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A Multisite Randomized Controlled Trial of Hand Arm Bimanual Intensive Training Including Lower Extremity (HABIT-ILE) for Children with Bilateral Cerebral Palsy

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Keywords: Cerebral palsy; motor training, rehabilitation, children

List of abbreviations:

CP, Cerebral palsy; HABIT-ILE, Hand Arm Bimanual Intensive Training Including Lower Extremity; GMFCS, Gross Motor Function Classification System; MACS, Manual Ability Classification System; CFCS, Communication Function Classification System; UC, Usual care; CP-QOL Cerebral Palsy Quality of Life Questionnaire

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Contributors Statement

Conceptualization and methodology: Sakzewski, Bleyenheuft, Novak, Elliott, Morgan, Pannek, Ware, Boyd. *Investigation:* Sakzewski, Reedman, Hines, Nolan, Dos Santos

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Project Administration: Sakzewski, Dos Santos, Reedman, Hines, Nolan. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Data Sharing Statement: Data will be made available to other researchers as necessary for the purposes of meta-analysis/systematic review and/or confirmation of statistical results. This data will be made available at group-level. If individual level data are required, a limited, codified dataset will be made available to reduce or eliminate the possibility of re-identification of the data. Data will be shared directly with individuals or institutions that approach the custodians.

Objective To test the efficacy of Hand Arm Bimanual Intensive Therapy Including Lower Extremity (HABIT-ILE) to improve gross motor function, manual ability, goal performance, walking endurance, mobility, and self-care for children with bilateral cerebral palsy (CP).

Study design This prospective, waitlist randomized controlled trial included children with bilateral CP, aged 6-to-16-years and classified Gross Motor Function Classification System (GMFCS) levels II to IV. HABIT-ILE delivered for 2 weeks (65 hours) was compared with usual care (UC). Primary outcomes post-intervention were gross motor function (Gross Motor Function Measure-66) and manual ability (ABILHAND-Kids). Secondary outcomes were goal performance (Canadian Occupational Performance Measure), self-care and mobility (Pediatric Evaluation of Disability Inventory-Computer Adapted Test), bimanual hand performance (Both Hands Assessment), and walking endurance (6 Minute Walk Test). Linear regression models were used to determine between group differences, adjusted for baseline scores.

Results 92 children were recruited; two were deemed ineligible after randomization and were excluded. 90 children (HABIT-ILE n=46, UC n=44), mean age 10.4 (SD 3.0) years, GMFCS II=32; III=31; IV=27 were included. HABIT-ILE led to superior gains in manual ability (mean difference 0.85, 95% CI 0.38-1.33; $P<0.001$) but not gross motor function. HABIT-ILE led to superior changes on goal performance, self-care, and mobility.

Conclusions HABIT-ILE was effective in improving manual ability, mobility, self-care, and goal performance, but not gross motor function. Significant gains immediately post-intervention were retained at 26 weeks. Large individual variability suggests further analyses need to be performed to understand characteristics of children who achieved clinically meaningful gains across outcomes.

Trial registration Australian and New Zealand Clinical Trials Registry (ACTRN12618000164291).

Cerebral palsy (CP) is a lifelong physical disability, with a prevalence of 1.4 in 1000 live births.[1] Over 60% of children with CP have a bilateral presentation of motor involvement.[2] Limitations in gross motor function and the ability to effectively use two hands together have significant ramifications for developing independence in daily life activities and participation in home, school and community life.[3]

Intensive, goal-directed therapies underpinned by motor learning and neuroplasticity principles have evidence for efficacy to improve gross and fine motor function and independence in daily life activities for children with unilateral CP.[4] There is less evidence however, for children with bilateral CP, as many of the intensive approaches have been designed for and studied in children with unilateral CP.[5, 6] Hand Arm Bimanual Intensive Therapy Including Lower Extremities (HABIT-ILE) is a goal-directed intensive intervention that simultaneously addresses coordination of the upper and lower limbs, involving mass practice and progressive shaping of voluntary movement using the principles of motor learning.[7] A small quasi-randomized trial of HABIT-ILE with 20 children with bilateral CP, Gross Motor Function Classification System (GMFCS) levels II to IV, demonstrated large effects in improving gross motor function and manual ability after 84 hours of therapy.[8]

The aim of this phase III randomized trial was to study whether HABIT-ILE was more effective than usual care (UC) to improve gross motor function and manual abilities of children aged 6-to-16-years with bilateral CP in a larger sample size in real-world conditions. We hypothesized that HABIT-ILE, compared with UC, would be more effective in improving gross motor function and manual abilities, and secondly would lead to greater gains in goal performance, mobility and walking endurance, self-care, and bimanual hand performance.

Methods

This multi-site, pragmatic, randomized controlled trial (RCT) was conducted in three Australian states (Queensland (QLD), New South Wales (NSW) and Western Australia (WA) between August 2018 and January 2022. Full ethical approval was granted by the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee, the Medical Research Ethics Committees of The University of Queensland and Cerebral Palsy Alliance. Parents provided informed signed consent for their participating child and children over 12 years who were able provided verbal assent. The study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The study protocol was published[9] and the trial registered with the Australian New Zealand Clinical Trials Register (ANZCTR12618000164291).

To be eligible for inclusion, children (a) had a diagnosis of bilateral CP, (b) were aged between six and 16 years, (c) were classified in GMFCS[10] level II (walks with limitations) to IV (limited self-mobility but able to do a standing transfer with assistance); (d) were able to grasp light objects and lift the most impaired hand ≥ 15cm above a table surface, as without some ability to grasp, the intervention may be too challenging and frustrating for participants; and (e) could understand instructions for all clinical outcome measures so that measure could be completed with valid data. Children were excluded if they had (a) uncontrolled epilepsy, (b) orthopedic surgery and/or neurological surgery six months prior to or scheduled during the study period, (c) a visual impairment that interfered with completion of assessments and likely to interfere with treatment (d) significant cognitive and/or behavioral impairments limiting their ability to follow instructions, and (e) were non-English speaking. The site study coordinator first screened for eligibility via telephone with the child's primary caregiver. If eligibility could not be confirmed, a face-to-face appointment was made and study therapists confirmed eligibility. If children were unable to follow instructions to complete baseline assessments, they were deemed ineligible and did not proceed to randomization.

Study Procedures

Following completion of baseline assessments, participants were stratified by site (QLD, NSW and WA) and GMFCS (level II versus III-IV) and individually randomized centrally using concealed allocation to either HABIT-ILE, or to a waitlist control group. An independent biostatistician generated a computer number sequence in random blocks ranging between 10 and 20. Assessments were conducted at baseline (T1), immediately post intervention (2 weeks after baseline, T2), six months after baseline (retention, T3). Following T3 assessments, the waitlist group completed the two-week HABIT-ILE intervention and the final assessment for the waitlist group occurred two weeks later (T4).

Study Outcomes

To describe the cohort, children were classified on the GMFCS,[11] Manual Abilities Classification System

(MACS)[12] and Communication Function Classification System (CFCS).[13] Each classification system comprises a 5-level ordinal scale.

Primary Outcomes. The primary outcomes were the between group difference immediately post-intervention (T2) for gross motor function (Gross Motor Function Measure-66) and manual abilities (ABILHAND-KIDS). The Gross Motor Function Measure-66 is a criterion referenced observation measure which was videorecorded and later scored by an experienced rater, masked to group allocation and timing of assessments. The ABILHAND-Kids is a Rasch-developed questionnaire of manual ability, completed by the child's primary caregiver and therefore cannot be blinded to group allocation.[14]

Secondary Outcomes. The Canadian Occupational Performance Measure[15] was used to define and evaluate individualized goals in the domains of self-care (eg, tying shoelaces), leisure (eg, riding a scooter) or productivity (eg, stabilizing paper whilst writing). Children, in collaboration with their caregiver, set three to seven functional goals and rated their goal performance and satisfaction with performance on a scale of 1-10. Mobility and self-care performance were measured on the Pediatric Evaluation of Disability Inventory-Computer Adapted Test,[16] which was completed by the child's caregiver. The Six Minute Walk Test[17] was used to measure walking endurance. The Both Hands Assessment was used to measure bimanual hand performance, was videorecorded and later scored by a certified, masked rater.[18] The BoHA has excellent internal construct validity[18] and external validity[19]. Quality of life was measured using the CP Quality of Life measure (CPQOL-Child for children up to 12 years of age and the CPQOL-Teen for those 13 years or older),[20] completed by caregivers. Children who were aged 9 to 12 years completed the self-report CPQOL-Child, and those 13 years or older completed the CPQOL-Teen. All secondary measures with the exception of the Both Hands Assessments were not blinded to group allocation.

Interventions

Intervention Group: HABIT-ILE. HABIT-ILE was delivered through a 2-week intensive group day camp, for 6.5 hours/day for 10 days, giving a total dose of 65 hours. This was less than the 84.5 hours in the original study[8] but was considered more feasible and acceptable in the Australian context and aligned with current understanding of optimum dosing in upper extremity studies.[21] The original dosing protocol was delivered over 13 days in a 2-week period for 6.5 hours per day, including weekends. This protocol would have been difficult to deliver under the terms and conditions of employment in Australia for allied health professionals and our adopted protocol of 65 hours reflects what would be considered appropriate in this context. The intervention was provided in groups of 6-12 children with a 2:1 therapist to child ratio. To ensure fidelity across sites, site leads (1 occupational therapist and 1 physiotherapist) received training and attended one full camp under the supervision of HABIT-ILE developer (YB). Site leads subsequently delivered one day of standardized training to undergraduate physiotherapy and occupational therapy students, and qualified therapists at each site prior to the commencement of each camp. The site leads provided ongoing mentorship and supervision to site interventionists. Prior to each camp, caregivers recorded video footage of their child performing goal activities at home. A video task analysis to identify goal limiting factors was performed by interventionists for each goal, supported by site leads and HABIT-ILE developer (YB). Further video footage was acquired during camp and reviewed every two to three days by YB to provide feedback and support to site leads on fidelity, intensity of delivery and incrementation of tasks to ensure the right level of challenge. Therapy activities were chosen to specifically target identified goal-limiting factors and tailored to the child's age, interests, upper and lower limb capacity and postural control. All activities were based on the child's functional goals, and most practice directly targeted the goals. The children were independently active within all tasks with minimal/no manual guidance from the therapists. A daily therapy log was completed outlining time spent in different positions (eg, sitting on a fit ball, standing on a balance ball) and activities (eg, gross upper limb activities, goal practice). Children in the HABIT-ILE group could continue their care as usual, although this was expected to be limited during the HABIT-ILE camp due to the intensive nature of the intervention.

Control Group: Usual Care. Children allocated to the control group received their UC, including their regular therapies (eg, occupational therapy, physiotherapy, exercise physiology). UC is highly variable in Australia, based on both the child's funding package through the National Disability Insurance Scheme, and availability of therapies within their local context. Usual care for both groups was collected via a parent-completed health resource use questionnaire at baseline and final six-month follow-up assessments. Data from the six-month follow-up assessment were used to determine usual care over the six-month study period.

Sample Size and Statistical Analysis

The sample size was calculated based on data from a small quasi-RCT of HABIT-ILE[8] with an expected difference of 1.6 logits and standard deviation of change of 3 on the ABILHAND-Kids. A sample size of 126 (63 in each group) would give 80% power, with a significance of 0.05 at a two-sided alpha level. Based on the same study with an expected difference of 5 points on the GMFM-66, and a pooled SD of 7.43, a sample size of 72 (36 in each group) would be required[8]. We chose the largest sample size from the ABILHAND-Kids to ensure that the study would be adequately powered for both measures.

Between group comparisons for primary and secondary outcomes were performed on an intention-to-treat basis using linear regression, with intervention group as the main effect and baseline score as the covariable. Secondarily, we explored within group changes using paired t test across the timepoints. We explored differences between and within groups for each GMFCS level. Analyses were conducted consistent with the study protocol.[9] Analyses were performed using Stata version 17.0 software (StataCorp, College Station, TX, USA).

Results

Of the 135 children assessed for eligibility, 92 met the eligibility criteria and were randomly allocated to HABIT-ILE (n=46) or waitlist control (n=46). One child allocated to the control group was later deemed ineligible due to unplanned orthopedic surgery and was excluded from all analyses. One child was randomized to the control group prior to baseline assessment, following confirmation of eligibility via Zoom, as they were located far from one of the sites. They withdrew after randomization without any baseline data as they were unable to travel. Forty-four children allocated to HABIT-ILE completed the intervention (95% retention). Two did not proceed due to illness and parental work commitments. Two children in the waitlist group withdrew after baseline assessment due to travel challenges and loss of interest (95% retention). A total of 13 HABIT-ILE camps were conducted (QLD n=5; NSW n=5; WA n=3). The participant flow in the study is illustrated in Figure 1. There were slightly more boys and children with dyskinetic motor type in the usual care group and more children classified in MACs level 1 in the HABIT-ILE group, however differences were not significant. Topographical distribution and classification of motor, manual ability and communication function was similar across groups (Table I).

Children allocated to HABIT-ILE received a mean of 65.4 hours of intervention (SD 3.6; range 56.3, 70.7 hours). Some children received more than the anticipated amount of therapy as they arrived early each day. Over the six-month study period, the HABIT-ILE group continued usual care and received a median of 10 hours (IQR 5-18 hours) of physiotherapy and median of 3 (IQR 0-9 hours) of occupational therapy. The majority of children (97%) received evidence-based interventions such as functional therapy and goal directed training. Children across both groups set 453 goals focused on mobility and gross motor (27%), self-care (58%), leisure (8%) school (4%), and other (3%) activities of daily living. The most common goals included dressing (eg, clothing, putting on shoes and socks, fastenings – 64 goals), and gross motor goals such as improving walking/running (22 goals). For the lower extremity, 16% of time was spent sitting on a fit ball, 40% on a bench, 17% standing, 16% on transitions, and 11% on a chair or other activities. For the upper extremities, 27% of time was spent on gross upper limb activities, 35% on fine, manipulative tasks, 31% practicing functional goals and 6% on arts, crafts, and card games.

Over the six-month study period, the control group received a median of 15.0 hours (IQR 6.5-26.0 hours) of physiotherapy and 6.0 hours (IQR 2.0-12.2 hours) of occupational therapy. Physiotherapy was described as using a number of different approaches, predominantly including functional training and strengthening. Occupational therapy involved goal directed training, equipment prescription and home modifications.

Children in the HABIT-ILE group, compared with the waitlist group, had significantly greater improvement in manual ability between T1 and T2 (ABILHAND-Kids; mean difference [MD] 0.85, 95% confidence interval [CI] 0.38, 1.33; $p=0.001$ and T1 and T3 (MD 0.99, 95% CI 0.47, 1.51; $p<0.001$). There were no significant differences between groups for gross motor function at either timepoint (Gross Motor Function Measure; MD 0.33, 95% CI -0.75, 1.41; $p=0.54$ T1 and T2 and MD 0.79, 95% CI -0.45, 2.04; $p=0.21$ T1 and T3) (Table II).

Children in the HABIT-ILE compared with control group had greater improvements on perceived performance of goals on the Canadian Occupational Performance Measure at both timepoints. There were similar findings for satisfaction of goal performance. HABIT-ILE, compared with the control group led to greater changes on the Pediatric Evaluation of Disability Inventory-Computer Adapted Test self-care domain at both timepoints. Compared with the control group, HABIT-ILE led to greater initial changes on the Pediatric Evaluation of Disability Inventory-Computer Adapted Test mobility domain between T1 and T2 but this difference was not retained at T3. There were no differences between groups on the Both Hands Assessment or walking endurance on the 6 Minute Walk Test at either time point (Table II). Domains in the CP-QOL are different for the Child or Teen versions, with additional domains in the parent proxy versions, therefore analyses were conducted separately. There were no between group differences for any of the domains of the parent proxy CPQOL-Child with the exception of parent-reported family health. The control group reported reduced family health over time (eg, parent perceptions of their own physical health, financial and work situation). There were no differences between groups for the CPQOL-Child or CPQOL-Teen self-report. For the CPQOL-Teen parent proxy measure, there were significant differences at 26 weeks favoring the HABIT-ILE group for the domains of General Health and Participation, Communication and Physical Health, School Well-being and Feelings about Function (Table III).

Based on GMFCS level, there was a significant difference between groups favoring HABIT-ILE for children classified GMFCS IV for walking endurance (6 Minute Walk Test) immediately post intervention, and GMFCS II on PEDI-CAT mobility at 26 weeks. There were no other between group differences for outcomes across GMFCS levels (Table IV).

Adverse Events

Forty-one adverse events were reported from 20 participants in the HABIT-ILE group including muscle soreness or joint pain (n=16), minor grazes or bruises (n=13), illness not related to the intervention (n=2), falls that did not result in injury (n=7) and rashes (n=3). All adverse events were minor and did not require any medical treatment.

COVID-19 Related Variations

COVID-19 related lockdowns and inability to see participants face-to-face, impacted T3 assessments, with 2 participants unable to complete and 7 delayed by two to three months. Nine participants missed 1 day of the HABIT-ILE camp due to a snap lockdown. Where possible, additional time was added to each day to attempt to make up any lost time. Study completion was delayed due to the inability to conduct HABIT-ILE groups in 2020.

Discussion

This large, pragmatic, multi-site Phase III RCT established that 65 hours of HABIT-ILE compared with UC was more effective in improving manual ability, self-care, mobility and goal attainment, but had no significant impact on gross motor function immediately post intervention. Gains in manual ability, self-care and goal performance were retained 26 weeks post-baseline. Our results differ from those of a small quasi-randomized trial of HABIT-ILE with 20 participants with bilateral CP which found significant differences between groups for gross motor function and walking endurance. There are a number of reasons which may explain these inconsistencies. The dose of HABIT-ILE in our study was 19.5 hours less than the 84.5 hours in the original HABIT-ILE study[7] and that additional time would have enabled greater repetition of gross motor goal practice. Our cohort comprised an equal distribution of functional severity with children classified in GMFCS levels II to IV, compared with 70% of children in GMFCS III and 10% in GMFCS IV in the Bleyenheuft study.[8] Consequently, our baseline measures for our cohort indicated greater variability in performance with larger standard deviations, and the response to intervention was highly variable. Moreover, it is known that the effect sizes in children classified at GMFCS IV are smaller and therefore with a higher proportion of GMFCS IV in our sample, this may have lowered the average score. In addition, UC is likely very different in Australia compared with Belgium where the original study was conducted. Usual care in Belgium is described as predominantly neurodevelopmental therapy,[7] which was rarely offered to our cohort and has been shown repeatedly in systematic reviews to be ineffective.[4, 6, 22] Rather, children in our control group received a combination of functional, strengthening and gait training, which more closely aligns with recommendations from a recent clinical practice guideline for interventions to improve physical function in children with CP, therefore likely to be effective.[23] These interventions are more similar to HABIT-ILE and therefore may have lowered the between group-differences. Our results demonstrated a trend for improvement for the HABIT-ILE group on gross motor function and a trend for decline for the control group. Based on our understanding of the natural history of gross motor function, following a peak at between six to seven years, a subsequent decline in function is to be expected for children classified in levels GMFCS III and IV.[24] Our results therefore need to be considered within the context of natural history, whereby a small gain in gross motor function against a backdrop of possible decline, may be considered clinically meaningful.

In addition, over half the goals set by children in our study focused on self-care and only 27% of goals addressed gross motor function and mobility. Although all children were continuously challenged posturally throughout the HABIT-ILE camp, improvements are unlikely to be detected on the Gross Motor Function Measure-66, which measures a child's motor capacity, and not the quality or efficiency of how they perform gross motor tasks. Exploration of children who achieved a clinically meaningful change for gross motor function may determine associations with intervention specific factors, for example, number and type of gross motor goals addressed, child related factors (eg, age, classification levels, motor type, motor distribution) and outcomes. Our post hoc analysis based on GMFCS Level demonstrated some differential effects. Children classified in GMFCS level IV had significantly greater improvement in walking endurance, which likely reflects the intensity of practice of walking during the camp which would be very different to their usual amount as defined by GMFCS IV level (eg, need help to mobilize therefore making it difficult to embed in everyday life). Those children classified in GMFCS II had greater gains in mobility. In this age group, these children are potentially declining, and an intensive program such as HABIT-ILE may give them a burst of intensive practice needed to improve and sustain activity over a longer period.

Children in our study made significant progress in their performance of functional goals, self-care and manual ability, consistent with previous results.[7] The magnitude of effect on the ABILHAND-kids, was on average higher than the smallest detectible difference of 0.81[25] suggesting a real change in function over and above measurement error. Similarly, the magnitude of change of >2 on the COPM performance indicates a clinically meaningful change. The significant and clinically meaningful change in both these outcomes may reflect the predominance of self-care goals set by children. The Both Hands Assessment, measuring bilateral hand performance, is a relatively new outcome measure, and this is the second study to report its use. In a study of HABIT in 41 children with bilateral CP, aged four to 16 years, 90 hours of HABIT (intensive upper limb bimanual therapy) did not lead to significant changes on the bimanual hand performance.[26] Based on developmental curves for the Both Hands Assessment for children with bilateral CP, children classified MACS levels I to III reach 90% of their potential by 30 months of age.[27] The test developers therefore questioned whether the measure would be sensitive to detect change in older children. In addition, there are no longitudinal data available to determine any changes in bimanual hand performance over time after six years of age.[27] Our results along with others[26] are suggestive that the Both Hands Assessment may not be sensitive enough to detect change in bimanual hand function in older children.

Implementation of HABIT-ILE requires training of therapists and significant resourcing in terms of staff/student time, equipment, facility use and consumables. Over 250 undergraduate physiotherapy and occupational therapy students implemented the intervention after completing standardized training, and with support and ongoing supervision from site therapist leads throughout each HABIT-ILE group. This level of staffing with a child to therapist ratio of 1:2 is considered necessary to ensure safety of the children. A subsequent health economic within-trial cost-utility analysis will be performed to synthesize the costs and benefits of HABIT-ILE compared with UC. Different models of HABIT-ILE will need to be developed and tested in low-resource settings and those without nationalized healthcare in order to find ways to enable equity of access to this intervention.

Although this study is much larger than past trials, our sample size fell short of the 120 proposed in our sample size calculation. The latter part of this study was run during COVID-19, and families may have been nervous for their child to engage in an intervention in a group setting. Whilst our sample size was adequate for the ABILHAND-Kids, our cohort was substantially more variable on the Gross Motor Function Measure-66 than the sample from which our power calculations were based.[7] We were underpowered for the Gross Motor Function Measure-66, and based on our baseline values, a sample size of 244 would be required to have 80 percent power to detect a 1.3-point difference (large effect size)[28] between groups. To conduct a study of that magnitude, both national and international sites and a significant funding commitment would be required, which is unlikely to occur. There are a number of studies of HABIT-ILE for children with bilateral CP currently being conducted worldwide.[29-31] An individual patient data meta-analysis pooling results from all trials may further provide evidence for the effectiveness of HABIT-ILE on gross motor function. The inclusion of the parent-reported ABILHAND-Kids as a primary outcome could be seen as a limitation as blinding to group allocation was not possible. This was pragmatic decision to align the primary outcomes with previous studies of HABIT-ILE. To address this, we did include the objective Both Hands Assessment as a secondary measure, which was scored by a rater masked to group allocation, cognizant that there were potentially questions surrounding responsiveness.

In summary, this large, pragmatic RCT of HABIT-ILE for 6-to-16-year-old children with bilateral CP found that 65 hours of HABIT-LE was more effective than usual care for improving manual ability, self-care, mobility and goal attainment, all important domains for children with CP (GMFCS II-IV). We found minimal differences between the groups on measures of gross motor function, however, based on the variability in performance of our cohort, we were likely underpowered to detect a difference on these measures. We found a trend for improvement for the HABIT-ILE group in gross motor function and decline for the control group, and greater numbers would be required to confirm these findings. Importantly, immediate gains in manual ability, self-care and goal performance were retained in the longer term. Further post hoc exploration of child and intervention factors associated with a clinically meaningful change across outcomes are warranted along with a health economic evaluation.

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Declaration of Generative AI and AI-assisted technologies in the writing process

The authors did not use AI during the preparation of this work. They take full responsibility for the content of the publication.

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Figure 1. Participant flow through the study

Table 1. Participant demographics characteristics of HABIT-ILE and usual care groups

Characteristics	HABIT-ILE (n=46)	Usual care (n=44)	P value
Age, years, mean (SD)	10.3 (2.9)	10.3 (3.2)	0.9
Sex, male, n (%)	25 (54)	29 (63)	0.3
Primary motor type, n			
(%)	38 (85)	29 (65)	0.09
Spastic	4 (9)	14 (31)	
Dyskinetic	2 (4)	1 (2)	
Ataxic	1 (2)	1 (2)	
Hypotonic			
Motor distribution			
Diplegia	16 (35)	18 (40)	0.9
Quadriplegia	26 (58)	25 (56)	
Triplegia	3 (7)	2 (4)	
GMFCS level, n (%)			
II	16 (35)	15 (33)	0.7
III	14 (32)	17 (38)	
IV	15 (33)	13 (29)	
MACS level, n (%)			
I	12 (26)	4 (9)	0.1
II	22 (48)	27 (61)	
III	11 (24)	10 (23)	
IV	1 (2)	3 (7)	
CFCS level, n (%)			
I	26 (57)	24 (55)	0.5
II	12 (26)	12 (27)	
III	6 (13)	8 (18)	
IV	2 (4)	0	
Comorbidities, n (%)			
Epilepsy	2 (4)	5 (11)	0.3
Autism	2 (4)	2 (5)	0.9
ADHD	1 (2)	3 (7)	0.3
Intellectual Disability	10 (22)	12 (27)	0.6
Learning Disability	7 (15)	5 (11)	0.6
HABIT-ILE Site, n (%)			
Brisbane	21 (53.5)	19 (48)	0.9
Sydney	15 (52)	14 (48)	
Perth	10 (48)	11 (52)	
Type of School, n (%)			
State School	28 (61)	32 (73)	0.6
Independent/Private	11 (24)	9 (21)	
School	7 (15)	3 (6)	
Special School			

Key: n, number; GMFCS, Gross Motor Function Classification System; MACS, Manual Abilities Classification System; CFCS, Communication Function Classification System; ADHD, Attention Deficit and Hyperactivity Disorder.

Table 1. Participant demographics of HABIT-ILE and usual care groups

Characteristics	HABIT-ILE (n=46)	Usual care (n=44)	P value
Age, years, mean (SD)	10.3 (2.9)	10.3 (3.2)	0.9
Sex, male, n (%)	25 (54)	29 (63)	0.3
Primary motor type, n (%)			
Spastic	38 (85)	29 (65)	0.09
Dyskinetic	4 (9)	14 (31)	
Ataxic	2 (4)	1 (2)	
Hypotonic	1 (2)	1 (2)	
Motor distribution			
Diplegia	16 (35)	18 (40)	0.9
Quadriplegia	26 (58)	25 (56)	
Triplegia	3 (7)	2 (4)	
GMFCS level, n (%)			
II	16 (35)	15 (33)	0.7
III	14 (32)	17 (38)	
IV	15 (33)	13 (29)	
MACS level, n (%)			
I	12 (26)	4 (9)	0.1
II	22 (48)	27 (61)	
III	11 (24)	10 (23)	
IV	1 (2)	3 (7)	
CFCS level, n (%)			
I	26 (57)	24 (55)	0.5
II	12 (26)	12 (27)	
III	6 (13)	8 (18)	
IV	2 (4)	0	
Comorbidities, n (%)			
Epilepsy	2 (4)	5 (11)	0.3
Autism	2 (4)	2 (5)	0.9
ADHD	1 (2)	3 (7)	0.3
Intellectual Disability	10 (22)	12 (27)	0.6
Learning Disability	7 (15)	5 (11)	0.6
HABIT-ILE Site, n (%)			
Brisbane	21 (53.5)	19 (48)	0.9
Sydney	15 (52)	14 (48)	
Perth	10 (48)	11 (52)	
Type of School, n (%)			
State School	28 (61)	32 (73)	0.6
Independent/Private School	11 (24)	9 (21)	
Special School	7 (15)	3 (6)	

Key: n, number; GMFCS, Gross Motor Function Classification System; MACS, Manual Abilities Classification System; CFCS, Communication Function Classification System; ADHD, Attention Deficit and Hyperactivity Disorder.

Table 2. Between and within group differences for HABIT-ILE and control groups at T2 and T3 (2- and 26-weeks post baseline) for clinical outcomes

Outcome	Baseline, mean (SD)	2 weeks, mean (SD)	26 wks, mean (SD)	2 wk between group difference MD (95% CI) *p* value	26 wk between group difference, MD (95% CI) *p* value	2 wk within group difference, MD (95% CI) *p* value	26 wk within group difference, MD (95% CI) *p* value
ABILHAND-Kids	0.73 (1.8)	1.43 (1.87)	1.77 (2.08)	**0.85 (0.38, 1.33) 0.001**	**0.99 (0.47, 1.51) <0.001**	**0.66 (0.27, 1.04) 0.002**	**0.90 (0.49, 1.32) <0.001**
HABIT-ILE	0.95 (2.0)	0.66 (2.00)	0.77 (2.05)			-0.21 (-0.52, 0.10) 0.18	-0.09 (-0.41, 0.23) 0.58
Usual care							
GMFM-66							
HABIT-ILE	56.45 (14.24)	58.31 (14.45)	58.06 (15.03)	0.33 (-0.75, 1.41) 0.54	0.79 (-0.45, 2.04) 0.21	0.89 (-0.03, 1.80) 0.057	0.98 (-0.01, 1.96) 0.052
Usual Care	56.41 (14.0)	56.35 (12.47)	55.21 (13.39)			0.53 (-0.04, 1.11) 0.069	0.12 (-0.66, 0.91) 0.75
BoHA							
HABIT-ILE	58.41 (13.00)	58.35 (11.55)	58.5 (11.69)	0.52 (-1.59, 2.63) 0.62	0.24 (-2.28, 2.76) 0.85	1.14 (-0.47, 2.75) 0.16	1.23 (-0.64, 3.09) 0.19
Usual Care	56.25 (11.08)	55.88 (9.37)	56.18 (10.96)			0.86 (-0.60, 2.32) 0.24	1.15 (-0.60, 2.90) 0.19
COPM Perform							
HABIT-ILE	2.84 (1.03)	7.81 (1.22)	7.05 (1.36)	**3.72 (3.04, 4.40) <0.001**	**3.46 (2.87, 4.05) <0.001**	**4.98 (4.53, 5.43) <0.001**	**4.20 (3.63, 4.77) <0.001**
Usual Care	2.68 (0.98)	4.01 (2.02)	3.57 (1.32)			**1.33 (0.76, 1.89) <0.001**	**0.85 (0.43, 1.28) <0.001**
COPM Sat							
HABIT-ILE	3.35 (1.46)	8.22 (1.16)	7.45 (1.42)	**3.60 (2.85, 4.36) <0.001**	**3.31 (2.60, 4.02) <0.001**	**4.89 (4.39, 5.39) <0.001**	**4.09 (3.45, 4.73) <0.001**
Usual Care	2.95 (1.19)	4.45 (2.36)	4.13 (1.79)			**1.48 (0.83, 2.12) <0.001**	**1.12 (0.65, 1.60) <0.001**
6MWT							
HABIT-ILE	269.4 (134.96)	274.21 (126.10)	285.98 (138.98)	4.73 (-21.86, 31.32) 0.72	10.82 (-15.9, 37.55) 0.42	3.55 (-18.97, 26.07) 0.75	8.15 (-11.90, 28.20) 0.41
Usual Care	233.4 (137.35)	223.89 (130.3)	222.29 (105.75)			4.08 (-12.32, 20.48) 0.62	2.43 (-16.35, 21.20) 0.79
PEDI-CAT DA							
HABIT-ILE	52.47 (4.27)	54.41 (3.96)	54.65 (4.46)	**2.17 (1.39, 2.94) < 0.001**	**2.43 (0.48, 4.38) 0.02**	**2.00 (1.36, 2.64) <0.001**	**2.18 (1.27, 3.10) <0.001**
Usual Care	52.76 (4.44)	52.60 (4.09)	52.614 (4.15)			-0.19 (-0.68, 0.29) 0.42	-0.56 (-1.27, 0.14) 0.11
PEDI-CAT Mob							
HABIT-ILE	56.33 (6.17)	57.09 (6.19)	56.35 (7.06)	**1.53 (0.02, 3.05) 0.05**	0.53 (-2.38, 3.44) 0.72	0.71 (-0.30, 1.72) 0.17	-0.18 (-1.37, 1.00) 0.76
Usual Care	56.95 (5.07)	55.98 (6.11)	55.73 (5.58)			-0.83 (-2.02, 0.35) 0.16	-0.63 (-1.61, 0.36) 0.20

Key: GMFM-66, Gross Motor Function Measure - 66; BoHA, Both Hands Assessment; COPM, Canadian Occupational Performance Measure; Perf, Performance; Sat, Satisfaction; 6MWT, 6 Minute Walk Test; PEDI-CAT, Pediatric Evaluation of Disability Computer Adapted Test; DA, Daily Activities; Mob, Mobility.
Sample size: ABILHAND-Kids HABIT-ILE T1=46, T2=44, T3=42; Control T1=44, T2=42, T3=40; GMFM HABIT-ILE T1=45, T2=43, T3 n=40; Control T1=44, T2=41, T3=38; BoHA HABIT-ILE T1=46, T2=43, T3=40; Control T1=44, T2=42, T3=39; COPM HABIT-ILE T1=45, T2=44, T3=42; Control T1=44, T2=42, T3=40; 6MWT Control n=38 T1, n=36 T2, n=31 T3; HABIT-ILE n=33 T1, n=33 T2, n=28 T3; PEDI-CAT HABIT-ILE T1=44, T2=43, T3=43; Control T1=40, T2=38, T3=38.

Table 3. Quality of life between and within group differences for HABIT-ILE and control groups at 12 and 13 (2nd and 26-weeks post baseline)

Outcome	**Baseline, mean (SD)**	**2 weeks, mean (SD)**	**26 wks, mean (SD)**	**2 wk between group difference MD (95% CI) *p* value**	**26 wk between group difference, MD (95% CI) *p* value**	**2 wk within group difference, MD (95% CI) *p* value**	**26 wk within group difference, MD (95% CI) *p* value**
Cerebral Palsy Quality of Life Questionnaire, Child Version, Parent Proxy							
Social Well-being							
HABIT-ILE	78.57 (10.12)	77.64 (9.51)	78.70 (9.90)	-0.19 (-4.49, 4.11) 0.93	1.21 (-3.23, 5.65) 0.59	-0.79 (-3.70, 2.11) 0.58	-1.02 (-4.25, 3.30) 0.52
Usual Care	78.39 (11.15)	78.04 (13.40)	76.83 (11.34)			-0.73 (-4.81, 3.34) 0.72	-1.84 (-5.83, 2.16) 0.35
Functioning							
HABIT-ILE	64.85 (13.36)	66.95 (12.32)	69.04 (11.84)	2.87 (-1.54, 7.29) 0.20	3.44 (-1.12, 7.99) 0.14	2.40 (-1.59, 6.39) 0.23	**3.16 (0.33, 5.99) 0.03**
Usual Care	69.28 (11.03)	67.39 (14.09)	68.09 (12.46)			-1.84 (-5.37, 1.70) 0.30	-1.61 (-5.41, 2.20) 0.39
Participation							
HABIT-ILE	58.38 (14.30)	60.33 (13.67)	60.34 (13.98)	2.75 (-2.09, 7.58) 0.27	2.80 (-2.17, 7.77) 0.27	2.37 (-1.09, 5.84) 0.17	1.50 (-2.00, 5.00) 0.39
Usual Care	60.17 (12.55)	59.23 (16.26)	58.22 (14.88)			-0.80 (-4.52, 2.91) 0.66	-1.07 (-5.70, 3.56) 0.64
Emotional Well-being							
HABIT-ILE	77.92 (9.87)	78.70 (10.81)	77.27 (9.87)	2.47 (-1.74, 6.67) 0.25	0.30 (-4.05, 4.64) 0.9	1.07 (-1.94, 4.07) 0.48	-0.65 (-3.77, 2.47) 0.67
Usual Care	79.23 (8.64)	77.22 (12.27)	77.49 (9.15)			-1.94 (-5.66, 1.77) 0.29	-1.26 (-5.09, 2.56) 0.50
Access to services							
HABIT-ILE	57.93 (14.59)	61.68 (15.50)	60.70 (13.04)	2.30 (-3.91, 8.50) 0.49	0.97 (-5.36, 7.30) 0.76	3.08 (-2.09. 8.26) 0.23	0.90 (-4.42, 6.21) 0.73
Usual Care	62.59 (14.68)	61.58 (16.91)	59.90 (15.48)			-0.78 (-5.44, 3.88) 0.74	-2.18 (-7.88, 3.52) 0.44
Pain and bother*							
HABIT-ILE	30 (17.03)	28.36 (14.52)	29.86 (16.87)	-2.80 (-8.45, 2.84) 0.33	-3.71 (-9.54, 2.11) 0.21	-0.96 (-5.25, 3.33) 0.65	0.43 (-3.65, 4.50) 0.83
Usual Care	32.69 (14.88)	32.91 (14.52)	34.20 (14.95)			0.70 (-4.30, 5.69) 0.78	3.97 (-2.02, 9.96) 0.19
Family Health							
HABIT-ILE	61.31 (18.17)	61.49 (16.69)	62.97 (16.16)	**7.37 (1.75, 13.00) 0.01**	5.01 (-0.76, 10.79) 0.09	1.23 (-2.83, 5.29) 0.54	0.60 (-4.06, 5.27) 0.79
Usual Care	61.12 (15.56)	55.59 (19.13)	58.54 (16.74)			**-6.44 (-11.09, -1.79) 0.008**	**-5.21 (-9.88, -0.54) 0.03**
Cerebral Palsy Quality of Life Questionnaire, Child Version, Child Self-report							
Social Well-being							
HABIT-ILE	81.39 (11.67)	86.06 (11.80)	79.43 (11.01)	-4.00 (-10.94, 2.94) 0.26	-6.17 (-12.94, 0.59) 0.07	2.11 (-2.56, 6.79) 0.34	-1.08 (-6.63, 4.47) 0.68
Usual Care	80.29 (10.47)	84.80 (8.22)	81.20 (8.95)			**8.21 (1.80, 14.63) 0.02**	7.02 (-1.77, 15.82) 0.10
Functioning							
HABIT-ILE	79.28 (12.56)	82.45 (15.97)	78.13 (13.24)	-1.06 (-9.09, 6.96) 0.80	0.04 (-7.83, 7.91) 1.0	2.93 (-1.18, 7.03) 0.14	1.98 (-4.02, 7.99) 0.49
Usual Care	80.42 (10.24)	79.63 (9.27)	74.45 (11.42)			4.67 (-0.18, 9.51) 0.06	2.39 (-10.50, 15.29) 0.67
Participation							
HABIT-ILE	74.95 (13.86)	79.81 (14.23)	69.85 (12.48)	0.05 (-10.94, 11.04) 1.0	-0.83 (-11.62, 9.95) 0.89	2.84 (-2.07, 7.75) 0.23	-5.33 (-13.22, 2.56) 0.17
Usual Care	73.13 (16.16)	77.15 (9.99)	64.66 (16.20)			7.06 (-6.20, 20.32) 0.24	-0.89 (-26.87, 25.09) 0.94
Emotional Well-being							
HABIT-ILE	86.79 (12.47)	88.78 (13.86)	81.53 (11.13)	-0.71 (-8.23, 6.80) 0.85	-6.07 (-13.49, 1.25) 0.11	4.38 (-0.14, 8.89) 0.06	-1.44 (-7.93, 5.05) 0.64
Usual Care	85.92 (10.24)	87.73 (12.39)	81.88 (15.12)			4.35 (-1.70, 10.39) 0.13	4.35 (-6.61, 15.30) 0.37
Pain and bother							
HABIT-ILE	30.28 (18.29)	28.73 (13.64)	30.21 (16.50)	-6.91 (-18.25, 4.43) 0.23	8.15 (-3.10, 19.40) 0.16	4.43 (-6.98, 15.83) 0.41	-2.64 (-12.54, 7.25) 0.57
Usual Care	28.39 (14.17)	37.85 (7.53)	24.53 (13.56)			8.18 (-8.02, 24.39) 0.26	-9.00 (-31.38, 13.37) 0.36

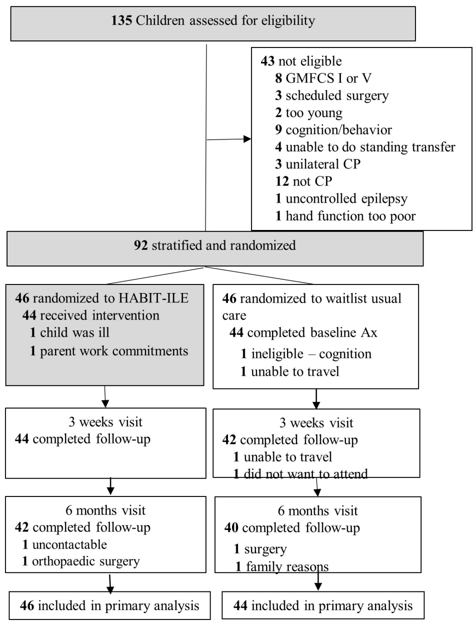
Cerebral Palsy Quality of Life Questionnaire, Teen Version, Parent Proxy							
General Health and Participation							
HABIT-ILE	55.05 (32.49)	62.04 (26.73)	66.47 (24.73)	2.81 (-5.50, 11.12) 0.51	**11.21 (2.95, 19.47) 0.008**	6.99 (-1.25, 15.23) 0.08	11.42 (-0.79, 23.63) 0.06
Usual Care	66.06 (15.82)	69.42 (10.64)	64.21 (13.18)			-0.44 (-4.76, 3.89) 0.82	-3,54 (-14.85, 7.77) 0.48
Communication and Physical Health							
HABIT-ILE	61.85 (27.06)	69.06 (23.00)	71.90 (20.58)	5.28 (-1.99, 12.56) 0.16	**12.77 (5.48, 20.05) 0.001**	**7.21 (2.48, 11.95) 0.01**	**10.05 (1.14, 18.96) 0.03**
Usual Care	69.32 (12.16)	70.41 (11.96)	65.63 (11.81)			-0.29 (-5.67, 5.08) 0.90	-5.37 (-15.42, 4.77) 0.25
School Well-being							
HABIT-ILE	57.81 (30.73)	58.33 (31.39)	65.44 (22.63)	2.94 (-5.79, 11.67) 0.51	**9.08 (0.31, 17.84) 0.04**	0.52 (-2.70, 3.75) 0.70	7.63 (-3.15, 18.41) 0.13
Usual Care	68.89 (15.20)	66.80 (13.94)	68.55 (10.04)			-5.08 (-11.31, 1.16) 0.10	-4.30 (-15.51, 6.91) 0.39
Social Well-being							
HABIT-ILE	69.05 (25.92)	76.49 (21.29)	75.89 (17.08)	4.92 (-4.10, 13.94) 0.29	7.27 (-1.81, 16.36) 0.12	7.44 (-0.89, 15.77) 0.07	6.85 (-5.89, 19.58) 0.23
Usual Care	81.79 (11.57)	82.37 (11.94)	79.69 (12.15)			-1.97 (-7.96, 4.02) 0.46	-5.88 (-15.52, 3.76) 0.19
Access to Services							
HABIT-ILE	58.10 (7.32)	62.32 (11.65)	58.45 (9.90)	-3.49 (-11.07, 4.09) 0.37	-7.09 (-14.66, 0.48) 0.07	4.22 (-4.36, 12.81) 0.26	0.35 (-8.32, 9.02) 0.92
Usual Care	59.97 (18.16)	66.49 (6.94)	65.45 (8.31)			6.08 (-7.04, 19.20) 0.31	7.64 (-7.51, 22.79) 0.27
Family health							
HABIT-ILE	62.5 (33.25)	60.94 (37.02)	61.98 (30.39)	-3.49 (-16.81, 9.84) 0.61	-0.93 (-14.23, 12.37) 0.89	-1.56 (-17.60, 14.47) 0.81	-0.52 (-21.31, 20.26) 0.95
Usual Care	68.47 (13.58)	70.31 (6.68)	69.53 (9.56)			-1.95 (-7.87, 3.96) 0.46	-1.56 (-13.90. 10.77) 0.77
Functioning							
HABIT-ILE	55.42 (23.63)	65.42 (18.53)	66.25 (17.94)	2.10 (-9.27, 13.46) 0.72	**11.67 (0.29, 23.04) 0.04**	10 (-5.48, 25.48) 0.16	10.83 (-1.32, 22.99) 0.07
Usual Care	55.91 (15.82)	64.06 (21.13)	55.94 (10.60)			7.5 (-4.89, 19.89) 0.20	-1.56 (-12.04, 8.91) 0.73
Cerebral Palsy Quality of Life Questionnaire, Teen Version, Self-report							
General Health and Participation							
HABIT-ILE	63.01 (25.29)	74.19 (17.77)	71.33 (19.23)	3.91 (-5.68, 13.50) 0.43	8.08 (-2.67, 18.82) 0.14	11.17 (-3.27, 25.61) 0.1	**14.05 (1.06, 27.04) 0.04**
Usual Care	69.31 (7.41)	75.88 (6.94)	75.69 (14.66)			3.80 (-1.70, 9.30) 0.14	0.30 (-23.84, 24.44) 0.97
Communication and Physical Health							
HABIT-ILE	69.79 (20.87)	75.97 (17.76)	73.28 (13.07)	2.85 (-6.79, 12.50) 0.56	1.45 (-8.61, 11.51) 0.78	6.18 (-4.33, 16.69) 0.19	8.59 (-5.55, 22.73) 0.17
Usual Care	72.22 (9.61)	74.05 (9.84)	77.34 (10.77)			1.88 (-9.47, 13.24) 0.69	4.49 (-22.25, 31.24) 0.63
School Well-being							
HABIT-ILE	65.10 (23.94)	73.59 (19.68)	67.19 (15.23)	6.86 (-3.62, 17.34) 0.20	6.32 (-5.97, 18.60) 0.31	**8.48 (1.18, 15. 79) 0.03**	9.06 (-0.38, 18.51) 0.06
Usual Care	76.56 (10.45)	76.34 (9.31)	74.48 (17.28)			-0.78 (-9.57, 8.00) 0.83	-0.39 (-29.41, 28.63) 0.97
Social Well-being							
HABIT-ILE	71.78 (24.38)	81.35 (14.00)	72.92 (13.83)	7.06 (-2.55, 16.68) 0.15	-2.93 (-13.05, 7.20) 0.57	9.57 (-5.28, 24.42) 0.16	5.36 (-11.82, 22.53) 0.44
Usual Care	82.41 (7.27)	80.61 (10.88)	81.30 (10.36)			-3.08 (-12.24, 6.09) 0.43	-1.86 (-20.44, 16.73) 0.77
Functioning							
HABIT-ILE	67.08 (19.58)	82.08 (11.23)	77.5 (16.01)	2.44 (-5.15, 10.02) 0.53	-3.16 (-11.90, 5.58) 0.48	**15 (3.99, 26.01) 0.02**	13 (-2.11, 28.11) 0.08
Usual Care	66.11 (15.37)	80 (10.10)	80.83 (6.06)			11.25 (-0.57, 23.07) 0.06	11.25 (-15.04, 37.54) 0.27

Key: CPQOL, Cerebral Palsy Quality of Life; SD, standard deviation; MD, mean difference; CI, confidence interval. * lower scores are better for Pain and bother domain. Sample size : CPQOL Child Parent: Control n=33 T1, n=33 T2, n=30 T3; HABIT-ILE n=34 T1, n=34 T2, n=32 T3 ; CPQOL Child: Control n=7 T1, n=7 T2, n=7 T3; HABIT-ILE n=13 T1, n=12 T2, n=13 T3 ; CPQOL Teen Parent Proxy: Control n=11 T1, n=8 T2, n=8 T3; HABIT-ILE n=6 T1, n=6 T2, n=6 T3 ; CPQOL Teen Self-report: Control n=9 T1, n=7 T2, n=6 T3; HABIT-ITL n=6 T1, n=6 T2, n=5 T3.

Table 4. Between and within group differences for groups at T2 and T3 (2- and 26-weeks post baseline) for gross motor outcomes by GMFCS level

Outcome	Baseline, mean (SD)	2 weeks, mean (SD)	26 wks, mean (SD)	2 wk between group difference MD (95% CI) *p* value	26 wk between group difference, MD (95% CI) *p* value	2 wk within group difference, MD (95% CI) *p* value	26 wk within group difference, MD (95% CI) *p* value
GMFCS II							
GMFM-66							
HABIT-ILE	71.94 (6.91)	73.83 (7.73)	74.26 (7.76)	0.98 (-1.25-3.22) 0.37	1.76 (-0.48-4.01) 0.12	**1.89 (0.31-3.47) 0.02**	**2.37 (0.69-2.06) 0.01**
Usual Care	72.28 (8.17)	71.63 (6.24)	71.88 (4.82)			0.95 (-0.69-2.58) 0.23	0.64 (-0.76-2.04) 0.33
6MWT							
HABIT-ILE	379.20 (66.82)	373.50 (88.75)	385.83 (83.88)	0.63 (-54.71-55.98) 0.98	30.71 (-14.07-75.48) 0.17	9.03 (-50.43-32.36) 0.65	3.86 (-25.04-32.76) 0.78
Usual Care	357.70 (83.27)	338.12 (78.18)	310.60 (50.04)			-1.13 (-34.20-36.46) 0.95	-17.62 (-51.17-15.93) 0.27
PEDI-CAT Mob							
HABIT-ILE	62.06 (2.17)	63.69 (2.50)	63.13 (2.97)	1.09 (-0.35-2.54) 0.13	**1.81 (0.35- 3.28) 0.02**	**1.47 (0.53-2.40) 0.005**	**1.27 (-0.17-2.36) 0.03**
Usual Care	61.47 (1.46)	62.00 (2.08)	60.82 (1.60)			0.54 (-0.80-1.88) 0.40	-0.55 (-1.41-0.32) 0.19
GMFCS III							
GMFM-66							
HABIT-ILE	54.95 (5.35)	55.20 (4.12)	55.21 (4.67)	0.60 (-0.95-2.15) 0.44	0.17 (-2.18-2.52) 0.89	0.25 (-1.54-2.04) 0.77	-0.16 (-2.19-1.88) 0.87
Usual Care	52.68 (5.93)	52.77 (5.61)	52.34 (7.41)			0.09 (-0.59-0.78) 0.78	-0.34 (-1.71-1.04) 0.61
6MWT							
HABIT-ILE	192.07 (80.76)	194.71 (71.62)	193.90 (91.74)	-2.23 (-36.47-32.00) 0.90	-13.06 (-57.29-31.16) 0.55	2.64 (-21.42-26.71) 0.82	2.00 (-32.13-36.13) 0.90
Usual Care	192.00 (80.24)	196.88 (96.90)	214.81 (86.34)			4.88 (-20.45-30.21) 0.69	14.69 (-14.27-14.27) 0.30
PEDI-CAT Mob							
HABIT-ILE	56.23 (2.62)	55.93 (2.43)	55.33 (4.64)	1.03 (-1.26-3.31) 0.36	-0.84 (-4.15-2.46) 0.60	-0.15 (-1.33-1.03) 0.78	-0.64 (-3.33-2.06) 0.61
Usual Care	56.08 (2.81)	55.47 (3.16)	56.13 (2.96)			-1.08 (-3.65-1.49) 0.38	0.08 (-2.36-2.53) 0.94
GMFCS IV							
GMFM-66							
HABIT-ILE	41.32 (6.00)	42.55 (6.02)	41.98 (5.26)	-0.40 (-2.27-1.46) 0.66	0.09 (-2.03-2.20) 0.93	0.35 (-1.30-1.99) 0.66	0.41 (-1.13-1.95) 0.57
Usual Care	41.88 (6.16)	43.81 (5.10)	41.74 (7.54)			**0.34 (0.01-1.44) 0.047**	0.34 (-1.31-2.00) 0.65
6MWT							
HABIT-ILE	39.83 (49.54)	115.67 (35.02)	41.98 (5.26)	**58.58 (7.63-109.55) 0.03**	36.56 (-39.63-112.75) 0.25	70.67 (-43.61-184.66) 0.12	48.67(-110.05-207.39) 0.32
Usual Care	45.00 (40.93)	52.92 (50.75)	41.74 (7.52)			13.08 (-5.35-31.52) 0.13	3.50 (-44.91-51.91) 0.83
PEDI-CAT Mob							
HABIT-ILE	49.86 (5.07)	50.71 (3.85)	49.46 (4.70)	2.62 (-0.84-6.08) 0.13	0.07 (-3.28-3.43) 0.96	0.69 (-2.36-3.75) 0.63	-1.58 (-4.35-1.19) 0.23
Usual Care	51.30 (4.60)	49.00 (5.58)	49.50 (5.66)			-2.30 (-4.76-0.16) 0.06	**-1.67 (-3.25- -0.08) 0.04**

Key: SD, standard deviation; HABIT-ILE, Hand Arm Bimanual Intensive Training Including Lower Extremity; 6MWT, 6 Minute Walk Test; GMFM-66, Gross Motor Function Measure – 66; PEDI-CAT, Pediatric Evaluation of Disability Inventory; Mob, mobility; wk, week.



CP indicate cerebral palsy; HABIT-ILE, Hand Arm Bimanual Intensive Training Including Lower Extremity; GMFCS, Gross Motor Function Classification System

Declaration of interests

☐ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☒ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Leanne Sakzewski reports financial support was provided by National Health and Medical Research Council. Roslyn N Boyd reports financial support was provided by National Health and Medical Research Council. Leanne Sakzewski reports a relationship with Australasian Academy of Cerebral Palsy and Developmental Medicine that includes: board membership. There are no If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.