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Constraint-Induced Movement Therapy in Obstetrical Brachial Plexus Palsy: A Single-Blind Pilot Randomized Controlled Trial

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ABSTRACT

Aim: To estimate the effectiveness of Constraint-Induced Movement Therapy (CIMT) vs. conventional therapy in improving the frequency, quality, and spontaneity of the affected arm usage and acquiring new motor programs in children with Obstetrical Brachial Plexus Palsy (OBPP).

Methods: Pilot, randomized, and controlled clinical trial with a blind evaluator. Twenty ($N = 20$) children with OBPP diagnoses were divided into Intervention Group (CIMT protocol, 5x/week, 3h/day, 3 wk) and Control Group (conventional Physiotherapy/Occupational Therapy 2x/week, 40 min/day, 3 wk). Pediatric Mal Activity Log – Revised (PMAL-R) was used for quality and frequency measures; Pediatric Arm Function Test (PAFT) was used to measure the spontaneous use of the affected upper limb; Inventory of New Motor Activities and Programs (INMAP) was used for the acquisition of new motor programs. All the evaluations were applied pre and post treatment.

Results: CIMT was superior compared to control in terms of frequency (mean change= 1.58; 95% CI 0.83 to 2.33; $p < 0.001$) and quality of movement (mean change= 1.53; 95% CI 0.78 to 2.28; $p < 0.001$), in spontaneity of use in unimanual tasks in PAFT (mean change= 2.9; 95% CI 1.29 to 4.5; $p = 0.022$) and in the INMAP (mean change= 1.4; 95% CI 0.70–2.10; $p < 0.001$). All the effect sizes for the differences were large, and MCID showed large effects for PMAL-R and PAFT.

Conclusion: CIMT is favored over standard care, with gains in terms of quality and frequency of movement, spontaneity of use, and acquisition of motor programs.

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KEYWORDS
Constraint-induced movement therapy; obstetric brachial plexus palsy; upper limb

Obstetric brachial plexus palsy (OBPP) is the paralysis of the upper extremity, usually unilateral, after an ipsilateral brachial plexus injury that occurs during labor (Aktaş et al., 2018). The incidence of OBPP is between 0.5 and 3 injuries per 1000 live births (Borschel & Clarke, 2009). In Brazil, the epidemiological data regarding the incidence of

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OBPP are inconsistent, and there are no officially published, nationally tabulated data available. Nevertheless, given the high rate of cesarean deliveries performed in the country, approximately 56% in 2023 (Braga et al., 2023), it is believed that Brazil may be closer to the lower end of the reported incidence range (Heise et al., 2015).

The most significant risks for OBPP are birth weight (more than 4 kilograms), shoulder dystocia, fetal position, maternal diabetes mellitus and operative vaginal deliveries (Zafeiriou & Psychogiou, 2008). The brachial plexus is formed by sensitive and motor cervical nerves (C5–C8) and the first thoracic nerve (T1), and the mechanism of injury occurs through the excessive stretching of the neck in childbirth, which causes traction on the brachial plexus and a variable range of lesions in this region (O'Berry et al., 2017). The OBPP is divided into four types, according to the area of injury, but the most common type is Erb-Duchenne type (Gherman et al., 2005). The Erb-Duchenne involves spinal nerves C5 and C6, resulting in paresis of the shoulder and biceps muscles (Pondaag et al., 2004). In contrast, Klumpke's palsy occurs in approximately 0.6% of cases and involves the lower roots of the brachial plexus (C8, T1), resulting in paralysis confined to the hand (Al-Qattan et al., 1995; Jennett et al., 2002).

The management of OBPP has changed in the past 25 years with the development of a variety of new, safe, and effective surgical techniques (B. W. Smith et al., 2018). Although these data point to an early approach (3–6 months of life), studies point out that this may be an overly aggressive strategy since there can be a spontaneous recovery of function by 12 months of age (Ali et al., 2014). There are no criteria or consensus in choosing between surgical or conservative treatment, but there is known significant morbidity associated with attempts at surgical reconstruction, such as pain and persistent weakness in the affected upper limb (Ali et al., 2014; Frade et al., 2019; Kirjavainen et al., 2007; Socolovsky et al., 2016). With or without surgical intervention, early therapy input is essential in preventing complications, maintaining a good range of movement and optimizing the use of the affected arm (K. Smith & Patel, 2016). Despite being a peripheral lesion, cortical reorganization may occur over time, limiting the expansion of cortical representation of the affected segment and promoting preferential use of the unaffected upper limb (DeLuca et al., 2015; Taub & Uswatte, 2014).

Among the techniques for rehabilitation of the affected upper limb (AUL) and management of learned nonuse, constraint-induced movement therapy (CIMT) is considered the gold standard, with a solid level of evidence in rehabilitation of unilateral cerebral palsy, based on use-dependent cortical reorganization (DeLuca et al., 2015; Hoare et al., 2019). Pediatric CIMT is based on four pillars, which are: 1) a behavioral transfer package, 2) restraint of the non-affected upper limb 24 h a day during 21 consecutive days, 3) intensive, repetitive, task-oriented training, and 4) structured practice using shaping and task practice (Deluca et al., 2012). Studies showed that CIMT applied to individuals with hemiparetic cerebral palsy promotes use-dependent cortical reorganization, evidenced by imaging exams and transcranial magnetic stimulation, being capable of promoting volumetric gain in cerebral gray matter, specifically in the sensorimotor cortex, anterior motor areas, and bilateral hippocampus (Sterling et al., 2013; Taub et al., 1994). The transfer package, which consists of a set of behavioral strategies that aim to ensure adherence to treatment by patients and caregivers, optimizes the transfer of gains obtained to the real world of children and adolescents

(Taub, 2012). This structured and theory-driven framework distinguishes the original protocol from modified versions that typically reduce daily dosage and omit key behavioral components, thereby limiting comparability and potentially influencing treatment outcomes.

In a similar argument, it is possible to infer that this cortical reorganization seen in patients with hemiparetic cerebral palsy would occur in cases of OBPP, and CIMT could be an intensive conservative alternative of great value to improve the use of the affected arm. At present, the evidence supporting the effectiveness of CIMT in obstetrical OBPP remains limited. The available literature includes one descriptive study and two case reports (Berggren & Baker, 2015; Buesch et al., 2010; Vaz et al., 2010). In one of the case reports, CIMT was combined with electrotherapy, while the other studies implemented an adapted CIMT protocol consisting of approximately six hours of daily practice (Berggren & Baker, 2015; Buesch et al., 2010; Vaz et al., 2010). In 2020, a randomized crossover trial was published; however, it did not implement the original University of Alabama CIMT protocol, which consists of a three-week structured intensive training program delivered for approximately three hours per day and grounded in its four pillars described above (Buesch et al., 2010). In 2021, a systematic review analyzed the effectiveness of modified CIMT in children with OBPP (Sicari et al., 2022). Modified CIMT involves the use of adapted restraint devices on the non-affected upper limb for fewer hours per day and a shorter overall therapy duration. The review analyzed 4 studies, predominantly case reports and case series, reflecting a generally low level of evidence, with a high risk of bias (Sicari et al., 2022). The included studies had small sample sizes and showed substantial methodological heterogeneity, particularly regarding daily restraint duration, total intervention length, and the inclusion of additional therapeutic components (Sicari et al., 2022). Although the findings suggested potential functional benefits, the authors concluded that the current evidence remains insufficient to confirm the effectiveness of CIMT in OBPP and emphasized the need for well-designed randomized controlled trials using more homogeneous and rigorous protocols (Sicari et al., 2022). More recently, in 2025, a study investigated the use of CIMT in patients with OBPP, discussing the implementation of different protocols tailored to a variety of clinical presentations, including post-surgical cases, with favorable outcomes (Gotlieb-Horowitz et al., 2025).

Based on the existing literature, the evidence supporting the use of CIMT for OBPP remains limited. This is primarily due to the limited number of available studies and the substantial variability in intervention protocols, which hinders the robust analysis of treatment efficacy. Additionally, to date, no study has applied the structured and theory-driven framework of the University of Alabama CIMT protocol to treat this population. Given that CIMT is an intensive intervention associated with increased institutional demands and higher direct and indirect costs, the implementation of a full-scale definitive randomized clinical trial must be supported by preliminary evidence of safety and positive clinical effects. Therefore, conducting a pilot study is warranted to examine initial outcomes, estimate effect sizes, and verify the potential benefits of this approach before committing substantial institutional resources. Thus, this pilot study will estimate the benefits of the original pediatric CIMT protocol when applied to patients with OBPP, to compare motor functional gains in patients receiving CIMT (intervention group) with those treated with conventional therapy (control group),

regarding the frequency, quality, and spontaneity of using the affected arm in the acquisition of new motor programs.

Methods

Methodological Design

This is a pilot randomized and controlled clinical trial with a control group and blinded evaluator, involving the Occupational Therapy and Child Physiotherapy sectors of the Associação de Assistência à Criança Deficiente/AACD Ibirapuera, São Paulo, Brazil. The present study has already been approved by the Institution's Research Ethics Committee with CAAE number 87532818.6.0000.0085 and entered the reBEC (Brazilian Clinical Trials Registry), under registration: RBR–8kwxbg.

The participants were recruited from a clinical population, and the screening was carried out based on records of care in the Children's Occupational Therapy sector of patients who underwent internal assessment and/or guidance procedures from January 2014 to January 2018. This list included 47 patients, of whom 27 fulfilled the inclusion criteria according to records in the institutional electronic medical record. Of these 27, three patients lived outside the city of São Paulo, two were not found after three contact attempts, and two were scheduled for screening *via* telephone, but did not show up, as shown in Figure 1.

The children and caregivers were called for the initial screening, in which the objectives and specificities of the treatment were explained and an invitation to participate in the work was made, with the signing of the free and informed consent form (FICT). After eligibility confirmation, randomization was performed to determine the allocation sequence of participants into the study groups. The random allocation sequence was generated independently using a validated random number generator in Microsoft Excel® (RAND function) by a researcher not involved in participant recruitment or assessment. Participants were assigned in a 1:1 ratio to the intervention or control group. Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes prepared by the same independent researcher. These envelopes were opened sequentially only after a participant was formally enrolled by the professional responsible for implementing the intervention, who was unaware of the upcoming assignment until that moment. The study groups were:

Intervention Group (IG): patients performed the original pediatric CIMT protocol, without any other motor therapy, for a period of three weeks, 3 h/day. Details are described below.

Control Group (CG): patients undergoing conventional Physiotherapy or Occupational Therapy 2x/week, around 40 min each, for a period of three weeks. Details are described below. These patients were offered the possibility of carrying out the CIMT protocol after the end of the study.

Participants

In this study, 20 children aged 2 to 8 years old diagnosed with OBPP were considered eligible meeting the following eligibility criteria: 1) Diagnosis of OBPP Erb-Duchene or

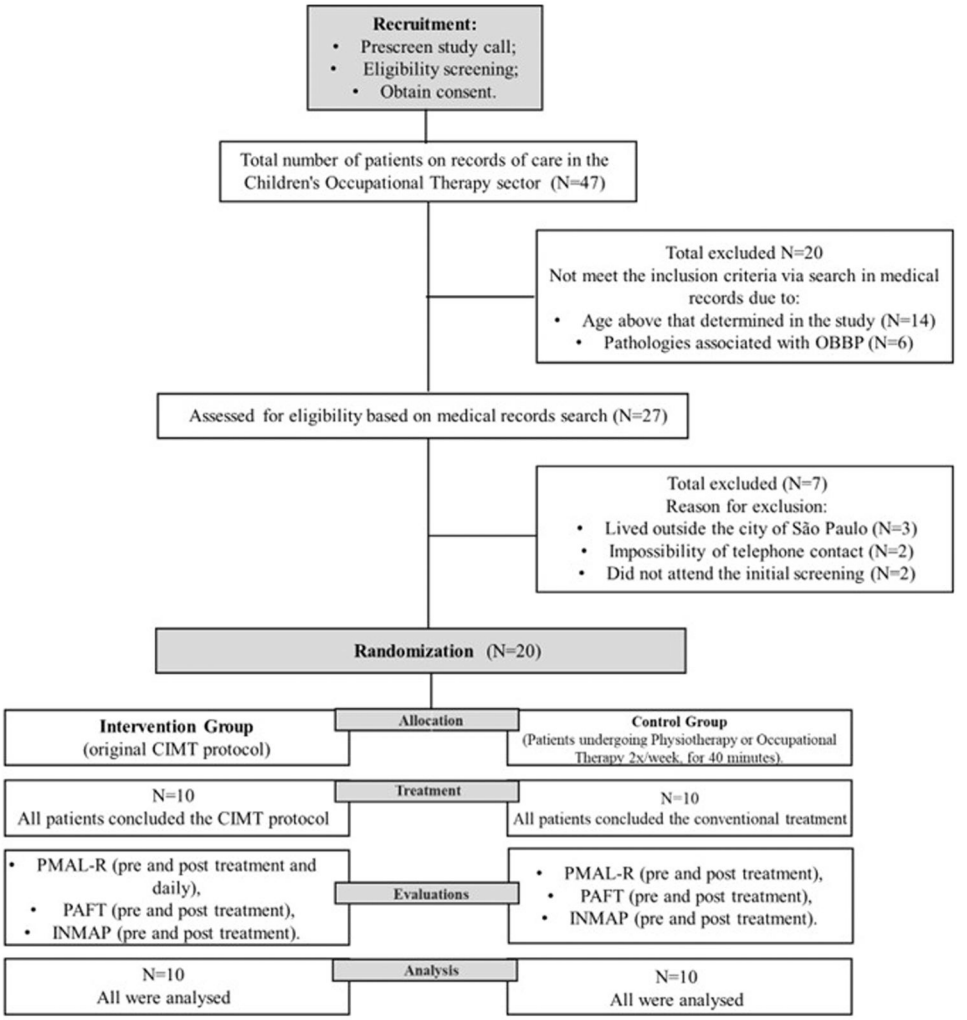


Figure 1. Consort flowchart (Schulz et al., 2010).

Klumpke type; 2) Both sexes and ages between 2 and 8 years; 3) Be able to follow commands requested by the therapist; 4) Attend to AACD for 3 wk, 3 h/day; 5) Patient whose legal guardian/caregiver has signed the informed consent form for participation in the study; 6) Motorically, be able to perform the active movement of the affected upper limb in at least 45° of shoulder flexion and abduction, 20° of elbow extension, 10° of wrist extension and movement of three fingers, including thumb.

The exclusion criteria were: 1) Unavailability to attend to all evaluations and to the proposed therapy; 2) Severe cognitive deficit; 3) Complete brachial plexus injury. No patients were excluded from the ongoing study.

In accordance with the CONSORT extension for pilot and feasibility trials, this study was not powered to test definitive efficacy but to assess feasibility, safety, and preliminary effect estimates to inform a future full-scale randomized clinical trial, particularly in the context of the scarcity of prior preliminary studies using the original CIMT protocol

in this population (Thabane et al., 2016). Recruitment was concluded at 20 participants due to pragmatic institutional factors, including high service demand and the intensive nature of the CIMT protocol, which requires substantial therapist time and institutional resources. Given the operational and cost implications of this intervention, it was necessary to complete the pilot phase and demonstrate preliminary positive results before expanding to a larger definitive trial. Thus, a sample of 20 participants was considered appropriate to evaluate feasibility and generate data for future sample size calculation and trial planning.

Standardized Assessments

All outcome assessments were conducted by a trained pediatric physical therapist or occupational therapist who underwent specific training for the standardized administration and scoring of all study outcome measures before data collection. The assessor was blinded to group allocation throughout the study and was not involved in treatment delivery or randomization procedures. All assessments were administered individually in a single session, pre- and post-treatment, following standardized instructions to ensure procedural consistency. In order to preserve blinding, families and participants were explicitly instructed before each assessment not to disclose any information regarding group allocation or details of the intervention received. In the event of unintentional disclosure, the assessor was instructed to avoid further discussion about treatment, document the incident, and continue the evaluation strictly according to the standardized protocol. If blinding was considered compromised, a second blinded assessor, trained in the same evaluation procedures, would conduct subsequent assessments whenever feasible.

1. Pediatric Mal Activity Log – Revised (PMAL-R): The PMAL-R assessment was revised by Uswatte et al. (2012) and consists of a semi-structured interview in which caregivers and family members who live with the child report, according to their perception of improvement or not, how the child uses the affected upper limb, assigning scores referring to the quality and frequency of the spontaneous movement of 22 functional activities, divided into basic and instrumental activities of daily living, performed unimanually or bimanually, in the individual's real world. The cross-cultural adaptation to the Portuguese language and the analysis of psychometric properties was carried out by Matuti et al. (2016). The scores given by caregivers in the 22 functional tasks range between 0 (zero) and 5 (five). For IG, PMAL –R was applied at the following times: pre and post-treatment and daily. As for the CG, caregivers answered questions regarding frequency and quality before and after the treatment.
2. Pediatric Arm Function Test (PAFT): It is an assessment in which the patient's performance is observed and scored; applied to children and adolescents up to 16 years of age, consisting of 15 unimanual and seven bimanual activities, in which the spontaneous use of the affected upper limb and qualitative functional ability are assessed by one examiner and scored by another (Uswatte et al., 2012). This is an assessment applied pre- and post-treatment. In the first attempt

of the test, no indication is given as to which of the upper limbs should be used to perform each task (spontaneous use). When the patient does not perform the activity using the affected upper limb on the first attempt, we ask for a second attempt, now using this lith. As an integral part of the assessment form, the functional ability is described, which scores the quality of the movement being performed with the affected upper limb, identically in description to the quality score mentioned in PMAL-R (Uswatte et al., 2012). PAFT is a widely used assessment tool for measuring the frequency of bimanual outcomes (David et al., 2025). The PAFT was even linked to ICF items and was considered a performance outcome highly comprehensive in relation to the different dimensions of coverage (Elfassy et al., 2024).

3. Inventory of New Motor Activities and Programs (INMAP): It is an inventory of ten previous motor programs or those acquired during treatment, applied with the child's guardian through a questionnaire administered on the first and last day of treatment (Taub et al., 2007). It is assumed that the patient acquired a motor program when the caregiver and another person (in this case, the therapist) saw him performing the movement in more than one situation. At the end of the protocol, it is recorded how many programs the individual already had on the first day of treatment (considered as previously), how many were acquired at the end, and those that were eventually not assimilated by the patient (Taub et al., 2007). This is a widely used tool for upper limb outcomes associated with CIMT protocols to evaluate new acquired motor programs (Sparrow et al., 2017; Taub et al., 2011).

Description of the Original Pediatric CIMT Protocol – University of Alabama; Birmingham/USA

The intervention followed the original CIMT protocol developed at the University of Alabama and comprised four core components: 1) a behavioral transfer package, 2) restraint of the non-affected upper limb 24 h a day during 21 consecutive days, 3) intensive, repetitive, task-oriented training, and 4) structured practice using shaping and task practice (Deluca et al., 2012). The behavioral transfer package included a behavioral contract signed by the participant, caregiver, and therapist prior to intervention; structured weekday and weekend activity schedules; a home diary reviewed daily to monitor adherence and progression of activities; and daily administration of the Pediatric Motor Activity Log–Revised (PMAL-R) (Taub, 2012). These measures supported caregiver engagement, treatment adherence, and systematic monitoring of affected upper limb use in real-world contexts.

Restraint of the non-affected upper limb was achieved using a custom-made synthetic cast applied during the pretreatment phase. The cast immobilized the non-affected limb from the axilla to the fingers, with the elbow positioned at 90° of flexion to preserve balance during ambulation (Figure 2). The restraint was worn continuously throughout the intervention period and was removed once daily by the therapist for hygiene and therapeutic procedures. Intensive task-oriented training was delivered through shaping and task practice. Shaping involved repetitive practice of functional tasks broken into progressively challenging components, with predefined progression parameters and

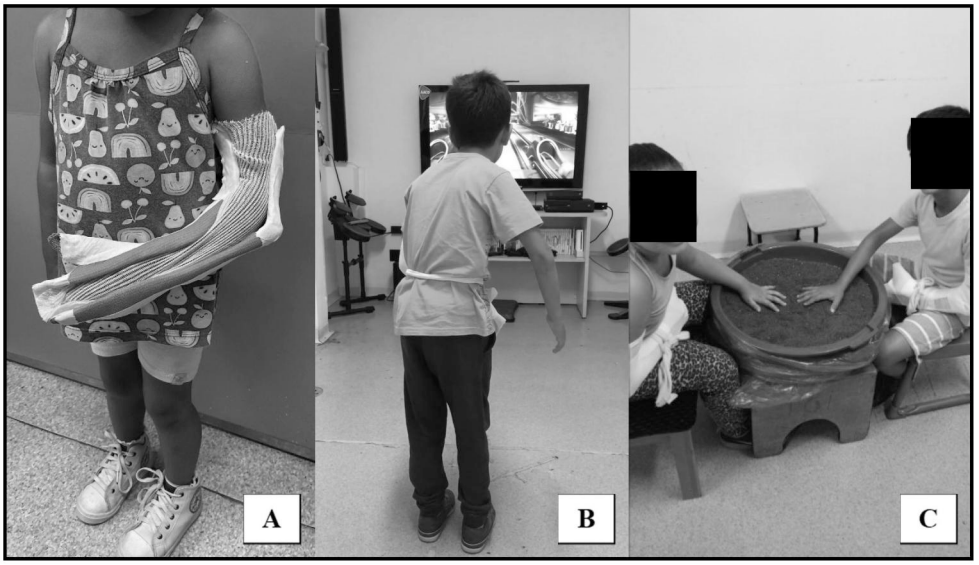


Figure 2. Illustration of children performing procedures related to pediatric constraint-induced movement therapy (CIMT) in a clinical setting. (A) Application of the casting apparatus on the non-affected upper limb, extending from the axilla to the fingers, with the elbow positioned at 90° of flexion; (B–C) examples of intensive, task-oriented practice performed with the affected upper limb, demonstrating structured, repetitive activities designed to promote functional use and motor skill acquisition.

positive feedback provided after each attempt. Tasks were individualized based on participant age, active range of motion, and baseline motor assessments. Task practice consisted of less structured functional activities resembling daily routines and was performed concurrently with shaping to promote motor transfer. All procedures were standardized and administered by trained therapists in accordance with the original CIMT protocol from the University of Alabama (Taub, 2012; Taub & Uswatte, 2003).

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, NY, USA), as well as R software (version 3.5.0, GUI 1.70 El Capitan build)(ref1) and RStudio (version 1.1.453, © 2009–2018 RStudio, Inc.).

All statistical analyses considered a two-sided α level of 0.05 ($p < 0.05$) and a 95% confidence interval (CI), with results interpreted cautiously given the pilot nature of the trial. The primary outcomes were defined a priori as the frequency and quality of affected upper limb use measured by the PMAL-R. Secondary outcomes included spontaneous use and performance scores from the PAFT and acquisition of new motor programs measured by the INMAP. Descriptive statistics were calculated separately for each group at baseline, including functional outcome scores. Continuous variables were summarized using means and standard deviations (SD), and categorical variables using absolute and relative frequencies. Baseline comparability between groups was assessed using the Mann–Whitney U test for continuous variables and the chi-square or Fisher's

exact test for categorical variables. No statistically significant baseline imbalances were observed; therefore, no covariate adjustment was performed in subsequent analyses.

Changes over time between the control and intervention groups were evaluated using a nonparametric analysis of variance–type statistic for longitudinal data, implemented through the nparLD package in R (Noguchi et al., 2012). This method estimates main effects of group and time, as well as the group-by-time interaction, without assuming normality of residuals. The primary inferential parameter was the group-by-time interaction, which reflects differential change over time between groups from pre- to post-intervention. Analyses were conducted within a repeated-measures framework rather than solely on change scores or post-treatment values; change scores (post minus baseline) were calculated only for descriptive purposes and effect size estimation. Formal normality testing was not conducted due to the limited reliability of such tests in small samples (Mohd Razali & Yap, 2011). Outliers were not excluded, as nonparametric methods are robust to distributional deviations and exclusion could introduce bias. No participants were lost after randomization; therefore, complete-case analysis was performed, and all randomized participants were analyzed in their allocated groups.

In addition to p-values, standardized effect sizes (Cohen's d) and 95% confidence intervals (CI) were calculated for all main between-group comparisons to provide estimates of magnitude and precision. Effect sizes were derived from the difference in mean change scores between groups divided by the pooled standard deviation of the change scores. Given the small sample size ($N = 20$; 10 per group), these estimates may be unstable and potentially inflated and should therefore be interpreted as preliminary.

The Minimal Clinically Important Difference (MCID) was estimated using a distribution-based approach, specifically the effect size method described by Wright et al. (2012). This method defines a threshold of meaningful change based on the variability of the observed data, rather than on an external clinical or patient-reported anchor. Given the absence of condition-specific or anchor-based MCID validation for OBPP, this distribution-based approach was adopted as a pragmatic strategy to estimate a threshold suggestive of potential clinical relevance. Since anchor-based or condition-specific MCID values are not available for OBPP, the distribution-based threshold used in this study should be interpreted cautiously and primarily as a statistical indicator of potential clinical relevance.

Results

The study included 20 participants diagnosed with OBPP, with an average age at the intervention group of 5.2 ± 1.4 years, and at the control group of 5.7 ± 1.5 years. Table 1 describes the characteristics of the included patients in both groups by sex, laterality, and motor degree as well as baseline outcome measures. No adverse effects related to the 24-h restraint component were observed.

A significant group and time interaction was observed for PMAL-R frequency ($p < 0.001$) and quality ($p < 0.001$). The intervention group showed greater improvement over time compared with the control group. The effect sizes for the difference in change between groups were large, with Cohen's $d = 5.35$ (95% CI 3.39 to 7.27) for frequency and Cohen's $d = 3.84$ (95% CI 2.30 to 5.34) for quality. These values represent the

Table 1. Baseline demographic and clinical characteristics of the participants.

Variable	N	% (IC 95%)
Group		
CG	10	50 (29.34–70.66)
IG	10	50 (29.34–70.66)
Sex		
Female	11	55 (33.77–74.9)
Male	9	45 (25.1–66.23)
Laterality		
Right	14	70 (48.28–86.39)
Left	6	30 (13.61–51.72)
OBPP Type		
Erb-Duchene	14	70 (48.28–86.39)
Klumpke type	6	30 (13.61–51.72)
Outcome	**N**	**Mean ± SD (IC 95%)**
PMAL-R Frequency Baseline		
CG	10	0.92 ± 0.78 (0.36–1.48)
IG	10	1.15 ± 0.57 (0.74–1.55)
PMAL-R Quality Baseline		
CG	10	0.95 ± 0.84 (0.36–1.55)
IG	10	1.29 ± 0.67 (0.81–1.77)
PAFT 1st Attempt (Unimanual) Baseline		
CG	10	7.5 ± 4.09 (4.57–10.4)
IG	10	9.8 ± 4.08 (6.88 – 12.7)
PAFT 2nd Attempt (Unimanual) Baseline		
CG	10	7.5 ± 4.09 (4.57–10.4)
IG	10	5.3 ± 4 (2.44–8.16)
PAFT Points 1st Attempt (Unimanual) Baseline		
CG	10	27.8 ± 16.5 (16 – 39.6)
IG	10	35.6 ± 17.3 (23.2–48)
PAFT Points 2nd Attempt (Unimanual) Baseline		
CG	10	24.6 ± 15.2 (13.7–35.5)
IG	10	16.2 ± 14.3 (5.99–26.4)
PAFT Points 1st Attempt (Bimanual) Baseline		
CG	10	23 ± 6.63 (18.3–27.7)
IG	10	19.4 ± 6.48 (14.8–24)
INMAP Baseline		
CG	10	4.2 ± 1.23 (3.32–5.08)
IG	10	4.8 ± 1.48 (3.74–5.86)

Categorical variables are presented as number (N) and percentage with 95% confidence intervals (CI). Continuous baseline outcome measures are presented as mean ± standard deviation (SD) and 95% confidence intervals (CI).

difference in mean change between groups, standardized by the pooled standard deviation of the changes. The overall mean change was 1.58 (95% CI 0.83 to 2.33) for frequency and 1.53 (95% CI 0.78 to 2.28) for quality. These data are illustrated in Figure 3.

The nonparametric longitudinal analysis revealed significant group and time interactions for unimanual PAFT tasks in the first attempt ($p = 0.022$) and for points acquired in the first attempt ($p = 0.006$). The intervention group showed greater improvement over time compared with the control group. The effect sizes for the difference in change between groups were large, with Cohen's $d = 0.874$ (95% CI −0.05 to 1.78) for unimanual PAFT tasks in the first attempt and Cohen's $d = 1.58$ (95% CI 0.55 to 2.58) for points acquired in the first attempt. The overall mean change in unimanual tasks during the first attempt was 2.9 (95% CI 1.29 to 4.51), and for points acquired in the first attempt was 12.2 (95% CI 4.71 to 19.69). Here, Cohen's d represents the difference in mean change between groups, standardized by the pooled standard deviation of the changes.

Table 2. Minimum clinically Important difference (MCID) calculations for the variables included in PMAL and PAFT with medium and large effects.

MCID			
Frequency			
Effect size	IG	CG	Total
Medium	0.43	0.01	0.84
Large	0.69	0.02	1.34
Quality			
Effect size	IG	CG	Total
Medium	0.74	0.02	0.85
Large	1.18	0.03	1.36
Unimanual tasks 1st attempt			
Effect size	IG	CG	Total
Medium	2.94	0.17	1.44
Large	4.70	0.27	2.30
Unimanual tasks 2nd attempt			
Effect size	IG	CG	Total
Medium	2.92	0.17	1.44
Large	4.68	0.27	2.30
Points 1st attempt unimanual			
Effect size	IG	CG	Total
Medium	9.78	0.13	6.63
Large	15.66	0.20	10.60
Points 2nd attempt unimanual			
Effect size	IG	CG	Total
Medium	11.43	0.49	5.17
Large	18.28	0.78	8.28
Points 1st attempt bimanual			
Effect size	IG	CG	Total
Medium	1.62	0.04	1.66
Large	2.60	0.07	2.66

For points in bilateral PAFT tasks, a significant interaction effect was observed for points acquired in the first attempt ($p < 0.001$), demonstrating superior gains in the intervention group relative to the control group. The effect sizes for the difference in change between groups were large, with Cohen's $d = 2.08$ (95% CI 0.96 to 3.17) representing the difference in mean change between groups, standardized by the pooled standard deviation of the changes. The overall mean change was 3.5 (95% CI 1.29 to 5.71).

Regarding motor program induction, INMAP scores also demonstrated a significant group and time interaction ($p < 0.001$), indicating a greater increase in the intervention group compared with the control group over time. The effect sizes for the difference in change between groups were large, with Cohen's $d = 1.61$ (95% CI 0.57 to 2.61) representing the difference in mean change between groups, standardized by the pooled standard deviation of the changes. The overall mean change was 1.4 (95% CI 0.70–2.10). Figure 2 illustrates these results.

Table 2 presents the calculated MCID values for PMAL-R (frequency and quality), spontaneous use and points in unimanual PAFT tasks (first and second attempts), and points in bimanual PAFT tasks (first attempt), while Table 3 summarizes the proportion of participants whose individual change scores exceeded these thresholds. In the intervention group, all participants exceeded the large MCID threshold for PMAL-R frequency, and 90% exceeded the large threshold for PMAL-R quality, indicating a consistent pattern of substantial individual-level improvement in real-world upper limb use. For points acquired in the first attempt of unimanual PAFT tasks, 60% of

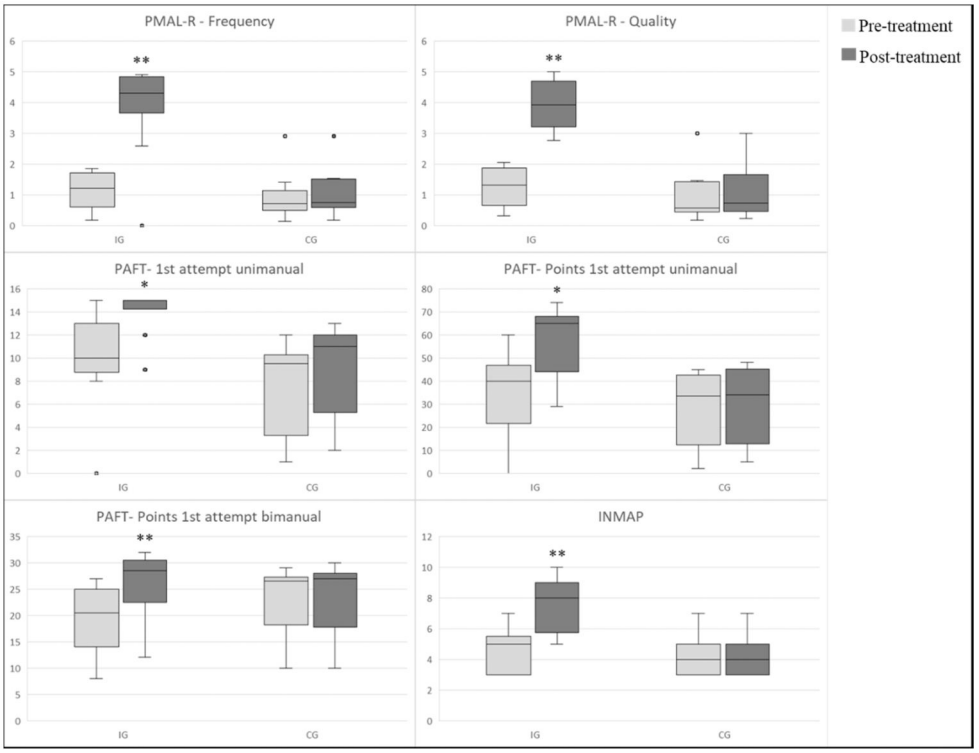


Figure 3. Quantitative variables of the study through the application of PMAL-R (quality and frequency), PAFT (first attempt unimanual and points of the first attempt in uni and bimanual tasks) and INMAP. for the groups and times evaluated. $^{**}p < 0.001$, $^{*}p < 0.05$.

participants exceeded the large MCID threshold, and an additional 20% exceeded the moderate threshold, suggesting relevant gains in task performance for most children in the intervention group. In contrast, for points acquired on the second attempt of unimanual tasks, all participants in both groups remained below the MCID threshold, indicating no relevant change in this specific performance condition. These distribution-based analyses complement the significant group and time interaction effects observed in the longitudinal nonparametric models, providing an estimate of the magnitude of individual-level change relative to baseline variability without implying anchor-based clinical validation.

There were no losses or exclusions after randomization.

Discussion

This is a single-blind controlled randomized clinical trial with 20 OBPP patients aged between 2 and 8 years old who presented with the learned nonuse of the affected upper limb. This study aimed to estimate the effectiveness of the original pediatric CIMT protocol when applied to patients with OBPP, to compare motor functional gains in patients receiving CIMT (intervention group) with those treated with conventional therapy (control group), regarding the frequency, quality, and spontaneity of using the affected arm as the acquisition of new motor programs. The sample of the present study

Table 3. Number (N) and percentage (%) of patients classified by Minimum Clinically Important Difference (MCID) identified in table 3 for this study in accordance with group of treatment.

	Large MDCI		Medium MDCI		Below MDCI		Total
	N	%	N	%	N	%	N
Frequency							
IG	10	100	0	0	0	0	10
CG	7	70	0	0	30	30	10
Total	17	85	0	0	15	15	20
Quality							
IG	9	90	1	10	0	0	10
CG	7	70	0	0	3	30	10
Total	16	80	1	5	3	15	20
Unimanual tasks 1st attempt							
IG	5	50	0	0	5	50	10
CG	8	80	0	0	2	20	10
Total	13	65	0	0	7	35	20
Unimanual tasks 2nd attempt							
IG	0	0	0	0	10	100	10
CG	0	0	0	0	10	100	10
Total	0	0	0	0	20	100	20
Points 1st attempt unimanual							
IG	6	60	2	20	2	20	10
CG	7	70	0	0	3	30	10
Total	13	65	2	10	5	25	20
Points 2nd attempt unimanual							
IG	0	0	0	0	10	100	10
CG	0	0	0	0	10	100	10
Total	0	0	0	0	20	100	20
Points 1st attempt bimanual							
IG	5	50	0	0	5	50	10
CG	8	80	0	0	2	20	10
Total	13	65	0	0	7	35	20

was balanced in relation to sex (55% female sex and 45% male sex) and baseline evaluation scores. On the other hand, regarding the degree of motor impairment, 14 patients (70%) were classified as having an Erb-Duchenne type injury, in which hand movement is preserved, and 6 as having a Klumpke type injury (30%), who had greater difficulty in extending fingers and maintaining a stable wrist position in neutral. Furthermore, 70% of patients were compromised in the right upper limb. This constitutes a limitation of our study, which used convenience sample recruitment. None of the patients studied presents structural bone alterations. All study participants were born at term, with no mention by caregivers of complications during pregnancy or the influence of high birth weight as a predisposing factor for shoulder dystocia.

In our sample, we can observe in PAFT that at the pretreatment moment, patients already presented adequate spontaneity of use of the affected upper limb in bimanual tasks, with impaired ability and the unaffected upper limb being used for most part of the task. The same was observed in the interview with caregivers through the PMAL-R, in which frequent use of the affected upper limb in bilateral tasks was reported before the intervention. In contrast, the same was not observed in unimanual tasks in the pretreatment. In the study of Werner et al, in which an adapted CIMT protocol was applied, we can observe that CIMT shows to be superior to conventional therapy in terms of the performance of bimanual activity, but the unimanual function was not evaluated (Werner et al., 2021). In our results, we can see a significant improvement in

the spontaneous use of the affected upper limb in unimanual and bimanual tasks, with higher quality and frequency of movement.

Our results demonstrate that CIMT provides additional benefits in quality and frequency of movement and in the spontaneous use of the affected upper limb in comparison to conventional physiotherapy or occupational therapy. This supports the theory that patients with peripheral injury may present the phenomenon of learned nonuse, as well as patients with central nerve injuries, with the possibility of cortical volume differences or asymmetry (Longo et al., 2020). Additionally, it is important to highlight that the management and surgical treatment indication for OBPP is still very difficult, since the surgical correction may not provide functional gains due to the maladaptive patterns and learned nonuse (Marcus & Clarke, n.d.).

In a Cochrane review of CIMT in children with cerebral palsy hemiparetic-type, there is evidence that CIMT is more effective for outcomes of bimanual and unimanual activities (dissociated finger movement, grip, and extension for protective reaction) than low-dose therapies, mostly described as conventional occupational therapy with an average dosage of 7.9 h of treatment in total (Hoare et al., 2019). In this same review, CIMT was shown to be superior in the outcome of bimanual activities when compared to individualized conventional intensive treatment, with an average of 37.5 h of treatment in total (Hoare et al., 2019). It can be stated that CIMT is effective due to its pillars that enable the generation of use-dependent cortical reorganization, evidenced by imaging tests and transcranial magnetic stimulation, and can promote volumetric gain of cerebral gray matter, specifically in the sensorimotor cortex, anterior motor areas, and bilateral hippocampus (Sterling et al., 2013; Taub et al., 1994). Regarding the use of CIMT in patients with OBPP, a systematic review published in 2021 identified 4 articles that used adapted and reduced protocols, showing no scientific evidence supporting this therapy in the management of OBPP because of a considerable heterogeneity of studies and protocols applied (Sicari et al., 2022). It is important to emphasize that the application of CIMT in its original protocol, structured according to its pillars and in an intensive manner, is what guarantees the cortical reorganization (Taub et al., 1994).

Our patients undergoing the CIMT protocol already had approximately five of the ten motor programs assessed by INMAP at the pretreatment stage and completed the protocol with approximately eight. This suggests that intensive practice, with a progressive increase in the degree of difficulty, achieved through shaping and task practice, may have been positively responsible for this acquisition, since repetitions with variability and encouragement to solve problems by the patients were essential for the construction of this executive memory base (Taub et al., 2007).

The study demonstrated very large effects of constraint-induced therapy on upper limb function. Cohen's d values exceeded 3 for PMAL-R outcomes and 2 for PAFT measures, reflecting consistent gains in the intervention group relative to minimal change in controls. Distribution-based analyses using the MCID further supported these findings: all participants exceeded the large MCID threshold for PMAL-R frequency, 90% for PMAL-R quality, and 60–80% for first-attempt unimanual PAFT points, indicating substantial individual-level improvements. In contrast, second-attempt unimanual tasks remained below the MCID threshold in both groups, highlighting task-specific limitations. These robust effects should be interpreted in the context of a small sample

size ($n = 20$), which increases the risk of overestimating effect sizes and the likelihood of type I error. Additionally, this was a pilot study with a discrepancy in therapy dosage (40 min of conventional therapy versus 3 h of constraint-induced therapy), which may further influence the magnitude of observed effects. The choice of comparing CIMT with conventional therapy was guided by the institutional and national healthcare context. In Brazil, public health services are often overburdened, and the provision of intensive therapies through the public system (SUS) is limited to interventions with strong evidence of clinical benefit due to the high costs involved. Therefore, comparing CIMT with the standard conventional therapy reflects both the real-world therapeutic options available to OBPP patients and the need to generate evidence supporting the allocation of intensive resources in this population. Overall, the results suggest clinically meaningful gains at both the group and individual levels, while acknowledging methodological factors that may inflate standardized effect sizes, and support the feasibility and rationale for conducting larger randomized clinical trials in this population.

In conclusion, this is the first study comparing CIMT in its original Alabama University protocol with conventional therapy in the upper limb function in patients with OBPP. This study was designed as a pilot randomized controlled trial and, consequently, the study is underpowered for definitive efficacy testing, with increased risk of both type I and type II errors, and findings should be considered hypothesis-generating. Despite these limitations regarding the low sample size, the imbalance in relation to motor status and laterality, and the therapy dosage discrepancy, CIMT was shown to be safe for patients with OBPP and we were able to observe that all patients in the IG showed significant improvement in bimanual and unimanual function, with an increase in quality and frequency of movement, beyond the spontaneity of use of the affected upper limb. Also, patients in the intervention group showed the acquisition of new motor programs through INMAP. Therefore, the results demonstrated an increase in the functional performance of the affected upper limb in OBPP patients. Future randomized clinical trials with larger sample sizes and follow-up assessments are warranted to evaluate the long-term maintenance of gains achieved through the CIMT protocol.

Author Contributions

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