A randomized clinical trial of strength training in young people with cerebral palsy

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This randomized clinical trial evaluated the effects of a home-based, six-week strength-training programme on lower limb strength and physical activity of 21 young people (11 females, 10 males; mean age 13 years 1 month, SD 3 years 1 month; range 8 to 18 years) with spastic diplegic cerebral palsy (CP) with independent ambulation, with or without gait aids; (Gross Motor Function Classification System levels I to III). Compared with the 10 controls, the 11 participants in the strength-training programme increased their lower limb strength (combined ankle plantarflexor and knee extensor strength as measured by a hand-held dynamometer) at 6 weeks ($F(1,19)=4.58, p=0.046$) and at a follow-up 12 weeks later ($F(1,18)=6.25, p=0.041$). At 6 weeks, trends were also evident for improved scores in Gross Motor Function Measure dimensions D and E for standing, running and jumping, and faster stair climbing. A relatively short clinically feasible home-based training programme can lead to lasting changes in the strength of key lower-limb muscles that may impact on the daily function of young people with CP.

Muscle weakness can be a major problem for many young people with spastic diplegic cerebral palsy (CP; Damiano et al. 1995, Wiley and Damiano 1998). The term 'diplegia' refers to weakness and movement incoordination involving the lower limbs more than the arms. People with spastic diplegia typically walk slowly and have difficulty in performing activities such as walking up and down steps or running (Abel and Damiano 1996, Damiano and Abel 1998). The most common gait patterns are characterized by excessive knee and hip flexion, implicating weakness of the ankle plantarflexors, knee extensors, and hip extensors (Rodda and Graham 2001).

An increasing number of studies have reported that strength-training programmes can improve strength (Healy 1958, McCubbin and Shasby 1985, Damiano et al. 1995, MacPhail and Kramer 1995, O'Connell and Barnhart 1995, Tweedy 1997, Damiano and Abel 1998, Darrah et al. 1999, Dodd et al. 2002), as well as physical activity in people with CP (O'Connell and Barnhart 1995, Damiano and Abel 1998). However, most of the relevant literature consists of single group pre- and post-study designs without adequate control for confounding variables. Only one randomized controlled trial has been conducted (McCubbin and Shasby 1985). Therefore, it is difficult to conclude that the positive outcomes reported are due to the muscle strengthening programmes. Also, many of the previous studies have evaluated programmes that have required close one-to-one professional supervision or have used expensive specialized equipment, such as machine weights and isokinetic dynamometers, limiting the clinical feasibility of the programmes.

Accordingly, the objectives of this study were to determine whether a home-based strength-training programme could (1) increase the strength of the ankle plantarflexors, knee extensors, and hip extensors and (2) improve physical activity and walking ability in young people with spastic diplegic CP.

Method

PARTICIPANTS

Potential participants were identified by one of the authors (KD) from the outpatient records of the Hugh Williamson Gait Laboratory at the Royal Children's Hospital, Victoria, Australia. The final sample comprised 21 children and adolescents with CP (11 females,10 males). To be included, participants had to be aged between 8 and 18 years with spastic diplegic CP. They had to be able to walk independently, with or without a gait aid, and to be able to follow simple commands. Exclusion criteria were a fixed flexion deformity at the knee, hip greater than 25°, or fixed equinus of more than 10°, current participation in other management strategies such as serial casting, botulinum toxin, or recent orthopaedic surgery (less than 12 months), and participation in a strength-training programme within the previous three months. The Human Ethics Committees of both the Royal Children's Hospital and La Trobe University approved this trial and written informed consent was obtained for each participant.

PROCEDURE

The procedure for this randomized clinical trial is summarized in Figure 1. Participants were allocated randomly to either the strength training or control group using a concealed method. Twenty-two identical pieces of paper were placed in an opaque container, 11 with the words 'experimental group' and 11 with the words ‘control group’ written on them. In another opaque container, the name of each participant was written on 21 separate pieces of paper. Allocation was achieved by drawing a piece of paper from each container. This process continued until all participants were allocated to a group.

After baseline measurements were taken, a physiotherapist taught each participant in the strength-training group three strengthening exercises. The exercises, designed to target the ankle plantarflexor, knee extensor, and hip extensor muscle groups, were: (1) bilateral heel raises in which the participant stood on the edge of a stable, light-weight portable step (height 20cm) and raised and lowered his or her heels through the full available range; (2) bilateral half squats in which from a standing position, the participant slowly squatted until knees were flexed to between 30 and 60°. A large inflatable ball (55cm diameter) was placed between the lower back of the participant and the wall to help guide and standardize the exercise; and (3) step-ups where the participant stepped onto and off portable steps.

At the first session, the training load was adjusted to ensure that each participant would obtain an optimal strengthening benefit. For strength gains loads should be such that the person can only complete between eight and 12 repetitions of the exercise with good form before fatigue sets in (American College of Sports Medicine 2002). The training load was adjusted by adding free weights to a backpack worn by the participant. Once the initial load was determined, participants were instructed to complete three sets of between eight and 10 repetitions of each exercise, three times a week for six weeks. Participants were provided with an exercise diary that detailed each exercise and enabled participants to record the weights used and the number of sets and repetitions completed at each exercise session. Each exercise session took between 20 and 30 minutes. At the end of the second and fourth week of the exercise programme the physiotherapist visited the participant at home to check the way in which exercises were being performed and to adjust the training load.

All participants, including those in the control group, were instructed to continue their normal daily activities, including school and sport. Participants were also able to attend their normal physiotherapy programme, provided therapy did not include a progressive resistance exercise programme. Typically, physiotherapy for school age children with CP in the state of Victoria is limited to a school consultation of around 45 minutes once or twice a month. It was expected that the amount of physiotherapy and the level of sport and physical activity the children participated in would not be different between the two groups due to the random allocation procedures. Normal physical activity, such as sport and physiotherapy, was not expected to increase muscle strength. A very specific training programme is required to increase muscle strength. The training intensity needs to be progressive (i.e. the load is increased over time as muscles become stronger) and the programme should comprise 1–3 sets of each exercise. Within each set, muscle fatigue is reached within 8–12 repetitions and exercise sessions are performed at least twice per week (Faigenbaum 2000, American College of Sports Medicine 2002). At the end of the trial the young people in the control group confirmed that they had not participated in a progressive strength-training programme during the trial.

To assess the effects of the six-week strength-training programme, participants in the experimental and control groups were tested immediately after the sixth week. To determine if the strength-training programme had longer-term effects, participants in the experimental and control groups were again tested 18 weeks after starting the programme. All baseline, six week, and 18-week measurement sessions were held in the La Trobe University Movement Rehabilitation Laboratory.

OUTCOME MEASURES

Baseline characteristics were assessed to measure the success of randomization. Characteristics measured were age, height, weight, sex, and severity of disability as classified by the Gross Motor Function Classification System (GMFCS; Palisano et al. 1997). Outcome measures included two components of the International Classification of Functioning, Disability and

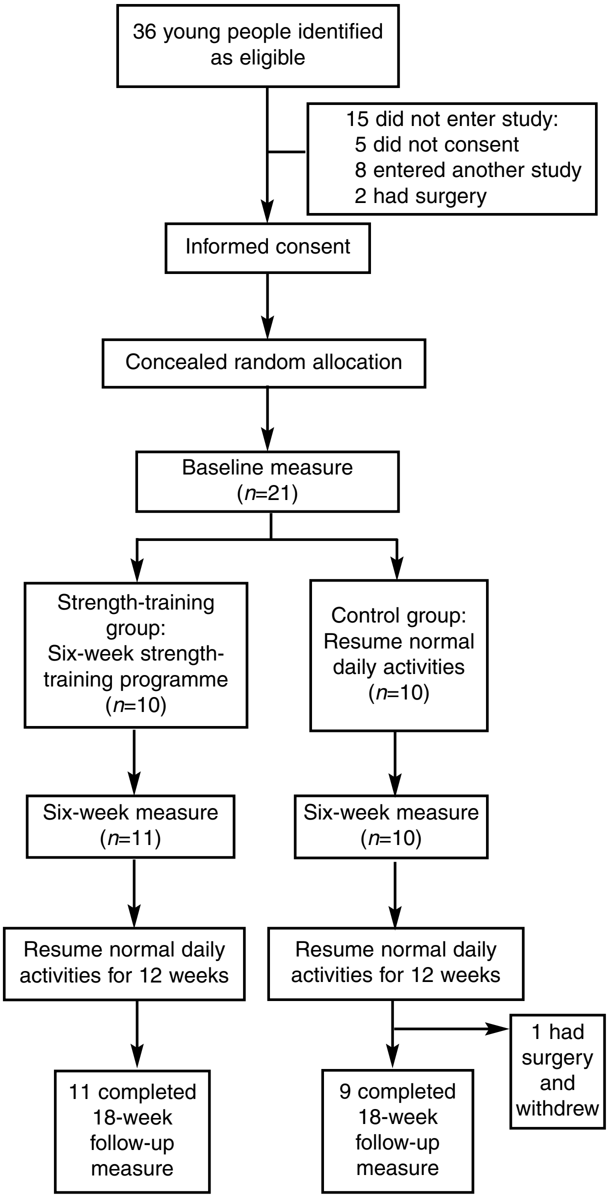

Figure 1: *Procedure for randomized clinical trial.*

Health (ICF; World Health Organization 2001). The ICF component of body structure and function was represented by the measurement of strength and the component of activity was measured by dimensions D and E of the Gross Motor Function Measure (GMFM; Russell et al. 1993), a timed stair test, and self-selected walking speed. A physiotherapist who was blind to group allocation and experienced in assessing movement disorders took all outcome measures. Blinding was maintained until after the final assessment had been completed.

STRENGTH

Strength of the ankle plantarflexors, knee extensors, and hip extensors was assessed using a hand-held dynamometer (Nicholas Manual Muscle Tester, Model 01160; Lafayette Instrument, Lafayette, IN). Hand-held dynamometers have been shown to be reliable instruments for measuring isometric strength in people with neurological disorders (Riddle et al. 1989), and have been used successfully to detect change after strength training in children with spastic diplegic CP (Damiano et al. 1995).

The protocol used to assess strength was based on a method described by Damiano and Abel (1998). Participants moved their body part to the specified position as described in Table I and maximally resisted the examiner's effort to move the body part. The examiner gradually applied force over one second to allow the participant to adjust and recruit a maximum number of muscle fibres. Three attempts at each muscle group were recorded. The first attempt was used for familiarization and a score was obtained by averaging the second and third attempts. As there was no significant difference between the strength of the left and right sides, and exercises in the strength-training group were performed bilaterally, the strength score for each participant was obtained by adding the left and right-sided score for each muscle group. As well as scoring the strength of the individual muscle groups, a combined ankle plantarflexor and knee extensor strength score was calculated. The ankle plantarflexor-knee extensor couple is thought to be a critical biomechanical concept for understanding abnormal gait patterns in spastic diplegia (Rodda and Graham 2001). In addition, a combined ankle plantarflexor, knee extensor, and hip extensor strength score (termed 'Total Extension') was calculated for each participant. Combined extensor strength of these key muscles has been attributed to maintaining an erect posture and providing support for the head, arms, and trunk during standing and walking (Winter 1991, Rodda and Graham 2001). Further, these combined strength scores more closely reflected the way in which the exercises were performed, i.e. as whole lower limb exercises, rather than as more isolated joint movement exercises.

ACTIVITY

In this study, change in activity was assessed using dimension D of the GMFM (Russell et al. 1993) which measures activities in standing (13 items), and dimension E which measured walking, running, and jumping activities (24 items). Separate scores were calculated for dimensions D and E, and a total goal score was calculated by combining dimensions D and E. These dimensions were chosen because they represented areas that many young people with spastic diplegia have difficulty with (Damiano et al. 1995), and they were activities that a lower limb strength-training programme was more likely to improve. As specified in the GMFM instruction manual (Russell et al. 1993), participants were asked to attempt each of the items up to three times without using any assistive devices. The best attempt was recorded.

THE TIMED STAIR TEST

The Timed Stair Test measured the ability to walk up and down stairs, a task that is commonly difficult for people with CP. The Timed Stair Test is based on items 84 and 87 of the GMFM. The test requires participants to walk up and down three steps of standard size (17.5cm) as quickly as possible, using rails if required. The time taken to complete the task was measured using a stopwatch.

SELF-SELECTED WALKING SPEED

Self-selected walking speed provides an indication of gait function in people with neurological disorders (Andriacchi et al. 1977), and can be measured with high retest reliability with a stopwatch in populations with neurological impairment (Wade 1992). Participants were given standardized instructions: 'Walk to the end of the walkway at your normal walking speed. This is not a race, don't go fast'. Participants used their normal walking aids if appropriate. The walk was timed over the middle 10 metres of a 14-metre linoleum covered walkway using a stopwatch.

STATISTICAL ANALYSIS

The sample-size calculation was based on a systematic review of strength training in CP (Dodd et al. 2002). Numbers in each group (n=11) were based on a conservative estimate of effect size of d=1.20, allowed for a significance level of 0.05, and a power of 0.80 (Howell 1987). Effects sizes (d) of greater than 1.2 have been reported for increasing muscle strength (Healey 1958, McCubbin and Shasby 1985, Tweedy 1997, Damiano et al. 1995, MacPhail and Kramer 1995, O'Connell and Barnhart 1995, Damiano and Abel 1998, Darrah et al. 1999) and activity (O'Connell and Barnhart 1995) in children with CP. Data were analyzed using SPSS (version 10.0). Baseline characteristics were compared in the two groups using the χ^2 test, Student's

Table I: Isometric strength test protocol

Muscle group	*Body position*	*Joint position*
Ankle plantarflexors	Supine	Knee flexed 90° and resting on bench; lower leg stabilized; resistance given across metatarsal heads
Knee extensors	Sitting	Knee flexed to 90°; resistance given anteriorly 5cm proximal to lateral malleolus. For comfort a towel was used between tester and tibia
Hip extensors	Prone	Knee extended and thigh extended off surface; pelvis stabilized; resistance given to posterior distal-thigh

t-test, or Mann-Whitney *U* test, as appropriate. The interaction effect of the two-way analysis of variance with one repeated factor (time) and one independent factor (group) was used to compare the groups for change from baseline to six weeks, and baseline to 18 weeks. Power analyses were completed on comparisons that approached statistical significance. Changes in training load from the self-report diaries were evaluated with paired *t*-tests and the association between amount of training (number of session and number of sets completed) and strength increases were explored with Pearson's product moment correlation coefficients (*r*).

Results

Participant details are shown in Table II. There was no significant difference between the experimental and control groups for age, height, weight, or sex. There was, however, a trend for children randomly assigned to the experimental group to be more physically disabled, as measured by the GMFCS (Mann-Whitney $U, z=1.96, p=0.07$). All of the participants had been involved in active orthopaedic management before participation in this trial. Seventeen of the 21 young people had undergone multilevel orthopaedic surgery a mean of 34 months (range 24–52 months) before the trial commenced. One young person had undergone isolated calf lengthening without multilevel surgery. Three of the younger participants had been managed with botulinum toxin for dynamic equinus on 1–3 occasions. At the time of the trial, all participants were orthopaedically well-aligned with no major equinus deformities.

Baseline measures of the experimental and control group strength and activity measures can be viewed in Tables III and IV. At baseline there was no significant between-group difference for measures of strength (Table III), nor activity (Table IV). All 21 participants completed baseline and six-week testing. One participant in the control group did not complete the 18-week follow-up test due to recent surgery on the lower limbs.

Participants in the strength-training group adhered to their prescribed programme, completing a mean of 16.8 (SD 2.4) of the scheduled 18 training sessions and a mean of 147.7 (SD 23.4) of the prescribed 162 sets of exercises. The self-report exercise diaries also demonstrated that training load increased significantly over the six weeks of the intervention. This training load represented isotonic 8–10 repetition maximum strength. The weight added to the backpack for the bilateral half squat exercise increased from a mean of 3.6kg (SD 1.4) to 8.2kg (SD 4.1), ($t_{(10)}=4.3$, $p=0.001$); for heel raise 3.6kg (SD 1.4) to 8.3kg (SD 4.1), ($t_{(10)}=4.4$, $p=0.001$); and step-ups 3.6kg (SD 1.4) to 8.1kg (SD 4.2) ($t_{(10)}=4.1$, $p=0.002$). All participants in the experimental group were questioned at the 18-week follow-up session about whether they had continued with the training programme after the six-week programme had been completed. None of the participants had continued training.

Results of the six-week strength-training programme on lower limb strength can be viewed in Table III. From baseline the experimental group increased their combined ankle plantarflexor-knee extensor strength more than the control group at six weeks ($F(1,19)=4.58$, $p=0.046$), and at 18 weeks ($F(1,18)=6.25, p=0.041$). From baseline there was a trend to increased total extensor strength in the experimental group compared with the control group at six weeks ($F(1,19)=3.12$, $p=0.094$), and 18 weeks ($F(1,18)=3.28, p=0.087$). With effect sizes maintained and sample size increased to $n=22$ in each group, there would be an 80% chance of detecting significant changes for the comparisons of total extensor strength. There was no significant interaction effect for the individual muscle groups. When isometric strength values were normalized for bodyweight, the results were similar with a significant change in favour of the experimental group for combined ankle plantarflexion or knee extensor strength ($F(1,18)=5.62, p=0.029$) from baseline to 18 weeks, and a trend for change in the same dependent variable over the first six weeks ($F(1,19)=2.55$, $p=0.13$). There was no correlation between the change in ankle plantarflexor-knee extensor strength and the number of

Table II: Participant characteristics

Characteristics	*Exp. group (n=11)*	*Control group (n=10)*
Age, y	12.7 (2.8)	13.5 (3.4)
Height, cm	146.7 (15.9)	152.5 (12.0)
Weight, kg	45.7 (15.3)	44.7 (8.7)
GMFCS level		
Level I	2	5
Level II	2	3
Level III	7	2
Sex, M/F	4/7	6/4

Values are mean (SD); Level III indicates more disability; GMFCS, Gross Motor Function Classification System (Palisano et al. 1997); Exp, experimental.

Table III: Results of strength assessment at baseline, 6 weeks, and 18 weeks

Muscles tested	*Baseline*		*6wk*		*18wk*	
	Exp. *n=11*	*Control* *n=10*	*Exp.* *n=11*	*Control* *n=10*	*Exp.* *n=11*	*Control* *n=9*
Ankle plantarflexors, kg	11.0 (15.8)	17.5 (13.1)	11.1 (12.5)	15.4 (11.6)	16.6 (15.2)	13.8 (9.0)
Knee extensors, kg	27.5 (10.9)	23.7 (11.5)	33.1 (15.8)	25.5 (9.9)	32.5 (11.4)	25.2 (7.8)
Hip extensors, kg	7.9 (7.6)	8.5 (8.4)	10.6 (10.2)	11.5 (10.7)	10.8 (9.1)	10.6 (8.3)
Ankle plantarflexors + knee extensors, kg	38.5 (23.2)	41.1 (20.0)	44.2 (25.5)[a]	40.9 (20.2)	49.2 (25.3)[a]	38.9 (15.0)
Total extensors, kg	46.5 (29.6)	49.6 (25.9)	54.8 (34.5)	52.4 (27.7)	60.0 (33.0)	49.5 (21.1)

[a] $p<0.05$ for group × time interaction; values are mean (SD). Total extensors, ankle plantarflexion plus knee extension plus hip extension. Exp, experimental.

sessions ($r=-0.05$, $p=0.89$) or sets (r–0.02, $p=0.95$) completed over the 6-week trial.

The results for measures of activity can be viewed in Table IV. There was no significant group by time interaction effect for measures of activity. For the GMFM dimension E measuring walking, running, and jumping, there was a trend for the experimental group to improve more than the control group over the first six weeks, but this comparison did not reach statistical significance ($F(1,19)=3.80$, $p=0.07$). There was also a trend for the strength-training group to walk faster up and down stairs over the first six weeks ($F(1,19)=2.97$, $p=0.10$). Power analysis revealed that if the effect size were maintained and the sample size increased to $n=26$ in each group, there was an 80% chance that the comparisons for dimension E of the GMFM and the timed stair test would have reached statistical significance.

There was no adverse event that led to participants missing a training session. One participant reported pressure on the shoulders from the backpack. As a result, weights were carried in a home-made vest to distribute the load more evenly. A further two participants reported mild foot and ankle discomfort during the heel raise exercise. To alleviate this, the physiotherapy trainer modified the exercise so that ankle dorsiflexion did not exceed the plantigrade position. This modification enabled these participants to continue without incident.

Discussion

CP is the most common cause of physical disability affecting children (Stanley et al. 2000). It results in an upper motor neuron syndrome characterized by positive features such as spasticity, co-contraction, and clonus. There are also negative features, such as weakness, loss of selective motor control, and balance deficits, that are probably relevant to locomotor prognosis and function.

This randomized clinical trial provides important new evidence that home-based strength-training programmes can be an effective and feasible strategy for increasing muscle strength in young people with CP. Trends suggest that it might also improve physical activity in these people. Apart from two home-based studies conducted by Damiano et al. (1995, Damiano and Abel 1998) previous trials reporting positive effects from strength training have evaluated programmes that have been expensive in terms of therapy resources. The cost of these programmes limits the ability to incorporate strength-training programmes on a more routine basis for young people with CP. Our programme was specifically designed with clinical feasibility in mind. The programme used simple, inexpensive equipment. In addition, rather than having a trained clinician supervise each session, our programme was supervised by the child's parent and only periodical monitoring was required by the therapist. Also, the training programme was conducted in the participant's own home and so required no travel on the part of the participants or their families. This was an important consideration particularly if the young person had siblings who required care or the therapy appointments were likely to interfere with social activities or school attendance. Despite our programme being based at home with minimal supervision, participation and adherence to the training protocol was excellent with participants completing a mean of 16.8 (SD 2.4) of the scheduled 18 training sessions. In addition, the programme was completed without any serious adverse events.

The strength changes found in our study support those reported by other studies (Healy 1958, Damiano et al. 1995, MacPhail and Kramer 1995, O'Connell and Barnhart 1995, Tweedy 1997, Damiano and Abel 1998, Darrah et al. 1999, Dodd et al. 2002), including those reported in the only previous randomized clinical trial (McCubbin and Shasby 1985). The results of McCubbin and Shasby's (1985) study showed that a six-week isokinetic strengthening programme increased the strength of the triceps muscle of the arm in a sample of 10 young people aged between 10 and 20 years with CP. Our findings, together with those of previous studies, provide evidence to counter the belief still held by some clinicians that people with CP who have impaired selective movement control are unable to participate successfully in progressive resistance exercise programmes.

Consistent with the principle of specificity of training, the strength changes found in this study more closely reflected the way in which the exercises were performed. For example, isotonic strength, as represented by the amount of weight carried in the backpack, increased significantly ($p<0.01$) in the experimental group over the six weeks of the trial. In addition, isometric strength changes from our programme were found when ankle plantarflexor and knee extensor strength were summed, rather than detected in isolated muscle groups. The majority of children with spastic diplegia walk in patterns characterized by excessive knee and hip flexion in the stance phase of gait (Rodda and Graham 2001). In crouch gait, the vertical component of the ground reaction force is directed behind the

Table IV: Changes in activity assessed at baseline, 6 weeks, and 18 weeks

	Baseline		*6wk*		*18wk*	
	Exp. *n=11*	*Control* *n=10*	*Exp.* *n=11*	*Control* *n=10*	*Exp.* *n=11*	*Control* *n=9*
GMFM D, %	75.2 (14.4)	74.6 (20.9)	80.1 (13.7)	80.5 (12.6)	80.4 (13.2)	80.7 (15.0)
GMFM E, %	52.8 (31.3)	68.3 (30.1)	57.2 (29.7)	69.5 (27.9)	58.2 (31.3)	67.8 (28.6)
GMFM total, %	64.2 (27.8)	71.7 (24.9)	69.0 (21.4)	75.3 (21.3)	69.6 (21.4)	74.3 (21.4)
Walking speed, m/min	47.4 (23.3)	49.5 (24.5)	48.0 (21.2)	50.5 (20.8)	48.6 (23.3)	51.4 (16.5)
Timed stair, s	27.4 (34.7)	22.4 (20.5)	21.1 (25.6)	21.7 (21.5)	25.1 (33.6)	19.7 (15.2)

Values are Mean (SD). GMFM, Gross Motor Function Measure (Russell et al. 1993). D: Standing dimension. E: Walking, running and jumping dimension. Total, goal total score for Dimensions D and E of GMFM. Exp, experimental.

knee, the knees and hips do not fully extend, and the ankles may be in dorsiflexion. Adequate knee extension is dependant on the ankle plantarflexor-knee extensor couple (Rodda and Graham 2001). Hence the rationale and relevance for combining the ankle plantarflexor and knee extensor strength data.

Trends also suggest that strength training had positive effects on activities in walking, running, and jumping as well as stair climbing. Power analyses showed that if the effect were maintained and the sample size were increased to $n=26$, these trends would have reached statistical significance. Previous studies reported significant changes in functional activities with sample sizes of less than or equal to $n=11$ (O'Connell and Barnhart 1995, Damiano and Abel 1998). One explanation for the lower effect sizes found in this study is that the intensity of training may have been less than optimal because of the minimal therapist supervision in this home-based programme. An alternative explanation is that the research design (a randomized clinical trial) controlled for any confounding series effects. Previous studies incorporating a single group pre-post test design may have overestimated the effect of strength training on increasing functional activities in children with CP.

Not only were there more immediate effects of strength training, but the benefits of training were maintained for a period of three months after the six week programme had finished. This is a very encouraging finding. The mechanisms for these longer-term effects are not known. As none of the young people continued specific training it should be considered whether natural maturation could have accounted for the increased strength over time. However, the study design (randomized clinical trial) controlled for this factor by showing that the follow-up benefits were significantly better in the experimental group than the control group. It is possible that participation in a strength-training programme might lead to more permanent changes in everyday physical activities that in turn might lead to maintenance of the strength and activity benefits. A number of anecdotal comments from the participants and their parents supported this idea. One parent reported that her 14-year-old daughter started walking to and from school for the first time. Another participant reported that after completing the strengthening programme he could more easily walk up and down the steps at his school. These personal achievements suggest that relatively short strength-training programmes can lead to meaningful changes in the lives of young people with CP and their families.

Optimal management of young people with CP may include strengthening in combination with other orthopaedic strategies. All of the young people in this study had been managed actively and at the time of the study had no major fixed musculoskeletal deformities, leaving weakness as the primary residual determinant of functional impairment. Functional limitations in people with CP can be due to a range of factors such as spasticity and fixed musculoskeletal deformities. In this context, strength training might be viewed as part of a comprehensive management plan rather than as an isolated intervention.

Conclusion

Results of this randomized clinical trial support the view that home-based strength-training programmes can improve muscle strength in young people with spastic diplegic CP. Trends also suggest that strength training may have beneficial effects on activities in walking, running, and jumping, as well as stair climbing. Until recently the importance of muscle weakness in CP has received little attention. Optimal management may require strengthening in combination with more traditional strategies such as the reduction of spasticity, surgical correction of deformities, and orthotic management.

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