Title: A community-based strength training program increases muscle strength and physical activity in young people with Down syndrome: a randomized controlled trial

Authors

Nora Shields,[1,2] Nicholas F. Taylor,[1,3] Elin Wee,[1] Dennis Wollersheim,[4] Simone D. O'Shea,[5] Bo Fernhall[6]

Affiliations

[1]Department of Physiotherapy, La Trobe University, Melbourne, Victoria 3086, Australia; [2]Allied Health Research Team, Northern Health, 1231 Plenty Rd., Bundoora, VIC 3083, Australia; [3]Allied Health Research Office, Eastern Health, 5 Arnold St., Box Hill, VIC 3128, Australia; [4]Department of Public Health, La Trobe University, Melbourne, Victoria 3086, Australia; [5]School of Community Health, Charles Sturt University, Albury, NSW 2640, Australia; [6]College of Applied Health Sciences, University of Illinois at Chicago, 808 South Wood St, 169 CMET, Chicago, IL 60612, USA

Corresponding Author

Prof Nora Shields,

Department of Physiotherapy, Health Science 3,

Kingsbury Drive, Bundoora,

Victoria 3086, Australia

Phone : +61 3 9479 5852

Fax: +61 3 9479 5768

Email: n.shields@latrobe.edu.au

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ABSTRACT

This randomized controlled trial investigated the effects of a student-led progressive resistance training (PRT) program in adolescents and young adults with Down syndrome. Sixty-eight young people with Down syndrome (30 female, 38 male; mean age 17.9±2.6 years) and mild to moderate intellectual disability were randomly allocated to a PRT program (n=34) or a social group (n=34). Participants in the PRT group trained twice a week for 10 weeks at a community gymnasium with a physiotherapy student mentor using pin-loaded weight machines. Participants in the social group completed a 10-week program of social activities also with a student mentor once a week for 90 minutes. Work performance, muscle strength and physical activity levels were assessed at weeks 0, 11 and 24 by an assessor blind to group allocation. Data were analysed using ANCOVA with baseline measures as covariate. Participants attended 92% of their scheduled sessions. There was no difference between the groups on work task performance. The PRT group increased their upper and lower limb strength at week 11 compared to the control group, but only their lower limb muscle strength at week 24. There was a significant difference in physical activity levels in favour of the PRT group at week 24 but not at week 11. PRT using a student mentor model helps young people with Down syndrome become stronger and more physically active but its effect on work task performance is unclear.

1. INTRODUCTION

Muscle strength in the upper (Pitetti, Climstein, Mays, & Barrett, 1992) and lower limbs (Croce, Pitetti, Horvat, & Miller, 1996) is up to 50% less in people with Down syndrome compared to their peers without disability and also compared to their peers with an intellectual disability but without Down syndrome. Adequate muscle strength is important for young people with Down syndrome as they make the transition from adolescence to adulthood because their workplace activities typically emphasise physical rather than cognitive skills (Shields, Taylor, & Dodd, 2008). Muscle weakness can make the physical component of these work tasks difficult and can also impact their ability to perform everyday activities (Cowley et al., 2010). Improvement in muscle strength has been associated with positive changes in functional activities in adults with Down syndrome (Carmeli, Kessel, Coleman, & Ayalon, 2002) and in work-related skills in people with intellectual disability (Zetts, Horvat, & Langone, 1995). Therefore, adequate muscle strength and physical ability might be an important factor in participation in employment for this group of people.

People with Down syndrome can improve their muscle strength by performing progressive resistance training (PRT). PRT is regarded as the best way to improve muscle strength and involves training with sufficient intensity and progression of load (American College of Sports Medicine, 2009). A small number of studies have investigated the benefits of PRT for people with Down syndrome including three randomised controlled studies (Cowley et al., 2011; Davis & Sinning, 1987; Shields & Taylor, 2010; Shields et al., 2008; Weber & French, 1988). These studies found improvements in muscle strength and reductions in the time taken to negotiate stairs (Cowley et al., 2011). However, none of these studies included a follow-up period or evaluated outcomes for work-task performance. If PRT had a positive impact on work-task performance, it may be important to the vocational development of young people with Down syndrome. In addition, if the benefits of PRT were sustained beyond the duration of the program, it would indicate that the outcomes were meaningful and had been incorporated into the daily lives of the participants.

Low levels of participation in exercise and physical activity have been consistently demonstrated in people with intellectual disability including adults with Down syndrome (Hilgenkamp, Reisa, van Wijckc, & Evenhuisa, 2012; Temple, Frey, & Stanish, 2006). World Health Organisation guidelines recommend adults, including those with Down syndrome, undertake 150 minutes of moderate intensity physical activity each week in at least 10 minute bouts (World Health Organisation, 2010). The reasons for the low levels of physical activity in people with Down syndrome are complex and multifactorial. Key barriers include the need for someone to exercise with (Heller, Hsieh, & Rimmer, 2002), a lack of motivation and a need for suitable programs (Menear, 2007). Having someone to exercise with provides the social interaction that makes exercise meaningful to people with Down syndrome (Mahy, Shields, Taylor, & Dodd, 2010; Menear, 2007). It also provides the supervision needed by some for motivational support and to help ensure exercise is performed at the correct intensity (Shields et al., 2008). PRT, a structured form of physical activity, can be performed with an exercise partner, which for young people with Down syndrome would provide the additional social support they need to exercise. A student mentor would make an ideal exercise partner for an adolescent or young adult with Down syndrome, as they are close in age so that the social relationship between the pair is meaningful. This model of exercise delivery has been found to be feasible and to result in improvements in muscle strength (Shields & Taylor, 2010). However, the effects of the model on changes in physical activity or changes in work-task performance have not yet been explored.

Youth with Down syndrome should be encouraged to participate in exercise as they transition to adulthood as they become even less active during this time (Shields, Dodd, & Abblitt, 2009). It is especially important for them to exercise because they are susceptible to chronic conditions such as diabetes (Hermon, Alberman, Beral, & Swerdlow, 2001; Hill et al., 2003), osteoporosis and obesity, and to premature and significant decline in function as they age (Rimmer, Heller, Wang, & Valerio, 2004). People with Down syndrome who are physically active live longer and healthier lives (Barnhart & Connolly, 2007) and require less health intervention. Therefore, it is not surprising that programs to increase physical activity among adults with intellectual disabilities have been recommended (Rubin, Rimmer, Chicoine, Braddock, & McGuire, 1998; World Health Organization, 2000). Given the dearth of literature to support the design and delivery of such programs, evidence is needed for exercise programs that can increase physical activity levels in people with intellectual disability, including Down syndrome.

Our primary aim was to investigate if a community-based PRT program designed to increase muscle strength improved work task performance in adolescents and young adults with Down syndrome. Our secondary aims were to investigate if (a) the program led to increased muscle strength and (b) if it led to an increase in the amount of physical activity.

2. METHODS

2.1 Research design

We conducted a randomized controlled trial that investigated the effects of a 10-week student-led community-based PRT program on work task performance, muscle strength and physical activity in young people with Down syndrome compared with an attention controlled social program. The research protocol for this randomized controlled trial has been published (Shields & Taylor, 2010) and includes a detailed description of the methods used. There were no major variations made to this protocol during the trial. Two minor variations, outlined below, were made to the analysis of the data collected. The trial received ethics approval from the University Human Ethics Committee and from the State Department of Education and Early Childhood Development. The trial was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12609000938202).

Participants were randomly allocated to either the intervention (PRT program) or the control group (social program) using a concealed allocation, block randomisation method (Altman & Bland, 1999). Participants were considered in blocks of 4, 6 and 8. The order of the blocks was generated from a web-based program (www.randomization.com) and assignments sealed in sequentially numbered opaque envelopes. Participants were assigned to a group by opening the next envelope in the sequence, once the recruiter had determined they were eligible, informed consent had been obtained, and baseline testing had been completed. A member of the research team not involved in recruitment, assessment or training was responsible for preparing assignments and opening the envelopes for group allocation.

2.2 Participants

Participants were included if they were adolescents or young adults with Down syndrome aged 14 to 22 years, had mild to moderate intellectual disability based on parental report, were able to follow simple verbal instructions in English and were fit and well enough to participate in a high intensity PRT program. Participants' readiness to participate in a PRT program was ascertained by asking parents to complete the 7-item Physical Activity Readiness Questionnaire on behalf of their child (Canadian Society for Exercise Physiology, 2002). If indicated by the questionnaire, they were asked to obtain medical clearance before taking part in the program.

Participants were excluded from the trial if they had taken part in a PRT program in the 3 months prior the trial, had a concurrent medical condition, such as chronic juvenile arthritis, autism, unrepaired congenital heart defect or Eisenmenger’s complex in addition to a diagnosis of Down syndrome, or if they had a history of violent outbursts, absconding, aggressive behaviour or antisocial behaviour.

Participants were recruited through local disability community groups and through specialist schools. Written informed consent was obtained from the next of kin (parent) of adolescents with Down syndrome. The adolescents with Down syndrome were invited to provide their own written assent to participate in the study. For young adults with Down syndrome aged 18 to 22 years, competence to give consent was determined in conjunction with their next of kin. Where a young adult usually provided their own consent, they provided their own informed consent to take part in this trial. Where a young adult was determined by their next of kin to not be cognitively able to provide their own consent, informed consent was sought from the next of kin. In this case, the young adult was also invited to provide their own written assent.

2.3 Intervention group

Participants allocated to the intervention group completed a 10-week, twice a week student-led PRT program at their local community gym. Exercising at a gym is a socially acceptable activity for young people and can be done in an integrated community setting, making it a reasonable recreation option for those with Down syndrome. PRT performed in a gym setting is an appropriate form of exercise for people with Down syndrome as the repetitive skills required can be easily mastered. Both the participant with Down syndrome and their student mentor completed the training program as our previous study found people with Down syndrome were more likely to exercise when a support person joined in the activity with them (Mahy et al., 2010). The training program conformed to the principles of PRT as outlined by the American College of Sports Medicine (American College of Sports Medicine, 2009). The program comprised 7 exercises, 3 for the upper body (for example, lat pull down, seated chest press, seated row), 3 for the anti-gravity support muscles of the lower body (for example seated leg press, knee extension, seated calf raise) and 1 trunk exercise. Participants completed 3 sets of 12 repetitions of each exercise, or until muscle fatigue. This intensity of training is approximately equal to training at an intensity of 60-80% of one-repetition maximum. The weight lifted during an exercise was progressed when the participant could perform 3 sets of 12 repetitions of that exercise. Two-minute rest periods were given between each exercise set. The training program took approximately 45-60 minutes to complete.

All exercises were performed on pin-loaded weight machines. The student mentor completed a log book to record the details of each training session, including exercises completed, weight lifted, number of repetitions, and number of sets. Details of any injuries or problems (adverse events) and any missed sessions were also recorded in the log book. A member of the research team contacted each student mentor every 2 weeks to ensure training was consistent and proceeding as planned, and to help address any issues.

The PRT program was led by student mentors recruited from the undergraduate physiotherapy student body at the university. Students were invited to become mentors through advertising flyers and short information sessions. Students were matched with a participant with Down syndrome based on where they lived and in some instances based on gender in the few cases where families indicated a preference. To ensure consistency, student mentors received training prior to their participation which included background information on Down syndrome, suggested strategies for working with young people with Down syndrome including motivational, problem solving and teaching strategies, and the content of both the PRT and the social programs, including program progression, and practical instruction in how to use gym equipment.

2.4 Control group

To control for the attention received by the participants in the intervention group, participants in the control group completed a social program with a student mentor once a week for 10 weeks. Each session of the social program ran for 90 minutes, so that the total time spent with student mentors was approximately equal in both groups. The social program comprised arts and recreational activities, such as watching movies, crafts, baking, music and social activities such as going for coffee. These sessions took place either in the participant's home or at a community venue such as a library, cinema or shopping centre.

2.5 Outcome measures

All outcome measures were assessed at baseline (Week 0), immediately post intervention (Week 11) and 3-months post-intervention (Week 24). All assessments were completed by an assessor blind to group allocation who had no involvement in the recruitment, randomization, or training of the participants.

Our primary outcome measure was work task performance, assessed using a weighted box stacking test and a weighted pail carry test. The weighted box stacking test measured the numbers of 10 kg boxes the participants could lift in one minute from the floor to a table 75 cm off the ground. The weighted pail carry measured the total distance the participants could walk in 30 seconds while carrying two 20 litre buckets each weighing 10 kg around an oblong 10 m course. These types of measures are recommended by the American College of Sports Medicine for simulated work testing (American College of Sports Medicine, 2013) and have demonstrated changes in people with intellectual disability after a strength training intervention (Smail & Horvat, 2006; Zetts et al., 1995).

Our secondary outcome measures were muscle strength and physical activity levels. Muscle strength was assessed using one-repetition maximum (1RM) force generation tests. These tests established the amount of weight each participant could lift in a single seated chest press and seated leg press respectively. Single 1RM chest press and leg press tests have high levels of retest reliability ($r>0.89$) and demonstrated no systematic change when measured over 3 weeks in adults with neurological impairment (Taylor, Dodd, & Larkin, 2004). These tests were used as a representative measure of upper and lower limb strength, respectively as they involve the major muscle groups exercising over multiple joints.

Physical activity levels were assessed with an RT3 activity monitor (Stayhealthy, Inc., Monrovia, CA), lightweight accelerometer worn on the participant’s waistband. Physical activity was measured as the average vector magnitude activity count per minute across the minutes the monitor was worn. Participants were asked to wear the activity monitor for 8 consecutive days (1 day familiarisation, 7 days data collection) during all waking hours. Participants were considered compliant with wearing the activity monitor if they wore it for at least 4 days including at least one weekend day. A day was considered valid when the participants wore the monitor for at least 10 hours. Non-wear time was classified as 60 minutes or more of continuous vector magnitude activity counts of 10 or less per minute with an allowance for 1-2 minutes of counts between 0 and 100. Accelerometers were fitted at each assessment and returned to the researchers by post. Parents also completed a short logbook to document the activities performed while the participant wore the accelerometer. The RT3 has demonstrated reliability (Powell & Rowlands, 2004) and its output is strongly correlated with oxygen consumption (SVO_2) (Rowlands, Thomas, Eston, & Topping, 2004). RT3 monitors have previously been used to measure physical activity in adolescents with Down syndrome (Shields et al., 2009).

2.6 Data analysis

We adopted a 25% increase in work task performance (weighted box stacking test), equivalent to an increase of 1.27 weighted boxes stacked per minute, as the minimum clinically important difference based on a previous trial by Zetts et al (1995). The standard deviation for this outcome measure in a similar population was 1.75 boxes per minute (Zetts et al., 1995). From this, we calculated that for power of 0.80 with a two-tailed significance level of 0.05, we required 32 participants per group to complete the study.

Intention to treat analysis was performed. Where data were missing, the carry forward technique was used, which assumes missing data remain constant (Hollis & Campbell, 1999). Outcomes were analysed using ANCOVA with the baseline measure of each variable used as the covariate (Vickers, 2005; Vickers & Altman, 2001) to determine if the intervention group improved more than the control group at the end of training (at Week 11) and 3-months after training (at Week 24). Preliminary checks were conducted to ensure there was no violation of the assumptions of linearity and homogeneity of regression slopes (Pallant, 2013). The mean difference within each group and between groups and the associated 95% confidence intervals were calculated.

Two minor variations were made to the data analysis described in the trial protocol. The first was that standardised mean differences (SMD) (otherwise known as effect sizes) were calculated. SMDs are useful to get an indication of the strength of a finding that is independent of sample size and the units of measurement (O'Halloran, 2013). SMDs were calculated by subtracting the post-intervention mean of the control group from the post-intervention mean of the intervention group and dividing by the pooled standard deviation using web-based software. The SMDs were interpreted as follows: 0.2 was considered small, 0.5 moderate, and 0.8 large (Cohen, 1977). The second variation was to help interpret the findings of the trial. We explored the association in the intervention group between changes at week 11 and week 24 in upper and lower limb muscle strength and the changes in work performance tasks and physical activity during the same period using Pearson's *r* correlation coefficient.

3. RESULTS

3.1 Flow of the participants through the trial

Sixty-eight young people (30 female, 38 male) with Down syndrome participated in the trial (Figure 1, Table 1). The participants had a mean age of 17.9 years (SD 2.6 years) and a mean body mass index of 27.2 kg/m^2 (SD 4.7, range 19.6 to 42.0). Thirty-four participants were randomly allocated to the intervention group and 34 participants to the control group. There were no apparent differences at baseline between the groups for most demographic factors and outcome measures (Tables 1 and 2). However, the proportion of young people with moderate intellectual disability appeared to be greater in the control group compared with the intervention group. The baseline distance for the pail carry test also appeared to be further in the intervention group compared with the control group.

Insert Figure 1, Table 1 and Table 2 here

3.2 Compliance with the trial method

Participants attended 92% (623/680) of the scheduled PRT sessions. No serious adverse events were recorded. Missed sessions were due to illness or vacation time. None of the sessions were missed due to soreness, injury or illness as a result of the training program. Twenty-two participants complained of muscle soreness during training and all recovered spontaneously without causing any sessions to be missed. The reported symptoms were mild and were to be expected in a group of novice trainees completing moderate to high intensity training. At the end of the training program, the intervention group had progressed the resistance for each exercise by an average of 89% (range 60-130%) of the initial training resistance.

Participants attended 98% (322/330) of the scheduled social group sessions. One participant who was allocated to the control group dropped out of the study after randomisation because they did not wish to participate in the social program (Figure 1) but this participant was included in the intention to treat analysis via the carry-forward approach (Figure 1). The social group sessions took place either in the participant's home (38%) or at a community venue (62%).

There was moderate compliance with wearing the RT3 physical activity monitors. Physical activity data were collected for 44 of the 68 participants. The reasons why physical activity data were not collected are shown in Table 3.

Insert Table 3 here

3.3 Effect of the intervention

There was no difference between the groups for either work task performance measure (box stacking and weighted pail carry) at weeks 11 or 24, although the difference between the groups for the box stacking test at the week 11 retest approached significance in favour of the PRT group (mean difference (MD) 1.0 box, 95% confidence interval (CI) -0.1 to 2.2, standardised mean difference (SMD) 0.5, p=0.07).The intervention group increased their upper limb strength at week 11 (MD 7 kg, 95% CI 3 to 11; SMD 0.8) but not at week 24 (MD 3 kg, 95% CI -3 to 8; SMD 0.5) compared to the control group. The intervention group also increased their lower limb muscle strength at week 11 (MD 25 kg, 95% CI 8 to 42; SMD 0.7) and at week 24 (MD 23 kg, 95%CI 2 to 43; SMD 0.6) compared to the control group. This represented a 21% increase in upper limb and a 30% increase lower limb baseline strength in the intervention group at week 11 compared to the control group. There was no difference in physical activity levels between the groups at week 11, but there was a significant difference between groups at week 24 in favour of the intervention group (MD 58 activity counts/min, 95%CI 5 to 112; SMD 0.8). The difference between the groups at week 24 appeared to be because the intervention group maintained their usual level of physical activity while there was a decrease in physical activity among the control group (Table 2).

There was a significant negative correlation at week 11 between the change in upper limb muscle strength and the change in physical activity (r=-0.46, p=0.03) suggesting participants who had greater positive changes in their upper limb muscle strength did less physical activity (Table 4). At week 24 there was a significant positive correlation between changes in upper (r=0.40, p=0.02) and lower limb (r=0.37, p=0.03) strength and performance of the box stacking test. There was also a significant positive correlation between changes in upper limb strength and performance of the weighted pail carry (r=0.62, p<0.01). This suggests that increases in muscle strength were associated with positive changes in work task performance.

Insert Table 4 here

4. DISCUSSION

The novel findings from our study are: (1) PRT using a student mentor model was effective and safe at making adolescents and young adults with Down syndrome stronger, (2) PRT may not have had an effect on the performance of work tasks, (3) the increase in lower limb strength achieved after PRT was maintained at 6 months, and (4) those who participated in PRT maintained their physical activity levels at 6-months compared to a corresponding decrease in the control group.

Our results concur with previously published randomized controlled trials investigating the effects of PRT for adolescents (Shields & Taylor, 2010) and adults with Down syndrome (Cowley et al., 2011; Shields et al., 2008). These studies reported changes in lower limb strength (Cowley et al., 2011; Shields & Taylor, 2010) and upper limb strength (Shields et al., 2008) compared to a non-intervention control group after PRT. Each of these studies used a similar intervention: PRT performed twice a week for 10 weeks according to guidelines published by the American College of Sports Medicine (2009). The magnitude of the changes in muscle strength in our study of 21 to 30% are also similar to previous studies. Cowley et al (2011) reported increases in isokinetic knee extensor and flexor strength of 19% and 27% respectively, Shields et al (2010) reported increases of 19% in lower limb muscle strength and Shields et al (2008) observed an increase of 25% in upper limb muscles. In addition, our study controlled for the attention of having a mentor train with the young person with Down syndrome, which increases confidence that the changes in muscle strength we found were due to PRT and not from having the attention of a trainer.

Our data also adds to the literature on the feasibility and safety of PRT in a community gymnasium for young people with Down syndrome using a student mentor model. Adherence to the program was excellent (92%), missed sessions were unrelated to the intervention, no serious adverse effects were reported and there were very few drop-outs (4%), one of which was prior to the intervention phase of the study. Data from the participant's exercise logbooks suggests the fidelity of the intervention was good; that is, the program was completed according to the guidelines of the American College of Sports Medicine. This reaffirms that PRT is a safe exercise choice for young people with Down syndrome, which can be effective in increasing muscle strength. Identifying appropriate exercise opportunities for young people with Down syndrome is important given they are at risk of chronic disease related to inactivity including diabetes and obesity. Indeed, the training program provided by our study is consistent with the World Health Organisation physical activity guidelines that recommend strengthening exercise for maintaining health and preventing disease.

The effect of PRT on the performance of work tasks is unclear. There were no differences between the groups for either of the two primary outcome measures. The increases in muscle strength of 21 to 30% from baseline may not have been large enough to improve the performance of the functional tasks of stacking boxes and carrying weighted pails. The specificity of training may also be relevant. The training comprised isotonic contractions of the upper limb, while the pail carry test requires an isometric contraction of the upper limbs. The pail carry test also tests mobility which was also not trained in the program. The box stacking test was more specific to the type of training the participants did, and the difference between the groups at week 11 for this test approached significance. In addition, at week 24, changes in upper and lower limb strength were positively associated with changes in performance of the box stacking test. These results may indicate that our sample size was not large enough to detect a true difference between the groups. Perhaps a longer duration of strength training is needed for an increase in muscle strength to carry over into an improvement in work task performance.

There was a significant difference in physical activity levels between the groups at week 24 in favour of the PRT group. This difference appears to be as the result of the intervention group maintaining their physical activity levels while there was a concurrent drop in the amount of activity performed by the control group. It is tempting to speculate that the intervention group was different to the control group because they had an increase in their lower limb muscle strength and so were able to do more activity in the time after the intervention. However, the associations between changes in muscle strength and changes in physical activity do not support this hypothesis (Table 4). It is interesting that the difference in physical activity levels between the groups did not happen immediately; there was a small decease in physical activity levels when participating in the program, followed by an increase in physical activity after participation ended. This might indicate that substitution of physical activity may have taken place, suggesting that the training program produced less physical activity during the training program but that the participants substituted more physical activity after PRT was completed. Another interpretation might be that participation in an exercise program meant the participants were more likely to continue with their usual levels of physical activity, that is creating a habit of being physically active may have helped adolescents and young adults with Down syndrome maintain their usual levels of activity as part of their routine.

Increases in lower limb strength were maintained at week 24. This is a significant finding because we would expect for the benefits of training to have dissipated after the training finished. A reason why this might have occurred is that the program encouraged the participants to maintain their usual levels of activity so that the participants did enough day to day functionally to maintain the improvement in their lower limb strength. An alternate explanation is that our participants were not given explicit instructions at the end of the intervention period about whether or not to continue PRT, nor did we document if participants had continued to train after the intervention period. Therefore, it is possible that some of the participants continued to train after the initial 10-week program and this is the reason why the increases in their lower limb strength were maintained at week 24.

Two features of our program are important for its generalizability and sustainability; it employed student mentors to deliver a major aspect of the program and it was community based. Having student mentors deliver the program tests the idea that a relatively low-skilled assistant can support physical activity behaviour change in young people with Down syndrome. The feasibility of this model indicates the potential for others, such as community based personnel, paid support workers, volunteers, friends or family members, to provide this part of the program with adequate and appropriate support. Our program was also successful in a ‘real-world’ community-based setting. A lack of appropriate programs can limit participation in physical activity for young people with disability particularly for group activities (Mahy et al., 2010; Menear, 2007). PRT requires access to a community gymnasium but does not require a special program or specialized supervision or equipment; with some initial support it may be possible for adolescents and young adults with Down syndrome to continue exercising on their own.

Strengths of our trial include its relatively large sample size compared to previous published randomised controlled trials in the area. Previous RCTs included 20-23 participants (Shields & Taylor, 2010; Shields et al., 2008). The key threats to bias were addressed through concealed random allocation, intention to treat, and low loss to follow up for the primary outcomes. Sixty-percent of studies investigating exercise interventions for people with disability are non-randomized controlled trials (Rimmer, Chen, McCubbin, Drum, & Peterson, 2010). Another strength was the relative homogeneity of the population (aged 14 to 22 years) and there was a good balance between female and males participants. Other trials have had a disproportionally high number of males in their sample, greater than the 10% difference between the naturally occurring numbers of males and females with Down syndrome.

The limitations of our study include that we investigated the effects of PRT on only a small number of outcomes. It is possible that PRT also has other health benefits including mental health or physiological health benefits that have not yet been described or that it can reduce the secondary conditions associated with Down syndrome (functional decline, diabetes, obesity), and participation in the community. Another limitation is that, despite random allocation, there appeared to be more participants with moderate level intellectual disability in the control group.

5. CONCLUSION

PRT is a safe and effective to increase muscle strength in adolescents and young adults with Down syndrome. The PRT conferred benefits in physical activity levels after the program stopped, but the effect of increases in muscle strength on work task performance were uncertain. Although there were no significant between group differences in work task performance participants who increased upper limb strength demonstrated greater improvements in the box stacking task.

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Table 1

Baseline characteristics of participants

Characteristic	Participants	
	Randomised (n = 68)	
	Int (n = 34)	Con (n = 34)
Participants		
Age *(yr)*, mean (SD)	17.7 (2.4)	18.2 (2.8)
Gender, n males (%)	19 (56)	19 (56)
Height (cm), mean (SD)	155 (8)	153 (10)
Weight (kg), mean (SD)	65 (9)	64 (14)
BMI	27.3 (3.8)	27.2 (5.6)
Level of perceived ID, n (%)		
Mild	19 (56)	15 (44)
Moderate	9 (26)	25 (74)
Vocational status, n (%)		
Mainstream school	3 (9)	3 (9)
Special school	23 (67)	18 (53)
TAFE	2 (6)	3 (9)
Working	3 (9)	1 (3)
Day program	3 (9)	9 (26)

Int = intervention group, Con = control group, ID = intellectual disability, BMI = body mass index, SD =standard deviation

Table 2

Mean (SD) score, mean (SD) difference within groups, and mean (95%CI) difference between groups for all outcomes for the intervention group (*n*=34) and the control group (*n*=34)

Outcome	Groups						Difference within groups				Difference between groups			
	Week 0		Week 11		Week 24		Week 11 minus Week 0		Week 24 minus Week 0		Week 11 minus Week 0†	Week 24 minus Week 0†	SMDs (95% CI)	
	Int	Con	Int	Con	Int	Con	Int	Con	Int	Con	Int -Con	Int -Con	Week 11	Week 24
Box stacking test (no of boxes)	11.9 (5.3)	10.3 (3.9)	14.0 (6.3)	11.3 (4.0)	14.5 (6.3)	12.2 (5.3)	2.0 (2.6)	0.9 (2.1)	2.5 (3.3)	1.9 (3.9)	1 (-0.1 to 2.2)	0.7 (-1.1 to 2.5)	0.5 (0.0 to 1.0)	0.4 (-0.1 to 0.9)
Weighted pail carry (m)	19.6 (7.7)	14.0 (8.1)	19.5 (7.2)	16.2 (7.8)	20.2 (9.4)	16.0 (8.7)	-0.1 (3.8)	2.2 (5.9)	0.6 (4.7)	2.0 (6.3)	-1 (-3.4 to 1.3)	-0.9 (-3.8 to 2.0)	0.4 (-0.1 to 1.0)	0.5 (0.0 to 0.9)
Chest press 1RM (kg)	35.9 (15.0)	30.0 (14.0)	43.6 (16.0)	32.0 (11.7)	42.7 (18.4)	35.0 (14.0)	7.7 (9.9)	2.0 (6.5)	6.8 (12.2)	5.0 (10.0)	6.9* (3.0 to 10.8)	2.7 (-2.7 to 8.1)	0.8 (0.3 to 1.3)	0.5 (0.0 to 1.0)
Leg press 1RM (kg)	92.0 (45.2)	79.4 (47.7)	128.1 (46.8)	92.4 (49.9)	133.3 (59.5)	101.3 (48.3)	36.1 (42.3)	12.9 (27.2)	41.3 (57.2)	21.8 (22.0)	26.3* (9.7 to 42.9)	22.6* (2.0 to 43.1)	0.7 (0.2 to 1.2)	0.6 (0.1 to 1.1)
Physical activity (counts/ min)$	336 (68)	300 (132)	326 (87)	304 (123)	337 (86)	265 (95)	-10 (67)	4 (85)	1 (76)	-35 (126)	-5 (-52 to 43)	58* (5 to 112)	0.2 (-0.4 to 0.8)	0.8 (0.1 to 1.4)

Int = intervention group, Con = control group, CI = confidence interval, 1RM = 1 repetition maximum, sec = seconds, SMD= standardised mean difference * p<.05

Note: †= derived from ANCOVA with dependent variable at baseline as covariate; $= no of participants in each group is 22 for this variable

Table 3

Reasons for missing physical activity data

Reason	Week 0	Week 11	Week 24
Refused to wear the activity monitor	12	16	13
Did not wear the activity monitor for at least 4 days (including 1 weekend day) for at least 10 hours each day	11	14	17
Data not retrievable from RT3	3		
Monitor not returned/ lost in mail		1	2
Participant unavailable for assessment		1	2
Total (*non-compliant participants*)	26	32	34

Table 4

Association between change in muscle strength, work performance and physical activity outcomes reported as Pearson's *r* (95% confidence intervals)

Outcome 1 (n=34)	Outcome 2 (n=34)	Association between outcomes (95% confidence interval)
Week 11	Changes in:	
Change in lower limb strength	Box Stacking test	0.28 (–0.06 to 0.57)
	Weighted pail carry	-0.01 (–0.35 to 0.33)
	Physical activity	–0.31 (–0.65 to 0.13)
Change in upper limb strength	Box Stacking test	0.11 (–0.24 to 0.43)
	Weighted pail carry	0.09 (–0.25 to 0.41)
	Physical activity	–0.46 (-0.74 to -0.05)*
Week 24	Changes in:	
Change in lower limb strength	Box Stacking test	0.37 (0.04 to 0.63)*
	Weighted pail carry	-0.02 (–0.35 to 0.32)
	Physical activity	–0.36 (–0.68 to 0.07)
Change in upper limb strength	Box Stacking test	0.40 (0.07 to 0.65)*
	Weighted pail carry	0.62 (0.36 to 0.79)*
	Physical activity	–0.19 (–0.56 to 0.25)

* $p < .05$

Figure 1

Design and flow of participants through the trial