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Can an online exercise prescription tool improve adherence to home exercise programmes in children with cerebral palsy and other neurodevelopmental disabilities? A randomised controlled trial

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ABSTRACT

Objective Determine the adherence to and effectiveness of an 8-week home exercise programme for children with disabilities delivered using Physitrack, an online exercise prescription tool, compared with traditional paper-based methods.

Design Single-blinded, parallel-groups, randomised controlled trial (RCT).

Setting Intervention took place in participants' homes in Western Australia.

Participants Children aged 6 to 17 years, with neurodevelopmental disabilities including cerebral palsy (CP), receiving community therapy services.

Intervention All participants completed an individualised home exercise programme, which was delivered to the intervention group using Physitrack and conventional paper-based methods for the control group.

Primary outcome measures Adherence to exercise programme, goal achievement and exercise performance.

Secondary outcome measures Enjoyment, confidence and usability of Physitrack.

Results Fifty-four participants with CP (n=37) or other neurodevelopmental disabilities (n=17) were recruited. Fifty-three were randomised after one early withdrawal. Forty-six completed the 8-week programme, with 24 in the intervention group and 22 in the control group. There was no difference between the two groups for percentage of exercises completed (intervention (n=22): 62.8% (SD 27.7), control (n=22): 55.8% (SD 19.4), between group mean difference −7.0% (95% CI: −21.6 to 7.5, p=0.34)). Both groups showed significant improvement in their self-rated performance of individualised goal activities, however there was no statistically significant difference between groups for goal achievement, quality of exercise performance, enjoyment, confidence or preferred method of delivery. There were no adverse events.

Conclusion Physitrack provides a therapist with a new means of providing an exercise programme with online tools such as exercise videos, but our preliminary findings indicate that it may be no better than a traditional paper-based method for improving exercise adherence or the other outcomes measured. Exercise programmes remain an intervention supported by evidence, but a larger RCT is required to fully evaluate online delivery methods.

Trial registration details Australian New Zealand Clinical Trials Registry; ACTRN12616000743460.

Strengths and limitations of this study

- This study was a randomised controlled trial comparing adherence to home exercise programmes among school-age children with disabilities across two delivery methods used by physiotherapists (online exercise prescription tool vs paper-based methods).
- Researcher and statistician blinding to group allocation was maintained.
- It was impossible to blind physiotherapists providing the intervention and participants to the intervention, however they were blinded to the aims of the study.
- Recruitment to the number specified in the power calculation (n=66) was not attained (n=54); similarly, the power calculation specified that 58 participants who completed the intervention (ie, after dropouts) was required, yet only 46 participants completed the study.
- Achievement of individualised goals was measured using the Canadian Occupational Performance Measure that has established reliability and validity evidence in past work, whereas the measure identified for evaluating the quality of exercise performance, Correctness of Exercise Performance scale, has not yet been formally evaluated.

INTRODUCTION

Home programmes are widely prescribed by therapists working with children with cerebral palsy (CP) and other neurodevelopmental disabilities as a means to increase the frequency of exercise practice between

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direct therapy sessions.[1–4] Therapy delivered via home programmes has been reported to account for 50% to 80% of the total dose of therapy received.[5] However, home programmes are not considered to be effective in isolation; they require a collaborative parent–therapist relationship to incorporate exercises into daily routines so the child may achieve mutually agreed goals.[3 6 7]

Goal-directed home programmes for children with CP encompass "therapeutic activities that the child performs with parental assistance in the home environment with the goal of achieving desired health outcomes".[8] Although there is evidence to support the effectiveness of home programmes for improving motor outcomes in children with disabilities,[3 9 10] clinical experience highlights that therapists and families find it challenging to achieve the level of adherence to the programme necessary for effectiveness.[4 6] Studies of adherence to home exercise programmes among children with CP tend to measure adherence via parent perceptions using self-report scales.[11–13] Where records of actual exercise completion have been used, small sample sizes (n=9 to n=10) and disparate reporting methods prevent knowledge transference for clinical practice.[14–16] Although adherence is recognised as a significant limitation to the effectiveness of home programmes, the extent of reduced adherence in children with neurodevelopmental disabilities is poorly understood.

Qualitative research has investigated the facilitators of adherence to home programmes provided to children using conventional paper-based methods.[4 6 7 17] A supportive therapist–parent relationship with open communication that values parents' input in planning the home programme has been identified as a key facilitator.[7 17] Similarly, a study of parents' perceptions about home exercise programmes highlighted the importance of a physiotherapist's teaching style and prescription method as facilitators of adherence to home programmes, in particular building parents' confidence, clear written instructions and the provision of regular monitoring and feedback.[6] These identified facilitators could be harnessed using new methods of programme delivery that encourage improved quality of exercise performance, clarity in understanding the exercise parameters and monitoring of progress.

Technological advances offer an alternative to paper-based home programmes in the form of online exercise prescription websites and appications. Mobile health (mHealth) applications are growing in both number and capability, and are considered an important delivery vehicle for health-related behavioural change.[18] There is early evidence that online therapy prescription may improve exercise programme adherence and confidence in adults with musculoskeletal conditions.[19] However, the effectiveness of online exercise prescription tools in children with disabilities has not been evaluated. The purpose of this study was to evaluate the effectiveness of an online exercise prescription tool with children aged 6 to 17 years with CP or other neurodevelopmental disabilities for improving their: adherence to physiotherapist prescribed exercise programmes, achievement of individualised goals and performance of prescribed exercises.

METHODS AND ANALYSIS

Our full trial protocol has been reported elsewhere.[20] The methods reported here follow the Consolidated Standards of Reporting Trials[21] and Template for Intervention Description and Replication[22] checklists.

Design

This single-blinded, 2-arm parallel, pragmatic randomised controlled trial (RCT) included an intervention group and control group with 1:1 allocation ratio, with participants in each group undergoing 8 weeks of an individualised, physiotherapist-prescribed home exercise programme. This RCT proceeded in accordance with the protocol registered on Australian New Zealand Clinical Trials Registry, except that we broadened our recruitment to multiple disability service providers in an effort to achieve our desired sample size.

Participants and recruitment

Participants in this study were children aged 6 to 17 years with CP or other neurodevelopmental disabilities living in Western Australia, recruited through community physiotherapy services. Community physiotherapists, registered with Australian Health Practitioner Regulation Agency, identified children who met the inclusion criteria: diagnosis of CP or other neurodevelopmental disability; family agreed to a home exercise programme; cognitively able to follow an exercise programme (with support from parents if needed); and children and parents/guardians are fluent in English. Exclusion criteria included: serial casting, orthopaedic surgery or other significant medical intervention scheduled during the intervention period; or receiving an intensive intervention service (ie, frequency greater than two times per week) during study period. Botulinum neurotoxin type A (BoNTA) injections were not an exclusion criterion because participation in an exercise programme following BoNTA is a recommended practice.[23]

Physiotherapist-identified families were sent information in the mail and were contacted by phone (RWJ) to be provided further explanation to assist them with making an informed choice about participation. Families chose to participate by signing the parent consent forms. Children aged 6 to 11 years were provided with a younger child information sheet and tacit agreement was obtained, and children aged 12 to 17 years were provided with older-age child information sheets and signed child assent forms. Consent and enrolment in the study was completed by the lead author (RWJ) with assistance of research associate (MB).

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Intervention

Prior to the beginning of the intervention—an 8-week home exercise programme—the participant's usual physiotherapist arranged two appointments at home or in the clinic with the participant. At the first appointment, families established up to three specific goals, using the Canadian Occupational Performance Measure (COPM),[24 25] during an informal interview with their physiotherapist. The goals were subsequently used to guide the individualised exercise programme and serve as the baseline assessment for goal achievement. The first appointment also included a trial of exercises planned for inclusion in the home exercise programme. At the second appointment physiotherapists reviewed the home exercises and delivered the programme based on the participant's group allocation. All participants were prescribed an 8-week, goal-directed, individualised home exercise programme provided by their regular treating physiotherapist, but were randomised to the delivery of this home exercise programme by either using Physitrack (intervention group), or using conventional paper-based means (eg, handwritten, typed or photo-programme) (control group).

Physitrack provides the same content as a conventional exercise programme via a website or application (Apple iOS or Android), alongside additional features, in particular videos of how to perform each exercise in the home programme. Videos are selected from an online exercise library which includes spoken audio instructions, or customised videos made by the physiotherapist within the application. Exercises are set to a weekly calendar, allowing each exercise to be assigned daily or on selected days of the week. Other features available in Physitrack that therapists and participants may choose to use (but were not specifically directed to use as part of the study), include: setting exercise reminder alerts, monitoring comfort/pain and participant–therapist messaging for feedback and guidance. For a visual overview of Physitrack see website address: physitrack.com and follow the link 'Try Demo'.

All participating physiotherapists received training on how to use Physitrack, were provided with documentation as a reference guide (see https://osf.io/7m3ta/), and were instructed to practice using the platform prior to data collection period. Follow-up support was made available from the research team or through the Physitrack office in Australia. Participants in both groups received follow-up clinical support from their physiotherapist (eg, home visits or phone calls), according to the therapist's usual practice and the participant's therapy plan. At the end of the intervention phase, children in the control group were offered the use of Physitrack by their treating physiotherapist (ie, equity of service).

Outcomes and procedures

Primary outcomes included: adherence to the prescribed exercise programme (via weekly logbook of exercise and repetition completion, and post-intervention participant responses to adherence questions using an 11-point Numeric Rating Scale (NRS),[26] achievement of individualised goals (rated using COPM[24 25] before and after intervention) and performance of prescribed exercises (researcher assessed following viewing videos of participants performing prescribed exercises at three different time points: pre-intervention, mid-intervention and immediately post-intervention and scored using Correctness of Exercise Performance (COEP)).[27] Secondary outcomes included: enjoyment of exercise (using Physical Activity Enjoyment Scale (PACES)[28] before and after the intervention), satisfaction with and confidence to complete programme (using 11-point NRS)[26] and process measures (using 11-point NRS).[26] In the intervention group only, we also measured the usability of Physitrack on a 5-point scale (using a modified System Usability Scale (SUS)).[29]

Sample size

Sample size was calculated using published data from a website-delivered intervention that measured adherence.[30] To detect a difference in adherence of 85% in the intervention group and 51% in the control group, with at least 80% power and significance level of 0.05, we required 29 children per group (58 total), using a two-tailed test. To allow for 15% attrition, we aimed to recruit 33 participants per group (66 in total).

Randomisation and blinding

Participants were stratified by their level of functional mobility (as indicated by a rating of their mobility over a distance of 50 m using the Functional Mobility Scale[31] (1=non-ambulant requiring wheelchair; 2 to 6=ambulant)) and by age (less than 12 years, or 12 years and older) for random allocation to one of two groups using a computerised random number generator.

Principal researchers were blinded to group allocation. Third-party assignment was used to conceal the participant allocation from the principal researchers. AMB implemented the randomisation process before contacting each treating physiotherapist directly by email to notify of group allocation, thereby maintaining blinding of researchers for the study duration. During data analysis, the principal researchers and biostatistician remained blinded to group allocation, with nominal group names assigned by AMB. It was impossible to blind the physiotherapists implementing the intervention, or the participants, to group allocation. However, physiotherapists and participants were blinded to the primary aims of the study until study completion.

Data analysis

Adherence data (variables: number of exercises, and number of repetitions completed) were calculated as a proportion of the prescribed programme. We used mixed effects models to assess weekly adherence that accounted for correlations among repeated measures with time as a continuous covariate, and allowing for missing observations for the three participants who provided incomplete

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data (4, 5 and 6 weeks of logbook adherence data, respectively). The COPM performance and satisfaction scores, and mean PACES score, were calculated for each participant and the difference between pre-test and post-test scores within each group were analysed using a paired t-test. Between group differences were compared using linear regression adjusting for baseline score. Clinically meaningful change in COPM scores[24] was assessed by calculating the proportion in each group who changed by a score of 2, and then analysed using the χ^2 test. COEP is measured on an ordinal scale, hence Wilcoxon signed-rank test was used to determine any changes from baseline to midway to post intervention and Wilcoxon rank-sum test to determine differences between groups at each time point. Statistical significance was set as $p<0.05$. All statistical analyses were performed using Stata V.15.1. Further exploratory analysis was implemented to supplement primary findings, including comparing the impact of adherence on self-reported activity performance and satisfaction.

Patient and public involvement statement

This study did not follow a specific consumer involvement framework. However, the study questions were informed by informal feedback from parents of children with disabilities regarding the difficulties of achieving adherence to exercise programmes over years of clinical experience. The outcomes of this study included seeking comments from participating families on their experience that has informed future research directions in the field of application-based exercise prescription.

Deviations from protocol

In the course of implementing the study we made several decisions to deviate from the published protocol.[20] First, we decided to rely on the per protocol analysis because we did not have sufficient sample size to implement intention-to-treat methods for such multiple imputations; furthermore, for five of the eight participants who dropped out, we did not have any adherence logbook data results to draw on. We used an intention-to-treat analysis methods for the exploratory analysis of change in adherence across the 8-week intervention period, where we could use adherence logbook data from three participants with incomplete data sets. Second, we did not conduct the extra adherence statistical analysis, using Poisson regression, of the logbook adherence data that was proposed because the linear regression initiated as our first analysis accurately reflected the data.

Third, our protocol specified that we would report on adherence using three methods: the number of exercise days completed, the number of exercises performed and the number of repetitions completed.[20] It was decided to report on adherence using the latter two methods only, because reporting on the number of exercise days completed may be misleading for this study. In this study the home exercise programmes were individualised in both the number of exercises performed per exercise day, and the number of exercise days per week. Furthermore, because we did not seek to take any steps to alter programmes from normal clinical practice, for some participants there were variation in the number of exercises performed by one participant on a day-to-day basis; for example, some participants could have a stretching activity performed everyday as well as strengthening activities on 3 days per week. Given this broad variety in home programme prescription, reporting on the number of exercises days was less specific than the other methods of reporting on adherence adopted, and potentially misleading, so it was not used.

RESULTS

Recruitment

A total of 26 physiotherapists participated in the study; 18 from Ability Centre and 8 from other service providers in Western Australia. Fifty-four participants (37 with CP, 17 with other neurodevelopmental disabilities) consented to participate in the study between August 2016 and February 2018. Forty-six participants (32 with CP, 14 with other neurodevelopmental disabilities) completed the 8-week intervention: 24 in the intervention group and 22 in the control group, with post-test data collected between October 2016 and June 2018 (see figure 1). Baseline characteristics for these participants are presented in table 1. The characteristics of the eight participants who dropped out were heterogeneous in terms of age (mean 10.3, SD 2.4), sex (female, n=4; male, n=4) and diagnosis (CP, n=5; autism spectrum disorder, n=2; rare syndrome, n=1). The recruitment period was determined by funding timeline agreements, and apparent exhaustion of the recruitment catchment pool. Efforts to increase recruitment included extending the recruitment period from 9 months to 21 months and expanding our recruitment location from Ability Centre to other community physiotherapy providers in Western Australia.

Intervention characteristics

The home exercise programmes for both the intervention group and control group were individualised by the treating physiotherapist to attain the goals identified by the family. Therapists could prescribe a number of exercises they deemed suitable. Across both groups the median number of exercises prescribed was 6 (IQR 5 to 8, minimum 2 and maximum 14). With regard to the number of exercises prescribed between groups, some variance was evident; the intervention group had a median of 6 (IQR 6 to 7) and the control group had a median of 5 (IQR 4 to 8). Physiotherapists could also set the programme frequency for the child; the median number of prescribed exercise days per week was 3 (IQR 3 to 5, minimum 2 and maximum 7). Considering the groups separately, the intervention group (IQR 3 to 4) and the control group (IQR 3 to 5) were similar having a median of 3 exercise days per week. We also considered the number of follow-up home visits or clinic visits during

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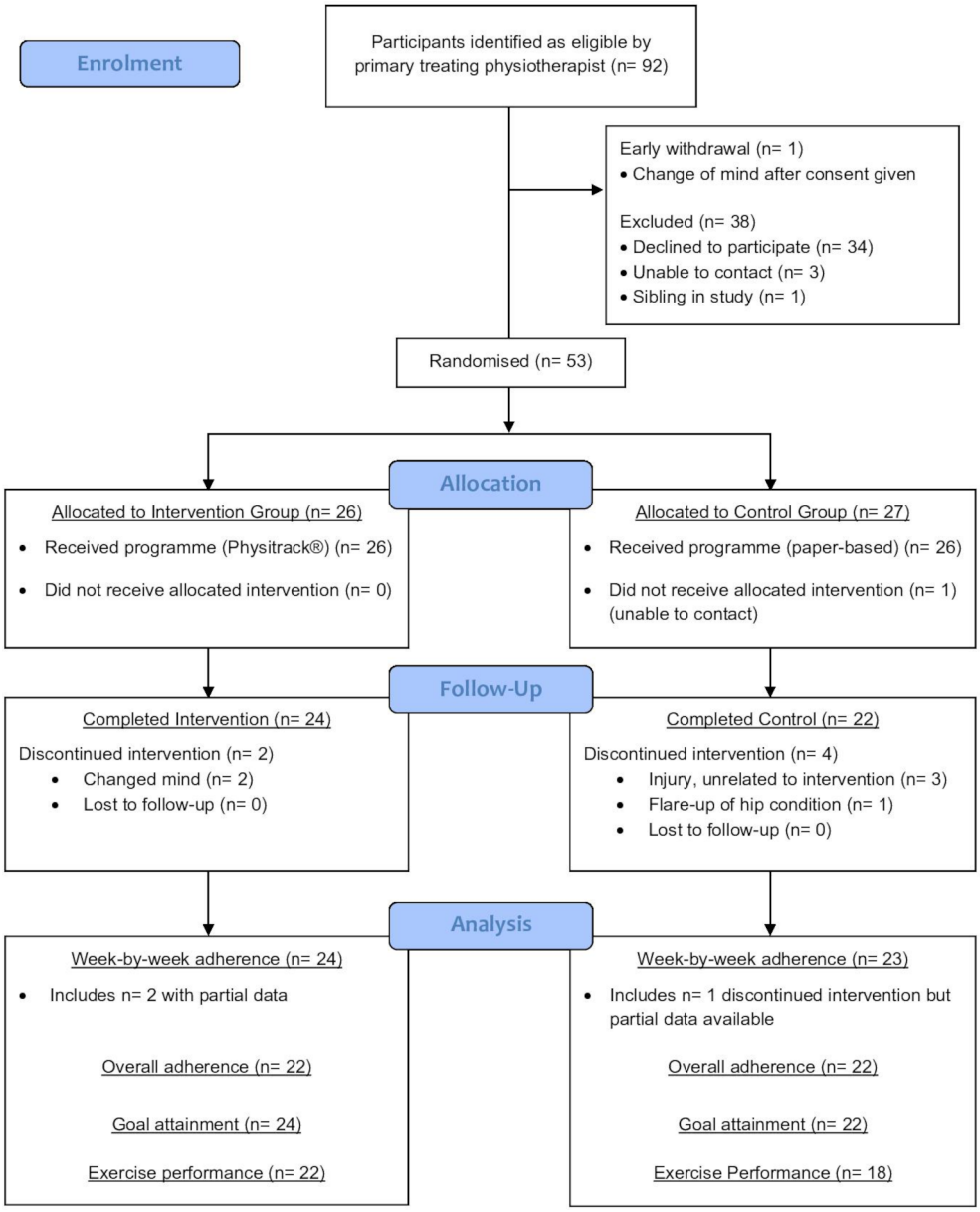

Figure 1 CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

the 8-week intervention period from the 37 participants (of the 46 who completed the study) for which this data was available. Overall, the median number of follow-up appointments was 0 (IQR 0 to 2), with 53% having 0, 39% having 1 to 3 and 8% having 4 to 7. Comparing groups, the median number of follow-up appointments in the intervention group was 0 (IQR 0 to 1) and the median in the control group was also 0 (IQR 0 to 2).

Adherence

Adherence was approximately 60% in both groups. There was no statistically significant difference in the proportion of exercises performed (between group mean difference −7.0 (95% CI −21.6 to 7.5, p=0.34)) or of exercise repetitions completed (between group mean difference −8.6 (95% CI −23.8 to 6.5, p=0.26)) between the intervention and control groups from our analysis of 44 participants whom provided complete adherence data: 22 in each group (see table 2).

As an exploratory analysis of change in adherence across the 8-week intervention period, adherence was analysed on a week-by-week basis in 47 participants employing intention-to-treat analysis: 24 in the intervention group, and 23 in the control group. Both groups displayed a downward trend over time for adherence. On average there was a downward weekly trend of −2.3% (95% CI: −3.3 to −1.3, p<0.001) for exercises performed and −2.0% (95% CI: −3.0 to −1.0, p<0.001) for repetitions completed (see figure 2). There were no significant differences between groups in adherence change both for exercises performed (between group difference coefficient: −7.4, 95% CI: −20.4 to 5.7, p=0.27) and repetitions completed (coefficient: −0.9, 95% CI: −22.5 to 4.5, p=0.19). We

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Table 1 Characteristics of study participants by group

	Intervention (n=24)	Control (n=22)
Age (years), mean (SD)	11.8 (3.2)	11.4 (3.3)
Sex, n (%)		
Female	11 (45.8)	10 (45.5)
Male	13 (54.2)	12 (54.5)
Diagnosis, n (%)		
Cerebral palsy (CP)	17 (70.8)	15 (68.2)
Autism spectrum disorder	1 (4.2)	4 (18.2)
Intellectual disability	1 (4.2)	1 (4.5)
Down syndrome	0 (0.0)	1 (4.5)
Other	5 (20.8)	1 (4.5)
CP classification, n (% children with CP)		
Hemiplegia	9 (52.9)	6 (40.0)
Diplegia	7 (41.2)	7 (46.7)
Quadriplegia	0 (0.0)	1 (6.7)
Ataxia	1 (5.9)	1 (6.7)
Functional Mobility Scale at 50 m, n (%)		
1	2 (8.3)	3 (13.6)
2	0 (0.0)	1 (4.5)
3	0 (0.0)	0 (0.0)
4	0 (0.0)	0 (0.0)
5	8 (33.3)	6 (27.3)
6	14 (58.3)	12 (54.5)
GMFCS, n (% children with CP)		
I	9 (52.9)	8 (53.3)
II	7 (29.2)	4 (26.7)
III	1 (5.9)	2 (13.3)
IV	0 (0.0)	1 (6.7)
V	0 (0.0)	0 (0.0)
BoNTA during 8-week intervention, n (% children with CP)		
Received BoNTA	3 (17.6)	1 (7.1)
Did not receive BoNTA	14 (82.4)	13 (92.9)

Note: Functional Mobility Scale (FMS)[31] is a tool for the classification of functional mobility in children, with a rating of 6 representing the most independently mobile, and a rating of 1 for children who are the least independently mobile and rely on wheeled mobility. FMS rates mobility at three distances: 5 m, 50 m and 500 m; for the purposes of this study we chose to use the FMS to rate the participants' mobility over a distance of 50 m only. GMFCS: Gross Motor Functional Classification Scale-Expanded and Revised,[38] is a functional mobility classification tool suitable for children with cerebral palsy. In the GMFCS 'Level I' represents the most independently mobile through to 'Level V' which represents the least mobile. BoNTA: Botulinum neurotoxin type A injections.

further investigated a sub-hypothesis that Physitrack may result in an early increase in adherence that may not be maintained. However, there was no difference in adherence between groups in the initial 1, 2, 3 or 4-week period between groups.

The responses to self-rated adherence from the NRS (intervention n=18, control n=17) was only significantly different for one question; 'For each exercise, I have been doing the number of repetitions that I was asked to by my physiotherapist' (see table 2).

Canadian Occupational Performance Measure

COPM findings were available and analysed from all 46 participants who completed the intervention. Goal achievement improved in both groups following the 8week home exercise programme (see table 3). Between group analysis of the improvement in COPM scores revealed that Physitrack did not improve goal achievement compared with conventional exercise programmes, in either the performance scores or the satisfaction score.

A change in COPM scores by 2 or greater is regarded as clinically meaningful. There was no difference between groups in clinically meaningful change (table 3).[24] For the total group (intervention and control considered together), clinical meaningful change in performance score occurred in 57% (n=26/46), and in the satisfaction scores 54% (n=25/46).[24]

Correctness of Exercise Performance

Complete COEP data was gathered from 40 out of the 46 (87%) participants who completed the intervention, with 212 exercises in total, for which the research team had available exercise videos of all three time points: baseline, midway and end. A total of 636 exercise videos were reviewed and scored on the COEP. There was little variation in the scores. The majority of exercises videos (70%) were completed by participants, in both groups, with 'performance sufficiently correct so as to achieve the purpose of the exercise'. Nevertheless, 25% of videos were rated with 'exercise performance that does not achieve the goal of the exercise', and 5% were rated as 'not achieving the goal and also may cause harm'. No statistically significant differences were found between groups at baseline (p=0.22), midway (p=0.20) or end (p=0.97), or between time-points within each group (p>0.05).

Physical Activity Enjoyment Scale

There were no significant changes within groups (n=16 for both groups) between pre-test (intervention=3.5±1.0, control=3.6±1.2) and post-test measures (intervention=3.4±1.1, control=3.5±0.9), and no significant difference between groups for enjoyment of exercise (0.1, CI −0.4 to 0.6, p=0.69).

Confidence, satisfaction and process measures

The children's confidence in being able to complete the exercises was moderate-to-high at the beginning (intervention (n=21)=median (IQR): 7.0 (6.0 to 8.0), control (n=20)=7.0 (5.0 to 8.0)) and end of the programme (intervention (n=17)=8.0 (6.0 to 10.0), control (n=18)=7.0 (7.0 to 9.0)). There were no significant differences between groups at the beginning (p=0.97) or the end (p=0.93). Satisfaction with the delivery of the exercise programme was also high in both groups (intervention (n=17)=8.0

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Table 2 Adherence to home programme: between group comparison on exercise logbook data and self-report adherence data for participants in the intervention group (Physitrack) and in the control group (paper-based methods).

Adherence: Exercise logbook findings	Intervention Mean (SD) (n=22)	Control Mean (SD) (n=22)	Between group Mean difference (95% CI)	P value
Proportion (%) of exercises attempted of total exercises prescribed	62.8 (27.7)	55.8 (19.4)	−7.0 (−21.6 to 7.5)	0.34
Proportion (%) of repetitions completed of total prescribed	62.1 (28.2)	53.5 (21.2)	−8.6 (−23.8 to 6.5)	0.26
Adherence: self-report questions (Numeric Rating Scale (0 to 10))	**Intervention Median (IQR) (n=18)**	**Control Median (IQR) (n=17)**	**Between group Median difference (95% CI)**	**P value**
'I have been doing my exercise programme exactly as I was asked to by my physiotherapist'	6.0 (4.0 to 8.0)	6.0 (4.0 to 7.0)	1.0 (−1.0 to 3.0)	0.35
'I have been doing my exercise sessions the number of times I was asked to by my physiotherapist'	7.0 (5.0 to 9.0)	6.0 (4.0 to 8.0)	1.0 (−1.0 to 3.0)	0.23
'Within each exercise session, I have been doing all of the exercises I was asked to by my physiotherapist'	9.0 (6.0 to 10.0)	8.0 (6.0 to 9.0)	1.0 (−1.0 to 2.0)	0.38
'For each exercise, I have been doing the number of repetitions that I was asked to by my physiotherapist'	10.0 (9.0 to 10.0)	9.0 (6.0 to 10.0)	1.0 (0.0 to 3.0)	0.03*

Note: * denotes statistical significance p<0.05.

(5.0 to 9.0), control (n=18)=7.5 (6.0 to 9.0)), with no significant differences between them (p=0.79).

Process measures were extremely high in both groups (n=17 for both groups), with no difference between groups (medians presented):

- 'therapist provides clear demonstration of exercise': 10.0 in both groups (p=0.87),
- 'therapist provided clear instructions on how to perform': 10.0 in both groups (p=0.80),
- 'therapist provided clear instructions on how often to complete exercises': 10.0 in both groups (p=0.58) and
- 'therapist monitored exercise programme': 10.0 in the intervention group and 9.0 in the control group (p=0.41).

One process measure had more moderate responses: 'physiotherapist prompted me to complete the exercise programme regularly': 6.0 in the intervention group and 8.0 in the control group, with no difference between groups (p=0.44).

Another post-intervention survey measure was completed that asked participants to rank different methods of exercise programme delivery.[26] Online options were the preference of the majority in both groups: 71% (n=12/17) of the Physitrack group and 53% (n=9/17) of the control group, with no significant differences between groups (p=0.30).

System Usability Scale

Intervention participants (13 of 24) reported high usability scores for Physitrack (mean=4.12, SD=1.08). Moderate usability sores were given by therapists (mean=3.38, SD=0.65).

Adherence and goal achievement

Exploratory analyses examined the degree to which goal achievement, as measured by the COPM, was related to adherence with the home exercise programme; the analysis revealed a small correlation between adherence and change in self-rated performance of goal activity (r=0.200, 95% CI: −0.103 to 0.469) and self-rated satisfaction in goal activity (r=0.050, 95% CI: −0.251 to 0.342).

Adverse events

No harms or unintended effects were recorded. Three participants reported a knee injury, and one participant reported a flare-up of Legg-Calve-Perthes disease, that caused them to drop out of the study (see figure 1); parents reported these events occurred outside of the context of the home exercise programme, with some of these injuries occurring while participating in sport.

DISCUSSION

This RCT investigated the effectiveness of Physitrack, an online exercise prescription platform, in children with CP and other neurodevelopmental disabilities compared with a conventional paper-based home programme. The hypothesis that Physitrack, which uses features such as exercise videos, adherence tracking and an application-based interface, would improve home programme adherence, quality of exercise performance and goal achievement was not supported by the preliminary findings in this study. The method of delivery of the exercise programme employed here, in children with CP, did not appear to significantly affect adherence or the other

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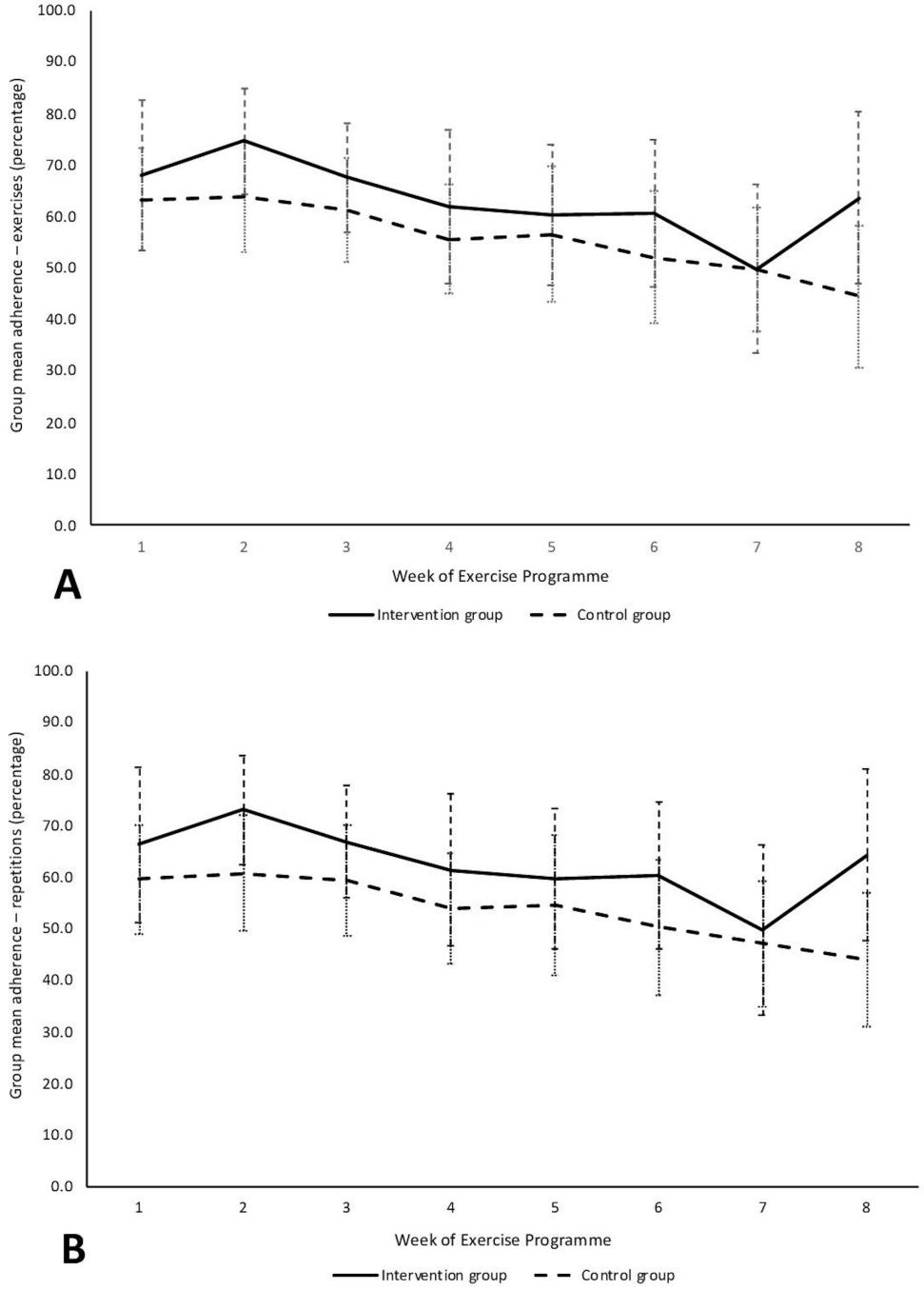

Figure 2 Mean adherence change, by group, over 8-week exercise program, with 95% CIs, in terms of number of exercises performed (A) and number of repetitions completed (B) performed as a proportion of prescribed.

outcomes. However, these findings need to be interpreted with caution given that we were unable to reach sufficient participation numbers in accordance with our power calculation.

Adherence to home exercise programmes are considered to be fundamental to their effectiveness, but poor adherence is an ongoing clinical issue for physiotherapists working with children with disabilities.[4 6] In the present study, adherence to the 8-week exercise programmes was similar across groups irrespective of whether an online or paper-based method of delivery was use. This result was the same for both exercise logbook records and responses to questions about adherence on a self-report rating scale. A study by Law *et al*, a 4-month home programme among 50 children with CP, provides a notable comparison in programme adherence findings. First, that challenges with the measurement of adherence itself were reported, with lower than expected completion of logbooks (68% completion).[32] Of those participants who did return logbooks, only 57% reported full programme completion.[32] The reporting of adherence in relation to the 'number of exercise days completed' in the study by Law *et al*,[32] does not afford the same level scrutiny as reporting on completion of individual exercises and repetitions

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Table 3 Canadian Occupational Performance Measure (COPM) individualised goal activity performance and satisfaction outcomes. Difference is calculated by post score minus pre score.

Pre and postperformance and satisfaction measure group comparison				
	Intervention Mean (SD) (n=24)	Control Mean (SD) (n=22)	Between group Mean difference (95% CI)	P value
Performance				
Pre	4.5 (1.3)	4.2 (1.5)		
Post	6.5 (1.9)	6.6 (1.8)		
Difference	2.0 (1.5), p<0.01	2.5 (2.4), p<0.01	0.5 (–0.7 to 1.7)	0.39
Satisfaction				
Pre	5.0 (1.6)	4.2 (2.2)		
Post	7.0 (2.0)	7.2 (2.0)		
Difference	2.0 (2.2), p<0.01	2.9 (2.7), p<0.01	1.0 (–0.5 to 2.4)	0.19
Clinically meaningful change group comparison				
	Intervention, n (%)	Control, n (%)	P value	
Performance	15 (62.5)	11 (50.0)	0.39	
Satisfaction	12 (50.0)	13 (59.1)	0.54	

Note: Within group change was analysed with paired t-test. Between group differences used linear regression adjusting for baseline score. A 2 point or greater change in COPM scores is considered a clinically meaningful change.[24] Clinically meaningful change was assessed as the proportion in each group that changed by a score of 2, and then analysed using the χ^2 test.

as has been undertaken in our study. Similarly, in other smaller studies in children with CP,[11–16] a large variability of adherence measurement and reporting methods are observed. Despite efforts taken in this study to report on adherence as fully and accurately as possible, the primary method of measurement—exercise logbooks—may have contributed to the similar adherence results between groups particularly when previous work has indicated that exercise logbooks can themselves be used as a reinforcer of adherence.[4] Similarly, the collection of exercise performance videos at three time-points (for COEP measure) may also have unintentionally reinforced adherence. The development of a valid measure of adherence to address the inconsistencies observed in the literature appears an important step to enable comparison of research findings for knowledge translation, as has also been recommended in other populations.[33] A second potential reason for the similarities in adherence findings between groups is the intervention itself. While Physitrack provides features to support exercise programmes that are unavailable with conventional methods, it is not designed specifically for children. A therapy prescription application designed for children with disabilities with features that will be engaging for them, such as a bright and playful colour scheme, games and rewards for completing exercises, may be more effective in improving programme adherence in children than Physitrack. Third, it is important to consider that interpersonal factors including the therapist's ability to listen and partner with parents, and to provide ongoing follow-up support have been identified as key contributors to adherence[6 17] and these are beyond the investigation of delivery method conducted here. Accordingly, our finding in both groups of weekly reductions in adherence across the 8 weeks of the programme highlights the need in clinical practice to have regular follow-up to home exercise programmes and avoid a 'set and forget' approach.

The measurement of the achievement of collaboratively set goals was another important component of our evaluation of Physitrack. We theorised that improved programme adherence could lead to a functional outcome of goal achievement, however, as Physitrack was congruent to paper-based methods in achieving adherence, the finding of no significant difference in goal achievement between groups is not altogether surprising. Both the Physitrack and conventional programme groups demonstrated statistically significant improvements in goal activity performance and satisfaction scores, in keeping with other studies in children with CP that demonstrate the effectiveness of goal-directed home programmes.[3 10]

We also investigated whether embedded exercise videos in Physitrack-delivered home programmes would improve the quality of exercise performance compared with paper-based methods that rely on still images. Our finding of similar results between the groups may be due to the challenge in identifying a suitably sensitive measure of quality of exercise performance. The COEP measure is a broad scale that can be applied to individualised programmes where each child is prescribed a different set of exercises to achieve their individual goals;[27 34] however, several shortcomings of the measure were revealed while reviewing the videos of participants performing their exercises. The most significant of these is the limited responsiveness in the measure. The COEP is an ordinal scale with only three levels. The distances between the scores of the COEP are measured in substantively different ways, that is, the difference between 1 and 2 is on *correctness to achieve outcome*, whereas 3 is about *risk*, thus the unit distance between

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adjacent categories varies in meaning across the scale. This clinimetric property is likely to lead to misleading results, as there was insufficient differentiation in the COEP levels to measure exercise performance. Developing a tool that achieves this requirement would be a significant challenge, particularly in the population being investigated; for many children with disabilities, 'perfect' performance is an unrealistic expectation. However, given the finding that 25% of the exercises reviewed were not performed correctly enough to achieve the exercise purpose and 5% of exercises were performed unsafely, we are able to recommend the use of video footage taken at home (eg, by parents) to review how children perform prescribed exercises, in order to improve effectiveness and safety of home programmes in clinical physiotherapy practice. Analysing the quality of performance is an important clinical observation skill for physiotherapists working with children with CP, but one that proves difficult to quantify across the broad range of exercises employed in an individualised programme.

Secondary outcome measures also did not yield between group differences. Enjoyment of exercise was moderately high, and confidence to complete the exercise programme was high at both the start and the end of the 8-week programme in both groups. In both cases it appears that participants started the trial already having a positive approach to exercise, and neither method of delivering the programme tested caused deterioration in this existing state. Process measures yielded high results in both groups indicating that the therapy programmes were provided with *clear demonstration*, *instruction* and *monitoring* by participating physiotherapists. The only exception to high results was for the item relating to *follow-up*, which yielded more moderate results. This latter result is not unexpected as physiotherapists were not instructed to follow-up in a particular fashion, and 53% of participants did not have any follow-up appointments. System usability of Physitrack was rated as high by participating families in the Physitrack group and moderate by physiotherapists. Physitrack has a different interface for therapists as it has for users, so we would not necessarily expect similar scores between the groups. Since the study execution period there have been a number of iterations on the Physitrack website and application interfaces, so these SUS findings may not reflect the platform at the time of publication.

This study was designed and conducted as a 2-arm, parallel, RCT with blinding of researchers and statistician to group allocation. Nevertheless, limitations should be kept in mind when interpreting these findings. First, it was impossible to blind participants and their primary physiotherapists to the intervention, yet they were blinded to the purpose of the study and the nature of the outcome measures. Second, we did not achieve the recruitment of participants to the level specified in the power calculation, even with a 12-month extension and also expansion of our recruitment beyond Ability Centre to other therapy providers. Third, our approach to assessing adherence was both a strength (eg, logbooks detailing every exercise and repetition completion) and potential weakness (eg, weekly reminders to submit logbook records might have served to reinforce adherence behaviour).[4] We were unable to capitalise on the automaticity of the adherence records within Physitrack because this option was unavailable to the control group who did not use this platform.

Physitrack is designed for broad use by physiotherapists and other health professionals who prescribe exercise. Although benefits to adherence have been reported in other adult (non-CP/neurodevelopmental) populations;[19] such benefits were not observed here among children with CP and other neurodevelopmental disabilities. Conversely, neither did the measures yield worse results, or adverse findings, for participants using Physitrack, hence the selection of programme delivery method (paper vs online) can remain at the discretion of the physiotherapist who is guided by the interests, needs and preferences of the child and parent with the disability. However, given challenges with recruitment, these findings are preliminary in nature and a larger RCT is recommended to verify or refute these conclusions. Adherence to prescribed exercise programmes for many children with disabilities is not a habitual behaviour, and therefore requires systematic attention to behaviour change. There remains untapped potential for a mHealth application that uses theory-based, health-related behaviour change in the prescription of exercise.[18] Furthermore, developing an mHealth application that exploits gamification—the use of electronic gaming features to motivate users in non-game contexts[35]—may be advantageous for health-related behaviour change[6 36 37] and particularly relevant for promoting exercise adherence in children. An opportunity remains for an exercise prescription application that is specifically designed for children with neurodevelopmental disabilities, incorporating their interests and needs, that will assist them to engage positively and actively in individualised therapy programmes.

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Contributors RWJ conceived the idea for the trial, reviewed literature, sought ethical approval, coordinated recruitment, implemented outcome measures, conducted analysis and drafted the paper. NG assisted development of the trial concept, reviewing literature, ethical approval, scoring and analysis of outcome measures and edited the paper. SAW and DFG provided supervision around the concept of the trial, literature review, ethics application, the outcome measure collection and edited the paper. NB provided consultation in statistical methods, performed the power calculation, planned and conducted the statistical analysis. AMB participated in the trial concept development, assisted in the grant application,

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participant randomisation and research process consultation. MB assisted in communications, recruitment, monitoring the collection of outcome measures and data entry and integrity.

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