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Research Protocol

Physiotherapy Section

Comparison of Modified Constraint-Induced Movement Therapy (mCIMT) Hand Arm Bimanual Intensive Training and Mirror Therapy to Improve Upper Extremity Function in Children with Hemiplegic Cerebral Palsy: A Double-blinded Randomised Clinical Trial

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ABSTRACT

Introduction: Hemiplegic Cerebral Palsy (CP), a non-progressive neurological disorder resulting from early brain injury, leads to unilateral motor deficits, predominantly impacting Upper Extremity (UE) function. Characterised by limited pincer grasp and wrist extension due to spasticity and learned non-use, this impairs daily activities such as play and self-care, thereby reducing Quality Of Life (QOL).

Need of the study: In children with hemiplegic CP, impaired UE function affects independence and QOL, prompting the need for advanced interventions beyond traditional therapies. Techniques such as modified Constraint-Induced Movement Therapy (mCIMT), Hand-Arm Bimanual Intensive Training (HABIT), and mirror therapy differ in their approaches to improving outcomes related to learned non-use and central nervous system plasticity. Current evidence on UE interventions is often rated low due to a scarcity of high-quality comparative trials, underscoring the necessity for a well-designed trial to determine the most effective technique for enhancing UE movement quality.

Aim: To compare the effects of mCIMT, HABIT, and mirror therapy on UE function in children with hemiplegic CP.

Materials and Methods: A double-blinded Randomised Controlled Trial (RCT) will be conducted from January 2023 to January 2026 at Dr Vithalrao Vikhe Patil Foundation's College of Physiotherapy, Ahilyanagar, special schools, and private clinics. Thirty-three children with hemiplegic CP, aged 3-12 years, meeting inclusion criteria, will be randomised into three groups (n=11 each): Group-A (mCIMT), Group-B (HABIT), and Group-C (mirror therapy). Interventions will be administered for five days/week for four weeks, alongside conventional therapy, with pre- and post-assessments at two and four weeks using the Quality of Upper Extremity Skills Test (QUEST). Data will be analysed with repeated measures Analysis of Variance (ANOVA) or Kruskal-Wallis tests at a 0.05 significance.

Keywords: Cerebral palsy, Exercise therapy, Hemiplegia, Motor skills, Recovery of function

INTRODUCTION

CP is a non-progressive neurological disorder caused by early brain injury, resulting in permanent movement and posture impairments [1,2]. Globally, the birth prevalence of CP is approximately 1.6 per 1000 live births in high-income countries, with higher rates (2-3.5 per 1000 live births) in low- and middle-income countries, including India at ~3 per 1000 live births [1]. Hemiplegic CP, affecting 20-30% of cases, involves unilateral motor deficits, primarily in the UE [3]. Children often favour the non-affected hand, keeping the affected hand fisted, which limits movements like pincer grasp, forearm supination, and wrist extension. Hemiplegic CP impairs UE function, hindering reaching, grasping, and object manipulation, which affects exploration, play, self-care, and daily activities. Abnormal movements, including wrist and elbow flexion, forearm pronation, and compensatory scapular or trunk motions, further impair task performance [2,3]. Addressing these challenges is essential to enhancing the QOL and reducing dependency.

Therapeutic interventions for enhancing UE function in children with CP include neurodevelopmental treatment, splinting, bilateral exercises, kinesio-taping, virtual reality, and sensory integration therapy [4]. Recently, modified Constraint-Induced Movement Therapy (mCIMT), Hand-Arm Bimanual Intensive Training (HABIT), and mirror therapy have emerged for their focus on precise, targeted outcomes and improved movement patterns [5-7]. The mCIMT restricts the unaffected limb to foster intensive utilisation of the affected limb, enhancing motor learning and neuroplasticity [8]. HABIT emphasises bimanual activities to improve coordination, mimicking daily tasks [6]. Mirror therapy employs visual feedback from the reflection of the unaffected limb to stimulate neurons, thereby encouraging movement in the affected limb [7].

Studies have shown that mCIMT, HABIT, and mirror therapy improve quantitative aspects of UE function, such as dexterity and fine motor skills, in children with hemiplegic CP, but research on movement quality is limited [5-11]. Current evidence indicates low to very low quality of UE interventions, with few well-designed RCTs comparing these therapies in matched populations and similar clinical settings [9]. The unique mechanisms of mCIMT (restraint-based), HABIT (bimanual coordination), and mirror therapy (visual stimulation) necessitate a comparative analysis to assess their effectiveness in enhancing movement quality [10,11]. This gap highlights the need for high-quality RCTs to inform therapists' intervention choices.

REVIEW OF LITERATURE

In children with hemiplegic CP, mCIMT, HABIT, and mirror therapy represent promising interventions for enhancing UE function by leveraging distinct neuro-rehabilitative mechanisms to promote neuroplasticity and overcome motor impairments [8-11]. Chen YP et al., conducted a meta-analysis on 27 RCTs confirming mCIMT's efficacy in enhancing arm function in children with CP, showing a medium overall effect size (d=0.546, p<0.001) versus conventional therapy, with larger benefits in studies without dose-equivalent comparators and home-based delivery [8]. Palomo-Carrión R et al., observed that mCIMT, incorporating restraint of the unaffected hand, enhanced functional abilities in children aged 4-8 years more effectively than unimanual therapy lacking such containment [9]. A previous review by Hoare BJ et al., of 36 RCTs showed moderate-quality evidence that mCIMT improved bimanual activity {Standard Mean Deviation (SMD) 0.44} and unimanual ability (SMD 0.51) versus low-dose interventions, with low-quality evidence indicating less evident or no benefits against high-dose or dose-matched therapies [12]. HABIT facilitates bimanual coordination through symmetric, goal-directed activities that integrate both limbs, enhancing interhemispheric communication, manual ability, and fine-motor performance in daily tasks [10,13]. Moreover, HABIT focusses on bimanual activities to improve coordination. In a comparative study (n=10 children aged 8-12 years with hemiparetic CP, 5 per group), 12 weeks of HABIT therapy (three hours/day) significantly improved manual ability. Between-group comparisons confirmed HABIT's superior gains in bimanual upper limb functions [13]. Mirror therapy utilises visual illusions from the unaffected limb's reflection to activate mirror neurons, stimulating voluntary paretic-limb movement, boosting strength, precision, and spontaneous use via perceived bilateral symmetry, as reported by a protocol combining mirror therapy with action observation therapy, which showed potential to enhance spontaneous use and movement quality in children aged 6-12 years [6]. Bruchez R et al., found that five weeks of daily mirror therapy (15 minutes/day) improved UE strength and function in 90 children, though outcomes were similar to a control group without a mirror [14]. Narimani A et al., reported significant improvements in dexterity, but not grasp, after 6 weeks of mirror therapy in 30 children aged 9-14 years [7]. Park EJ et al., review of nine studies found that 77.8% reported positive effects of mirror therapy on hand strength, movement speed, and accuracy [15]. However, a comparative study by Sharan D et al., of 80 children found mCIMT more effective than mirror therapy in improving UE function, as measured by the Besta scale and Melbourne Assessment [16]. Notably, a prior experimental study demonstrated mCIMT's superiority over HABIT and conventional therapy alone [17], underscoring the value of direct comparisons and the potential for mirror therapy to offer a low-cost, home-adaptable alternative warranting further evaluation. Despite evidence supporting mCIMT, HABIT, and mirror therapy, few studies focus on movement quality, with limited high-quality RCTs comparing these interventions in matched populations.

Due to the paucity of direct three-way comparisons between mCIMT, HABIT, and mirror therapy in hemiplegic CP children on UE movement, the present study aims to evaluate and compare the effects of mCIMT, HABIT, and mirror therapy on UE function in children with hemiplegic CP.

Primary objective:

- To evaluate the effect of mCIMT therapy on the quality of UE function in children with hemiplegic CP.
- To evaluate the effect of HABIT therapy on the quality of UE function in children with hemiplegic CP.
- To evaluate the effect of mirror therapy on the quality of UE function in children with hemiplegic CP.

Secondary objectives:

- To compare the effects of mCIMT, HABIT, and mirror therapy on the quality of UE function in children with hemiplegic CP.

Null Hypothesis (H_0): There is no significant difference in the quality of UE function among children with hemiplegic CP receiving mCIMT, HABIT, or mirror therapy.

Alternate hypothesis (H_1): There is a significant difference in the quality of UE function among children with hemiplegic CP receiving mCIMT, HABIT, or mirror therapy.

MATERIALS AND METHODS

A double-blind RCT will be performed at the outpatient department of Dr Vithalrao Vikhe Patil Foundation's College of Physiotherapy, Ahilyanagar, special schools and private clinics in Ahilyanagar, Maharashtra, India, from January 2023 to January 2026. The Institutional Ethical Committee of Smt. Kashibai Navale College of Physiotherapy, Pune (41/2022) and DVVPF's College of Physiotherapy, Ahilyanagar (IEC/COPT/PhD–09/A–25/10/2021) provided ethical approval for the conduction of the study, and the trial is registered with the Clinical Trials Registry of India (CTRI/2023/03/050287). Before the recruitment, the purpose and methodology will be explained to the parents or legal guardians of children aged 3-12 years, and verbal assent will be taken from younger patients where applicable. Those satisfying the requirements for inclusion will be required to provide informed consent in written format. Throughout the study, the confidentiality of the children will be maintained.

Inclusion criteria: Children with hemiplegic CP, age group 3-12 years, children with score III or less on Manual Ability Classification System (MACS) [18,19], ability to achieve minimum of 10 degrees of active wrist extension, 10 degrees finger extension (criteria for CIMT) [5], Gross Motor Function Classification System (GMFCS) level I (Walks without limitations), II (Walks with limitations) and III (Walks using a hand-held mobility device) [20], spasticity grade 0, 1 and 1+ according to Modified Ashworth scale [21], and able to understand and follow commands.

Exclusion criteria: Fixed UE deformities, previous orthopaedic surgery in the affected UE, visual or auditory impairments, Botulinum toxin injections within the last six months in the UE, neurological or orthopaedic conditions unrelated to CP, and epilepsy.

Withdrawal criteria: Withdrawal of consent, and if children start taking any other therapy for improving involved UE function during the course of the allocated treatment duration.

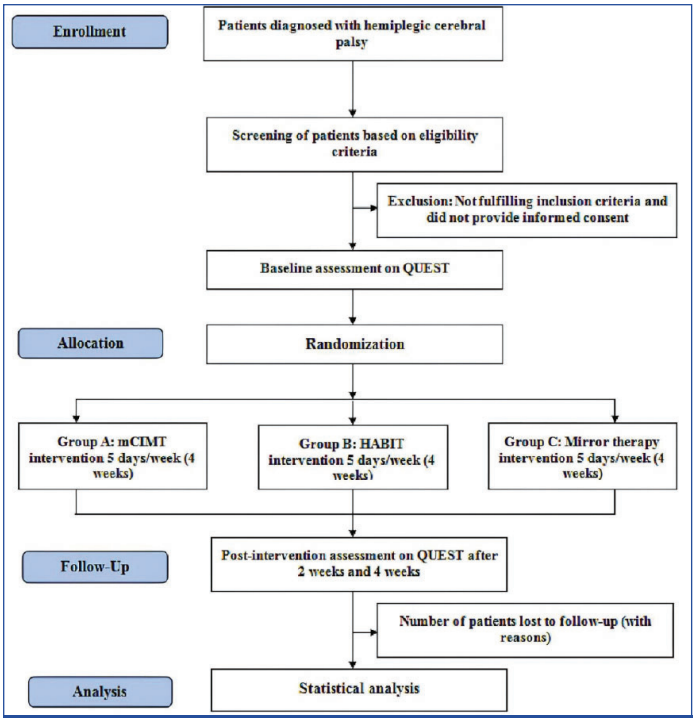
Sample size calculation: The sample size estimation was performed using the formula $N=2\{(Z\alpha+Z\beta)\times SD / D\}^2$, where $Z\alpha=1.96$; $Z\beta=1.28$; D=4.9 {the Minimal Clinically Important Difference (MCID) for the QUEST scale in children with CP=4.89}; SD=2.8 [22]. Hence, $N=2\{(1.96+1.28)\times(2.8) / (4.9)\}^2$, $N=2\{3.24 \times 2.8/(4.9)\}^2$, $N=2\{9.1 / 4.9\}^2$, $N=2[2]^2$, N=2×4, N=8 with 30% dropouts N=8+0.24, N=10.2 (as sample size cannot be in decimals), N=11 in each group consisting total of 33 patients with CP. The total sample required for this study will be 11 (n=11) in each group, considering 90% power at 5% level of significance.

The children will be assigned to: Group A (mCIMT), Group B (HABIT), and Group C (mirror therapy). Allocation will be randomised using a computer-generated random number table. At all centres, group assignments will be concealed in opaque, sealed envelopes. They will then be referred to an independent assessor, a qualified physiotherapist, blinded to group allocation and intervention. The assessor will conduct pre-treatment evaluations, including demographic and baseline data, along with post-intervention assessments using the QUEST and handle data entry [Table/Fig-1].

The principal investigator will administer the intervention five days a week for four weeks. All groups will receive conventional therapy, including static stretching of tight UE muscles (30-second hold,

three repetitions), manual dexterity exercises (e.g., grasp/release, pegboard activities), and weight-bearing tasks for the affected UE.

Group A (N=11) will undergo mCIMT, which entails securing the unaffected UE with a sling attached to the trunk, its distal end stitched closed to prohibit use, thereby promoting the use of the affected UE. The sling will be worn constantly, except during pre-approved activities or requested breaks. Toys will be openly available for children to select their preferred tasks, which will gradually increase in difficulty as their performance increases by enhancing speed, accuracy, and repetition. The children will participate in unimanual activities for three hours daily (1 hour supervised by the principal investigator, and two hours at home under parental supervision). A diary will document home sessions [3,5,9]. An additional 15-minute duration of sham treatment will be given to the child, which will mimic the other two interventions (HABIT and mirror therapy). The child will be encouraged to perform Range Of Motion (ROM) exercises bilaterally, and object transfers from one place to another at a distance from a mirror, which will be present at the treatment area [Table/Fig-2].



[Table/Fig-1]: CONSORT flow diagram for the study.

Activities	Graded constraints
Board games (Active wrist extension)	Arrange the card deck to promote wrist extension, adjusting its position to vary the level of difficulty.
Card games (Precision grasp)	Easier with bevelled cards on the deck for simpler gripping; difficulty increases when the cards are not bevelled.
Functional tasks (Pronation and supination)	For turning a key in a lock, the starting position of the key will be adjusted to progress from utilising only supination to employing both supination and pronation.
Gross motor (Shoulder flexion)	It will be encouraged by transitioning the child from a simpler, wall-supported position to a free-standing stance that demands greater control.
Manipulative games (Precision grasp)	To heighten difficulty, the child will be given more intricate or progressively smaller objects to handle.
Puzzles (Release accuracy)	Difficulty will be escalated once proficiency in releasing puzzle pieces is achieved by introducing a puzzle featuring smaller pieces.
Arts and crafts (Maintaining grasp)	The child will start at an easier level using a built-up brush, and difficulty will rise by eliminating assistance, with smaller brushes being introduced thereafter.

[Table/Fig-2]: Activities introduced for mCIMT intervention.

Group B (N=11) will receive HABIT, involving bimanual tasks promoting coordinated use of both hands, with the affected limb used similarly to a typically developing child's non-dominant hand. Each task and correct hand usage will be explained beforehand to prevent compensatory strategies. Task difficulty will be gradually increased by enhancing speed, accuracy, or repetitions as the performance of the child improves. The HABIT intervention will be given for three hours per day, which will include one hour of training given by the principal investigator and the rest two hours will be performed by the child at home under the supervision of the parents/caretaker [7,10,15]. An additional 15-minute duration of sham treatment will be given to the child, which will mimic the other two interventions (mCIMT and MT) [Table/Fig-3] [7,10,15].

Activities	Description
Clay activities	The patient will simultaneously roll two equal-sized clay balls using both hands on the table or roll a large ball of clay between both palms.
Ball activities	The child will engage in throwing and catching balls of varying sizes.
Cube activities	From the non-affected hand to the affected hand, the child will transfer cubes and build towers, beginning with three cubes and progressing to six. Tower construction will first be performed using the non-affected limb, followed by the affected limb.
Bottle and marble activities	The child will place marbles into a bottle, initially stabilising the bottle with the affected hand while using the non-affected hand to complete the task. Difficulty will be increased as the task progresses, by having the child use the affected hand to place the marbles.
Stacking rings	The child will begin by holding and stacking larger rings using the non-affected hand, and will gradually progress to placing rings using the affected hand.
Stringing beads	The child will begin by stabilising the rope with the affected hand while stringing beads with the non-affected hand. As the task becomes more challenging, the non-affected hand will hold the rope while the affected hand performs the stringing. The activity will start with large beads and a thick cord, gradually progressing to smaller beads and a thinner cord.
Manipulation activities	The child will perform alternating clapping and banging movements, followed by fastening clothing, buttoning and unbuttoning, opening and closing zippers, twisting jar lids, turning and pressing locks with keys, and cutting paper using scissors.

[Table/Fig-3]: Activities introduced for HABIT intervention.

Group C (N=11) will receive mirror therapy, a visual feedback-based approach using the reflection of the unaffected limb to stimulate the affected side. The child will sit with a 30 x 30 cm mirror placed on the table, positioning the unaffected hand in front and the affected hand behind it. The reflection will create the illusion of normal movement in the affected limb. Before therapy, the child will be guided on the procedure and instructed to focus on the mirror image while performing exercises. The child will perform fine motor tasks, full ROM exercises, and strengthening activities targeting the fingers and forearms. The primary investigator will instruct the child to carry out these movements using both hands and arms simultaneously, encouraging synchronous motion, even if the paretic side does not move fully or easily, and to maintain visual focus on the paretic side throughout the tasks. Each movement will be repeated 10 times, followed by a 20-second rest before proceeding to the next. The mirror therapy intervention will be given for one hour per day by the principal investigator [6,7,11,14]. An additional 15 minutes duration of sham treatment will be given to the child, which will mimic the other two interventions (mCIMT and HABIT) [Table/Fig-4] [6,7,11,14].

Outcome measure (Primary outcome): The QUEST will be used across four domains to assess UE function: dissociated movements (19 items, each with a single response level), grasp (6 items with 3-5 response levels), weight-bearing (5 items with 6 response levels), and protective extension (3 items with 6 response levels). Scoring

will be based on: 2="Yes" (able to complete), 1="No" (unable), and 1="NT" (not tested), with a deduction of 1 point for abnormal postural movements. The principal investigator will acquire the necessary licensed kit directly from the resource organisation, in compliance with their distribution guidelines. The QUEST is validated for children aged 18 months to eight years and has demonstrated reliability for children aged two to 12 years, with test-retest reliability ranging from 0.75 to 0.95 and concurrent validity of 0.84 with the Peabody Developmental Motor Scale (PDMS) [23,24].

Activities	Description
Symmetrical exercises (bilateral ROM and strengthening)	Forearm supination/pronation, wrist/finger extension/flexion, shoulder antepulsion–retropulsion, abduction–adduction; child performs synchronous motions focusing on mirror reflection of unaffected limb to simulate affected-side movement; progress by increasing repetitions or adding resistance (e.g., light weights) as symmetry improves.
Wrist rotations	Clockwise and anticlockwise rotations with both hands, emphasising visual focus on the mirror for paretic-limb activation; start slow, advance to faster speeds or combine with supination/pronation.
Foam palmar squeezing	Bilateral squeezing of foam balls or sponges, promoting grip strength and endurance; the child maintains a mirror gaze to encourage paretic-hand participation; progress from large to smaller foams.
Sequential thumb-index pinch and extension	Finger-by-finger opposition (thumb to each finger) and full extension, performed bilaterally while viewing the mirror illusion, advancing to faster cycles or integrated with object pinch.
Finger-by-finger pressure (modelling clay)	Pressing clay with individual fingers bilaterally, targeting dexterity; focus on the mirror for perceived symmetry; start with large clay pieces, progress to finer manipulations.
Functional tasks	Assembling puzzle pieces, removing Lego blocks, squeezing specially designed balls, wringing a towel, drawing circles; bilateral execution with mirror feedback to stimulate voluntary paretic-limb use; difficulty increased by smaller objects or timed challenges.

[Table/Fig-4]: Activities introduced for mirror therapy intervention.

Manual Ability Classification System (MACS): The MACS is a standardised framework used to describe how children with CP manage everyday tasks that require hand use. It provides a clear, five-level scale ranging from children who handle objects easily and successfully (Level I) to those who are completely dependent on assistance for manual activities (Level V) [18,19].

Gross Motor Function Classification System (GMFCS): The GMFCS is a widely used framework that categorises the mobility and motor function of individuals with CP into five distinct levels. It focuses on everyday movements such as sitting, walking, and transferring, rather than isolated motor skills, making it highly relevant for real-life functioning [20].

The Modified Ashworth Scale (MAS) is a clinical tool designed to measure spasticity, which refers to the increased resistance of muscles when they are passively stretched. It is commonly used in patients with neurological conditions such as CP, stroke, multiple sclerosis, and spinal cord injuries. The scale ranges from 0 to 4, with 0 indicating no increase in muscle tone and 4 representing a limb that is rigid in flexion or extension [21].

Data collection procedure will involve baseline data and post-intervention assessments using QUEST will be conducted at two weeks and four weeks.

STATISTICAL ANALYSIS

The data will be analysed using SPSS version 17.0. Descriptive statistics will be used to summarise baseline characteristics such as age, gender, and MACS level. Between-group comparisons at baseline, two weeks, and four weeks will be conducted using repeated measures ANOVA for normally distributed data, whereas, Kruskal-Wallis test will be employed for data that is not distributed normally. All tests will be conducted at a 0.05 level of significance with a 95% confidence interval.

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