

Effectiveness of routine physical therapy with or without home-based intensive bimanual training on clinical outcomes in cerebral palsy children: a randomised controlled trial

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Abstract

Introduction. This study aimed to test how normal physical treatment, with or without home-based intense bimanual training, affected hand coordination and daily living activities in children with cerebral palsy.

Methods. A randomised controlled experiment was carried out at DHQ Hospital in Kasur, Pakistan. Thirty children with unilateral spastic cerebral palsy took part in the study. The first group received standard physical treatment, whereas the second group received bimanual training along with routine physical therapy. Follow-ups were performed in the fourth and sixth weeks. The paediatric motor log activity scale and the ABILHAND questionnaire were used to assess daily activities and coordination, respectively.

Results. At baseline, no significant association was seen between treatment groups and hand coordination outcome among the patients ($p = 0.0450$) and no significant difference was seen in patients in both treatment groups regarding their activities of daily living. In group A, no significant improvement was seen in hand coordination from baseline until the 6th week ($p = 0.257$) while in group B, a significant difference was seen in hand coordination from baseline until the 6th week follow-up ($p = 0.000$).

Conclusions. This study concluded that the combined effect of home-based bimanual exercises and routine physical therapy shows significant achievements in hand coordination and activities of daily living.

Key words: cerebral palsy, bimanual intensive therapy, hand coordination, activities of daily life

Introduction

Cerebral palsy (CP) is a broad term that is explained as a group of neurodevelopmental disorders that affect the central nervous system at developing and immature stages, resulting in improper functioning of the motor unit, postural deficits, and cerebral and mobility changes [1].

According to population-based studies, the overall occurrence of cerebral palsy is measured at approximately 2.1/1000 live births around the globe. Approximately 1 in 278 newly born children is diagnosed with CP every year in the United States [2]. In Khyber Pakhtunkhwa-Pakistan, the occurrence of CP in children was 1.22 per 1000 infants. The majority of the children affected with CP were in the age group of 9 to 10 years [3]. Spastic cerebral palsy is the most common type of CP, which affects 87% of the children with CP. Dyskinetic and ataxic CP occur less frequently in children with CP as compared to spastic CP [4].

Hand-Arm Bimanual Intensive Therapy (HABIT) is a type of intensive bimanual training which plays an important role in enhancing the quality and amount of functioning of affected upper extremity use. Rigorous interventions such as HABIT are mostly provided in surroundings that require adequate observation by an interventionist for many hours a day [5].

The purpose of the study was to explore the effects of bimanual intensive training of the hand at home along with conventional therapies in order to discover functional strategies of self-sufficiency among cerebral palsy children. Bimanual training methods at home are intentionally disregarded in Pakistan for many reasons, such as the high cost and cultural and logistical barriers, which are very significant

for the early success of motor function. This study showed that the involvement of the caregivers along with the physiotherapist in the intervention would lead to better enhancements in coordination, amount of use of both hands, and activities of daily living compared to treatment administered at a clinic.

Subjects and methods

Following the acceptance of the synopsis, a Randomised Controlled Trial was conducted in DHQ Hospital, Kasur, for the duration of the nine months. The sample size determined for both groups was 32, i.e., $n = 32$ (16 patients in each group).

After adding 20% to cover the assumed drop-out rate, the final sample size was 40 (20 in each group). The sample size was calculated using the following information and formula (Figure 1):

$$n = \frac{(Z_{1-\beta} + Z_{1-\alpha/2})^2 (\delta_1^2 + \delta_2^2)}{(\mu_1 - \mu_2)^2}$$

$Z_{1-\alpha/2}$	level of significance	95%
μ_1	expected mean ABILHAND Score in experimental group	6.8 [6]
μ_2	expected mean ABILHAND Score in conventional group	4.70 [6]
δ_1	expected standard deviation in experimental group	1.24 [6]
δ_2	expected standard deviation in conventional group	1.94 [6]
$Z_{1-\beta}$	power of the study	95%
n	expected sample size in a group	16

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Sample Size For Comparing Two Means

Input Data			
Confidence Interval (2-sided)	95%		
Power	95%		
Ratio of sample size (Group 2/Group 1)	1		
	Group 1	Group 2	Difference*
Mean	6.8	4.7	2.1
Standard deviation	1.24	1.94	
Variance	1.5376	3.7636	
Sample size of Group 1	16		
Sample size of Group 2	16		
Total sample size	32		

*Difference between the means

Figure 1. Sample size calculation.

Source: <https://www.openepi.com/SampleSize/SSMean.html>

The non-probability purposive sampling technique was used in this study, which used the following selection criteria: (1) spastic CP children, (2) both male and female, (3) aged 4–7 years, and (4) capable of actively grasping objects from a table, such as stuffed toys and building blocks, while being fully attentive in performing the task. The exclusion criteria were (1) children with cognitive delays preventing them from following two-step instructions, (2) those who have been diagnosed with a disease unrelated to USCP, (3) parents who are unable to commit to the entire duration of the intervention, and (4) children with visual problems that prevent them from performing the intervention task.

In this single blinded randomised controlled trial, registered with ClinicalTrials.gov on 16th February 2021, Trial Registry No. NCT04755556 ABILHAND, a questionnaire was assessed for collecting data. First of all, informed consent was taken from the parents and they were informed about the objectives of the study. After the informed consent, demographic information was filled out by each parent, including name, sex, age, and other related personal data of the cerebral palsy children. A therapist collected data at baseline, at the end of the 4th week and after the 6th week.

Screening

Patients with clinical presentation consistent with the selection criteria were screened by a physiotherapist with more than 5 years of experience and their fulfilment of the selection criteria was verified.

Randomisation

Patients fulfilling the selection criteria were randomly allocated into two groups by using the lottery method.

Intervention

The groups of participants of the home-based training programs included children with USCP aged 4–7 years. Following a modified setup, the children received task- and goal-specific bimanual training from their parents in their home setting for 3 hours per week for 6 weeks. Total treatment sessions were 18 and follow-up was done at the end of the 4th week and after the 6th week. Both programs comprised a preliminary stage (home visit, instruction of parents, introductory meetings with training specialists, design of the modified program and goal setting) and home-based training phase

(home visits by the training team, tele-coaching and video recordings). The program was dissimilar with respect to the training strategy, i.e., how the parents provided assistance to their child during training.

Group 1: Routine physical therapy i.e., EMS, stretching spastic muscles, normalising muscle tone. Exercise for 30 minutes daily for 6 weeks.

Group 2: Physical therapy on a regular basis, supplemented by intensive bimanual training at home, i.e. functional activities building blocks, building beads, play with a ball, etc.

Outcome measures

Activities of daily living (ADL):
Paediatric motor activity log (PMAL) scale

The PMAL is a systematic interview intended to audit how often and how well a child uses his/her affected upper extremity in their familiar habitat outside the therapeutic setting. The parents are asked regulated questions about the extent of use of the affected child’s arm, the How Often Scale, and the capacity of the child’s movement during the functional tasks specified in the instrument, the How Well Scale. These two scales are scored from 0 to 10 [7].

Coordination: ABILHAND

The ABILHAND-Kids Questionnaire was made to assess manual ability in a group of children with cerebral palsy. It delves into the most illustrative list of manual tasks. The ABILHAND-kids questionnaire’s 21 items were defined as a valid and reliable manual ability scale.

Scoring keys

N/A – no activity attempted, 0 – not at all
1 – with great difficulty or only partially, 2 – easily and fully [8].

Data analysis procedure

SPSS Version 20 (IBM Corp, Armonk, NY, USA) was used for data entry and to analyse the data. Quantitative variables such as age and income were presented in the form of mean and standard deviation (SD), whereas qualitative variables, such as sex, etc., were displayed in the form of percentage and frequencies. The Chi-square test was applied to determine the difference in Hand Coordination and Activities of Daily Living in both treatment groups. The Friedman test was applied to calculate the difference in Hand Coordination and Activities of Daily Living in both treatment groups from baseline until the final follow-up, with $p < 0.05$ taken as significant.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Institutional Review Board, Faculty of Allied Health Sciences of the University of Lahore (approval No.: IRB-UOL-FAHS/718-XI/2020). Clinical Trial number: NCT04755556 (<https://clinicaltrials.gov/ct2/show/NCT04755556>).

Informed consent

Informed consent has been obtained from all individuals included in this study.

Results

The results showed that the mean age of the patients in group A was 4.80 ± 0.69 and in group B was 4.85 ± 0.81 years. The minimum and maximum age of the patients ranges between 4–6 years (Table 1). In group A, 9 (45%) patients were male and 11 (55%) patients were female, while in group B, 8 (40%) patients were male and 12 (60%) were female (Table 2). At baseline in group A, 14 (70%) patients and in group B, 6 (30%) patients had not attempted any activity, while 6 (30%) patients in Group A and 14 (70%) in group B had attempted no activity at all. At baseline, no significant association was seen between treatment groups and hand co-ordination

Table 1. Age of patients in treatment groups

Scale	Group A	Group B
N	20	20
Mean	4.80	4.85
SD	0.69	0.81
Minimum	4	4
Maximum	6	6

Table 2. Sex * group cross-tabulation

Categorisation		Group A	Group B	Total	
Sex	male	count	9	8	17
		% within group	45%	40%	42.5%
	female	count	11	12	23
		% within group	55%	60%	57.5%
Total	count	20	20	40	

Table 3. Hand co-ordination in treatment groups during follow ups

Months duaration	Group A	Group B	p	
Baseline	no activity attempted	14 (70%)	6 (30%)	0.011
	not applicable	6 (30%)	14 (70%)	
	only partially / with great difficulty and slowly	0 (0%)	0 (0%)	
	fully and easily	0 (0%)	0 (0%)	
4 th week	no activity attempted	11 (55%)	0 (0%)	< 0.001
	not at all	9 (45%)	5 (25%)	
	only partially / with great difficulty and slowly	0 (0%)	15 (75%)	
	fully and easily	0 (0%)	0 (0%)	
6 th week	no activity attempted	8 (40%)	0 (0%)	< 0.001
	not at all	12 (60%)	0 (0%)	
	only partially / with great difficulty and slowly	0 (0%)	9 (45%)	
	fully and easily	0 (0%)	11 (55%)	

Table 4. Activities of daily living in treatment groups during follow-ups

Months duration	Group A	Group B	p	
Baseline	not used	15 (75%)	0 (0%)	0.690
	very poor	5 (25%)	1 (5%)	
	poor	0 (0%)	19 (95%)	
	fair / moderate	0 (0%)	0 (0%)	
	almost normal	0 (0%)	0 (0%)	
	normal	0 (0%)	0 (0%)	
4 th week	not used	7 (35%)	0 (0%)	< 0.001
	very poor	12 (60%)	0 (0%)	
	poor	0 (0%)	1 (5%)	
	fair / moderate	1 (5%)	15 (75%)	
	almost normal	0 (0%)	4 (26.7%)	
	normal	0 (0%)	4 (20%)	
6 th week	not used	7 (35%)	0 (0%)	< 0.001
	very poor	13 (65%)	0 (0%)	
	poor	0 (0%)	0 (0%)	
	fair / moderate	0 (0%)	3 (15%)	
	almost normal	0 (0%)	11 (55%)	
	normal	0 (0%)	6 (30%)	

outcome among the patients (Table 3) ($p = 0.011$). At baseline, no significant difference was seen in the patients in both treatment groups regarding their activities of daily living (Table 4). In group A, no significant improvement was seen in hand coordination from baseline until the 6th week ($p = 0.223$) while in group B, a significant difference was seen in hand coordination from baseline until the 6th week follow-up ($p = 0.000$).

Discussion

While treating cerebral palsy patients, it is very important to work on developing the gross motor functioning of their affected limb. Evidence suggests that there are four basic components of any exercise prescription: frequency, intensity, time, and type. Among these, studies have proven that the intensity of an exercise plays a vital role in determining the success of any rehabilitation program [9]. Similarly, in this study, intensive bimanual training was prescribed to the patients to achieve a better prognosis and to improve hand coordination and hand grip. This study was related only to the upper extremity, and the results of Bleyenheuft et al. [10] were in line with our results, as they used HABIT-ILE therapy for developing motor skills in the upper and lower extremities of cerebral palsy patients.

Although there is significant evidence suggesting that the exercise intensity is an important component for any rehabilitation program [11], where the paediatric population is concerned, there are several other important factors to be kept in mind as well, such as the resources available. While keeping these scenarios in mind, the rehabilitation program of the child is developed while using the approach called 'family-centred care', which suggests that the treatment should

be able to fulfil the needs of both parties, i.e. the child and their family. It has been seen that the parents find home-based exercise programs a very useful resource for maximising the gross motor skills of their children [12]. The current study adds to the growing body of intensive interventions rooted in naturalistic settings. Some of the examples of these programs include intensive bimanual training [13, 14], modified constraint induced therapy [13, 15, 16], intensive occupational therapy [16–18], task-oriented exercise training [29], cross training [30] and intensive suit training [31]. All the above-mentioned studies used a distributed practice model, where either parents or caregivers were providing home-based therapy activities to the children. Our study also used a similar approach and good prognostic results were obtained. Moreover, a study by Bleyenheuft et al. [19] concluded that the combined effect of home-based rehabilitation and goal-based training has a positive impact on the daily functional activities in children with unilateral CP.

Home-based rehabilitation provides the opportunity for parents to be fully involved in the training of their children. This is in accordance with the family-centred care model, in which care depends on a partnership between parents and physiotherapists [5]. The results of this study are similar to those of Ferre et al. [5], who worked on determining the impact of the family-centred approach on the efficacy of bimanual intensive training. Ferre et al. [6] concluded that intensive training not only improved performance but also the dexterity of functional goals, however, the results of this study did not show any improvement in the bimanual performance of unilateral spastic cerebral palsy children. Hence, the home-based rehabilitation models are not only a valuable asset for treating patients but also a family-centred approach to achieving improved treatment results [5]. Many studies have shown very good results in the prognosis of the cerebral palsy children, although this cannot be generalised as many cerebral palsy children might become frustrated easily and might not cooperate with the therapist and family [20].

In the current study, one group of children with unilateral CP was given routine physiotherapy and the other group of participants was given routine therapy along with home-based intensive bimanual training by their patients. The primary measures that were used in this study were the ABILHAND questionnaire and the PMAL scale. The results align well with the evidence discussed above that the combined effect of home-based bimanual exercises along with routine physical therapy showed a significant enhancement in motor skills development in the cerebral palsy children as compared to the control group. Improvements were seen in daily activity of living in the 4th and 8th week follow-ups. Similarly, hand coordination was improved more in group B than in group A. Similar results were shown when intensive bimanual therapies were applied in the cerebral palsy children and enhanced activity levels of the participants were also reported [21–25]. Another study carried out by Bleyenheuft et al. [19] also showed good scores on the ABILHAND-Kids questionnaire, measuring manual ability in daily life. With the progression of technology and advancement of the field of rehabilitation, the evidence is becoming stronger, and it has been shown in studies that bimanual training and constraint-induced movement therapy have been proven to be one of the best approaches to improving upper-extremity function [26].

In fact, after the successful implementation of HABIL [27], the main focus during training was to induce neuroplasticity in the brain of cerebral palsy children through the repetition and practice of movements.

As the results were found in previous studies of modified forms of CIMT training in young children with a combination of parents, school teachers, and therapists across different environments to fulfil the requirements of treatments [31]. The participants in this study improved dramatically following an intensive period of training. It was investigated how the children responded when their parents or caregivers were trained to provide intensive therapy at home alongside the physical therapist at the clinic.

Because children with hemiplegic CP have one well-functioning hand and have impairments in bimanual coordination in addition to their unimanual impairments, impaired bimanual coordination is likely to be the most difficult challenge to improving function in this population. HABIL was created to focus on improving two-hand coordination in children with hemiplegia while maintaining the high intensity of CIMT. In the current study, the HABIL group showed greater improvement in bimanual coordination (greater movement overlap and shorter goal synchronisation), while the control group, using routine physical therapy, also showed some improvements. As a result, the complexity of movements grew over time [28]. Additionally, in this study, effort was made to fill the gap in the practice and limitations of the past similar studies by providing instructions to caregivers/parents regarding the bimanual conduct of their child and interaction between the parent and child during exercise.

Conclusions

The study concluded that the combined effect of home-based bimanual exercises and routine physical therapy show significant achievements compared to clinical trials. It has previously been suggested that providing home-based training alone reduces parental stress and helps in reducing the costs of clinical treatments. In this study, the children's hand coordination and activities of daily living were much improved due to the combined effect of the two therapies.

Limitations

This study included only unilateral Cerebral Palsy children. Further studies with larger sample sizes on different types of cerebral palsy should be performed to measure the effect of this therapy on different types of Cerebral Palsy. Also, in this study, the GMFCS scale was not used to classify gross motor function.

Disclosure statement

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Conflict of interest

The authors state no conflict of interest.

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