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Original Article

A pilot study to evaluate the efficacy of robotic biofeedback based upper limb rehabilitation in children with hemiplegic cerebral palsy

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ARTICLE INFO

Article history:
Received 24 September 2024
Accepted 15 January 2025
Available online 11 March 2025

Keywords:
Cerebral palsy
Physiotherapy
Robotic biofeedback-based rehabilitation

ABSTRACT

Background: Robotic biofeedback-based Cerebral Palsy (CP) rehabilitation is a novel rehabilitative modality. This single (assessor) blind randomized controlled multicentric pilot trial compared the efficacy of robotic biofeedback-based therapy as an add-on therapy along with conventional physiotherapy versus conventional physiotherapy alone in children with hemiplegic CP between 5-18 years.

Methods: The trial was conducted in two centres for 2.5 years. Hepiplegic CP children with Gross Motor Function Classification System (GMFCS) scores: I-III children were enrolled. Enrolled children's baseline paretic limb Hand-Grip Strengths and Quality of Upper Extremity Skills Test (QUEST) scores were recorded. Children in Intervention Arm received robotic biofeedback-based therapy and conventional physiotherapy. In Control Arm, only conventional physiotherapy was administered. Differential changes in mean hand-grip strengths after 12 months were compared between the two groups (primary outcome). Secondary outcomes included changes in grip strength at 15 months and QUEST scores at 12 and 15 months.

Results: 60 children were enrolled (30 in each Arm). There were 5 dropouts (2 from Intervention Arm). The difference of mean hand-grip strengths between the two groups at 12 months was (-) 0.05, which was insignificant ($p = 0.40$). The difference in secondary outcomes between the two groups was not significant either. No adverse effects were noted.

Conclusion: Add-on robotic biofeedback-based upper limb rehabilitation does not improve hand-grip strength (at 12 and 15 months) and QUEST scores (at 12 and 15 months) of hemiplegic CP children undergoing conventional physiotherapy. The study demonstrated the feasibility, acceptability and lack of adverse effects of this hybrid modality.

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https://doi.org/10.1016/j.mjafi.2025.01.010

Introduction

Cerebral Palsy (CP) is a common neurodevelopmental disorder with far-reaching implications.[1,2] Despite physical therapy being the core of CP management, there is no agreement on a singularly effective, universal physical therapy regimen.[3,4] Conventional physiotherapy targets mobility, strength, coordination and flexibility enabling neuroplastic remodelling.[5] Robotic biofeedback-based CP rehabilitation is a novel modality that employs robotic limb(s)/whole-body robotic devices of varying complexity and sensory biofeedback for physical therapy.[6–8] Except for anecdotal reports, there is a paucity of robust data about this modality. This randomized controlled trial (RCT) was conceptualized to address knowledge gaps regarding the feasibility and efficacy of this modality as an add-on intervention along with conventional physiotherapy in children with hemiplegic CP. The study's research hypothesis was that this hybrid, add-on therapy is more efficacious for upper limb rehabilitation in hemiplegic CP children compared to isolated conventional physiotherapy.

Materials and methods

This multicentric, randomized controlled, single (assessor) blinded, prospective pilot trial with two parallel arms was conducted simultaneously in two tertiary-care government teaching hospitals over 30 months (December 2018 to June 2021). Trial population comprised of clinically diagnosed hemiparetic CP (GMFCS: I – III) children aged 5–18 years presenting to pediatric/pediatric neurology outpatient departments of either study centre. Prior ethical clearances were obtained from Institutional Ethics Committees of both centres. Trial was registered with Clinical Trials Registry -India (CTRI/2021/06/034399) and informed written consent obtained from parents. Principles of Good Clinical Practice (GCP) and Declaration of Helsinki were abided by.

The aim of the study was to compare the efficacy of robotic biofeedback-based rehabilitation for upper limb and conventional physiotherapy with that of conventional physiotherapy alone in 5–18-year-old children with hemiplegic CP with Gross Motor Function Classification System (GMFCS) Scores: I – III.

Children (5–18 years) clinically diagnosed as hemiplegic CP (GMFCS: I-III) with minimum visual acuity of 6/60, ability to follow two-step commands, and parent(s) willing and capable of following instructions and maintaining an activity log were included in the study. 'Hemiplegic CP' included those children who had unilateral motor impairment of the upper and lower extremities with objective signs of hyperreflexia and spasticity originating from static insult to their developing brains. Those children who had received botulinum toxin injection or undergone orthopaedic surgery up to one year prior or who had chronic/acute systemic illnesses that can interfere with the execution of intervention were excluded. A sample size of 30 (Intervention group) + 30 (control group) was adopted as a convenience sample in view of the study being a pilot trial. Variable block-size randomization was done using computer-generated randomization sequence by independent staff.[2,4,6] Serially numbered sealed opaque envelopes were used for group allocation. Data analysis was carried out on anonymized data by an individual who was blinded to the treatment and clinical details.

Consecutive children brought to the study centres were screened for eligibility. Informed parental consent was obtained prior to their enrollment. Their clinico-demographic data were recorded and ID numbers were allotted serially to each child. Hand-grip strength (using a sensor-based dynamometer) and Quality of Upper Extremity Skills Test (QUEST) scores of the paretic upper limb of each child were recorded. Then blinded group-allocation was done.

Specifications of the robotic biofeedback device (Figs, 1 and 2) and intervention schedules are outlined in Table 1. Intervention sessions were logged and deviations, if any, were noted.

The audio-visual- tactile feedback-based, goal-directed games targeted movement training with grip-strength and movement angle estimation. Activities targeted pure and complex movements of the shoulder, elbow, wrist and fingers besides strength and coordination activities like ball-rolling. The games included the following:

(a) Apple collection: While performing this activity, the child had to use his/her affected hand (where a wireless hand sensor was attached) to move a cart in order to load apples falling from trees. The level of difficulty was gradually increased and incorporated visual, auditory and sensory biofeedback. The arm movements involved flexion, extension of the elbow, flexion and extension of wrist and internal and external rotation of the shoulder.

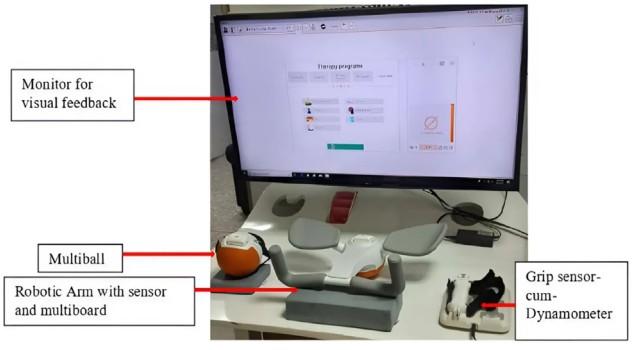

Fig. 1 – Robotic biofeedback-based upper limb rehabilitation device (PABLO X2 ®).

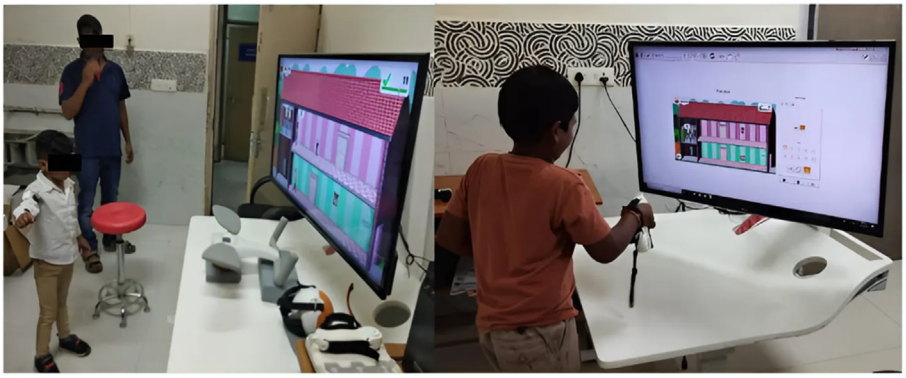

Fig. 2 – Robotic biofeedback-based upper limb rehabilitation session in progress.

Total duration of the activity was 5 min. The activity was individualized using baseline angle and force measurements.

(b) Elevator boarding: This game involved manipulation of a multidirectional sensor-fitted ball to play a simulated game where passengers at different levels of a building had to board a lift. The level of difficulty was increased in subsequent games. Movements involved flexion and extension of elbow, flexion and extension of wrist, internal and external rotation of shoulder, and activities for improving of upper limb strength and coordination. Total duration of activity was 5 min. The activity was individualized using baseline angle and force measurements.

(c) Arrow shooting: This activity involved loading and shooting arrows at a moving target using a cylindrical, sensor-fitted device which was strapped around the wrist and hand of the affected side. The activity was reinforced with visual, auditory and sensory biofeedback. The exercise targeted wrist mobility, hand grip and hand-eye coordination. Total duration of the activity was 5 min. The activity was individualized using baseline angle and force measurements.

(d) Cloud matching: This activity encompassed matching stationary clouds having a particular letter or colour with a similar moving cloud. Here, visual, auditory and sensory feedback were used. As the level of difficulty increased, the child was required to keep pace with the activity by raising the hand above the head and increasing his/her grip on the cylindrical sensor-fitted device. Total duration of the activity was 5 min. The activity was individualized using baseline angle and force measurements.

(e) Car-racing: This is a multi-sensor-based activity where visual, auditory and sensory biofeedback was used. The child who had sensors strapped on his/her forearm and upper arm as well as handled a sensor-fitted ball device had to navigate a car through multiple levels of difficult terrains. This activity encouraged hand-eye coordination, rapid decision-making and hand mobility. Total duration of the activity was 5 min. The activity was individualized using baseline angle and force measurements.

Table 1 – Table depicting interventions given in the Intervention and Control Arms.

Interventions performed	Duration/session	Sessions/week	Total duration
Conventional physiotherapy (Performed in occupational therapy room under supervision of trained occupational/physiotherapy team)			
(a) Gross motor strengthening of affected upper limb (b) Fine motor functions of affected upper limb (c) Constraint induced movement therapy (d) Range of movement activities (e) Occupational therapy activities (eg. Peg board-based activity)	30 min/day	3 sessions/week	12 months
Robotic biofeedback-based therapy Device specifications: Model name: PABLO ® X 2 hand-arm therapy system manufactured by M/S tyromotion GMBH, Austria.Device components include hand sensors (wireless), motion sensors (wireless), Multiboard, robotic arm, multiball with inbuilt wireless motion sensor, Central Processing unit, HD monitor, biofeedback modes (visual, auditory, tactile), age-appropriate complexity-graded interactive games, sensor-fitted hand grip device with dynamometry.			
Group	**Interventions done**		
Intervention arm (group A)	Conventional physiotherapy + robotic biofeedback-based therapy (details as above)		
Control arm (group B)	Conventional physiotherapy (details as above)		

A semi-structured interview was administered to the parents/primary care-givers following each session, which included an open-ended query for any adverse event/physical discomfort. A standardized adverse event assessment form was reserved for recording adverse effects. Interventions were supervised by any one investigator for a period of twelve months. These interventions were performed thrice weekly over and above conventional institutional physiotherapy which the children underwent as prescribed by the physiotherapist. The intervention schedule was considered to be complete if at least one session per week was performed. If the entire week's sessions were missed or more than one session was missed in any two weeks, it was taken as incomplete and the therapy session was extended by another week. In addition, parental counselling was done after root cause analysis for missing sessions. Follow-ups were conducted at 2 weeks (telephonic) and 3, 6,12 and 15 months (physical). Hand-grip strength and QUEST scoring were done at 12 and 15-month follow-ups. The primary objective was to compare the efficacy of robotic biofeedback-based rehabilitation for upper limb and conventional physiotherapy with that of conventional physiotherapy alone in 5–18-year-old children and adolescents with hemiplegic CP (GMFCS: I – III) by estimating the differential changes in mean hand-grip strengths (in Newtons) of affected hand at one year of therapy initiation.

Secondary Objectives involved the comparison of differential changes in mean 'Quality of Upper Extremity Skills Test (QUEST)' scores (at 12,15 months) and mean hand-grip strength (in Newtons) of affected hand at 15 months between the two groups.

Statistical analysis was performed using SPSS 22.0 (IBM) software. Paired t-test was used for analysis of primary and secondary outcomes. Baseline clinical and demographic characteristics were summarized using descriptive statistics. Intention-to-treat (ITT) analysis was performed by including all participants who completed at least one session.

Results

The flow of the study population is depicted in Fig. 3. hemiplegic 556 CP children were screened for eligibility; 135 among whom satisfied the inclusion criteria and 60 were enrolled in the study. Two children [Study Identification numbers (ID): 5,27] from Intervention Arm (Group A) were lost to follow-up due to the relocation of their father and COVID-19 infection-related issues, respectively. Three children from Control Arm (Group B) were lost to follow-up (IDs: 10,54- parental relocation; ID: 8- voluntary withdrawal). ITT analysis was done wherein their baseline assessment scores were used for the purpose of primary and secondary outcomes analysis. 30 children each were randomized to the Intervention Arm (Group A) and Control Arm (Group B).

Baseline demographic characteristics of the study population are depicted in Table 2. Overall, the mean (±SD) age of children in the trial was 7.5 (±3) years. The mean (±SD) age of children in the Intervention and Control Arms was similar, being 8.7 (±3.6) years and 6.2 (±1.7) years, respectively. Gender distribution was skewed towards males in the entire study population with male to female ratio being 3:1 for the complete cohort. The two arms were comparable with respect to their gender distributions, gestational maturity at birth, presence of epilepsy, behavioural issues and parental educational status. The stratification of the groups based on GMFCS and MACS scores was comparable.

Primary outcome

Mean hand-grip strength (in Newtons) of children in Group A (Intervention Arm) at baseline (initiation of study) was 4.32 N (S.D = 2.50N) [median = 4.15N (IQR = 2.85N)]. Mean hand grip strength of children in Group B (control) at baseline was 4.14N (S.D = 1.86N) [median = 3.4N (IQR = 2.4N)]. Inter-group mean baseline hand grip strength difference was (–) 0.18N (95% C.I: −1.32 N to 0.96N) (p = 0.75; insignificant). Mean hand-grip strengths of children in Intervention Arm (Group A) and Control Arm (Group B) at 12 months after therapy initiation were 4.37 N (S. D = 2.49N) [median: 4.15N (IQR = 2.83N)] and 4.15N (S. D = 1.85N) [median: 3.4N (IQR = 2.4N)], respectively. Inter-group mean hand-grip strengths' difference at 12 months was (–) 0.22N (95% C.I: −1.35N–0.92N) (p = 0.70; insignificant). Changes in mean hand-grip strengths at 12 months (from baseline) in the Intervention Arm (Group A) and Control Arm (Group B) were 0.05N(±0.07N) [median = 0 (IQR:0.1N)] and 0.003N (±0.3N) [median = 0 (IQR:0)] respectively. Differential change in mean hand-grip strengths between the two arms at 12 months (primary outcome) was (–) 0.05N(95% confidence intervals between −0.16N and 0.07N) (p = 0.40; insignificant) (Table 3, Fig. 4).

Secondary outcomes

The differential changes in mean QUEST scores at 12 months (from baseline) in the two arms was (–)0.35 (95% CI: −1.57 to 0.87) (p = 0.56; insignificant). Hence there was no difference between the QUEST scores of children in the intervention and control arms at 12 months of therapy from study initiation (Table 4) The inter-group differential change in mean QUEST scores at 15 months (from baseline) was (–)0.26 (95% CI: −1.44 to 0.92) (p = 0.66; insignificant) (Table 4). The difference between the mean hand-grip strengths of children in Groups A and B at 15 months (from baseline) was 0.44N (95% C.I: −0.92N–1.80N) (p = 0.52; insignificant) (Table 3).

Discussion

There is a burgeoning interest in technology-intensive biofeedback and robotic-based CP rehabilitation due to perceived advantages over conventional physiotherapy.[6,9–12] There are sporadic studies evaluating the feasibility/efficacy of similar add-on/hybrid therapy in hemiplegic CP children.[13] Our study was designed to address this knowledge gap from the perspective of a resource-constrained setting.

Wiart, et al studied the role of robotic gait therapy in CP children aged 5–18 years.[14] A systematic review on robotic upper limb rehabilitation on children with CP reported nine studies on children ranging between the ages of 4 to 18 years. [15] Our study age bounds were based on the above with a lower cut-off limit of 5 years as it was anticipated to be the

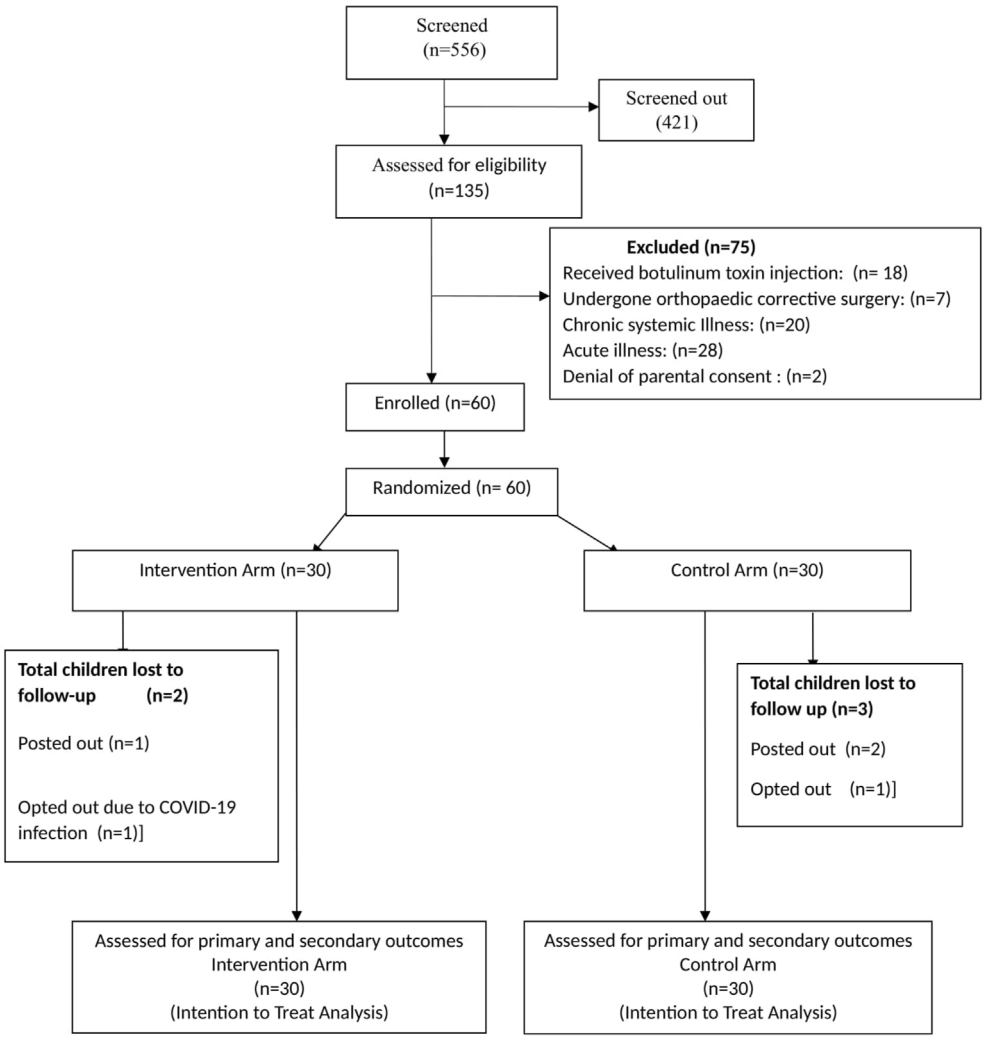

Fig. 3 – CONSORT diagram showing flow of study population.

least age for adequate cooperation. Children with severe functional impairment (GMFCS IV-V) were excluded due to non-suitability issues. Potential confounders, namely recent orthopaedic surgery, severe contractures and botulinum toxin A administration within a year of enrolment were excluded. Minimum visual acuity of 6/60 and the ability to follow commands were taken into cognizance as they are logical prerequisites for cooperation. Parental willingness, capability of following instructions and maintaining activity-log were adopted as prerequisites to ensure adequate compliance.

Children in both the arms of the study had comparable age, gender and functional status (GMFCS and MACS scores) profiles making the results comparable. The non-probability convenience sampling of the study was advantageous due to its efficiency and simplicity of sampling, its disadvantages being non-generalizability. As ITT was performed using the last observation carried forward (LOCF) method for 5 (8 %) dropouts, there is a possibility of effect dilution. As the comorbidities were higher in the intervention arm, though statistically insignificant, there is a possibility of confounding by the above.

Simple, interesting activities were incorporated into the robotic biofeedback-based rehabilitation regime. A systematic review of 31 RCTs on visual feedback-based motor rehabilitation has demonstrated that visual feedback increased motivation, promoted interaction and resulted in the sustained interest of CP subjects.[16] Visual biofeedback was the key component of intervention in our study and in addition to auditory and sensory feedback. Simple, interesting, child-friendly activities with catchy background scores were adopted for our intervention arm along the same lines to make the intervention schedules appealing for the children. These activities varied in their key target muscle activity of the affected upper limb with collateral beneficial effects on domains like hand-eye coordination, cognition, decision-making and memory. The common denominator in all of these was a direct or sequential effect on the hand-grip and an indirect effect on fine motor and manual dexterity skills. The activity schedule employed in the intervention arm is novel. Hand-grip strength is an objective parameter correlating with the performance of fine motor activities in CP.[17,18] It was perceived that a major element of functional limitation in hemiplegic CP owes to poor hand-grip strength. Hence

Table 2 – Table depicting demographic characteristics of the study population.

Characteristic	Study Population (n = 60)	Intervention Arm (Group A) (n = 30)	Control Arm (Group B) (n = 30)	p value
Gender				
Male	44	21	23	0.7
Female	16	9	7	
Male: Female	3:1	2:1	3:1	
Age (years)				
Mean age (SD)	7.5[3]	8.7 (3.6)	6.2 (1.7)	0.06
Median age	6	8	5	
Age range	5 to 16	5 to 16	5 to 11	
Inter Quartile range (IQR)	4	5	2	
Gestational age at birth				
Term	39 (88.6%)	28 (93.3%)	27 (90%)	0.65
Preterm	5 (11.4%)	2 (6.7%)	3 (10%)	
Comorbidities				
Epilepsy	5 (8.3%)	4 (13.3%)	1 (3.3%)	0.16
Prominent behavioural issues	3 (5%)	2 (6.6%)	1 (3.3%)	0.25
Feeding issues (requiring gastrostomy feeds	7 (11.7%)	3 (10%)	4 (13.3%)	0.33
Impaired vision (one eye) requiring corrective glasses ± occlusive patching[a]	10 (16.7%)	7 (23.3%)	3 (10%)	0.08
Impaired vision (both eyes) requiring corrective glasses[a]	28 (46.7%)	11 (36.7%)	17 (28.3%)	0.13
Clinical status				
GMFCS I	35 (58.3%)	19 (31.6%)	16 (53.3%)	0.09
GMFCS II	15 (25%)	7 (23.3%)	8 (26.7%)	0.76
GMFCS III	10 (16.7%)	4 (13.3%)	6 (20%)	0.49
MACS 1	32 (53.3%)	16 (53.3%)	16 (53.3%)	1.0
MACS 2	14 (23.3%)	6 (20%)	8 (26.7%)	0.54
MACS 3	6 (10%)	3 (10%)	3 (10%)	1.0
MACS 4	8 (13.3%)	5 (16.7%)	3 (10%)	0.45
Prior injection botulinum toxin A given	8 (13.3%)	4 (13.3%)	4 (13.3%)	1.0

[a] Impaired vision refers to vision without correction. These children receives various therapies such as corrective glasses, occlusive patching, etc as advised by ophthalmologist and they had functional working vision less than 6/60.

hand-grip strength was chosen as a target area that needed to be improved through rehabilitation. The robotic biofeedback-based device used for providing intervention involved multiple activities requiring the child to hold and manipulate a tubular control rod. It was hypothesized that prolonged use of the device would lead to an improvement in hand-grip strength. MacIntosh et al had adopted this parameter as a primary outcome measure in an RCT on a biofeedback-enhanced therapeutic video game in CP.[19] As hand-grip strength is reliable, valid, and easily measurable, it was selected as a primary outcome measure.

In a systematic review involving 20 different trials pertaining to upper limb rehabilitation based on video games, the duration of intervention varied from 2 weeks to 1.5 years.[19] The 'Mitii' trial studied the effects of intervention on hemiparetic CP children subjected to the intervention for 20 weeks along with a delayed follow-up at 40 weeks.[20] The 'INCITE' trial compared constraint-induced movement therapy and bimanual training for one year in children with hemiparetic CP.[21] In our study, the primary outcome was assessed at 12 months considering the aforementioned literature with an underlying premise that therapy for the prescribed period

Table 3 – Table depicting Mean Hand-Grip Strength (Newtons) of study population at baseline, 12 months of therapy initiation and change (12 months-baseline) (Primary Outcome).

Assessment time point	Intervention Arm (Group A, n = 30)		Control Arm (Group B, n = 30)		Difference between mean grip strength of Group B and Group A (Confidence intervals)	p Value
	Mean ± S.D.	Median (IQR)	Mean ± S.D.	Median (Interquartile Range)		
Baseline	4.32 ± 2.50	4.15 (2.85)	4.14 ± 1.86	3.4 (2.4)	−0.18 (−1.32 to 0.96)	0.75
12 months of therapy initiation	4.37 ± 2.49	4.15 (2.83)	4.15 ± 1.85	3.4 (2.4)	−0.22 (−1.35 to 0.92)	0.70
Change in mean hand-grip strength (12months-Baseline)[a]	0.05 ± 0.07	0.0 (0.1)	0.003 ± 0.3	0.0 (0.0)	−0.05 (−0.16 to 0.07)	0.40

[a] Primary outcome variable.

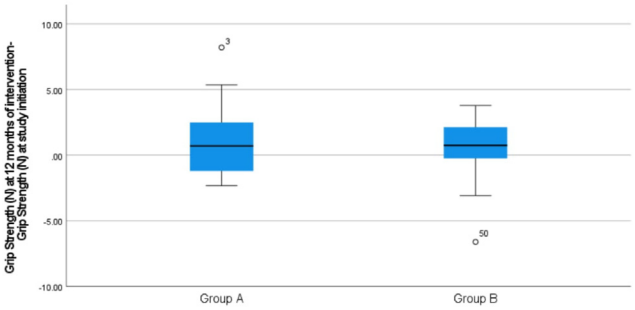

Fig. 4 – Boxplots showing differences in Mean Grip Strength (Newton) at 12 months from baseline (study initiation) in Intervention Arm (Group A) and Control Arm (Group B).

would lead to appreciable change in hand-grip strength. Though desirable, a longer follow-up was not feasible due to administrative constraints. QUEST gives an objective assessment modality for the upper extremity.[22] Hence change in QUEST scores was selected as a secondary outcome measure. Change in hand-grip strength at 15 months (secondary outcome) was planned to be evaluated for sustained effects of the intervention (offered till 12 months).

Absence of significant change in the primary outcome variable may be due to factors like sub-optimal duration of rehabilitative therapy, less intensive regime, dilutional effects of spasticity and dyskinesias, and choice of hand-grip strength as a primary outcome measure. A systematic review had observed that among 37 studies on biofeedback-based rehabilitation in children with CP, only five had taken hand skills as a primary outcome measure.[23] The interventions were designed to target only the hemiparetic upper limb (right or left). In this sense, it was somewhat akin to Constraint Induced Movement Therapy (CIMT) which aims to improve the functionality of the hemiparetic limb based on neuroplasticity and synaptogenesis. Hence, the distinction between right and left limbs was not analysed.

The secondary outcomes were insignificant possibly due to similar reasons.

No rehabilitation-related adverse event was reported in our study. Multiple studies on similar lines performed on CP children have also reinforced the safety profiles of these robotic, biofeedback-based rehabilitation programmes, provided the activities in the regime and the schedules have been standardized and tailored to the age profiles of the study population.[23–25]

Despite dropouts, the study demonstrated the feasibility and acceptability of robotic biofeedback-based therapy as an add-on therapy in CP. The investigators noted that CP children could operate the device with sustained cooperation. However, acceptability, quality of life and interest in the interventions were beyond the study's purview.

Strengths of the study included its multicentric model, randomization, allocation concealment, unambiguous inclusion and exclusion criteria, estimation of hand-grip strength using computerized hand-held dynamometer and the use of a simple, user-friendly device in the intervention arm. Study limitations include unquantified factors like parental motivation, spasticity, dyskinesias, variable patient cooperation, open-label model and convenience sampling-based sample size.

Despite the limitations, the RCT has pioneered the assessment of the feasibility and efficacy of a novel add-on therapy in CP children of a resource-constrained setting. The acceptance, simplicity of use and favourable safety profile of this modality demonstrated its feasibility and opened the avenues for its further application in the field of rehabilitation, not necessarily restricted to CP alone. Factors like neurological diversity, comorbidities, social determinants and altered neuroplasticity profiles would be challenges in designing a uniform rehabilitation programme.

To conclude, this multi-centric RCT which is designed to compare the efficacy of robotic biofeedback-based upper limb rehabilitation in children with hemiplegic CP between the ages

Table 4 – Table depicting secondary outcomes of the study.

Assessment timepoint	Intervention Arm (Group A, n = 30)		Control Arm (Group B, n = 30)		Difference between mean scores Group B and Group A (95% Confidence intervals)	p Value
	Mean ± S.D.	Median (IQR)	Mean ± S.D.	Median (Interquartile Range)		
Hand grip strength (Newton)						
Baseline	4.41 ± 2.47	4.2 (2.38)	4.14 ± 1.86	3.4 (2.4)	−0.18 (−1.32 to 0.96)	0.75
15 months	4.37 ± 2.49	4.15 (2.83)	4.85 ± 2.78	4.85 (1.95)	0.44 (0.92–1.80)	0.52
Change in scores (15months-Baseline)[a]	0.09 ± 0.12	0.10 (0.20)	−0.07 ± 0.36	0.0 (0.20)	−0.16 (−0.29 to −0.02)	0.05
QUEST scores						
Baseline	36.11 ± 9.40	34.01 (15.62)	37.04 ± 7.83	36.28 (10.12)	0.93 (−3.45 to 5.31)	0.67
12 months	37.09 ± 8.32	35 (15.28)	37.68 ± 7.02	37 (9.23)	0.59 (−3.39 to 4.57)	0.78
Change in scores (12months-Baseline)[a]	0.99 (±2.51)	0.7 (4.0)	0.64 (±2.21)	0.73 (2.0)	(−)0.35 (−1.57 to 0.87)	0.56
15 months	37.20 ± 8.29	34.90 (15.3)	37.86 ± 7.15	37.30 (9.63)	0.66 (−3.34 to 4.66)	0.74
Change in scores (15months-Baseline)[a]	1.08 (±2.58)	0.70 (4.0)	0.82 (±1.92)	1.0 (2.0)	(−)0.26 (−1.44 to 0.92)	0.66

[a] *Secondary outcome variables.*

of 5–18 years (GMFCS I-III) as an add-on therapy along with that of conventional physiotherapy alone did not reveal any significant difference in the primary outcome measure (change in mean hand-grip strengths at 12 months) between the intervention and control arms. Further, it did not reveal any significant difference in the secondary outcomes between the two arms. However, this novel pilot trial demonstrated the feasibility and acceptability of using a robotic biofeedback-based CP rehabilitation programme as an add-on therapy along with conventional physiotherapy in resource-limited settings.

Recommendation

It is recommended to conduct similar RCTs with prolonged, more intensive and focused therapy regimes, stringent compliance checks, larger sample size, crossover model, incorporation of younger children with age-appropriate regime and objective response assessment using functional magnetic resonance imaging (fMRI) and diffusion tensor imaging (DTI) to arrive at a universally acceptable model.

Patients/ Guardians/ Participants consent

Patients/parents informed consent was obtained.

Ethical clearance

Institute/hospital ethical clearance certificate was obtained.

Source of support

This paper is based on Armed Forces Medical Research Committee Project No. 5063/2018 funded and granted by the office of Directorate General Armed Forces Medical Services and Defence Research Development Organisation, Government of India.

Disclosure of competing interest

The authors have none to declare.

Acknowledgment

None.

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