical therapy (CPT) to improve gait parameters and functional outcomes in ambulatory children with dCP. It was hypothesized that the FES-C intervention that in addition to CPT would result in significantly higher functional muscle strength, improved gait parameters when compared to CPT.

Material and methods

This study was designed as a RCT to investigate the effect of an 8-week FES-C on lower extremity in dCP compared with the CPT programme. The permission of the University Ethics Committee was received (GO14/119-10) and was registered with U.S National Library of Medicine Clinical Trials Registry (NCT03600012). Written consent was obtained from all parents based on the principles of the Helsinki Declaration.

Participants

The study was conducted on children with dCP who were referred by paediatric neurologists to the Turkish Armed Forces Rehabilitation and Care Centre. The inclusion criteria were (1) classification at levels I or II in the Gross Motor Function Classification System (GMFCS), (2) 7–16 years of age, (3) ability in following and accepting verbal instructions. The exclusion criteria were (1) any kind of lower extremity orthopaedic surgery or botulinum toxin injection in the past 6 months, (2) motion limitations (at any level) or hip displacement preventing from using the ergometer in the lower extremity, and (3) any contraindications in children for FES-C or known cardiac and respiratory problems or uncontrolled epilepsy.

Procedure and randomization

The children were stratified according to two variables: GMFCS level (I-II), and age (youngest: 7–11 years; oldest: 12–16 years). They were subsequently randomized into one of two groups using the method of block randomization with a computer-assisted randomization programme (https://www.randomizer.org/). Evaluations and interventions in this study were carried out blindly by researchers. All evaluations carried out by physical therapist and physiatrist researchers with 20 years' experience. A researcher (D.T.) with 10 years' experience paediatric rehabilitation as a physical therapist carried out all interventions. Twenty-four participants were randomized to the FES-C and control group as shown in the flow chart (Figure 1). Finally, 10 children in both groups completed the study.

Intervention

Control group

Children included in the control group received the CPT programme. Programme included weight bearing exercises in different positions for symmetric and equal weight transfer on lower extremities, functional strengthening exercises for hip and knee extensors, stair climbing-descending exercises, vestibular and proprioceptive training on balance board, standing on a single leg, functional reaching in various directions, and stepping exercises in different directions. Gait training was provided by providing appropriate support and warnings. The programme was diversified by crossing obstacles while walking and walking on different surfaces. Children received 45 min of PT three days per week non-consecutive days for an 8-week period for a total of 24 sessions. The exercises were done in three sets with 10 repetitions. All therapy sessions were aimed to increase the use of the lower extremity in daily life activities.

FES-C group

The children included in the FES-C group received the CPT applied to the control group. This programme was applied for 45 min of PT 3 days per week non-consecutive days for an 8-week period for a total of 24 sessions, just like the children in the control group. Children included in the FES-C group received 30 min of FES-C training in each session using motorized FES bike RT 300 SLSA FES system (RT300-SL cycle, Restorative Therapies Inc., Baltimore, MD, USA) same days following in addition to the CPT programme. The children

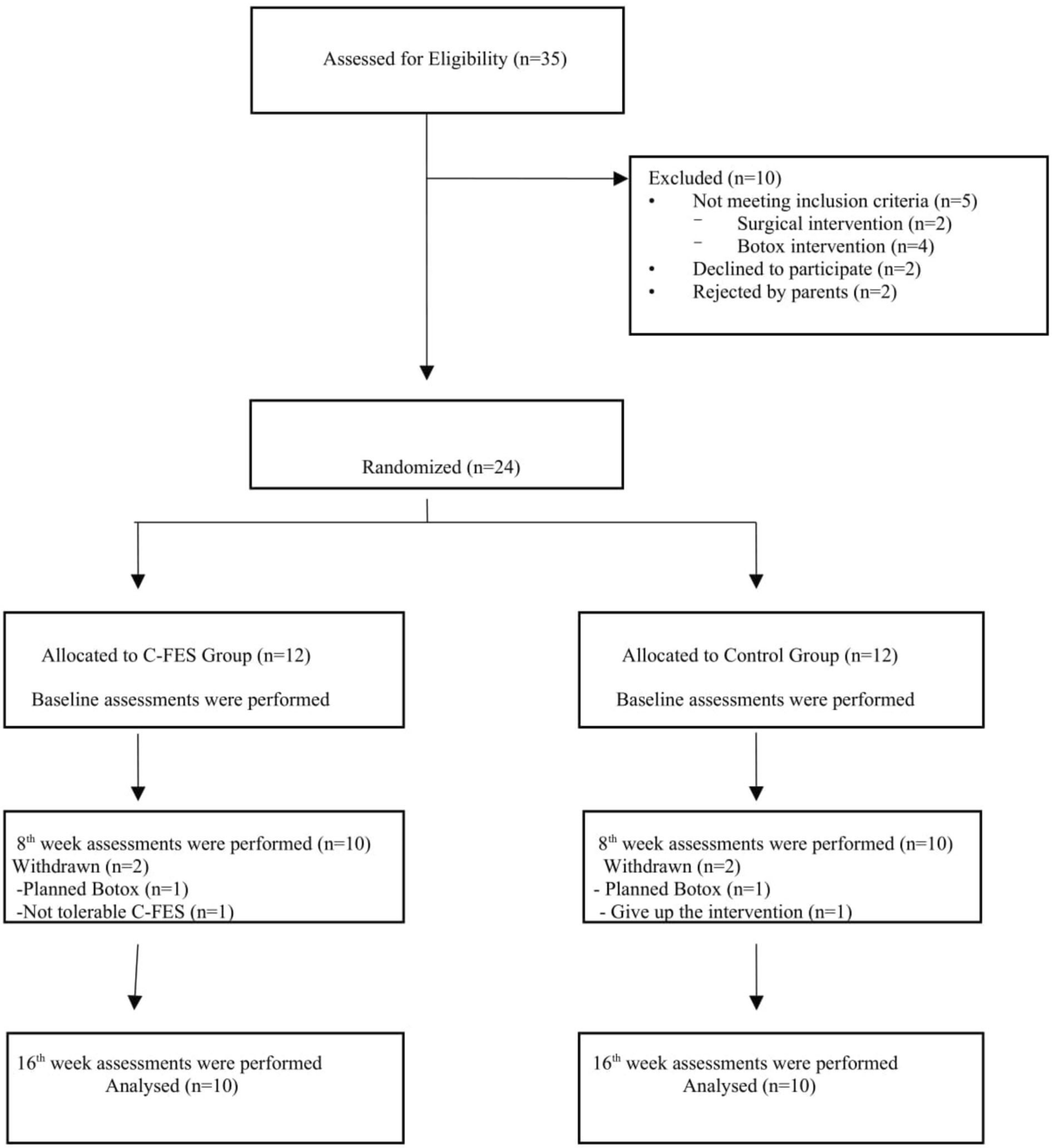

Figure 1. Flow-Chart the present study.

were seated in a chair with a back in front of the FES-C system.

The feet and legs of the patients were securely strapped to the pedals and calf rests of the cycling system. Adhesive surface electrodes were placed bilaterally on participant's quadriceps, hamstring, glutaeal muscles, and these muscles were stimulated bilaterally with six channels *via* $5 \times 5\,\text{cm}^2$ adhesive surface electrodes to provide muscle contraction for cycling. Active electrodes were placed in the midpoint of the muscles. Reference electrodes were placed 2 cm above the patella, 2 cm above the popliteal fossa and 2 cm above the iliac tuberosity on the quadriceps, hamstrings, and glutaeal muscles, respectively. Stimulation frequency was adjusted as 40 - 50 Hz, pulse width was 200––250 μs, and the amplitude was set based on tolerance (Yaşar et al. 2015).

Cycling sessions was divided into three phases. The sessions were a 2-min warm-up period, 30 min of active cycling, and with a 2-min cooling period. The RT300 system is set up in such a way that the clinician chooses a goal speed, and the internal software changes the degree of motor assistance and resistance based on the user's ability to maintain it. Motor help is automatically activated if the user is unable to maintain the intended speed. The amount of resistance increases when the user surpasses the goal speed. In current study, because of the variety in participants cycling skills, power output (PO), which was a product of speed and resistance and displayed on the RT300 monitor, was utilized to calculate target training intensity. A polar heart rate (HR) wrist monitor was used to ensure that participants were achieving a therapeutic training intensity. During 30 min of active cycling phases, participants was aimed to cycle at 50–60% (HR of >60% of the age-predicted HR max.) of the maximal PO achieved during a cycling performance. Target PO was achieved first by increasing the speed and then by adding resistance if the child was able to cycle faster than 35 rpm. The warm-up and cooling periods did not include resistance. If a participant fatigued, the activity was stopped until the individual felt ready to continue cycling.

Outcome measures

Physical characteristics of the children (gender, age, weight, height, and body mass index (BMI)) were recorded. A stadiometer (*Detecto,6439*) was used to assess weight and height. Outcome measures were assessed at baseline, after intervention at 8 weeks, and at 16 weeks (follow up).

Primary outcomes

Muscle strength measures

The 30 s Repetition Maximum Test, which has been found to be reliable in children with CP, was used to assess functional muscle strength of the lower extremity. The three closed kinetic chain exercises of lateral step-up test sit to stand and attain stand through half knee were used. The children were instructed to perform as many repetitions as possible in 30 s for each of the exercises. The repetition maxima for each side were used to calculate total scores for the left and right side and thus five final scores were obtained (Kara et al. 2015).

Gait parameters (spatiotemporal and sagittal plane kinematics)

Gait was assessed using a 3D, seven-camera VICON 512 motion measurement system (Oxford Metrics Ltd., Oxford, UK). VICON Clinical Manager software was used to calculate and plot the data. In total, 15 reflective markers were placed bilaterally according to the marker protocol (Davis et al. 1991). Each child was instructed to walk at a self-selected speed along on walkway and they walked on the 10 metres walkway until three clean trials were obtained by barefoot. Temporospatial parameters including cadence, velocity, step length, stride length, double support time, and single support time were selected for the analysis. The kinematic parameters including the ankle dorsiflexion (initial contact and mid-stance), knee flexion (initial contact), maximum knee extension (stance), hip flexion (initial contact), hip extension (terminal stance), pelvic tilt (loading response) selected.

Secondary outcomes

Gross motor function measurement

The Gross Motor Function Measure (GMFM) is a reliable and valid parameter to assess changes in gross motor function in children with CP aged between 5 months and 16 years. Dimensions D (Standing) and E (Walking, Running and Jumping) of the GMFM-88 were utilized (Rusell et al. 2002).

Energy expenditure

Energy expenditure measurement was performed *via* the breath-by-breath method, using an open-circuit indirect calorimeter (Vmax 29c, SensorMedics, Yorba Linda, CA, USA). After an adequate rest period with the facemask, measurements were obtained during 5 min of treadmill walking at its own walking speeds (average 0.60 m/s). It is known that after 2 min of submaximal walking, children with CP can attain a steady-state plateau. Therefore, the first 2 min taken to reach the steady state during a 5-min walk was not included in the calculation (Yaşar et al. 2015).

Statistical analysis

Statistical analyses were performed using Statistical Package for the Social Sciences software, version 21 (SPSS Statistics; IBM Corporation, Armonk, NY, USA). Descriptive analyses were performed using the median and interquartile range for the nonnormally distributed and ordinal variables. Physical characteristics in the FES-C and control groups were compared using the chi-squared test for categorical variables (gender, GMFCS) and the Mann–Whitney *U* test for continuous variables (age, height, weight, and BMI). Numerical variables were expressed as mean (standard deviation); categorical variables were expressed as number. Normality was tested using Kolmogorov–Smirnov test. Two group comparisons were performed by Mann–Whitney *U* test. Baseline, post-treatment (8 weeks), and follow up (16 weeks) data were compared using the Friedman test. The Wilcoxon test was used to assess the significance of pairwise differences (baseline – 8 weeks, baseline – 16 weeks, 8 weeks – 16 weeks) using the Bonferroni correction to adjust for multiple comparisons. The corrected p value was <0.017. Effect sizes were determined for statistically significant comparisons by using Cohen's d calculation, with a value of 0.8 considered a large effect, 0.5 to be a medium, and 0.2 to be a small effect. For all statistical tests, significance was set at $p < 0.05$.

For the determination of the appropriate sample size, the value of 'walking speed' was used referred from Arya et al. studies which investigate the effects of neuromuscular electrical stimulation on walking in children with CP (Arya et al. 2012). Accordingly, in our sample size calculation (alpha 0.05, beta 0.20, with 80% power), the number of individuals to be included in the study was determined as at least 8 for each group. However, a total of 10 patients were included for each group, considering a dropout rate of 25%.

Results

Participants of 20 children with dCP were randomized and divided equally between the FES-C group (seven males, three females; mean age 9.3 ± 3.2 years) and the control group (five males, five females; mean age. 9.7 ± 3.1 years). Descriptive statistics are reported in Table 1. Baseline values showed

Table 1. Characteristics of participants at baseline.

	FES-C Group ($n = 10$) X ± SD	Control Group ($n = 10$) X ± SD	$p^{a,b}$
Age (years)	9.30 ± 3.20	9.70 ± 3.10	0.969[a]
Weight (kg)	29.9 ± 11.86	32.50 ± 15.71	0.910[a]
Height (cm)	130.30 ± 20.99	132.50 ± 20.22	0.940[a]
BMI (kg/m^2)	16.92 ± 1.71	17.85 ± 3.83	0.762[a]
	n (%)	*n* (%)	
Gender			
Male	7 (70)	5 (50)	0.645[b]
Female	3 (30)	5 (50)	
GMFCS Level			
I	4 (40)	4 (40)	1.00[b]
II	6 (60)	6 (60)	

BMI: body mass index; GMFCS: gross motor function classification system.
[a]Mann–Whitney *U* test for continuous variable.
[b]Chi-squared test for categorical variable.

that each group was well-matched. There were no statistically significant differences between the FES-C and control groups for all baseline scores ($p > 0.05$).

Primary outcomes

Muscle strength

The FES-C group demonstrated significantly increased functional muscle strength in lower extremity at 8 weeks and 16 weeks when compared to the baseline; however, the control group did not show significant changes at 8 weeks and 16 weeks when compared to the baseline (Table 2).

From baseline to eighth week, functional muscle strength in the FES-C group was improved when compared with the control group (Table 3). The improved results were lateral set up, sit to stand, attain stand through half kneel ($p < 0.05$). At 16-week follow-up, functional muscle strength in the FES-C group had improved when compared with the control group (Table 3). The improved results were lateral set up, sit to stand, attain stand through half kneel ($p < 0.05$).

Gait parameters

From baseline to eighth week and from baseline to sixteenth week there was no difference between the FES-C and control groups for any values of temporospatial and sagittal plane kinematics of gait ($p > 0.05$) (Table 4). There was a significant reduction in pelvic tilt after 8 weeks of training compared to baseline measurements in the FES-C group. No significant change obtained in the control group over time when compared to the baseline (Table 2).

Secondary outcomes

Gross motor function

The FES-C group significantly increased in GMFM-D and E dimensions at 8 weeks and 16 weeks when compared to baseline measures; however, the control group did not significantly change over this period when compared to baseline levels (Table 2). From baseline to 8 weeks, GMFM-D and GMFM-E of the FES-C group was significantly improved when compared with the control group ($p < 0.05$). Furthermore, from baseline to 16 weeks, GMFM-D and GMFM-E of the FES-C group was significantly improved when compared with the control group ($p < 0.05$) (Table 3).

Energy expenditure

The FES-C group demonstrated a significant decrease in energy consumption in gait at eighth week and sixteenth week when compared to baseline measures; however, the control group showed no significant changes at weeks 8 and 16 when compared to the baseline (Table 2). From baseline to eighth week, energy consumption in FES-C group significantly decreased ($p = 0.005$) compared with the control group (Table 3). From baseline to sixteenth week, energy consumption in the FES-C group was also significantly decreased compared with the control group ($p = 0.050$) (Table 3).

Discussion

This study is the first single-blind RCT investigating the effects of FES-C in addition to CPT on gait parameters, functional muscle strength, gross motor function and energy consumption in children with ambulatory dCP. The results of showed that FES-C improved functional muscle strength in lower extremity, gross motor function, and energy expenditure; however, it was unable to improve temporospatial parameters and sagittal plan gait kinematics in children with dCP.

Lower extremity muscle weakness is one of the main elements of the decrease in gait capacity, which is critical in increasing the functionality and participation in daily life in children with dCP. Recently, FES-assisted or standard stationary cycling are utilized in children with CP for improving lower extremity strength, endurance, and function, since they have similarity with kinematic pattern of gait including repetitive rhythmic motor activity (Damiano et al. 2017). In the present study, after 8 weeks post-treatment, there was an improvement in functional muscle strength in the lower extremity. Although a small decrease in functional muscle strength is observed during the follow-up period (16 weeks), the improvement gained with FES-C training and continued in the follow-up period. Previous FES-cycling case studies in patients with CP have shown immediate improvements in cycling performance as well as longer term increases in lower limb muscular strength when FES was used (Johnston and Wainwright 2011; Trevisi et al. 2012). Although the results of current study are parallel with these two case reports, the main difference is that the muscle strength assessment focuses on functional muscle strength rather than one muscle. Today, rehabilitation practices and evaluations within the framework of International Classification of Functioning focus on the gains of the individual in the activity dimension rather than the body structure and function dimension. Therefore, it is important to emphasize that the FES-C application is also effective at the activity level since muscle strength is evaluated in three different closed kinetic functions in the lower extremity and positive results were

Table 2. Mean quartiles of groups for gross motor function, functional muscle strength, temporospatial characteristics of gait parameters.

		E-FES group ($n = 10$)				Control group ($n = 10$)			
		Baseline	Post- *T* (8-week)	Follow up (16-week)	p^a	Baseline	Post- *T* (8week)	Follow up (16 week)	p^a
Functional muscle test									
Lateral Set Up	R	11.00 (9.00–14.25)	13.50 (11.00–15.75)	12.50 (10.75–15.50)	$0.001^{b,c}$	10.50 (6.75–15.25)	11.00 (6.75–15.25)	11.00 (7.75–14.00)	0.264
	L	10.00 (9.00–15.25)	14.00 (11.00–16.50)	13.50 (10.75–16.25)	$0.002^{b,c}$	10.50 (6.75–15.25)	11.50 (6.75–15.25)	11.50 (7.75–14.25)	0.169
Sit to Stand		6.00 (4.75-8.25)	9.00 (7.75–11.25)	9.00 (7.75–10.00)	$0.003^{b,c}$	6.00 (5.00–9.00)	6.50 (5.00–10.00)	8.00 (4.75–11.25)	0.519
Attain Stand Through Half Kneel	R	9.00 (7.75–10.00)	11.50 (9.00–13.00)	11.00 (8.00–12.25)	$0.000^{b,c}$	8.50 (4.75–11.25)	9.00 (4.75–11.25)	9.00 (5.00–11.25)	0.229
	L	9.00 (6.75–10.00)	12.00 (8.00–13.00)	11.50 (8.00–12.25)	$0.000^{b,c}$	9.00 (4.75–11.25)	9.00 (5.00–11.25)	9.00 (5.00–11.25)	0.504
Temporospatial characteristics of gait									
Cadence (steps/min)		101.50 (95.37–105.50)	104.75 (97.00–111.25)	106.50 (97.75–113.25)	0.323	111.50 (101.87–123.87)	116.75 (102.25–131.37	117.50 (108.25–123.25)	0.682
Velocity (m/sec)		0.54 (0.34–0.72)	62.00 (0.48–0.74)	0.57 (0.36–0.81)	0.584	0.65 (0.53–0.85)	0.72 (0.58–0.86)	0.77 (0.56–0.91)	0.417
Step Length (m)		0.32 (0.22–0.42)	0.34 (0.28–0.39)	0.36 (0.29–0.44)	0.584	0.37 (0.32–0.43)	0.36 (0.33–0.44)	0.38 (0.32–0.49)	0.245
Stride Length (m)		0.65 (0.45–0.84)	0.69 (0.56–0.78)	0.71(0.49–0.87)	0.832	0.74 (0.63–0.88)	0.72 (0.68–0.89)	0.72(0.56–0.93)	0.225
Double Support (sec)		0.30 (.23–0.44)	0.23 (0.17–0.27)	0.27(0.17–0.34)	0.307	0.29 (0.23–0.38)	0.24(0.21–0.32)	0.29(0.25–0.34)	0.140
Single Support (sec)		0.44 (0.41–0.46)	0.45 (0.35–0.48)	0.45(0.40–0.49)	0.704	0.41 (0.35–0.43)	0.40 (0.36–0.43)	0.34 (0.32–0.40)	0.552
Sagital plane kinematics of gait									
Hip Flexion at Initial Contact	R	39.60 (31.05–43.72)	31.60 (30.27–36.45)	34.950 (29.65–40.40)	0.087	46.25 (35.60–50.17)	43.70 (32.20–46.30)	37.75 (33.05–44.30)	0.956
	L	37.90 (31.27–44.57)	35.95 (33.35–38.05)	32.85 (27.22–36.27)	0.255	41.95 (35.35–48.92)	40.75 (33.17–47.27)	38.15 (30.00–44.47)	0.185
Hip Extension at Terminal Stance	R	2.44 (−4.75–7.32)	4.40 (−16.97–8.87)	−1.68 (−11.15–10.15)	0.717	4.75 (−2.67–9.80)	1.17 (−2.75– 11.20)	1.05 (−7.42–11.20)	0.779
	L	0.65 (−4.02–9.92)	−1.05 (−12.14–7.72)	2.40 (−9.27– 7.02)	0.836	4.75 (−2.67–9.80)	1.17 (−2.75– 11.20)	1.05 (−7.42–11.20)	0.779
Pelvic Tilt at Loading Response	R	21.35 (12.02–27.36)	16.50 (6.85–20.40)	18.00 (12.77–23.52	0.015^{b}	26.25 (22.95–29.32)	24.45 (20.90–28.00)	22.35 (18.15–24.87)	0.507
	L	21.35 (12.02–27.36)	16.70 (6.85–20.70)	18.20 (12.85–23.10)	0.012^{b}	24.85 (23.30–29.32)	23.50 (21.12–28.00)	22.55 (20.27–23.87)	0.507
Knee Flexion at Initial Contact	R	19.20 (15.37–34.27)	20.75 (17.45–27.85)	22.90 (13.02–29.50)	0.575	26.10 (14.07–33.80)	27.30 (11.47–32.20)	20.15 (10.87–28.40)	0.267
	L	20.25 (12.90–24.27)	19.70 (15.25–24.22)	19.55 (10.40–24.25)	0.527	19.10 (8.92–29.95)	22.90 (6.10–30.55)	17.50 (11.20–30.55)	0.898
Maximum Knee Extension at Stance	R	11.00 (−3.05–26.27)	5.90 (1.52–20.00)	8.20 (2.37–17.02)	0.500	11.45 (3.22–14.82)	12.50 (5.00–19.50)	11.75 (2.82–19.50)	0.146
	L	8.31 (−3.00–16.35)	7.95 (4.57–14.72)	7.20 (2.62–14.67)	0.975	8.60 (−9.37–17.15)	8.00 (−9.00–14.52)	8.90 (−5.62–14.52)	0.215
Ankle Dorsiflexion at Initial Contact	R	0.95 (−3.72–5.32)	1.65 (−0.15–8.80)	1.20 (−1.01–4.87)	0.232	4.75 (−5.32–10.05)	6.10 (−0.62–10.25)	2.40 (−1.90–8.00)	0.174
	L	0.50 (−4.10–4.36)	2.80 (−1.12–5.66)	2.92 (0.50–7.72)	0.452	−1.85 (−6.91–5.02)	−4.80 (−8.70–8.02)	−1.85(−10.50–6.42)	0.641
Ankle Dorsiflexion at Mid Stance	R	11.50 (9.27. 22.00)	16.35 (11.32–20.50)	14.60 (9.70–19.52)	0.125	18.30 (16.70–22.00)	14.70 (10.87–18.72)	15.50 (10.82–17.47)	0.091
	L	12.95 (7.97–16.97)	15.46 (10.65–18.95)	10.20 (7.75–10.95)	0.055	12.45(8.20–24.60)	12.50 (6.42–17.20)	12.25 (5.40–15.40)	0.113
Gross motor function									
GMFM-D		82.04 (73.07–88.45)	85.88 (76.29–92.94)	85.89 (74.39–92.94)	$0.000^{b,c}$	79.48 (69.61–91.02)	79.48 (71.79–91.02)	80.76 (71.79–90.99)	0.196
GMFM-E		81.24 (67.70– 89.59)	82.63 (72.56–90.97)	82.63 (72.22–90.97)	$0.000^{b,c}$	80.52 (66.97–88.88)	81.22 (66.97–88.88)	80.52 (66.97–88.88)	0.174
Energy expenditure									
VO_2 ml kg^1 min^1		10.05 (8.12–11.22)	7.85 (4.95–8.90)	8.80 (7.55–8.90)	$0.002^{b,c}$	7.45 (5.75–9.25)	7.30 (5.02–8.40)	8.20 (6.22–8.67)	0.387

R: right; L: left; min: minute; m: meter; sec: second; Vo_2: oxygen consumption per unit time.
[a]Friedman test $p < 0.05$.
[b]Wilcoxon test (8 weeks between baseline), $p < 0.017$ Bonferroni-adjusted.
[c]Wilcoxon test (16 weeks between baseline) $p < 0.017$ Bonferroni-adjusted.

Table 3. Mean difference (95% confidence interval) within and between groups for gross motor function, functional muscle strength, temporospatial characteristics of gait.

		Difference between groups									
		Difference between groups (8 weeks minus baseline)					Difference between groups (16 weeks minus baseline)				
		E-FES Groups	Control Groups	Difference between groups (intervention minus control) (95% confidence interval)	p	d	E-FES Groups	Control Groups	Difference between groups (intervention minus control) (95% confidence interval)	p	d
Functional muscle test											
Lateral set up	R	2.00 (0.75–3.00)	0.00 (−0.25–1.00)	1.80 (0.71–2.88)	0.005	0.62	1.50 (1.00–2.25)	0.00 (−0.25–1.00)	1.30 (0.34–2.25)	0.012	0.56
	L	2.50 (1.50–4.00)	0.50 (−0.00–1.00)	1.90 (0.75–3.04)	0.008	0.60	2.00 (1.00–3.25)	1.00 (−0.25–1.00)	1.40 (0.19–2.60)	0.023	0.51
Sit to stand		2.50 (2.00–4.00)	0.00 (0.00–1.00)	2.50 (1.81–3.18)	0.000	0.87	2.00 (0.75–3.25)	1.00 (−1.00–2.50)	1.00 (−0.85–2.85)	0.024	0.54
Attain stand through half kneel	R	2.00 (1.00–3.00)	0.00 (0.00–1.00)	1.90 (1.14–2.65)	0.000	0.80	2.00 (1.00–2.25)	0.00 (0.00–1.00)	1.40 (0.46–2.33)	0.008	0.60
	L	2.50 (1.00–3.25)	0.00 (0.00–0.25)	2.20 (1.37–3.02)	0.000	0.83	2.00 (1.75–2.25)	0.00 (−0.25–1.00)	1.80 (0.94–2.65)	0.001	0.73
Gross motor function											
GMFM-D		3.85 (1.93-8.33)	0.00 (0.00–0.51)	4.41(1.74–7.08)	0.002	0.70	5.12 (1.92–7.69)	0.00 (0.00–2.18)	3.90 (1.53–6.27)	0.003	0.67
GMFM-E		2.08 (1.37-3.82)	0.00 (0.00–0.00)	2.77 (0.98–4.56)	0.001	0.75	2.08 (1.37–3.47)	0.00 (00.00–0.03)	2.63 (0.97–4.29)	0.002	0.69
Energy expenditure											
Vo_2 ml kg^{-1} min^{-1}		−2.35 (-3.82- -1.15)	0.10 (−0.55–0.65)	−2.13 (−5.34–4.90)	0.004	0.63	−0.90 (−1.80– −0.50)	0.60 (−0.97–1.27)	−1.31 (−2.72–0.10)	0.050	0.43

Values are median (25 th 75 th çentile). p values for between-group difference in weeks 8–0 and week 16–0 scores were calculated using the Mann–Whitney U test, $p < 0.05$; d: effect size cohen's d. R: right; L: left; Vo_2: oxygen consumption per unit time.

obtained. It has been reported in previous studies that cycling provide strengthening by facilitating reciprocally flexion and extension movements of the lower extremity (Lauer et al. 2008; Trevisi et al. 2012). Therefore, in the current study, the FES-C might have contributed to the strengthening of the previously inactive or weak muscles due to the repetitive activity of the reciprocally movements. It can be thought that the applied FES-C affects the excitability of interneuronal space and motor neurons and contributes to the capacity to generate more force than can be provided voluntarily by providing sensory input at the right time (Trevisi et al. 2012).

Although existing studies have proven that functional strengthening training increases muscle strength, studies have not reported positive changes in gait capacity. This is due to the complexity of the relationship between muscle strength and walking capacities (Pouliot-Laforte et al. 2020). When the temporospatial variables of gait were examined in the present study, it was seen that there was no difference after treatment in both groups. Given the task specificity of gait training, this finding is not surprising. Croce and DePaepe (1989) suggested that a child's acquired skill should become automatic before combining it with other activities. This may be related to be the intensity and frequency of the training. We think that one of the reasons why the functional strengthening we obtained with FES-C in our study was not carried to a complex activity such as gait may be due to the limited maximum total training dose for participants. In the present study, the FES-C group demonstrated significantly decreased pelvic tilt after 8-week training when compared with baseline measures. Anterior pelvic tilt is often associated with weakness of the hip extensors and lack of shock absorption more distally and can be attributed to reduced performance in the critical event of hip stability during loading response (Wolf et al. 2014). In the light of the information in the literature we know that the increase in GMFM is mostly correlated with the increase in knee and hip extension strength (Engsberg et al. 2000) and we think that the gain in pelvic tilt may be a result of the increase of these muscles' strength. Shin et al. (2016) investigated the relationship between isometric muscle strength and gait parameters and gross motor functions in individuals with CP. They proved that muscle strength in especially hip and knee extensors is highly correlated with decreased pelvic tilt and pelvic obliquity during gait. Although we did not measured muscle strength isometrically in our study, the gains were obtained by Shin et al. corroborates our results.

When previous studies that investigated the effectiveness of cycling in CP are examined, there was no clear evidence found on its effects on gross motor function. Flower et al. identified that the PEDALS study only included ambulatory children with CP and improved GMFM-66 scores found for the cycling group support greater functional strength (Fowler et al. 2010). Williams and Pountney (2007) reported large improvements in dimensions GMFM-D&E in their study including in non-ambulant children with CP. Armstrong et al. (2020) compared the FES-C with usual care to improve activity capacity and function in children with cerebral palsy,

Table 4. Mean difference (95% confidence interval) between groups for temporospatial characteristics and sagittal plan kinematics of gait.

		Difference between groups							
		Difference between groups (8 weeks minus baseline)				Difference between groups (16 weeks minus baseline)			
		E-FES Groups	Control Groups	Difference between groups (intervention minus control) (95% confidence interval)	p^a	E-FES Groups	Control Groups	Difference between groups (intervention minus control) (95% confidence interval)	p^a
Temporospatial characteristics of gait									
Cadence (steps/min)		5.00 (−1.25–11.75)	0.00 (−0.50–14.00)	1.55 (−6.32–9.42)	0.565	7.00 (−1.00–10.50)	1.05 (−5.12–10.75)	0.09 (−9.95–10.13)	0.705
Velocity (m/sec)		0.12 (−0.07–0.17)	0.00 (0.00–0.06)	0.03 (−0.09–0.15)	0.399	0.00 (−0.06–0.20)	0.01 (−0.09–0.23)	0.01 (−0.17–0.19)	0.733
Step length (m)		−0.01 (−0.04–0.06)	0.00 (−0.01–0.07)	−0.06 (−0.07–0.06)	0.939	0.03 (−0.03–0.10)	0.00 (−0.05–0.10)	0.01(−0.06–0.08)	0.566
Stride length (m)		0.03 (−0.08–0.14)	0.00 (−0.01–0.13)	−0.18(−0.15–0.11)	0.939	−0.04 (−0.10–0.18)	−0.01 (−0.10–0.16)	0.05(−0.14–0.24)	0.940
Double support (sec)		−0.25 (−0.28–0.00)	0.00 (−0.07–0.00)	−0.08(−0.21–0.03)	0.585	0.02 (−0.02–0.18)	0.05 (−0.00–0.12)	−0.00 (−0.12–0.10)	0.970
Single support (sec)		−0.01 (−0.04–0.03)	0.00 (−0.03–0.00)	0.00 (−0.04–0.05)	0.877	−0.01 (−0.04–0.06)	−0.02 (−0.11–0.01)	0.05(−0.02–0.13)	0.256
Sagital plane kinematics of gait									
Hip flexion at initial contact	R	−5.00 (−10.72–0.70)	0.00 (−8.82–2.67)	−1.15 (−8.21–5.91)	0.405	−5.00 (−10.72–0.07)	−3.55 (−7.52–0.50)	1.58 (−6.46–9.62)	0.650
	L	−0.35 (−8.37–2.82)	0.00 (−2.37–4.07)	−1.13 (−7.26–5.00)	0.650	−4.30 (−10.52–0.42)	−0.95 (−8.40–0.57)	−2.18 (−8.86– 4.50)	0.406
Hip extension at terminal stance	R	−2.10 (−9.35–2.60)	0.00 (−5.84–3.35)	−2.48 (−8.85–3.89)	0.449	−0.75 (−7.20–3.13)	−2.65 (−11.92–5.12)	0.07 (−7.39–7.54)	0.705
	L	0.75 (12.24–3.28)	0.00 (−13.70–2.42)	1.00 (−7.16–9.17)	0.705	−1.50 (−8.05–3.55)	−3.94 (−12.17–1.95)	2.37 (−4.73–9.49)	0.427
Pelvic tilt at loading response	R	−3.65 (−8.70– −1.05)	0.00 (−3.12–3.30)	−3.84 (−9.64–1.95)	0.082	−1.95 (−6.47–0.09)	−3.50 (−7.40–1.32)	−0.28 (−5.50 −4.94)	0.940
	L	−3.65 (−8.40– −1.05)	0.00 (−3.52–2.02)	−3.81 (−9.98– 2.36)	0.069	−1.95 (−6.45– −0.02)	−3.55 (−6.05–2.02)	−1.17 (−6.69–4.34)	0.791
Knee flexion at initial contact	R	−3.29 (−9.75–3.95)	0.00 (−8.42–2.90)	−0.99 (−7.18–5.18)	0.762	−3.25 (−11.80–1.71)	−4.45 (−11.67–2.70)	2.81 (−6.69–12.31)	0.940
	L	0.90 (−1.67–6.60)	0.00 (−4.05–2.42)	1.42 (−4.13–6.92)	0.596	−2.35 (−5.57–6.77)	0.00 (−4.20–2.41)	0.10 (−6.13–6.33)	0.650
Maximum knee extension at stance	R	−2.20 (−7.15–4.12)	0.30 (−1.15–6.12)	−2.77 (−9.02–3.48)	0.325	−1.75 (−3.25–1.40)	0.00 (−5.50–4.02)	−0.13 (−6.22–5.96)	0.570
	L	−0.15 (−2.74–6.37)	0.00 (−1.80–0.32)	1.96 (−3.58–7.50)	0.596	1.08 (−2.30–4.15)	0.15 (−1.12–3.70)	0.29 (−4.10–4.68)	0.940
Ankle dorsiflexion at initial contact	R	2.20 (−1.77–7.30)	0.00 (−9.07–6.97)	0.58 (−5.43–6.59)	0.820	0.92 (−20.00–3.43)	0.00 (−9.07–5.77)	1.37 (−4.60–7.35)	0.545
	L	1.10 (−3.31–6.76)	0.00 (−5.35–2.30)	2.95 (−3.98–9.90)	0.325	2.57 (−3.29–8.22)	0.75 (−1.60–4.05)	3.18 (−4.09–10.45)	0.650
Ankle dorsiflexion at mid stance	R	1.55 (−3.02–4.85)	−1.30 (−11.50–0.35)	6.33 (0.28–12.38)	0.058	−2.15 (−4.75–4.30)	−0.80 (−11.65–0.00)	4.09 (−2.75–10.94)	0.406
	L	0.85 (0.12–3.97)	−0.60 (−6.65–0.00)	4.64(−1.38–10.66)	0.057	−2.20 (−5.77.−0.67)	−1.15 (−8.15–0.55)	1.14 (−4.37–6.65)	0.820

Values are median (25 th 75 th çentile). p^a values for between-group difference in weeks 8–0 and week 16–0 scores were calculated using the Mann–Whitney U test $p < 0.05$. min: minute; m: meter; sec: second; R: right; L: left.

aged 6–18 years and GMFCS II-IV, and they found statistically significant improvements of GMFM-88 and -66 in the FES-C group.

Studies in the literature have proven that the increase in lower extremity muscle strength obtained as a result of functional strengthening training targeting lower extremity muscles in children with cerebral palsy is reflected as statistically significant improvements in the D and E subsections of GMFM (Damiano and Abel 1998). For this reason, significant improvements in GMFM-D&E are not an unexpected finding. In our study, we found that FES-C contributed to positive improvements in functional muscle strength increase in GMFM and its long-term effect continues in GMFM-D&E dimension in the follow-up. Ross et al. emphasized that in children with dCP, GMFM-66 and GMFM-E dimensions were related as moderate-to-high with the lower extremity muscle strength and explain GMFM-66 by 69% (Ross and Engsberg 2007). Similarly, the increase in GMFM-D&E scores in our study can be thought to result from the increase in functional muscle strength. Studies in the literature argue that strength development improves the individual's functions by increasing gross motor function (Damiano and Abel 1998; Dodd et al. 2003).

In the present study, after 8 weeks post-treatment, there was a decrease in energy consumption and this decrease was sustained in the follow-up period. It is well known that inappropriate muscle activity contributes to increased energy expenditure of gait in children with CP (Steele et al. 2017). During the cycling, in research has shown that coordination of muscle activity, rather than intensity of muscle activity, is related to improper timing contributing to higher energy expenditure (Wakeling et al. 2010). Thus, the magnitude of muscle force and the coordination among muscle groups may influence energy expenditure and performance. FES-C training may have contributed to the reduction in energy consumption by enabling the agonist/antagonist muscles to perform muscle activation in a well-timed and coordinated manner with the sequential contractions of the appropriate muscle groups, thanks to the electrical stimulation it creates in the lower extremity to provide the bicycle pedal cycle. Cycling is an enjoyable activity, and 'enjoyment' is a strong predictor of long-term engagement in physical activity (Baksjøberget et al. 2017; Armstrong et al. 2020). Therefore, FES-C training may be useful method that increase children's motivation since it is fun for children, it is a training method that can be applied in addition to conventional physiotherapy to increase muscle strength, motor function, and reduce energy consumption.

Strengths of our study are the randomized controlled design; using objective, validated, and reliable measures; the evaluators are blind to interventions, and follow-up period to long term effects to treatments. There are some potential limitations to consider when interpreting our results. The current study focussed only on body structure and function of ICF in children with CP with minimal functional impairment (GMFCS levels I and II). In this study, participants training three times per week for 8 weeks, and thus we do not know whether similar or various benefits would be gained with a longer duration. It is also possible that longer programmes will lead to even greater benefits over time than those reported here. Therefore, in future studies, it will be beneficial to keep the treatment period and total training dose longer. Moreover, the participation dimension of the ICF, which emphasizes the independence of the child in about participant should be focussed.

Conclusion

FES-C is a promising additional therapeutic method to increase functional muscle strength, improve gross motor function, and energy consumption in children with dCP. The use of FES-C in addition to the CPT protocol should be useful in children with ambulatory dCP. However, this can be thought of as a supportive tool, not as a stand-alone therapeutic method.

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Author contributions

D.T. contributed to every step of study planning, rehabilitation applications, data collection, and data analysis. Y.Y. was the supervisor of the doctoral dissertation and contributed to the study planning, evaluations of all parameters, statistical analysis of data, and manuscript writing, conduct of the study; E.Y. contributed to every step of study planning, the applications and evaluations of gait and energy consumption, and manuscript writing on the subject. M.K.G. contributed to the study planning, evaluations of all parameters conduct of the study, and manuscript writing. B.Y. and A.K.T. contributed to the study planning and conduct of the study and manuscript writing. All authors had complete access to the study data that support the publication.

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ORCID

Duygu Türker http://orcid.org/0000-0003-2470-5737
Yavuz Yakut http://orcid.org/0000-0001-9363-0869
Evren Yaşar http://orcid.org/0000-0002-6134-4865
Mintaze Kerem Günel http://orcid.org/0000-0003-4942-5272
Bilge Yılmaz http://orcid.org/0000-0003-1173-9399
Arif Kenan Tan http://orcid.org/0000-0001-6752-0607

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