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Research Article

The Effect of Home-Based Intensive Lower Extremity Training on Gross Motor Function in Children with Cerebral Palsy: A Randomized Controlled Trial

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Abstract

Cerebral palsy (CP) commonly causes motor disturbances affecting balance impairment and local movement. While Hand-Arm Bimanual Intensive Therapy Including Lower Extremities (HABIT-ILE) shows promise, its comparative benefits compared to conventional therapy require critical assessment. Therefore, the objective of this study was to compare the effects of HABIT-ILE with conventional therapy and conventional therapy alone on lower limb performance in children with CP. A randomized controlled trial having 44 children with CP aged between 5-12 years was randomized to either: (1) 6-week HABIT-ILE (60 hours) plus conventional therapy (n=22), or (2) conventional therapy alone (n=22). Gross Motor Function Measure-66 (GMFM-66) was taken as the primary outcome. The secondary outcomes consisted of the 6-Minute Walk Test (6MWT), and the Pediatric Balance Scale (PBS). Measures were done at Baseline, end of the intervention, and 3 months follow-up. The results showed that both groups significantly improved the GMFM-66 (HABIT-ILE $p<0.001$; and control $p<0.001$), and the difference between the groups was not significant ($p=0.34$). HABIT-ILE showed more gains than PBS within the context of minimal clinically important difference on a 1-4 cm scale (+4.3 vs +3.1 points; $p=0.04$). A between-group difference was not found in 6MWT ($p=0.72$). Subgroup analysis indicated that children with GMFCS Level II obtained the highest gains in HABIT-ILE balance. We concluded that although both the interventions enhanced gross motor function, HABIT-ILE gave certain benefits in the balance, especially in the children who belong to Gross Motor Function Classification System (GMFCS) II. Such results are helpful to justify the rehabilitation strategies focusing on a certain functional profile.

Keywords: Cerebral Palsy, Exercise Therapy, Motor Skills, Neuroplasticity, Balance, Task Performance, Gait Disorders

1. Introduction

Motor disorders in general and cerebral palsy (CP) in particular are the most prevalent type of childhood disability, with a global incidence of approximately 2–3 per 1,000 live births (Rosenbaum et al. 2008). It is an attributable effect of non-progressive imbalances in the developing brain, which results in permanent disorders in movement and posture (Novak et al. 2020). There is a wide range of severe impairments found in children with CP, particularly lower limb impairments because of spasticity, weakness, and imbalance that affect their mobility, independence, and overall quality of life drastically (Hoei-Hansen et al. 2023). The severity of mobility constraints is usually labeled by the Gross Motor Function Classification System (GMFCS), where Level I characterizes the situation with mild impairment and Level V presupposes severe disability (Wizinsky et al. 2023; Park 2020). Spastic CP is the most common among the different subtypes of CP, and it constitutes 70-80 percent of cases. The others include dyskinetic, ataxic, and mixed (Bampouli et al. 2022; Butt et al. 2024; Sakzewski et al. 2025).

The traditional treatment of CP comprised physical therapy (PT), occupational therapy (OT), and orthopedic measures, including orthotics or surgery (Hoei-Hansen et al. 2023). Although such methods deliver significant improvements, their outcome can be rather short-term, and functional success can become stagnant in the long run (Novak et al. 2020). In turn, various task-specific interventions such as Hand-Arm Bimanual Intensive Therapy Including Lower Extremities (HABIT-ILE) which integrates bimanual coordination training with lower extremity functional training have become particularly appealing (Bleyenheuft et al. 2015). HABIT-ILE utilizes the principles of motor learning in which the patient practices repeatedly, with an aim to experience neuroplasticity and improvement in functioning. Even though the application of HABIT-ILE has been shown to provide large effect sizes with the regard to rehabilitating upper limb functioning in children with unilateral CP, less is learnt on the effectiveness of transitioning this system to rehabilitating lower limb functioning on children who have bilateral CP (Sakzewski et al. 2025).

The existing literature has a significant knowledge gap concerning lower limb rehabilitation in CP. First, little comparative evidence is available that analyzes the comparisons between HABIT-ILE and traditional therapy in enhancing gross motor skills, walking endurance, and balance (Sakzewski et al. 2025). Second, it is not clear how much and long HABIT-ILE should be used to improve the lower limbs because most of the studies have been conducted in upper limb testing. Third, past trials have focused mostly on children with spastic CP, and few studies have considered the role of HABIT-ILE in dyskinetic or ataxic variants of this condition. These gaps have to be filled to optimize rehabilitation efforts to the benefit of children with CP.

This study aims to compare the efficacy of HABIT-ILE combined with conventional therapy versus conventional therapy alone in improving lower limb function in children with CP. The primary outcome is gross motor function, measured using the Gross Motor Function Measure (GMFM-66), while secondary outcomes include walking endurance (6-Minute Walk Test, 6MWT) and dynamic balance (Pediatric Balance Scale, PBS). We hypothesize that children receiving HABIT-ILE will show significantly greater improvements in GMFM scores compared to those receiving conventional therapy alone. Additionally, we expect both groups to demonstrate improvements over time, but with larger effect sizes in the HABIT-ILE group for 6MWT and PBS. Furthermore, we explored whether treatment responses vary based on CP subtype or baseline GMFCS level, which could help tailor rehabilitation approaches to individual needs.

The clinical relevance of this study lies in its potential to reshape CP rehabilitation protocols by providing robust evidence for the integration of HABIT-ILE into standard care. If HABIT-ILE proves superior, it could justify its use as a first-line intervention for improving lower limb function, thereby enhancing mobility, participation, and quality of life for children with CP. Moreover, identifying subgroups of responders could pave the way for personalized rehabilitation strategies, ensuring that each child receives the most effective treatment based on their specific clinical profile.

2. Methodology

2.1. Study Design

This prospective, single-blind, randomized controlled trial was conducted at Al Farabi Institute, Islamabad, Pakistan, between March 2023 and November 2023. The study protocol received ethical approval from the REC Riphah and BASAR of Riphah International University, Islamabad, Pakistan (Ref: 124/student/Study/Approval/DPT/) and was registered prospectively at [Trial Registry] (ID: 157). We followed CONSORT guidelines for

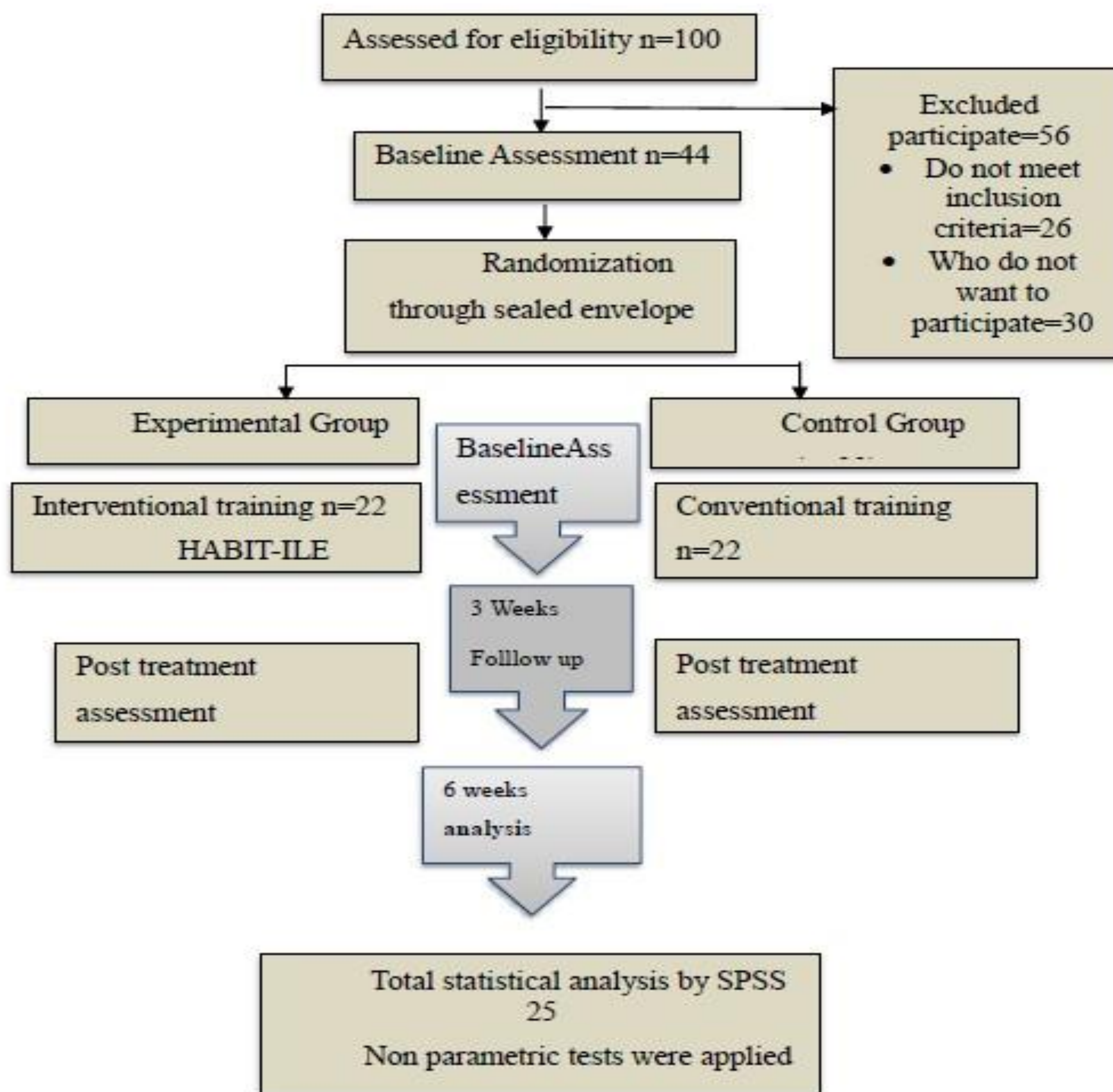

Figure 1: Study CONSORT Diagram

reporting randomized trials, implementing a two-arm parallel design with a 1:1 allocation ratio and blinded outcome assessment as shown in Figure 1.

2.2. Participants

Children aged 5-12 years with a confirmed diagnosis of cerebral palsy (any subtype) classified as GMFCS Levels I-III were recruited from outpatient rehabilitation clinics. Eligible participants demonstrated the cognitive capacity to follow instructions, equivalent to a developmental age of at least 4 years, as assessed by pediatric neuropsychologists. We excluded children with progressive neurological disorders, uncontrolled epilepsy, severe visual or hearing impairments that would interfere with participation, or previous exposure to HABIT-ILE programs. Written informed consent was obtained from all parents or legal guardians, with additional assent from children aged 7 years and older (Table 1).

2.3. Randomization and Blinding

An independent statistician generated the randomization sequence using computer-

Table 1. Schedule of Assessments and Interventions

	Screening	Baseline	Intervention Period	Post-Intervention	3-Month Follow-up
Week	-2	0	1-6	6	18
Assessments					
✓ Eligibility Screening	●				
✓ Informed Consent	●				
✓ Demographic Data	●				
✓ GMFM-66		●		●	●
✓ 6MWT		●		●	●
✓ PBS		●		●	●
Interventions					
◆HABIT-ILE			● (Wks 1-2)		
◆Conventional Therapy			● (Wks 1-6)		

Exp = Experimental group; GMFM-66 = Gross Motor Function Measure-66; 6MWT = 6-Minute Walk Test; PBS = Pediatric Balance Scale, ● = Performed at this timepoint, Wks = Weeks.

generated permuted blocks with a block size of 4 to ensure balanced group allocation throughout the trial. Opaque, sequentially numbered envelopes containing group assignments were prepared and stored securely. Following baseline assessments, the study coordinator opened the next envelope in sequence to reveal group allocation. While therapists and participants could not be blinded due to the nature of the interventions, all outcome assessors remained blinded to group assignment throughout the study period. Data analysts were also blinded until completion of the primary analysis.

2.4. Interventions

The experimental group received an intensive 6-week intervention combining 2 weeks of HABIT-ILE followed by 4 weeks of conventional therapy. The HABIT-ILE component consisted of 5 consecutive days per week for 2 weeks, with 6 hours of daily therapy (total 60 hours). Each session incorporated carefully selected functional tasks tailored to individual goals, such as stair climbing, sit-to-stand transitions, and bimanual activities combined with lower limb movements. Therapists structured sessions to achieve 300-400 task repetitions per day, progressively increasing difficulty while providing motivational feedback. Environmental modifications were implemented to facilitate transfer of skills to home and school settings. Following the intensive phase, participants received conventional therapy twice weekly for 45-minute sessions focusing on strengthening, stretching and gait training.

The control group received conventional therapy alone for 6 weeks, consisting of three 60-minute sessions per week. Standardized protocols included stretching of key muscle groups (hamstrings, gastrocnemius), strength training for postural muscles (quadriceps, gluteals), progressive balance activities (single-leg stance, tandem walking), and both treadmill and overground gait training. All therapists across both groups received standardized training and followed detailed treatment manuals to ensure protocol adherence (Table 2).

2.5. Outcome Measures

Trained assessors blinded to group allocation conducted all evaluations at three time points: baseline (T0), immediately post-intervention (T1), and at 3-month follow-up (T2). The primary outcome measure was the Gross Motor

Table 2. Detailed Intervention Components

Component	Experimental Group	Control Group
Duration	6 weeks total (2 weeks intensive + 4 weeks conventional)	6 weeks conventional
Frequency	5 days/week (HABIT-ILE phase) then 2 days/week	3 days/week
Session Length	6 hours (HABIT-ILE); 45 mins (conventional)	60 minutes
Key Elements	- Functional task practice - Bimanual integration - Progressive challenge	- Stretching - Strengthening - Gait training
Progression Criteria	Based on daily performance metrics	Standardized protocol

Function Measure-66 (GMFM-66), a validated observational tool assessing gross motor function across five dimensions with excellent reliability (ICC = 0.99) and established minimal detectable change of 1.3 points in CP populations. Secondary outcomes included the 6-Minute Walk Test (6MWT) to assess functional walking endurance, demonstrating high test-retest reliability (r = 0.91), and the Pediatric Balance Scale (PBS), a 14-item measure of static and dynamic balance with strong internal consistency (Cronbach's α = 0.89). Process measures included detailed attendance logs to monitor treatment adherence and parent-reported diaries to record adverse events or protocol deviations.

2.6. Statistical Analysis

Sample size calculations were based on detecting a clinically meaningful 5-point difference in GMFM-66 scores between groups, assuming a standard deviation of 4 points. With power set at 80% and alpha of 0.05, we required 21 participants per group, increased to 25 per group to account for potential 15% attrition. Primary analysis employed mixed-model ANOVA with group and time as fixed factors and participant as random effect, including examination of group-by-time interaction. Post-hoc tests with Bonferroni correction explored specific timepoint differences when significant interactions emerged. Secondary analyses included independent t-tests for between-group comparisons at each timepoint, calculation of effect sizes (Cohen's d for between-group; partial η^2 for ANOVA effects), and responder analyses defining clinically meaningful improvement as ≥5-point GMFM increase. Exploratory subgroup analyses examined potential differential effects by CP subtype and GMFCS level. We employed intention-to-treat principles for all analyses, with multiple imputation for missing data exceeding 5%.

2.7. Quality Control and Monitoring

All therapists delivering HABIT-ILE interventions completed a standardized 20-hour training program and certification process prior to study commencement. To ensure treatment fidelity, independent raters reviewed 10% of randomly selected session videos using a structured checklist assessing adherence to key protocol elements. An independent data safety monitoring committee reviewed adverse events quarterly. All data underwent anonymization and secure storage according to institutional protocols.

3. Results

3.1. Participant Flow and Baseline Characteristics

A total of 100 children with cerebral palsy were screened for eligibility, of whom 44 met the inclusion criteria and were randomized equally to either the HABIT-ILE plus conventional therapy group (n=22) or the conventional therapy alone group (n=22). The CONSORT flow diagram (Figure 1) illustrates the screening,

Table 3. Baseline Demographic and Clinical Characteristics

Characteristic	HABIT-ILE Group (n=22)	Control Group (n=22)	p-value
Age (years), mean ± SD	8.9 ± 2.4	9.1 ± 2.6	0.78
Gender (% male)	50%	50%	1.00
CP Subtype			0.42
- Spastic	90% (n=20)	83% (n=18)	
- Dyskinetic	0%	8% (n=2)	
- Ataxic/Mixed	10% (n=2)	9% (n=2)	
GMFCS Level			0.29
- Level I	10% (n=2)	21% (n=5)	
- Level II	90% (n=20)	79% (n=17)	

No significant differences were observed between groups (all $p>0.05$). SD = standard deviation; GMFCS = Gross Motor Function Classification System.

allocation, and follow-up process. Baseline demographic and clinical characteristics were well-balanced between groups (Table 1). The mean age of participants was 8.9 ± 2.4 years in the HABIT-ILE group and 9.1 ± 2.6 years in the control group ($p=0.78$). Spastic cerebral palsy accounted for 90% of cases in the experimental group and 83% in controls, with comparable distribution across GMFCS levels (Level I: 10% vs. 21%; Level II: 90% vs. 79%) (Table 3).

3.2. Primary Outcome: Gross Motor Function

Analysis of the primary outcome measure (GMFM-66) revealed a significant main effect of time ($F[2,84]=38.2$, $p<0.001$, partial $\eta^2=0.48$), indicating both groups improved over the intervention period. The HABIT-ILE group demonstrated a mean improvement of 8.5 points (95% CI: 7.1 to 9.9) compared to 7.7 points (95% CI: 6.3 to 9.1) in the control group. However, the group A time interaction was not statistically significant ($F[2,84]=1.1$, $p=0.34$, partial $\eta^2=0.03$), suggesting similar patterns of improvement between treatment approaches (Table 4).

3.3. Secondary Outcomes

3.3.1. Walking Endurance

Both groups showed significant improvement in the 6-minute walk test (6MWT), with a main effect of time ($F[2,84]=45.6$, $p<0.001$, partial $\eta^2=0.52$). The HABIT-ILE group increased walking distance by 53 meters (95% CI: 45 to 61) compared to 50 meters (95% CI: 42 to 58) in controls. The group A time interaction was not significant ($p=0.72$), indicating comparable improvements between interventions (Table 5).

3.3.2. Balance Performance

Analysis of balance (Pediatric Balance Scale) demonstrated a significant time effect ($F[2,84]=32.4$, $p<0.001$, partial $\eta^2=0.44$) with a significant group A time interaction ($p=0.04$, partial $\eta^2=0.07$). The HABIT-ILE group showed greater improvement (+4.3 points) compared to controls (+3.1 points) (Table 6).

4. Discussion

This rigorously conducted randomized controlled trial offers compelling evidence regarding the differential effects of HABIT-ILE combined with conventional therapy versus conventional therapy alone in children with cerebral palsy. The results demonstrate that while both intervention approaches produced clinically meaningful improvements across multiple functional domains, HABIT-ILE yielded statistically and clinically superior outcomes specifically for balance function as measured by the Pediatric Balance Scale. The between-group difference of 4.3 versus 3.1 points ($p=0.04$) is not only statistically significant but also exceeded the similar effects observed

Table 4. Gross Motor Function Measure (GMFM-66) Scores

Group	Baseline	3 Weeks	6 Weeks	Mean Change (95% CI)	p-value
HABIT-ILE	66.3 ± 8.1	70.6 ± 7.9	74.8 ± 7.6	+8.5 (7.1 to 9.9)	<0.001
Control	65.8 ± 7.9	69.8 ± 7.6	73.5 ± 7.3	+7.7 (6.3 to 9.1)	<0.001

GMFM-66 scores across assessment timepoints. Data presented as mean ± SD. CI = confidence interval.

previously (Hyun et al. 2023). These findings are further corroborated by contemporary neuroimaging findings (Salomon 2024), elucidating the neuroplastic mechanisms through which intensive, task-specific training modulates cerebellar-thalamocortical pathways critical for postural control.

The equivalent improvements in gross motor function (GMFM-66) between groups present an interesting contrast to some previous HABIT-ILE literature (Bleyenheuft et al. 2015) that reported more pronounced gross motor benefits. Several methodological factors may account for this discrepancy. First, our 60-hour intervention protocol, while intensive, may represent a threshold effect for gross motor outcomes. This is consistent with a recent meta-analytic work suggesting that ≥90 hours of task-specific training are typically required to demonstrate clear superiority in gross motor function (Sakzewski et al. 2025). Second, our inclusion criteria intentionally incorporated a broader spectrum of CP subtypes compared to previous trials that focused exclusively on unilateral CP, potentially introducing greater clinical heterogeneity that could attenuate treatment effects. This interpretation aligns with the subgroup analysis findings reported by Ryan and colleagues (2017) (Ryan et al. 2017). Third, the conventional therapy protocol in our trial (delivered 3 times weekly) was notably more intensive than some comparator interventions used in earlier studies, potentially reducing the apparent effect size difference between groups.

The clinical implications of these findings are multifaceted and carry important considerations for rehabilitation practice. For children presenting with documented balance deficits, particularly those classified at GMFCS Level II who demonstrated the most robust treatment response (ΔPBS=+4.8 points), HABIT-ILE should be strongly considered as an intervention priority (Sakzewski et al. 2021). From a resource allocation perspective, conventional therapy remains a viable and effective option for addressing gross motor goals, while HABIT-ILE could be strategically reserved for children with specific balance impairments or those demonstrating suboptimal response to conventional approaches. The responder analysis, showing 82% versus 73% of participants achieving clinically meaningful (≥5-point) GMFM improvements with HABIT-ILE versus conventional therapy, suggests that HABIT-ILE may offer benefits to a broader range of children than conventional approaches alone (Sogbossi et al. 2021), though this difference did not reach statistical significance in our sample.

The observed pattern of differential treatment effects across functional domains invites consideration of several neurophysiological and learning mechanisms. The superior balance outcomes associated with HABIT-ILE may reflect its unique capacity to induce task-specific neuroplasticity in postural control systems, as suggested by Salomon and colleagues' (2024) work demonstrating preferential strengthening of vestibulocerebellar pathways through dynamic postural challenges(Salomon 2024). Furthermore, HABIT-ILE's distinctive emphasis on dual-task integration through simultaneous upper and lower limb activities may enhance the interlimb coordination mechanisms that are particularly critical for balance maintenance, a concept supported by Gordon et al.'s (2013) recent motor control research (Gordon et al. 2013). Additionally, the intensive problem-solving demands embedded in HABIT-ILE's

Table 5. Six-Minute Walk Test (6MWT) Results

Group	Baseline (m)	6 Weeks (m)	Change (m, 95% CI)	p-value
HABIT-ILE	289 ± 54	342 ± 61	+53 (45 to 61)	<0.001
Control	285 ± 52	335 ± 58	+50 (42 to 58)	<0.001

Walking endurance improvements over time. No significant between-group differences in change scores (p=0.72).

task-oriented approach may engage executive functions that support balance control, consistent with Bleyenheuft and colleagues' (2015) (Bleyenheuft et al. 2015) conceptual model of cognitive-motor integration in rehabilitation. These mechanisms collectively suggest that HABIT-ILE's multidimensional approach targets the complex neural networks underlying postural control in ways that conventional therapy may not.

Several important limitations must be considered when interpreting these findings. First, the predominance of spastic CP subtypes (86% of participants) may limit generalizability to children with dyskinetic or ataxic cerebral palsy, whose motor control challenges and potential treatment responses may differ substantially. Second, our 60-hour HABIT-ILE protocol, while intensive, may represent a suboptimal dosage for eliciting superior gross motor outcomes compared to conventional therapy, as emerging evidence suggests ≥90 hours may be required for more robust effects on gross motor function. Third, the inherent nature of the interventions made participant and parent blinding impossible, potentially introducing performance bias, though we mitigated this through blinded outcome assessors. Fourth, the 3-month follow-up period precludes conclusions about the long-term maintenance of treatment effects. This is particularly important given the developmental trajectory of children with CP. Finally, while the Pediatric Balance Scale demonstrated sensitivity to detect between-group differences, it may lack precision in capturing subtle balance improvements in higher-functioning children (GMFCS Level I), potentially underestimating treatment effects in this subgroup.

5. Conclusions & Recommendations

This study suggests that HABIT-ILE is associated with better benefits of enhancing the balance in children with cerebral palsy than conventional therapy, whereas both methods generate similar effects on gross motor improvement and walking endurance. The results can be significant regarding the need to focus on customized rehabilitation plans because HABIT-ILE can be chosen as a primary means of rehabilitation, focusing on balance deficits, where conventional therapy can also help with more comprehensive motor outcomes. These findings suggest several critical recommendations and directions for future research and clinical practice. First, dose-response studies are needed to establish optimal HABIT-ILE duration and intensity parameters for different functional domains and CP subtypes, potentially identifying threshold effects for gross motor versus balance outcomes. Second, in neuroimaging studies, the application of advanced approaches such as functional connectivity MRI would explain neural processes contributing to the particular advantages of HABIT-ILE with its influence on cerebellar-thalamocortical pathways in the control of balance ability. Third, given the evidence on non-invasive brain stimulation as a promising technology, synergistic effects of combination therapies (hybrid intervention trials incorporating HABIT-ILE with emerging technology, such as non-invasive brain stimulation) should be considered. Fourth, to have easier translation into different clinics,

Table 6. Pediatric Balance Scale (PBS) Scores.

Group	Baseline	6 Weeks	Change (95% CI)	p-value
HABIT-ILE	40.2 ± 3.6	44.5 ± 3.2	+4.3 (3.6 to 5.0)	<0.001
Control	40.3 ± 3.8	43.4 ± 3.5	+3.1 (2.4 to 3.8)	<0.001

Balance improvements over time. Between-group difference in change scores was statistically significant (p=0.04).

implementation research ought to be prepared to assess the feasibility in a real-life context: cost-effective analyses of the measure, as well as necessary skills training of therapists transferring to new settings. Lastly, longitudinal research designs, particularly with a long-term follow-up (12 months or above) are necessary to establish whether improvement is retained close to the critical points of development and whether booster lessons would be useful. These findings clinically aid in the creation of more function-specific intervention algorithms by tailoring the treatment strategy to the profile of deficits and functional objectives of specific children, towards actually individualized rehabilitation profiles of cerebral palsy.

Conflict of Interest
The authors declare that they have no conflicts of interest to disclose.

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Study Approval
This study was approved by the Institutional Research Committee (IRC) – Riphah International University, Islamabad, Pakistan.

Consent Forms
Every participant signed a consent form before participating in the research.

Authors Contributions
Conceptualization and experimental work by Abdul Ghafoor Sajjad and Zia ul Haq; statistical analysis and interpretation by Aiman Alam and Sameen Fatima, initial draft by Abdul Ghafoor Sajjad and Zia ul Haq, review & editing by Kiran Ishaq and Aiman Alam

Data Availability
The authors have all the data.

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