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Title:

The effects of progressive resistance training on daily physical activity in young people with cerebral palsy: a randomised controlled trial

Abstract

Purpose: To examine if individualised resistance training increases the daily physical activity of adolescents and young adults with bilateral spastic cerebral palsy (CP).

Method: Young people with bilateral spastic CP were randomly assigned to intervention or to usual care. The intervention group completed an individualised lower limb progressive resistance training programme twice a week for 12 weeks in community gymnasiums. The primary outcome was daily physical activity (number of steps, and time sitting and lying). Secondary outcomes included muscle strength measured with a one-repetition maximum (1RM) leg press and reverse leg press. Outcomes were measured at baseline, 12 weeks, and 24 weeks.

Results: From the 36 participants with complete data at 12 weeks there were no between-group differences for any measure of daily physical activity. There was a likely increase in leg press strength in favour of the intervention group (mean difference 11.8 kg; 95%CI: -1.4 to 25.0). No significant adverse events occurred during training.

Conclusions: A short-term resistance training programme that may increase leg muscle strength was not effective in increasing daily physical activity. Other strategies are needed to address the low daily physical activity levels of young people with bilateral spastic CP.

Introduction

Daily physical activity levels of people with cerebral palsy (CP) are low [1,2]. Like the rest of the population, low levels of physical activity increases the risk of people with CP developing secondary health problems such as cardiovascular diseases, obesity or osteoporosis [3]. Low physical activity can also exacerbate some of the problems commonly associated with CP such as muscle weakness, stiffness and decreased mobility [4,5]. Therefore, strategies and interventions that can increase daily physical activity levels in people with CP are important.

Physical activity has been defined as “any bodily movement produced by contraction of skeletal muscles that results in energy expenditure” [6]. When investigating the relationship between physical activity and health it is necessary to measure daily physical activity [7]. Accelerometers have been widely accepted as useful objective measurement tools of daily physical activity [8]. Daily physical activity outcomes measured using accelerometer-based activity monitors include steps per day and time spent standing. Outcomes derived from activity monitors such as time sitting/lying are representative of a lack of daily physical activity or sedentary behaviours.

Evidence from a systematic review we conducted suggested that participating in exercise programmes such as aerobic training can increase the daily physical activity of people with CP [9,10]. Currently, however, there are no studies measuring the effects of resistance training on the daily physical activity of people with CP using objective outcome measures. Despite that, there is a rationale that exercise that focuses on strengthening weakened muscles to make movement easier might potentially be a useful intervention for increasing the low physical activity levels of young people with CP. For example, lower limb flexor muscle strength has been

found to be an important predictor of daily physical activity in young people with bilateral spastic CP [11].

Considering the above, the aim of this study was to determine whether a 12-week progressive resistance training programme for the lower limbs increased the daily physical activity levels of adolescents and young adults with CP who had difficulty walking.

Method

Study design

The research design was a single-blind randomised controlled trial of progressive resistance training compared with usual care. The results of the trial on outcomes of walking performance, functional mobility, gait characteristics and muscle performance outcomes have been reported elsewhere [12]. The current paper reports the results of the intervention of progressive resistance training on daily physical activity.

Sampling and recruitment

Participants had to have bilateral spastic CP, be 14-22 years old and be classified as Gross Motor Function Classification System (GMFCS) level II or III. Volunteers were excluded if they had undergone single or multi-level orthopaedic surgery within the previous 2 years, if they had participated in progressive resistance training within 6 months prior to the start of the trial and if they had contractures of more than 20° at the hip and knee [13]. The trial was registered (ACTRN12607000553471), was approved by the relevant university and health services ethics committees and all participants provided written informed consent. Participants were randomly allocated

to the intervention or to the control group receiving usual care using a concealed method.

Intervention

Participants allocated to the intervention group completed a 12-week progressive resistance training programme with weight machines in community gymnasiums under the supervision of a physiotherapist, either individually or in pairs. Participants completed 2 to 3 sets of 10 to 12 repetitions of each prescribed exercise twice weekly [14]. The load was the weight that participants could lift for 10 to 12 repetitions before they reached muscle fatigue [14]. When participants could complete 3 sets of 12 repetitions of an exercise without reaching muscle fatigue, the amount of weight lifted was increased at the next session. At the end of each training session, participants and their physiotherapist filled in a log book describing details of each exercise they had completed, as well as any adverse events such as pain due to training. Participants also completed a rating of perceived exertion at the end of each session to ensure they were training at sufficient intensity [15].

The exercises prescribed to each participant were determined in a gait analysis session at a gait laboratory. To identify muscles that could be contributing to impaired walking, kinetic data from the 3-D gait analysis were examined by a panel of three clinicians and researchers who were experienced in interpreting gait data. This assessment was supplemented by observation of a video of the participant walking plus a clinical examination report, including a lower limb joint range of motion and a muscle strength clinical assessment. Based on all these assessments, the panel made a decision about which muscle(s) should be targeted for strengthening to improve walking. A median of 5 (range 4-6) exercises were prescribed for each

participant and a median of 4 (range 2-5) muscle groups were targeted. A description of typical exercises prescribed is provided in Table 1. Intervention group participants were advised to stop training after the 12-week training period but to continue with their usual activities until the final testing session at 24 weeks.

Insert table 1 about here

Participants assigned to the control group continued their usual care during the 12-week intervention period. In that time they could continue with their usual recreation and physiotherapy provided these did not include progressive resistance training.

Outcome measures

Activity monitor (ActivPAL™) data were collected at baseline, immediately after the intervention (week 12), and again 12 weeks later (week 24). ActivPAL™ does not need individual calibration and uses an accelerometer to sense limb position and activity [16]. ActivPAL™ has demonstrated evidence of criterion validity in children, adolescents and young adults with cerebral palsy [17-19]. In our laboratory, the monitor predicted video observation measurements for physical activity outcomes ($R^2 \geq 0.96$) providing evidence of criterion validity in a group of 10 adolescents and young adults with bilateral spastic CP [19]. Retest reliability of the activity monitor was also tested in our laboratory on a group of 21 adolescents and young adults with bilateral spastic CP over 12 weeks and was found to be high for number of steps (*Intraclass Correlation Coefficient (ICC)* =0.87), and moderate for daily time spent in sitting and lying (*ICC*= 0.66) [19].

Participants had an activity monitor attached on their right thigh at a gait laboratory at all three assessments by research assistants blind to group allocation. Participants

were instructed to wear the activity monitor for 7 consecutive days at each data collection period. They were advised to keep the monitor on all the time except during bathing, and swimming and were asked to continue with their usual activities during the recording period. They were also given a daily logbook to record when the monitor was taken off. The primary outcome measures (daily physical activity) comprised number of steps taken, and time spent in sitting and lying (including sleeping).

Secondary outcome measures were one repetition maximum (1RM) of a leg press (combined hip extension, knee extension and ankle plantarflexion), and a reverse leg press (combined hip flexion, knee flexion and ankle dorsiflexion) as composite measures of lower limb strength. One repetition maximum can be measured with high levels of association ($r= 0.89$) and responsiveness in people with CP [20].

Data analysis

For the current study, based on an observed effect size of $d=1.05$ of daily physical activity measured as energy expenditure after an aerobic exercise programme in young people with CP [9], a significance level of 0.05, and a power of 0.80 [21], 15 participants would be required in each group. Effect size d is the difference between the experimental and control group post-intervention means divided by the pooled standard deviation.

Participant physical activity data were included for analysis if at least 2 full days (24 hours each day) of data were available. Periods as short as two days of monitoring have been used successfully to describe daily physical activity in people with CP [22,23]. Also, physical activity data collected for at least 2 full days with the ActivPAL™ monitor provided reliable measurements in groups of young people with

bilateral spastic CP [19].

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 12 weeks and 24 weeks. Normality of distribution of the data was tested for each group. If data did not fulfil the assumption of normality, these data were transformed with natural log transformation and analysis was performed with both raw and log transformed data. Spearman's rho (r_s) was used to explore the associations between physical activity outcomes (baseline to 12 week differences) and lower limb strength (baseline to 12 week differences) for the intervention group (n=15).

Results

Figure 1 summarises participant flow through the study and reasons for missing data at 12 week and 24 week assessments. Forty-nine participants (intervention group: 24, control group: 25) were randomised. One participant withdrew from the intervention group after allocation but before the start of the training because surgery was scheduled unexpectedly. Daily physical activity data were collected on 15 participants in the intervention group and 21 participants in the control group at 12 weeks, and on 13 participants in the intervention group and 20 participants in the control group at 24 weeks. Main reasons for missing data were failure of the monitor to collect data (n=3), loss of the monitor when returning by mail (n=3), water damage of the monitor (n=2), taking off the monitor due to itching (n=2) and participant withdrawal from the trial due to surgery (n=2). At 12 weeks, physical activity data were available for at least 5 full days for 31 participants and for at least 3 full days for 35 participants.

Insert figure 1 about here

At baseline the groups were relatively well-matched apart from weight where the control group was, on average, 9.9 kg (18%) heavier (Table 2). However, as weight was not found to be significantly associated with the daily physical activity of young people with bilateral cerebral palsy in a previous study [11], weight was not included as a covariate in the main analysis (Table 2). At baseline, on average, participants in the intervention group took 5,808 steps/day and spent 19.4 hours/day in sitting/lying, while participants of the control group took 4,589 steps/day and spent 20.1 hours sitting/lying (Table 3).

Insert table 2 about here

Initially, an intention to treat analysis was planned for the main analysis of the outcomes [24]. However, because more than 10% of the data were missing in the intervention group at both post-intervention and follow-up assessments and cases with complete physical activity data were not different from cases with missing data regarding baseline characteristics ($p \geq 0.3$, Table 2), analysis was carried out using complete cases [25].

From baseline to 12 weeks, there was no difference between the intervention and control groups for any measure of daily physical activity or 1 RM leg press and reverse leg press strength (Table 3). However, there was an observed increase in 1 RM leg press strength in the intervention group compared to the control group (11.8 kg; 95%CI: -1.4 to 25.0) (Table 3). Data analysis for number of steps with log transformed data also did not find any difference between groups ($p= 0.20$). A per protocol sensitivity analysis was performed excluding two participants from the analysis who completed less than 80% of the 24 scheduled sessions during the 12-

week intervention period. These results also did not show any between group differences for any of the daily physical activity measures ($p \geq 0.23$). No significant associations were observed between changes in physical activity and changes in lower limb muscle strength for the intervention group (r_s ranged in magnitude from 0.04 to 0.36).

Insert table 3 about here

At 24 week follow-up, there were no significant differences between the intervention and control groups for measures of daily physical activity or for 1 RM leg press and reverse leg press (Table 4).

Insert table 4 about here

There were no serious adverse events during the resistance training programme apart from minor musculoskeletal aches. No sessions were missed due to injury related to the training.

Discussion

The results of this trial suggest that participating in a 12-week progressive resistance training programme held in a community gymnasium might increase lower limb muscle strength, but does not increase the daily physical activity of adolescents and young adults with bilateral spastic CP and mild to moderate walking disabilities.

The results of the current study appear inconsistent with qualitative and subjective reports of improved activity after progressive resistance training. Improvements attaining statistical significance at 5% in self-reported functional mobility were reported in the young people with bilateral CP after the same 12-week resistance training programme (Functional Assessment Questionnaire mean difference: 0.8 units

(95%CI 0.1-1.6); Functional Mobility Scale at 5 m mean difference: 0.6 units (95%CI 0.1-1.1) [12]. Also, increases in walking distance and the ability to perform physical activities such as jumping up or doing squats after progressive resistance training have been reported by people with CP in previous qualitative studies [26,27]. Although participants have reported improved functional mobility and this might be reasonably expected to increase the related construct of daily physical activity, when measured objectively with an activity monitor these improvements were not observed. To explain this discrepancy, it is possible that participants believed their functional mobility and therefore perhaps their daily physical activity had improved because they expected that doing such a strenuous programme should improve this aspect of their performance. It is also possible that when participants of the qualitative studies reported increased physical activity they actually commented on improved functional ability/mobility and not on aspects of daily physical activity that were measured in the current study. For example, although their amount or intensity of daily physical activity had not changed, they may have been highlighting that they felt more confident to perform physical activities (e.g. "I could just walk easier, it was more flowing ... I think everything was easier") [27].

Significant increases in the daily physical activity of young people with CP have been reported in two previous quantitative studies that did not implement progressive resistance training as an intervention [9,28]. One of these studies reported there was a significant increase in daily energy expenditure in children with CP after a 9-month aerobics exercise programme (effect size $d=1.1$; 95%CI 0.12-1.99) [9,10]. A possible reason for finding a significant increase in daily expenditure after an aerobics exercise programme may be that the programme was three times as long as the programme investigated in the current study. Maybe a long term programme is needed to embed

changes in daily physical activity. Also, an aerobic intervention that involves more daily energy expenditure may be closer to the phenomenon being measured in daily physical activity so it is possible that such a programme could result in greater improvement in daily physical activity than resistance training.

Another quantitative study demonstrated significant increases in weekly step counts (effect size $d=0.62$; 95%CI 0.0-1.25) and weekly minutes spent in moderate to vigorous physical activity (effect size $d=0.81$; 95%CI 0.17-1.45) after an on-line behavioural programme [28,10]. Daily physical activity is complex and related to psychological, social or environmental factors [29-31] as well as physical factors. It is, therefore, possible that a behavioural programme providing tailored activity feedback and specific activity goals [28] may be more effective in increasing daily physical activity in young people with CP than a resistance training programme. Addressing lower limb muscle strength alone, without addressing psychological, social or environmental factors, may not have been sufficient to bring about increases in daily physical activity.

Another explanation for our results may be the observed phenomenon of resting after a bout of exercise [32]. It is possible that participants in the intervention group may have felt they had worked hard during the 12-week training period and that once this was completed they deserved or needed a rest. Hence, the reduction observed in daily physical activity immediately after finishing the 12-week training programme.

In the current study, no significant difference between the two groups was found for 1 RM leg press at post-intervention, although there was a tendency for an increase in 1 RM leg press strength in the intervention group compared to the control group (mean difference: 11.8 kg; 95%CI: -1.4 to 25.1). The increase in 1RM leg press in

the intervention group was 20% larger than in the control group. A significant difference in leg press strength was found in favour of the intervention group at post-intervention in the report of the main trial outcomes (mean difference: 14.8 kg; 95%CI: 4.3 to 25.3) [12], suggesting the current trial may have lacked power for muscle strength due to its smaller sample size.

A limitation of this study is that physical activity data were missing at 12 weeks and 24 weeks raising issues about the practicality of the activity monitor and methods used. However, the baseline characteristics of participants with missing data were not different to the baseline characteristics of participants with daily activity data.

Therefore, the missing data were unlikely to have biased the conclusion that there was no difference in daily physical activity between the groups after 12 weeks. Another limitation is that data were collected without taking into consideration whether the ActivPAL monitor was attached on the more or the less affected leg; there is now evidence that the ActivPAL monitor is less accurate when it is worn on the more affected leg [33]. Finally, the content and amount of other therapy provided to both groups during the trial was not documented. However, the fact that the control group did not demonstrate within-group changes in muscle strength (Table 3) suggests that, as instructed, they were not receiving muscle strengthening interventions that may have obscured any true differences between the groups.

In conclusion, although increased muscle strength in targeted muscles was observed in the intervention group, this clinical trial did not provide evidence that a progressive resistance training programme can increase daily physical activity in adolescents and young adults with bilateral spastic CP.

Ethical approval

This study was reviewed and approved by the relevant university and health services ethics committees (ref: 08-012 and 28006C)

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Declaration of interest

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