Pediatric Endurance and Limb Strengthening (PEDALS) for Children With Cerebral Palsy Using Stationary Cycling: A Randomized Controlled Trial

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Background. Effective interventions to improve and maintain strength (force-generating capacity) and endurance are needed for children with cerebral palsy (CP).

Objective. This study was performed to examine the effects of a stationary cycling intervention on muscle strength, locomotor endurance, preferred walking speed, and gross motor function in children with spastic diplegic CP.

Design. This was a phase I randomized controlled trial with single blinding.

Setting. The interventions were performed in community-based outpatient physical therapy clinics. Outcome assessments were performed in university laboratories.

Participants. Sixty-two ambulatory children aged 7 to 18 years with spastic diplegic CP and Gross Motor Function Classification System levels I to III participated in this study.

Intervention and Measurements. Participants were randomly assigned to cycling or control (no-intervention) groups. Thirty intervention sessions occurred over 12 weeks. Primary outcomes were peak knee extensor and flexor moments, the 600-Yard Walk-Run Test, the Thirty-Second Walk Test, and the Gross Motor Function Measure sections D and E (GMFM-66).

Results. Significant baseline-postintervention improvements were found for the 600-Yard Walk-Run Test, the GMFM-66, peak knee extensor moments at 120°/s, and peak knee flexor moments at 30°/s for the cycling group. Improved peak knee flexor moments at 120°/s were found for the control group only, although not all participants could complete this speed of testing. Significant differences between the cycling and control groups based on change scores were not found for any outcomes.

Limitations. Heterogeneity of the patient population and intrasubject variability were limitations of the study.

Conclusions. Significant improvements in locomotor endurance, gross motor function, and some measures of strength were found for the cycling group but not the control group, providing preliminary support for this intervention. As statistical differences were not found in baseline-postintervention change scores between the 2 groups; the results did not demonstrate that stationary cycling was more effective than no intervention. The results of this phase I study provide guidance for future research.

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Children with cerebral palsy (CP) have decreased capacity to participate in play and sports activities at intensities sufficient to develop and maintain adequate levels of muscular strength (force-generating capacity) and cardiorespiratory fitness.[1–3] The interaction of these factors can lead to a continuous cycle of deconditioning and decreased functional ability.[4] These findings are of concern because they can exacerbate secondary effects associated with CP[5] and reduced overall health and well-being.[6] Therefore, safe and effective interventions to improve and maintain strength and endurance are needed.[5,7] Although the overall level of research evidence supporting exercise interventions for children with CP is low, positive results, particularly for strengthening, have been reported.[7,8]

The problem of reduced endurance in children with CP has received little attention. In a systematic review of the literature, only 5 studies were found that addressed lower-extremity aerobic exercise for children with CP.[7] Interventions included lower-limb cycling,[9–11] walking,[12] running,[10,12,13] jumping,[13] stepping,[12] swimming,[10] and mat exercises.[10] Only 1 study was a randomized controlled trial (RCT).[10] The other 4 studies were given the lowest evidence rating level.[7] Three of these 5 studies demonstrated statistically significant improvements in aerobic capacity following interventions at frequencies of 2 or 4 times per week.[10,11,13] Additionally, interventions that combined strengthening[14,15] or anaerobic[16] exercises with cardiorespiratory training have been investigated. The largest of these studies[16] was an RCT that examined the effect of a school-based program of aerobic and anaerobic exercise for 65 children with spastic CP over an 8-month period. Significant improvement ($P<.05$) was found for aerobic capacity, anaerobic capacity, agility, strength, participation, and quality of life. Outcome measures varied considerably among all of these studies. Some researchers focused on measures of oxygen consumption or heart rate (HR),[9–15] whereas others used field tests,[16,17] such as the 10-m shuttle run test or the 600-Yard Walk-Run Test. These field tests require the child to walk or run as fast as possible. Correlations between field tests and laboratory measures of aerobic capacity have been reported for children with disability.[17] Results of field tests may convey more about a child's ability to keep up with his or her peers during school, sports, and play activities.

Lower-extremity cycling is a rehabilitation tool used by physical therapists to improve strength and cardiorespiratory fitness and appears well-suited as a therapeutic intervention for children with CP. Simultaneous strengthening of hip, knee, and ankle musculature may be achieved without the need to perform isolated joint movement out of the basic flexion and extension movement synergies. In contrast to aerobic exercises that require walking or running, cycling is less dependent on balance, coordination, and motor control. Cycling may induce positive speed-related changes in neuromotor control and muscle physiology by promoting higher speeds of movement than are possible during daily activities of most children with CP.

Although cycling has been recommended as an appropriate exercise for individuals with CP,[6,18] research is limited. Children with CP exhibiting a wide range of disability were able to improve oxygen uptake, at a given HR, following an intervention emphasizing stationary cycling.[9] Six adolescents with mild CP improved their physical endurance during cycling, as evidenced by increased oxygen consumption at the anaerobic threshold, following the first 3 months of a stationary cycling intervention.[11] Benefits also have been reported for children with more severe physical disability. Following a 6-week intervention using an adapted stationary bicycle, 11 nonambulatory adolescents with CP improved their gross motor function (P=.01).[19] None of these studies reported the effect of cycling on lower-extremity strength, preferred walking speed, or walking and running endurance.

Considering the limited research in this area, the Pediatric Endurance Development and Limb Strengthening (PEDALS) project for children with CP was designed as a phase I preliminary investigation to examine the effectiveness of a community-based stationary cycling intervention. Stationary cycling allows precise definition of exercise intensity, duration, and systematic guidelines for exercise progression—important factors for research. Our goal was to improve strength and walking and running endurance in ambulatory children with spastic diplegic CP. To generalize the results, the intervention was conducted in partnership with pediatric physical therapy clinics under "typical clinical conditions." Our hypothesis was that children who participated in a 12-week, stationary cycling intervention would improve their preferred walking speed, walking and running endurance, gross motor function, knee extensor and flexor strength, and gait kinematics.

Method

A detailed description of the PEDALS RCT protocol has been reported elsewhere.[20]

Participants

All participants had spastic diplegic CP. Inclusion criteria were: (1) between 7 and 18 years of age; (2) ability to follow simple verbal directions; (3) ability to walk independently, with or without an assistive device, for short distances (Gross Motor Function Classification System [GMFCS] levels I–III)[21]; and (4) good or fair selective voluntary motor control for at least one limb. *Good selective voluntary motor control* was defined as the ability to isolate both knee and ankle movement out of synergy (knee extension with the hip positioned in flexion; ankle dorsiflexion with the knee positioned in extension). *Fair selective voluntary motor control* was defined as the ability to isolate knee extension but not ankle dorsiflexion. Exclusion criteria were: (1) orthopedic surgery, neurological surgery, or baclofen pump implantation within the preceding 12 months; (2) botulinum toxin injections within the preceding 3 months; (3) serial casting or new orthotic devices within the preceding 3 months; (4) initiation of oral medications that affect the neuromuscular system (eg, baclofen) within the preceding 3 months; (5) initiation of physical therapy, exercise, sports activity, or change in assistive devices for walking within the preceding 3 months; (6) inability or unwillingness to maintain age-appropriate behavior; (7) serious medical conditions such as cardiac disease, diabetes, or uncontrolled seizures; (8) current participation in a fitness program that included a minimum of once-weekly cardiorespiratory endurance exercise; (9) significant hip, knee, or ankle joint contractures preventing passive movement of the lower limbs through the pedaling cycle; and (10) bilateral poor selective voluntary motor control (inability to isolate knee or ankle joint motion out of synergy).

Participants were recruited from southern California and southwest Missouri via flyers and brochures placed in clinics and schools, mailed, or posted on disability-related Web sites. A telephone screening was performed for potential participants who contacted the investigators. Children meeting the study criteria received an in-person screening to confirm their diagnosis and assess GMFCS level, selective voluntary motor control, and range of motion. An interpreter translated for parents or guardians who did not speak English. The institutional review board of each institution approved the study protocol and consent procedures. Informed consent was obtained from a parent or guardian and from participants over the age of 14 years. Assent was obtained from each participant under the age of 14 years. If formal physical therapy had been initiated or discontinued recently, we postponed baseline data collection until 3 months had elapsed. For the duration of the study, participants who were receiving physical therapy were asked to maintain their present regimen.

Study Design

This study was a phase I, multi-site RCT with single blinding. Power analyses determined that a sample size of 58 participants (29 intervention, 29 control) would have 80% power to detect a moderate effect size of 0.7 associated with a 15% strength improvement. This gain was a conservative estimate based on improved peak knee extensor and flexor moments following an isokinetic knee strengthening program.[22] Outcome measurements were assessed at baseline and following the 12-week intervention period. Children were randomly assigned to either an intervention (cycling) group or a control (no cycling) group. Randomization was blocked by age group (7–11 years, 12–18 years) and selective voluntary motor control ability (good, fair)[20] to minimize the effects of maturation and physical impairment. Participants who demonstrated good selective voluntary motor control bilaterally were placed in the "good" selective voluntary motor control category for stratification. Those with fair motor control for at least one limb were placed in the "fair" category.

Outcome Measures

A conscious effort was made to select outcome measures that differed from the skill practiced during the intervention and that had functional meaning to the families and clinicians. This article reports the results for PEDALS primary outcome measures at the body function and activity levels of the *International Classification of Functioning, Disability and Health*[23]: (1) the 600-Yard Walk-Run Test,[17] (2) the Thirty-Second Walk Test (30sWT),[24] (3) the Gross Motor Function Measure sections D and E (GMFM-66),[25] and (4) peak knee extensor and flexor isometric and isokinetic moments. In addition, gait analysis results, obtained for a subset of participants, are included.

Data collection took place at the University of Southern California and Missouri State University. Evaluators were blinded to participant group assignment and had to pass a rigorous standardization procedure for each outcome measurement protocol by demonstrating 90% competency. Each participant's height and weight were recorded. Walking and running tests were performed on a circular path at a nearby track or school gymnasium. For the 600-Yard Walk-Run Test, children were directed to walk or run as fast as they could, and the time to complete the distance was recorded. If a participant could not complete the test within the 15-minute time limit, the distance covered and time elapsed were recorded. For the 30sWT, children were asked to walk at their preferred speed. The distance completed in 30 seconds was recorded. The GMFM-66 scores were obtained using sections D (standing) and E (walking, running, and jumping).

We examined peak knee extensor and flexor moments across a range of speeds to capture changes reflective of muscle strength, power, and endurance. A KinCom dynamometer* was used at the Los Angeles site, and a Biodex Multijoint System† was used at the Missouri site. Five repetitions of knee joint extension and flexion at 0, 30, 60, and 120°/s were performed bilaterally.

A subgroup of 16 children (8 from each group) underwent gait analysis. Three-dimensional motion analysis was performed using a Vicon motion system‡ at 60 Hz. Calibration markers were placed over specific anatomical landmarks to define lower-extremity segments, and tracking clusters consisting of 3 or 4 markers were placed on the lateral surface of the thigh, leg, and lateral calcaneus. Calibration markers were removed following collection of measurements for a standing trial. Measurements for 3 walking trials at a self-selected speed were collected for each participant.

Physical Activity Calendars

All participants were provided with physical activity calendars for the 12-week intervention period so that differences in physical activity between the 2 groups could be quantified. Participants were instructed to place a sticker on each day of the calendar that corresponded to the following activity levels. Running or jogging, participating in contact sports, hiking, dancing, climbing stairs, or biking for approximately 1 hour per day was considered a high level of activity. Participating in the same activities for 30 minutes per day or in activities such as swimming, skateboarding, scooter riding, or walking for approximately 1 hour was considered a moderate level of activity. A low activity level indicated a sedentary day that included schoolwork, watching television, or playing computer games. Bed rest indicated that a child was inactive due to illness or injury. Participants assigned to the cycling group were instructed to exclude the cycling intervention when recording their daily activity levels.

Cycling Intervention

The cycling intervention occurred in community-based pediatric physical therapy clinics. Standardization was ensured by using detailed intervention protocols. Each intervention physical therapist demonstrated 90% competency for the performance of critical components. The stationary bicycle† used for this study was designed for rehabilitation. Features included a semirecumbent design with a wide padded seat, trunk support, foot straps, and a unique "cyclocentric" lower-limb–loading feature to provide resistance.[26]

The cycling intervention was performed 3 times per week, for a total of 30 sessions, within a 12-week period. A generalized stretching program was performed prior to cycling. Ankle-foot orthoses, if used for walking, were worn during cycling. Resting HR was recorded prior to cycling. If the participant could not cycle independently, manual assistance was provided until independence was achieved. If limb movement was not maintained in the sagittal plane, corrections were made using physical guidance by the therapist, verbal cueing, or adaptations, such as modification of the foot position on the pedal. Each 60-minute cycling session was divided into 2 phases: (1) lower-extremity strengthening and (2) cardiorespiratory endurance.

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† Biodex Medical Systems, 20 Ramsay Rd, Shirley, NY 11967-4704.

‡ Oxford Metrics Ltd, 14 Minns Business Park, West Way, Oxford OX2 0JB, United Kingdom.

Phase 1: lower-extremity strengthening. The cyclocentric strengthening protocol was initiated after independent cycling was achieved. The bicycle seat was unlocked and allowed to slide backward along a linear track. Up to 10 tension cords, each providing 10 lb (1 lb=0.4536 kg) of force, acted to pull the seat forward. Lower-limb extension was required to prevent the seat from being pulled forward and to maintain the seat in a range demarcated as the "cyclocentric exercise zone." Training began with the attachment of one tensioning cord. Resistance was progressed to the next higher cord when 10 revolutions were performed in a smooth pattern while keeping the seat within the desired zone. Subsequent sessions began with a warm-up at previously attained resistance levels prior to progressing to a higher level of resistance. For each session, minimal and maximal resistance and the number of revolutions for each cord were recorded. If a participant could not cycle with the seat unlocked or if the maximum resistance (10 cords) was reached, a "constant power" resistance mode, typical for most stationary bicycles, was used.

Phase 2: cardiorespiratory endurance. The goal of this phase was to gradually increase duration and intensity. The seat was locked in a location that positioned the participant's knee in 15 to 20 degrees of flexion when maximally extended. Heart rate was monitored using a sensor attached to the participant's ear or the chest. A target HR range of 70% to 80% of maximum heart rate (HRmax) was calculated for every session using the Karvonen formula: target HR = [(HRmax − HRrest) × 0.70–0.80] + HRrest, where HRrest = resting heart rate and HRmax = 220 − age. Typical exercise heart rate (TEHR) was documented at the conclusion of all sessions. Cycling was initiated at the lowest level of constant power mode resistance and was adjusted according to the participant's ability. Children were verbally encouraged to cycle as fast as they could with a goal of increasing their HR to within their target range. Each participant reported perceived exertion throughout the cycling session using the Children's Effort Rating Table (CERT), a 1 to 10 scale with verbal descriptions corresponding to each number.[27] Resistance and pedaling rate were adjusted based on HR and CERT rating. The exercise duration goal was 15 to 30 minutes. A cool-down period consisted of pedaling without resistance until HR decreased to within 20 bpm above the baseline measurement.

Data Analysis

The 600-Yard Walk-Run Test data were converted to speed (m/min). The GMFM-66 scores were calculated using the gross motor ability estimator software. Peak joint moments from the left and right limbs were averaged for each speed. If limb movement did not meet the specified speed, a joint moment could not be obtained, thus decreasing the number of limbs included for analysis. Peak hip extension, knee extension, and ankle dorsiflexion angular positions during the stance phase of gait, as well as peak hip and knee flexion angles during the swing phase of gait, were calculated from joint marker data.

Statistical tests were conducted using JMP version 6.0 software[§] and SAS version 9,[§] with significance level set at $P<.05$. Demographics, mobility level, anthropometrics, related medical history, and baseline primary outcome measurements were compared between the cycling and control groups using chi-square tests for comparison of proportions and one-way analysis of variance for continuous variables. Baseline-postintervention change scores were calculated for each outcome measure. Paired *t* tests were applied to examine baseline-postintervention differences within the cycling and control groups. Independent *t* tests were used to examine between-group differences in change scores. For data that were not normally distributed, Wilcoxon rank sum tests were used.

[§] SAS Institute Inc, PO Box 8000, Cary, NC 27513

Role of the Funding Source

This study was supported by a grant from the Foundation for Physical Therapy to establish PTClinResNet, a clinical research network to evaluate the efficacy of physical therapist practice.

Results

Recruitment and Retention

The Figure summarizes our trial profile. Of 129 individuals (88 in California, 41 in Missouri) who responded to the recruitment efforts, 65 individuals were excluded during telephone or in-person screening; specific reasons are reported in Table 1. Of the 64 individuals who were randomly assigned to the cycling and control groups, 6 later withdrew from the study. Two participants withdrew for personal reasons prior to baseline data collection. During the intervention period, an additional 2 participants withdrew for personal reasons, and 2 others did not maintain the criteria necessary for inclusion and were withdrawn by the investigators. One child initiated an intensive sports program, and the other child underwent a medical treatment for vision during the study. A total of 58 participants (29 in the cycling group, 29 in the control group; 37 from the California site, and 21 from the Missouri site) completed the study.

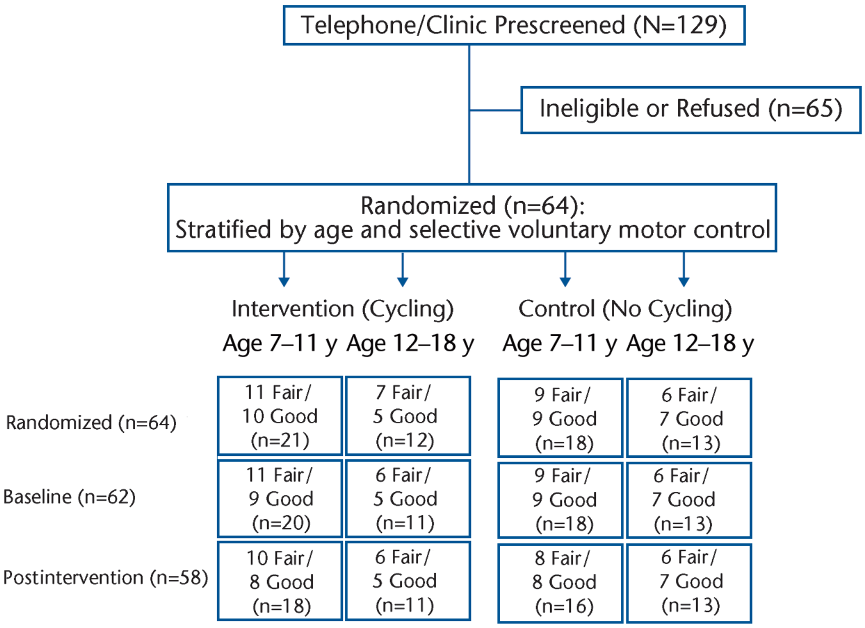

Figure.
CONSORT diagram illustrating the flow of participants through the trial.

Table 1.
Summary of Recruitment Efforts and Ineligibility by Site[a]

Reason for Exclusion	California	Missouri
Total no. of contacts	88	41
Protocol-specific reasons		
Age <7 y	4	4
Age >18 y	1	2
Diagnosis other than CP	1	0
Has CP, but not spastic diplegic CP	4	4
Unable to follow simple verbal directions	3	4
GMFCS levels I to III not met	5	2
Musculoskeletal or neurosurgical surgery or baclofen pump implantation within the past year	5	0
Casted or received braces in past 3 mo	2	0
Serious medical conditions		
Health complications	3	1
Legally blind	1	0
Participant-specific reasons		
Lack of transportation	1	0
Personal reasons or failed appointments	3	0
Family not interested	12	3
Total no. of exclusions	45	20
Total no. of participants enrolled	43	21

[a] CP=cerebral palsy, GMFCS=Gross Motor Function Classification System.

Demographics, Participant Characteristics, and Baseline Outcome Measures

Significant differences were not found for demographic data, participant characteristics, and baseline measures between the cycling and control groups (Tab. 2). A history of visual impairment was the most commonly reported medical problem, and the incidence was higher in the control group, but not significantly different (P=.07) from the cycling group. There was considerable racial and ethnic diversity; 49% of participants reported their race as African American, Asian, or "other" and 31% reported Hispanic ethnicity. Although all children were fluent in English, 19% of their parents or guardians were not. Due to difficulty in recruiting participants for the older age category (12–18 years), the constraint for equality between age groups was dropped, resulting in a greater number of participants in the younger age category (7–11 years). Blocking was maintained for selective voluntary motor control categories; therefore, similar numbers of participants were classified as "fair" or "good." Participants at GMFCS level III had greater representation than those at levels I and II. A history of speech, learning, attention, or behavioral problems and asthma were common.

Adherence, Protocol Variations, and Adverse Events

The adherence rate for cycling group session attendance was 89.6%. Protocol variations occurred for 3 participants who missed 1, 3, or 4 of the 30 scheduled sessions. Fifty-eight adverse events were reported. Twenty-eight mild events, for 18 participants, were potentially related to the study procedures. These events were 6 observed falls; 17 complaints of mild pain, soreness, or muscle cramping; 4 reports of feeling fatigued; and 1 report of skin rash related to the HR sensor. Thirty ad-

Table 2.
Demographics, Characteristics, and Primary Outcome Measures for Cycling and Control Group Participants at Baseline (N=62)[a]

Variable	Cycling Group (n=31)	Control Group (n=31)	P^b
Demographics			
Sex: male	18 (58%)	11 (36%)	.13
Age (y)	11.1 (9.9–12.3)	11.6 (10.6–12.6)	.59
Ethnicity: Hispanic	12 (39%)	7 (23%)	.27
Race			
African American	5 (16%)	3 (10%)	.52
White	18 (58%)	15 (48%)	
Asian	1 (3%)	5 (16%)	
Other	7 (23%)	8 (26%)	
Parental language			
English	24 (77%)	26 (87%)	.79
Spanish	6 (19%)	4 (13%)	
Other	1 (3%)	1 (3%)	
Age categories (y)			
7–11	20 (65%)	18 (58%)	.80
12–18	11 (36%)	13 (42%)	
Selective voluntary motor control			
Fair	17 (55%)	15 (48%)	.80
Good	14 (45%)	16 (52%)	
Mobility			
GMFCS level I	11 (35%)	8 (26%)	.52
GMFCS level II	8 (26%)	6 (19%)	
GMFCS level III	12 (39%)	17 (55%)	
Anthropometrics			
Height (m)	1.38 (1.32–1.44)	1.38 (1.3–1.4)	.94
Weight (kg)	38.8 (32.9–44.6)	37.9 (33.0–43.0)	.83
Related medical history			
Asthma	11 (36%)	6 (19%)	.25
Attention/behavioral problems	8 (26%)	8 (26%)	>.99
Mental retardation	4 (13%)	4 (13%)	>.99
Seizure disorder	2 (7%)	4 (13%)	.67
Learning problems	10 (32%)	16 (52%)	.20
Speech problems	11 (36%)	10 (32%)	>.99
Vision problems	15 (48%)	23 (74%)	.07
Hearing problems	1 (3%)	2 (7%)	>.99
Primary outcomes at baseline			
30sWT speed (m/min)	66.0 (57.9–74.0)	57.7 (50.4–65.1)	.13
600-Yard Walk-Run Test speed (m/min)	87.7 (73.4–102.0)	80.3 (65.9–94.7)	.46
GMFM-66 (maximum score=100)	69.0 (64.9–73.1)	68.8 (64.7–72.9)	.96
Peak knee extensor moments (N·m/kg)			
0°/s (n=28/28)	1.23 (1.04–1.42)	1.12 (0.99–1.26)	.34
30°/s (n=31/31)	1.03 (0.91–1.17)	1.09 (0.92–1.26)	.63
60°/s (n=30/31)	0.86 (0.75–0.97)	0.87 (0.71–1.02)	.92
120°/s (n=27/28)	0.65 (0.57–0.74)	0.70 (0.58–0.81)	.55
Peak knee flexor moments (N·m/kg)			
0°/s (n=26/27)	0.44 (0.33–0.54)	0.39 (0.27–0.52)	.61
30°/s (n=30/28)	0.29 (0.22–0.35)	0.34 (0.24–0.44)	.39
60°/s (n=27/29)	0.28 (0.21–0.34)	0.28 (0.20–0.37)	.93
120°/s (n=22/23)	0.21 (0.16–0.30)	0.21 (0.14–0.28)	.98

[a] Values are mean (95% confidence intervals) for continuous variables, frequency (%) for categorical variables. Related medical history was obtained from the parent Pediatric Outcomes Data Collection Instrument (PODCI) questionnaire. GMFCS=Gross Motor Function Classification System, 30sWT=Thirty-Second Walk Test, GMFM-66=Gross Motor Function Measure (66 items).
[b] Chi-square test for categorical variables; one-way analysis of variance for continuous variables.

Table 3.
Gait Speed and Gross Motor Function Outcomes[a]

Measure	Cycling Group	Control Group	P^b
600-Yard Walk-Run Test speed (m/min)	n=27	n=28	
Baseline	85.0 (69.7 to 100.4)	81.6 (65.9 to 97.4)	
Postintervention	90.6 (75.4 to 105.7)	84.1 (67.6 to 100.7)	
Change[c]	5.6 (1.6 to 9.5)	2.5 (−1.1 to 6.0)	.24
P	.008[d]	.16	
30sWT speed (m/min)	n=29	n=29	
Baseline	66.9 (58.6 to 75.1)	58.7 (51.0 to 66.5)	.
Postintervention	68.0 (60.4 to 75.7)	62.1 (54.4 to 69.8)	
Change	1.2 (−3.9 to 6.2)	3.4 (−1.7 to 8.4)	.52
P	.64	.18	
GMFM-66	n=29	n=29	
Baseline	69.6 (65.4 to 73.8)	68.8 (64.5 to 73.0)	
Postintervention	70.8 (66.6 to 74.9)	69.3 (65.4 to 73.3)	
Change	1.2 (0.5 to 1.8)	0.5 (−0.2 to 1.3)	.23
P	.002[d]	.12	

[a] Values are mean (95% confidence intervals). 30sWT=Thirty-Second Walk Test, GMFM-66=Gross Motor Function Measure (66 items).
[b] *P* value for between-group comparisons using independent *t* tests.
[c] Postintervention change calculated by subtracting baseline value from postsession value.
[d] $P<.05$ for baseline-postintervention comparison using paired *t* tests.

verse events not related to the study were illness (colds, flu), tooth loss, headache, stomachache, tonsillectomy, and skin irritation due to orthotic wear. Physical activity calendars indicated that the number of days with high or moderate levels of activity were similar for the cycling and control groups (64.8 and 64.4%, respectively). There was a shift toward high levels of activity for the cycling group (32.3% versus 21.7%). Reports of bed rest were slightly higher for the cycling group (4.9% versus 1.2%). “Flu” and “colds” were most the most commonly recorded comments on these days.

Cycling Group Training Intensity

The majority of participants were able to perform the strengthening task for phase 1 using the cyclocentric feature of the bicycle. The child with the lowest level of physical function (8 years of age, GMFCS level III, lowest baseline GMFM-66 score=47.5) did not develop this ability. In contrast, the child with the highest level of function (17 years of age, GMFCS level I, highest GMFM-66 score=100) reached the maximum load capability (100 lb) of the bicycle during the first session. Twelve additional participants reached the maximum load later in the intervention (sessions 9–30). For these participants, resistance was provided or enhanced using the constant power mode resistance feature described for phase 2. The average maximum load, over the first 3 days of the intervention, was 26.9 lb (SD=26.6, 30% of body weight). The maximum load reached by the end of the intervention was 65.5 lb (SD=34.2, 74% of body weight). The average gain was 38.6 lb (SD=25.7, range=0–90).

For phase 2, initial cycling ability of the participants was variable. Some children cycled independently at a high rate with minimal cueing, achieving HRs between 70% and 80% of HRmax within the first session. Other children required considerable verbal cueing, adaptations, and physical assistance to complete a single cycling revolution. Alignment of the limb such that the knee was either medial or lateral to the cycling plane was a common problem requiring correction. Regardless, all children were able to cycle independently by the end of the intervention. The primary strategy used to intensify physical effort was increased cycling cadence, rather than increased resistance, as a majority of children could not maintain cycling speed when resistance was increased. Mean TEHR across all sessions was 147.2 bpm (SD=14.4, range=117–176), representing a mean of 52.2% of HRmax (SD=12.2%, range=8%–77%). Mean TEHR exceeded 50% of HRmax for the majority of the participants. Only one child had an average HR below 30% of HRmax.

Outcomes

Walking and running endurance, preferred walking speed, and GMFM-66 results are presented in Table 3. As we anticipated that some children would not be able to complete the 600-Yard Walk-Run Test, speed for the distance completed, rather than time, was the outcome measure for the test. At baseline, all but 6 of the 62 participants tested were able to complete the 600-Yard Walk-Run Test within the 15-minute time limit. Five children were GMFCS level III, and 1 child was level II. The speed of 1 child, at GMFCS level I, was within normal values for this test[28] (baseline speed=240.3 m/min). A significant baseline-postintervention improvement of 5.6 m/min (*P*=.008) was found for the 600-Yard Walk-Run Test for the cycling group but not for the control group (Tab. 3). Preferred walking speed did not change significantly within either group based on the 30sWT. A significant baseline-postintervention improvement was found for the GMFM-66 within the cycling group but not the control group. Specific test items that demonstrated the most improvement were unilateral standing with arms free, attaining a squat position from standing, stepping over a stick at knee level, running 4.5 m, jumping 30 cm high with both feet simultaneously, and walking up stairs alternating feet. Significant differences were not found between change scores for the cycling and control groups.

Higher peak moments were found for the knee extensors than for the knee flexors (Tab. 4). Isometric (0°/s) values were highest. As speed of concentric muscle contraction increased, peak moments decreased. The cycling group showed a significant baseline-postintervention improvement in peak knee flexor moments at 30°/s (P=.025) and in knee extensor moments at 120°/s (P=.006). At 120°/s, the number of limbs that could generate recordable knee flexor moments bilaterally decreased substantially. Fifteen participants (8 in the cycling group, 7 in the control group) were not able to generate measurable knee flexor joint moments with either limb at this speed. For the subset of participants who could produce measurable knee flexor joint moments at this speed, a significant increase was found for the control group (P=.01) but not the cycling group (P=.09). Significant differences were not found between change scores for the cycling and control groups for strength. Significant differences were not found in baseline-postintervention gait kinematics within either group or between groups (P>.05, data not shown).

Discussion

We were unable to demonstrate that stationary cycling was better than no

Table 4.
Knee Extensor and Flexor Moments Normalized to Body Weight[a]

Variable	Cycling Group	Control Group	P[b]
Knee extensor moments (N·m/kg)			
0°/s	n=26[c]	n=26[c]	
Baseline	1.24 (1.04 to 1.45)	1.14 (1.0 to 1.28)	
Postintervention	1.25 (1.10 to 1.41)	1.19 (1.02 to 1.36)	
Change[d]	0.01 (−0.11 to 0.12)	0.05 (−0.04 to 0.14)	.55
P	.88	.25	
30°/s	n=29	n=29	
Baseline	1.05 (0.91 to 1.19)	1.09 (0.91 to 1.27)	
Postintervention	1.09 (0.95 to 1.22)	1.01 (0.83 to 1.19)	
Change	0.04 (−0.05 to 0.12)	−0.08 (−0.19 to 0.03)	.08
P	.39	.13	
60°/s	n=28	n=29	
Baseline	0.88 (0.76 to 0.99)	0.88 (0.72 to 1.05)	
Postintervention	0.89 (0.76 to 1.0)	0.86 (0.69 to 1.04)	
Change	0.01(−0.06 to 0.09)	−0.02 (−0.09 to 0.06)	.58
P	.76	.63	
120°/s	n=26	n=26	
Baseline	0.66 (0.57 to 0.75)	0.72 (0.60 to 0.84)	
Postintervention	0.75 (0.64 to 0.85)	0.75 (0.59 to 0.92)	
Change	0.09 (0.03 to 0.15)	0.03 (−0.05 to 0.12)	.27
P	.006[e]	.45	
Knee flexor moments (N·m/kg)			
0°/s	n=24[c]	n=25[c]	
Baseline	0.46 (0.36 to 0.57)	0.40 (0.26 to 0.54)	
Postintervention	0.47 (0.36 to 0.58)	0.45 (0.32 to 0.58)	
Change	0.01 (−0.06 to 0.08)	0.05 (−0.01 to 0.11)	.41
P	.69	.11	
30°/s	n=28	n=26	
Baseline	0.30 (0.23 to 0.37)	0.34 (0.23 to 0.44)	
Postintervention	0.35 (0.27 to 0.42)	0.35 (0.24 to 0.46)	
Change	0.05 (0.01 to 0.09)	0.01 (−0.04 to 0.07)	.31
P	.025[e]	.57	
60°/s	n=25	n=27	
Baseline	0.29 (0.22 to 0.36)	0.28 (0.19 to 0.36)	
Postintervention	0.29 (0.21 to 0.36)	0.27 (0.18 to 0.37)	
Change	0.00 (−0.06 to 0.06)	−0.01(−0.04 to 0.04)	.99
P	.95	.94	
120°/s	n=21	n=22	
Baseline	0.21 (0.16 to 0.26)	0.20 (0.13 to 0.28)	
Postintervention	0.26 (0.19 to 0.32)	0.28 (0.17 to 0.38)	
Change	0.04 (−0.01 to 0.10)	0.08 (0.02 to 0.12)	.43
P	.09	.01[e]	

[a] Values are mean (95% confidence intervals).
[b] P value for between-group comparisons using independent t tests.
[c] 3/29 participants did not undergo isometric testing, as it was added after the start of the study.
[d] Postintervention change calculated by subtracting baseline value from postsession value.
[e] P<.05 for baseline-postintervention comparison using paired t tests.

intervention; however, significant baseline-postintervention improvements within the cycling group provided preliminary support for cycling in this phase I study. Other recent RCTs that examined exercise interventions in children with CP did not find between-group differences for some[29,30] or all[31,32] outcome measures. Using this design, between-group statistical significance can be most easily detected when: (1) intersubject and intrasubject variability is minimal, (2) control group outcomes are stable, and (3) there is a large treatment effect. If these factors are not optimal, the inclusion of larger number of participants may be required to obtain sufficient power to realize between-group effects, increasing the expense and effort required for research. In examining our primary outcome data, there were moderate effect sizes for the 600-Yard Walk-Run (0.33) and the GMFM-66 (0.38). In order to show a statistically significant difference between the 2 groups for these effect sizes, 130 participants in each group (a 2-sided test at the .05 level with 80% power) would be required.

Intersubject variability between the 2 groups was addressed by random assignment and blocking by selective motor control. A significant correlation between selective voluntary motor control and GMFCS levels[33] has been reported (Spearman $r=-.83$, $P<.001$), but other measures of CP severity, such as balance and spasticity (a velocity-dependent hyperexcitability of the muscle stretch reflex), may have been more disproportionate. Intrasubject variability is more difficult to anticipate and was high, as evidenced by the large confidence intervals observed for the change scores. Consistent performance during outcome evaluations may have been challenging for participants with comorbidities, including asthma and intellectual, behavioral, and visual deficits. Additionally, there is evidence that children with CP have increased sensitivity to environmental alterations during testing. Heat consistent with a warm climate was found to increase metabolic rate and body temperature in children with CP (GMFCS levels I and II) during treadmill exercise but not in children without disability.[34] Biological factors such as mood, comfort, and amount of rest can differ between testing sessions. Although it is difficult to control all factors, we informed families about the testing procedures, performed repeat testing at the same time of day, and ensured that each child had adequate nutrition and rest during data collection.

Clinical trials for other pediatric populations who exhibit both physical and intellectual disabilities have addressed intrasubject variability by conducting multiple baseline sessions and either averaging measures[35] or excluding participants who exhibit excessive performance variability from further testing.[36] Future RCTS for children with CP might identify intrasubject variability through the performance of at least 2 baseline evaluations prior to the beginning of the intervention. Once identified, statistical analyses could be performed to determine the effect of these data on the results.

The control group in the present study was not exposed to the cycling intervention, yet their mean baseline-postintervention scores increased for walking and running tests, the GMFM-66, and 5 out of 8 isokinetic tests. Mean improvements often were associated with fairly low P values (Tabs. 3 and 4). Statistically significant improvement ($P<.05$) was limited to peak knee flexor moments at 120°/s. That significance was reached for this one outcome measurement is likely a spurious result. The change in the cycling group was not significant ($P=.09$). Possible reasons for the control group's improvements are: (1) accommodation, (2) practice, (3) physical activity level, (4) attention, and (5) a desire to compete with the first performance. Accommodation occurs when a participant changes his or her performance after becoming comfortable with testing conditions. In the present study, participants were tested by physical therapists previously unknown to them, in unfamiliar environments, and were asked to perform novel, physically challenging activities. Becoming comfortable with the environment and testing procedures may have positively affected postintervention measurements for some participants. Andersson et al[37] addressed this issue in their study of Six-Minute Walk Test reliability in adults with CP. As significant improvement was found between test 1 and test 2 but not between tests 2, 3, and 4, a practice test was recommended when using this test for intervention studies. In our test of locomotor endurance, 68% of the control group participants improved in the 600-Yard Walk-Run Test, and 39% improved by more than 10%. The effect of accommodation and practice in the present study could have been examined with 2 baseline assessment sessions.

Self-report measures of physical activity were similar between the 2 groups. Activity calendars indicated a similar frequency for sports and play activities, although fewer days at high-level, as opposed to moderate-level, categories were reported for the control group. The use of more quantitative measures, such as accelerometers,[1] may better characterize physical activity and prevent the possibility of underreporting or overreporting. Participants agreed to maintain their present level of exercise, sports, and physical therapy during the study. Their attitude toward intensity, however, may have been affected by information detailing the potential benefits of exercise that was provided during the recruitment and consenting process. Finally, considerable positive attention and anticipation of receiving an adapted bicycle may have influenced the effort of control group participants during the postintervention session. A desire to exceed their baseline performance was expressed by several participants during postintervention testing.

A large treatment response in the intervention group is desired for RCTs examining exercise interventions in CP. The response to therapeutic interventions in children, however, is complex and likely influenced by factors such as impairment, inherent characteristics of the child, and family dynamics.[38] Motivation and comorbidities, particularly intellectual, attentional, and behavioral problems, can limit the child's ability to fully engage in the intervention and tolerate the feeling of physical effort associated with intense exercise. In pediatrics, parents typically initiate physical therapy, and the child may not be inherently motivated to exercise. Motivation techniques were individualized in this study using music, verbal praise, cheering, or rewards, and, overall, participants appeared to be engaged and motivated.

A diagnosis of mental retardation was reported for 2 cycling group participants who elected to withdraw from the study. Two other children with this diagnosis, however, successfully completed the intervention. As there is a high prevalence of intellectual and other comorbidities in children with CP, their effect on choice of optimal treatment interventions warrants further study. A walking and running intervention would have been more specific to our goal of improving walking and running endurance; however, balance, coordination, and selective motor control deficits are factors that made cycling more desirable. The cycling intervention was consistent with specificity of training principles due to its effect on the energy systems used.[39] Prolonged stimulation of the cardiorespiratory system results in changes in heart, vascular, and blood function. These adaptations can improve performance in all types of endurance activities.

Intensity threshold is the level of exercise that must be obtained to discern a training effect,[40] but intensity is rarely described for physical therapy interventions in children with CP.[5] The exercise intensity for the present study appeared sufficient to improve walking and running endurance, gross motor function, and a subset of strength measurements. The cyclocentric method of strengthening, with the addition of constant resistance features for stronger participants, allowed the progression of intensity throughout the intervention duration, for an average gain in resistance that approximated 54% of body weight. For cardiorespiratory training, an intensity threshold of 70% to 80% of HRmax is recommended for young adults and is at least that high for children.[40] Although the average TEHR for the cycling group did not reach this threshold, improved walking and running endurance indicates a training effect occurred.

The intensity threshold for children with CP may be below 70% of HRmax due to the reduced peak aerobic capacity reported for this population.[41] The TEHR findings were consistent with those of Darrah et al,[14] who reported that most adolescents with CP attained HRs above 145 bpm during an aerobic dance intervention. Another consideration is that HRmax may not equal 220 − age for this population. There is controversy over the estimation of HRmax using the formula HRmax = 220 − age, which was not based on original research.[42] Despite the widespread acceptance of this formula, research has revealed a large standard error of estimate (Sxy=7–11 bpm). Actual HRmax is the HR that cannot be surpassed despite continued increases in exercise intensity—a challenge for children with CP and, therefore, a limitation of our study.

Training duration is another important consideration. Verschuren et al[16] demonstrated between-group differences in an RCT with a longer study duration (8 months) than that of our study. Improvements in the exercise group over this time period were accompanied by a decline in most measures by the control group, enhancing the detection of between-group differences. Mean anaerobic and aerobic performance increased in the control group over the first 4 months but declined to below baseline values by the end of the study by Verschuren and colleagues. Their findings suggest that interventions exceeding 4 months may be required to discern a treatment effect in children with CP.

A large treatment response may occur but not be identified without sensitive outcome measurements. We chose outcome measures that were specific for cardiorespiratory endurance and strength but differed from the intervention task to avoid practice of the test procedures. Two other RCTs[29,30] did not find between-group differences in their 6-week interventions using outcome measures that differed from the intervention task. In contrast, Verschuren et al[16] demonstrated between-group differences in an RCT with training exercises that appeared similar to some of the outcome assessments. Isokinetic strength testing in the present study may not have fully captured the training effects. Although this is the standard method for strength measurement throughout a range of speeds, it requires isolated joint movement, which is problematic because children with CP have impaired selective voluntary motor control. Strength assessment of full limb extension and flexion across a range of speeds might be preferable; however, a standardized, objective method was not available. Previous research has shown that children with CP have increasingly greater strength deficits as speed increases from 0 to 120°/s compared with those without impairment.[43] In the present study, we found that fewer participants could generate recordable joint moments for one or both limbs at the highest speed, particularly for knee flexors. Other researchers have noted that children with CP have difficulty moving at sufficient speeds for isokinetic testing.[44,45] In one study,[45] 4 of 12 children with CP were considered "too weak" to participate in isokinetic testing.

Improvements in peak knee joint moments for the cycling group were consistent with training speeds and the specificity of training principles for skeletal muscle.[39] In skeletal muscle, different motor unit types are recruited in response to alteration in intensity and duration of load and stimulus. Adaptation is specific to joint actions, specific muscle groups recruited, and the velocity of contraction. The inclusion of strength testing across a range of speeds proved important, as we did not find changes with isometric testing. Previous research has shown that improvements in peak joint moments are specific to the training velocity.[46] College-aged students who trained at 60°/s demonstrated significantly greater peak moments ($P<.05$) than a placebo group at this speed. High-speed training (300°/s) resulted in a significant effect at 180°/s but not at slower speeds (0 or 60°/s). Cycling during the PEDALS strengthening phase was performed at relatively slow speeds, most comparable to isokinetic testing at 30°/s. We found selective improvement of the cycling group knee flexors at this speed. The postintervention hamstring muscle to quadriceps muscle peak torque ratio for the cycling group (32%) was well below normative data for children at 30 to 60°/s (>60%)[47]; therefore, increased strength in this typically spastic muscle group was not a concern.

Johnston et al[48] reported a greater duration of hamstring muscle activity during recumbent stationary cycling for adolescents with CP compared with adolescents without disability. Hamstring muscle recruitment duration and intensity during cycling may have exceeded recruitment demand during daily activities for children with CP, who often have a crouch gait, walk slowly, or do not participate in sports.

Cycling speed during the cardiorespiratory phase was most comparable to isokinetic testing at 120°/s. Improved peak knee extensor strength for the cycling group was found at this speed. Higher cycling cadences, typically used during the cardiorespiratory phase, may have challenged the knee extensors beyond speeds typically encountered during normal activities. Participants chose to maintain the lowest level of resistance and increased cycling cadence to elevate their HR. The alternative strategy of increasing resistance proved too strenuous for most children. Research examining children without disability showed that lower loads were optimal for obtaining peak power output during cycling, as higher loads induced fatigue.[49]

Improved GMFM-66 scores found for the cycling group support greater functional strength. The 1.2-point gain observed for the cycling group was between medium (0.8) and large (1.3) effect sizes, corresponding to minimum clinically important differences for ambulatory children with CP (GMFCS levels I, II, and III).[50] Williams and Pountney[19] reported a larger increase in mean GMFM-66 of 3 points for 11 children with dyskinetic or spastic CP following a cycling intervention. These participants had GMCFS levels of IV or V and lower gross motor function (mean GMFM-66 score=39.2) at baseline. The investigators attributed this substantial gain to a lack of other opportunities for physical activity. Participants in the present study were ambulatory with higher baseline functional ability (mean GMFM-66 scores=69.6 and 68.8 for the cycling and control groups, respectively) and, therefore, had more opportunities for physical activity.

Lack of improvement in preferred walking speed suggests either that the intervention was not task specific for this parameter or that it is an innate behavior that is somewhat impervious to change in children with CP. Improved preferred walking speeds have not been a consistent finding following progressive resistive exercise programs for individuals with CP; some authors reported significant improvements,[51–53] whereas other authors did not.[22,54] Our findings are similar to those of Sullivan and colleagues,[26] who compared body-weight–supported treadmill training and stationary cycling, both combined with lower-extremity strength training, in adults poststroke. They found that, although all participants had improved walking endurance (on the Six-Minute Walk Test), those participants assigned to the cycling intervention did not have improved walking speed over a short distance (10 m). In the present study, gait improvements were not found for preferred speed or kinematics.

Conclusions

Stationary cycling is an exercise that can address impairments in both strength and endurance. It can be incorporated into physical therapy programs for children with CP and transitioned into independent physical activity at home or school or in the community. Although access to adaptive physical education, sports, and recreation varies, most children with CP are followed during their childhood by a physical therapist, who can include fitness exercise in therapy sessions and assist in the design of independent programs.

The PEDALS intervention took place in community pediatric physical therapy settings. A specialized stationary bicycle was used in order to precisely document increases in load; however, alternative methods of increasing and quantifying resistance are standard features of most stationary bicycles. Training children to increase their HR, progressively increase resistance, and rate their feelings of exertion are skills that can empower them to become self-sufficient in lifelong fitness programs. At the conclusion of this study, all participants received adapted overground or stationary bicycles. It is hoped that long-term exercise will promote general health and prevent secondary conditions as children with CP age and mature. Questionnaires addressing health-related quality of life and participation were administered to all participants in this study and may provide additional information about factors that affect outcomes for this population. These results will be reported in a separate publication.

There has been a recent growth in research examining strengthening and cardiorespiratory fitness interventions for children with CP. The current level of evidence supporting exercise programs is low, and results have been inconsistent, particularly for RCTs. This phase I study provides information to help guide future research. As considerable diversity of personal and environmental factors exists within this patient population, research must be carefully designed. Identification of participants who are inconsistent in their performance, consideration of accommodation and practice effects, sufficiently intense interventions, and selection of highly sensitive outcome measures may improve the detection of between-group differences in future RCTs. The results of this study stress the importance of including a control group to examine potential improvements that are not due to the intervention. Otherwise, the evidence supporting interventions may be overstated. We failed to prove that the intervention was better than no intervention using an RCT design, but the results for the cycling group were promising and offer guidance for future research. The benefits of exercise for health and well-being are well established in the general population. Individuals with CP should be provided with exercise protocols that maximize health, promote functional improvement, and minimize secondary conditions.

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