Effectiveness of a Clinic-Based PCIMT Program on Upper Extremity Function and Movement Quality

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By: Regan L. Blankenship, MS, OTR/L

Approved by:

Lori Breeden, EdD, OTR _____
Committee Chair

Katy Mitchell, PT, PhD _____
Committee Member

Stephanie C. DeLuca, PhD _____
Committee Member

Accepted by:

Laura Santurri, PhD, MPH, CPH _____
Director, DHSc Program
Chair, Interprofessional Health & Aging Studies
University of Indianapolis

Stephanie Kelly, PT, PhD _____
Dean, College of Health Sciences
University of Indianapolis

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Regan L. Blankenship

Department of Interprofessional Health and Aging Studies, University of Indianapolis

Abstract

Pediatric constraint induced movement therapy (PCIMT) is a largely growing treatment method being utilized around the world, however, there are limited programs that are utilizing this type of program to meet the needs of children with unilateral hemiparesis. A vast majority of children who receive this type of intervention are enrolled in randomized controlled trials, or families seeking-out facilities who provide this service. The purpose of this study was to determine the effectiveness of a clinic-based PCIMT program on upper extremity function and movement quality utilizing standard assessments geared towards this specific population. Children who have unilateral hemiparesis are at a higher chance of developing unilateral neglect and being developmentally delayed in gross motor, fine motor, and visual motor milestones. Delays in these areas will impact a child's ability to participate in self-help skills and participate with peers which is critical for a child's development. A quantitative, retrospective study was used to gather data for comparison and analysis. This study examined a total of 31 children ages 2.5 through 8 years of age who were referred to the PCIMT program at a large pediatric hospital in the south. The children were measured using two standardized assessment tools (1) pediatric motor activity log and (2) Melbourne 2 assessment at the time of their initial evaluation and following the 3-week long intervention. Children were categorized by their Manual Abilities Classification Scale (MACS) or the Mini-Manual Abilities Classification Scale (Mini-MACS). Results from this study provide evidence to support clinic-based PCIMT programs to improve both function and movement quality for children with unilateral hemiparesis.

Table of Contents

Effectiveness of a Clinic-Based PCIMT Program on Upper Extremity Function and Movement Quality

Children with hemiparesis have decreased strength, movement quality, and function on one side of their body (Gordon & Okita, 2010; Reidy et al., 2012). Hemiparesis can be caused by a stroke or other lateralized brain injuries (Gordon & Okita, 2010; Reidy et al., 2012). Since upper limb function has a significant impact on a child's ability to participate in self-care tasks, play, and participate in developmental activities, hemiparesis can significantly impact functional skills (Jackman et al., 2020). Resultantly, children's inability to fully participate in daily skills can create social isolation, lowered self-esteem, and add to feelings of being marginalized (Mandich & Rodger, 2006; Novak & Honan, 2019). These feelings and the deficits associated with hemiparesis can impact a child's ability to be independent across the lifespan (Mandich & Rodger, 2006).

Therapeutic efforts such as occupational and physical therapy are meant to ameliorate these impairments by using current evidence-based treatment approaches to improve movements, function, and skill (Mandich & Rodger, 2006; Novak & Honan, 2019). For the treatment of hemiparesis, one evidenced-based treatment approach is pediatric constraint-induced movement therapy (PCIMT; Boyd et al., 2017; Coker-Bolt et al., 2013; DeLuca et al., 2003; Novak et al., 2013; Pidcock et al., 2009; Reidy et al., 2012; Taub et al., 2004; Taub et al., 2011). The efficiency of PCIMT is supported through a wide array of research, including many randomized controlled trials. PCIMT is also increasingly used clinically (DeLuca et al., 2017).

Descriptively, PCIMT is a treatment approach assumed to influence development of neural pathways by promoting connectivity within the brain to improve motor function. The therapeutic processes are based on behavioral approaches and learning theories (Pidcock et al.,

2009). For adults, Morris et al. (2006) established three main components to constraint-induced movement therapy (CIMT). The first is constraining the use of the less affected upper extremity; this could be using a mitt or a different method to continually remind the participant to use the more affected upper extremity (Morris et al., 2006). Second, repetitive, task-oriented training, including shaping and task practice (Morris et al., 2006). Third, adherence to behavioral strategies for carryover to the in-home environment; these include but are not limited to behavioral contract, home skill assignment, home practice, and daily schedule (Morris et al., 2006). For PCIMT, Ramey et al. (2013) proposed five main components as necessary for a protocol to be considered PCIMT: 1- Constraint of the less involved arm and hand; 2- High dose therapy efforts that are given for multiple hours a day, multiple days a week, for multiple weeks; 3- the use of shaping or operant conditioning to guide therapeutic activities; 4- treatment occurring in natural environments; and 5- the inclusion of a post-treatment planning transfer package. Ramey and colleagues (2013) further delineated that variation in the literature could be divided into approaches based on traditional or signature approaches of PCIMT, including all of the above components at sufficient levels, and modified and alternative PCIMT approaches that varied one or more of the components above.

One approach to PCIMT has been titled ACQUIREc therapy (**A**cquisition of new motor and functional skills through **C**ontinuous practice and shaping to produce **Q**uality movement in the **U**pper extremity through **I**ntensive therapy that is **R**einforced in the child's **E**veryday patterns and places) (DeLuca et al., 2013; DeLuca et al., 2007). This is a signature PCIMT protocol that has been rigorously tested in multiple randomized controlled trials (DeLuca et al., 2013; DeLuca et al., 2007; DeLuca et al., 2003; Ramey et al., 2013). ACQUIREc therapy was based, initially, on the adult versions of CIMT, but there were specific processes added in

recognition of children's developmental needs. Despite the widespread research investigation into ACQUIREc Therapy and other forms of PCIMT, there has been little investigation into the clinical translation of PCIMT. This creates a significant knowledge gap because we cannot be sure that the efficacy and effectiveness of PCIMT found in research efforts can be duplicated in clinic-based settings where the heterogeneity of potential participants is broad. Pediatric clinics often see a broad array of etiologies that result in hemiparesis, and variations in classifications of severity levels can also be broad. Whereas some studies include a more homogeneous sample of children in order to increase the power of the sample to identify an effect if one exists.

Deluca et al. (2017) explicitly called for more investigation into the use of clinic-based PCIMT, requesting that clinics gather data to inform pediatric rehabilitation and develop practice-based evidence. This project seeks to explore the effectiveness of a clinic-based PCIMT program on function and movement quality as measured by two standardized assessments, the Pediatric Motor Activity Log (PMAL) and Melbourne-2, and to examine the potential difference in change based on age-based classification scales called the Manual Abilities Classification Scale or the Mini-Manual Abilities Classification Scale (MACs or Mini-MACs; Imms et al., 2009; Randall et al., 2013; Uswatte et al., 2012). The clinic-based program was derived from the ACQUIREc Therapy protocol principles following four of the five components listed above. The only missing component is using a natural environment as the children in the program are being seen in an outpatient therapy clinic, and thus would be considered a modified PCIMT protocol. The program uses a long arm bivalve cast for constraint and children are required to wear it for 24 hours a day seven days a week for two weeks. The cast is to only be taken off if it gets wet or causing harm. The dosage level of the program consists of two weeks unimanual and one-week bimanual training. All tasks during treatment utilizes the MR3 cycle which is an acronym for

movement, immediate and direct reinforcement, repetition, and refinement (DeLuca et al., 2013), which is explicitly defined in the ACQUIREc Therapy model, and the family is provided an extensive home exercise program for a transition package post-treatment to help children and families maintain and or improve on skills learned during therapy.

Research Questions

1. Is there a significant difference in upper extremity function as measured by the PMAL before and after a three-week clinic-based PCIMT intervention?
    a. Does MACS or Mini-MACS level predict change on the PMAL following clinic-based CIMT treatment in upper extremity function based on MACs or Mini-MACs classification as recorded prior to treatment?
2. Is there a significant difference in upper extremity movement quality measured by the Melbourne-2 before and after a three-week clinic-based PCIMT intervention?
    a. Does Macs or Mini-MACS level predict change on the Melbourne-2 following clinic-based CIMT treatment in upper extremity movement quality based on MACs or Mini-MACS classification as recorded prior to treatment?

Objectives

To answer the research questions, the following objectives were addressed:

1. To determine if a three-week PCIMT program will change the upper extremity function measured by the PMAL in children 30 months to eight years old.
2. To determine if a three-week PCIMT program will change upper extremity movement quality measured by the Melbourne-2 in children 30 months to eight-years-old.

3. To determine if MACS or Mini-MACs, predicts upper extremity function measured by the PMAL when children 30 months to eight years old receive a three-week clinic-based PCIMT intervention.
4. To determine if MACS or Mini-MACs, predicts upper extremity movement quality measured by the Melbourne-2 when children 30 months to eight-years-old receive a three-week clinic-based PCIMT intervention.

Significance of the Study

Understanding the benefits of clinic-based PCIMT will significantly impact PCIMT programs' importance and overall benefits to children with unilateral upper extremity limitations. Additionally, understanding the benefits of PCIMT when looking at classification levels of upper extremity involvement can shape the ongoing development and research behind PCIMT and the possibility of predicting intervention outcomes. This study has the potential to benefit caregivers/parents of children with unilateral upper extremity deficits, therapists/clinics, physicians, and insurance companies.

Definition of Terms

- Pediatric constraint-induced movement therapy - is a form of therapy where a child's unaffected upper extremity is casted for a specific period to force the affected upper extremity to complete daily activities to regain use and function of the involved upper extremity (Morris et al., 2006).
- Hemiplegia - is a partial or complete paralysis of one side of the body (DeLuca et al., 2003).
- Hemiparesis - is a weakness of one side of the body (DeLuca et al., 2003).
- Upper extremities - arms (Morris et al., 2006).

- Neurological impairments - an injury to the brain, spine, or the nerves that connect them. There are more than 600 different types of neurological impairments. The most common injuries seen for PCIMT programs are stroke, traumatic brain injuries, and cerebral palsy (Pedersen et al., 2016).
- Transfer package – is a formal post-treatment plan to increase the likelihood of carryover of therapeutic gains made during treatment to use in daily life (DeLuca et al., 2013).

Literature Review

CIMT is a rehabilitation treatment that has been shown to improve affected upper extremity use following a neurological injury (Morris et al., 2006). CIMT has been suggested as the most highly recommended form of intervention for children with hemiparetic cerebral palsy (DeLuca et al., 2017). CIMT has been reviewed and researched in multiple randomized control trials (Boyd et al., 2017; DeLuca et al., 2003; Pidcock et al., 2009; Reidy et al., 2012; Taub et al., 2011), yet minimal research has been done to determine the effectiveness of CIMT in clinic-based settings (DeLuca et al., 2017). Despite the lack of research, there have been numerous workshops geared towards CIMT, and clinics have started using varying protocols to provide CIMT to their patients (DeLuca et al., 2017). There is a critical need to determine if clinic-based PCIMT programs can produce the same magnitude of results as rigorous randomized controlled trials (DeLuca et al., 2017).

Original Pediatric Constraint-Induced Movement Therapy Protocol

CIMT has evolved since it was initiated over three decades ago (Morris et al., 2006). Morris et al. (2006) stated that there are three main elements and multiple sub-elements of the original PCIMT protocol that are still used today. The elements of CIMT include: repetitive, task-oriented training (shaping and task practice); adherence-enhancing behavioral strategies

(daily administration of the motor activity log, home diary, problem-solving to overcome apparent barriers to use of the more affected upper extremity in the real-world situation, behavioral contract, caregiver contract, home skill assignment, home practice, and daily schedule); and constraining the use of the more affected upper extremity (mitt restraint, any method to remind the participant to use the more-affected upper extremity continuously). CIMT has been researched in pediatrics with a focus on developing the ideal protocols and programs based on age, diagnosis, treatment dosage, and the number of times the application should be completed for most optimal outcomes (Coker-Bolt et al., 2013; Morris et al., 2006).

ACQUIREc Protocol

ACQUIREc (**A**cquisition of new motor and functional skills through **C**ontinuous practice and shaping to produce **Q**uality movement in the **U**pper extremity through **I**ntensive therapy that is **R**einforced in the child's **E**veryday patterns and places (DeLuca et al., 2013) is a form of pediatric constraint-induced movement therapy tested in multiple randomized control trials (Boyd et al., 2017; DeLuca et al., 2003; DeLuca et al., 2007; DeLuca et al., 2013; Pidcock et al., 2009; Reidy et al., 2012; Taub et al., 2011), with a published manual (REF). The acronym is used to capture the protocol elements, which has now been trialed by over 400 children ages 12 months to 21 years (DeLuca et al., 2013). The ACQUIREc was the first protocol developed to apply all of the principles used in the adult version of CIMT that could be replicated for the pediatric population (DeLuca et al., 2013). This protocol, provides a framework which encourages participants to complete all of the required components of PCIMT with systematic documentation about each child's daily treatment, including duration, activities, and progress (DeLuca et al., 2013).

The five main components of the ACQUIREc protocol includes: 1) constraint of the child's less involved upper extremity and hand with a long-arm cast to be worn continuously for approximately 3.5 weeks, 2) intensive therapy for 3-6 hours a day for five consecutive weekdays over four weeks, 3) therapeutic activities guided by operant conditioning, 4) treatment in naturalistic environments, and 5) joint development by the family and the therapist of a transfer package to support maintenance and continued improvement (DeLuca et al., 2013). Joint development and transfer package include and home-based exercise program that has been developed by the treating therapist and family to promote carryover of therapeutic gains into the home environment and to continue to demonstrate improvements of the involved upper extremity (DeLuca et al., 2013).

Clinic-Based Constraint-Induced Movement Therapy

Reidy et al., (2012) evaluated clinic-based constraint-induced movement therapy. The author aimed to evaluate the functional outcomes of a CIMT protocol implemented in an outpatient therapy center. The study consisted of 29 participants with hemiplegia, ages 1.6-19.1 years of age (Reidy et al., 2012). Participants were assigned to one of two protocols: a 6-hour per day protocol or a 3-hr per day protocol based on age, ambulatory status, and ability to follow commands (Reidy et al., 2012). Children who were over the age of three, ambulated independently, and consistently followed commands received the 6-hour protocol. Children under the age of three years, limited ambulation, or limited ability to follow commands received the 3-hour protocol (Reidy et al., 2012).The outcomes were measured at baseline and following the CIMT program using the Melbourne Assessment of Unilateral Upper Limb Function (MAUL), Quality of Upper extremity Skills Test (QUEST), Assisting Hand Assessment (AHA), and the Canadian Occupational Performance Measure (COPM; Reidy et al., 2012). The protocol

was consistent over 23 days and scheduled based on parent preference of a consistent day and time and clinic availability (Reidy et al., 2012). Reidy et al. (2012) found the protocol to be effective in improving unimanual and bimanual hand skills in children with hemiplegia. However, there was no difference in outcomes between the three and six-hour groups and between younger and older participants.

Based on the limited replication of CIMT in clinical practice DeLuca et al., (2017) aimed to determine if moderate to large size effects could be replicated in clinical practice for PCIMT. At the time of this study, there had been minimal evidence confirming effective use of PCIMT in clinical practice for a more heterogeneous clinical population (DeLuca et al., 2017). This prospective study included 88 children age 18 months to 12 years of age and received high-intensity CIMT using ACQUIREc protocol. Children who were chosen for this study never received CIMT treatment previously were evaluated for medical stability (DeLuca et al., 2017). The outcomes were measured at baseline and following CIMT treatment (DeLuca et al., 2017). The assessments used for this study were: The PMAL, the Emerging Behaviors Scale (EBS), and the AHA (DeLuca et al., 2017). Results from this study reported a statistically significant positive difference for all outcomes (DeLuca et al., 2017). The authors of this study compared the percentage of change from baseline of the participants from this study to previous randomized controlled trials (RCTs); the results were highly similar; however, the magnitude was somewhat reduced in the more heterogeneous clinical sample (DeLuca et al., 2017). The authors state this difference could be due to several factors, including impairment levels, the sensitivity of the outcome measures, and measures on varying impairment levels (DeLuca et al., 2017).

The outcomes of these two studies (DeLuca et al., 2017; Reidy et al.2012) demonstrate the possibility of paradigm shift to the use of therapeutic resources such as CIMT into clinic-based settings. These studies are foundational to the current project because results achieved in these two studies show a research environment can be replicated in a clinical setting. Further research needs to be completed to demonstrate the effectiveness of this treatment method in a clinical environment (Reidy et al., 2012). This current study endeavors to contribute to the literature on the effectiveness of PCIMT in a controlled clinic-based setting.

Single Treatment of Constraint-Induced Movement Therapy

Multiple studies have been published to discuss motor improvements of children with hemiplegia following a single episode of CIMT, concluding that there is strong evidence supporting its efficacy (Boyd et al., 2017; DeLuca et al., 2003; Pidcock et al., 2009; Reidy et al., 2012; Taub et al., 2011). Dickerson & Brown (2007) described a single-subject design for a 24-month-old child diagnosed with chronic hemiparesis caused by a prenatal stroke with no active range of motion in the right shoulder, elbow, or wrist. The child participated in an applied behavioral analysis (ABA) design with one follow up evaluation, a 21-day home intensive PCIMT program consisting of six-hour treatments five days a week (Dickerson & Brown, 2007). Additionally, the child received 2 hours a week of physical therapy and one hour a week of speech therapy (Dickerson & Brown, 2007). Results indicate the participant made significant gains in right upper extremity function and specifically progressed from neglecting the right side to using the right arm for simple play activities (Dickerson & Brown, 2007). Additionally, the researchers observed an improvement in lower extremity mobility and speech (Dickerson & Brown, 2007). It was noted that the participant went from relying on a walker before study participation to walking independently (Dickerson & Brown, 2007). The sample size of this

study limits generalizability; however, the improvements support the use of CIMT treatment for children with limited upper extremity function (Dickerson & Brown, 2007).

Three Hour Treatment, Verse Six-Hour Treatment.

Reidy et al.'s (2012) objective of their study was to investigate the effectiveness of a CIMT protocol in an outpatient clinic using a pretest and posttest design, which evaluated three-hour and six-hour treatment sessions with full-time cast. The COPM, MAUL, AHA, and QUEST were the outcome measures used to determine the effectiveness of the protocol (Reidy et al., 2012). Not all protocols were used for each child due to the assessments (Reidy et al., 2012). The outcomes between the three and six-hour daily therapy protocols showed no statistically significant clinical significance between younger and older participants (Reidy et al., 2012). Case-Smith (2012) hypothesized that this might have been an effect of the 24 hours a day casting, which provided continuous opportunities for refining hand skills outside of treatment times.

Case-Smith et al. (2012) investigated CIMT on the functional use of affected upper extremity between children with unilateral cerebral palsy. The authors compared outcomes over time, measured at pre-intervention, post-intervention, three-month, and six-month follow. There were two groups, participants who received therapy six hours a day for 21 days, and participants who received intervention three hours a day for 21 days (Case-Smith et al., 2012). In both groups, children showed significant improvements ($p \leq .01$) immediately after treatment and three months (Case-Smith et al., 2012). The significant improvements were maintained at the six-month follow-up (Case-Smith et al., 2012). Post hoc tests revealed a significant difference for both groups from pre-intervention to 6-months post-intervention (Case-Smith et al., 2012). Participants lost a small amount of post-intervention improvements; however, the decrease was

not statistically significant, indicating moderate-to-high level effects were sustained following CIMT treatment, regardless of the treatment time (Case-Smith et al., 2012).

Constraint-Induced Movement Therapy for Children with Acquired Brain Injury

Pedersen et al. (2016) sought to generate new knowledge about the pedagogical initiatives and frameworks involved during CIMT for children with acquired brain injury (ABI). This was novel since previous literature has focused on children with neurological impairments such as stroke and cerebral palsy. With these studies, the participants have never had a normal function of the involved upper extremity. Children with ABI had typical brain function and motor capacity before the brain injury. Given the time of the damage, certain neuropsychiatric disorders, including cognition, are impacted, which separate pedagogical challenges between these diagnoses (Pedersen et al., 2016). Pedersen et al. (2016) studied results for four children with ABI from 10 to 12 years of age who participated in 10 sessions for six hours each session (2 weeks; 60 hours total). The restraint used was a custom-made sling that was removed during eating, bimanual activities, and breaks (Pedersen et al., 2016). Grip strength, box, and blocks, and the COPM were used to determine improvements from pretest to posttest. Significant improvements in grip strength ($p < .001$) and in the Box and Blocks Test ($p < .001$) (Pedersen et al., 2016). All four children showed clinically significant changes in their COPM results for personal goals in performance and satisfaction. The results also indicate that children are able to find goal-specific CIMT interventions both meaningful and relevant to their daily lives, which increases the likelihood of maintaining skills and motivation (Pedersen et al., 2016).

Multiple Treatments of Constraint-Induced Movement Therapy

A case report outlined one child's improvements following two episodes of CIMT (DeLuca et al., 2003). Each treatment of CIMT consisted of a single long arm bivalve cast with

three weeks of intensive intervention six hours a day. Following the first treatment, the second three week treatment was completed five months later (DeLuca et al., 2003). The authors described detailed improvements between both three-week treatments. During the first treatment of CIMT, the child developed independent reach, grasp, release weight-bearing (prone on elbows) gestures, self-feeding, sitting, and interactive play (DeLuca et al., 2003). During the second three-week treatment, the child increased independence and improved UE movement quality, supported by clinical evaluations and parent ratings (DeLuca et al., 2003). This case report provides evidence to support multiple episodes of Pediatric CIMT may be a useful intervention for young children with hemiparesis as improvements were gained in both interventions.

In a pretest-posttest study, DeLuca et al., (2015) Investigated if more than one treatment of PCIMT would produce additional benefits. This was the first study to measure a third PCMIT treatment. Children in this study wore a full-length cast on their involved upper extremity full time for the first 18 days of treatment and participated in bimanual training for the last 3-4 days of treatment (DeLuca et al., 2015). The authors chose two assessment tools to measure performance during this study: The EBS and PMAL. All children participated in the full treatment of six hours a day, five days a week, for four consecutive weeks. DeLuca et al. (2015) found following the first treatment, there were functional improvements, which produced a mean (SD) gain of 13.2 (4.2), following the second treatment produced a mean increase of 7.3 (4.7). Following the third treatment, a mean increase of 6.5 (4.2) was achieved. These results indicate that multiple PCIMT treatments can produce clinically critical functional gains for children with hemiparetic CP (DeLuca et al., 2015).

Long-Term Benefits of CIMT

The purpose of a study by Nordstrand and Eliasson (2013) was to describe the hand function in young adults who had previously participated in a two-week CIMT camp six years earlier. Nordstrand and Eliasson (2013) had concerns that hand function might decrease with age. Eleven participants were re-assessed six years after participating in the CIMT camp (Nordstrand & Eliasson, 2013). Results were compared to baseline and post-intervention results (Nordstrand & Eliasson, 2013). Results showed hand function remained unchanged, grip strength increased and was comparable between hands, and grip strength improved in the affected hand almost as much as in the unaffected hand (Nordstrand & Eliasson, 2013). Concerns for decreased hand function were not supported by the results (Nordstrand & Eliasson, 2013).

Occupational Therapist Perceptions on PCIMT

Chakraborty et al. (2019) utilized a qualitative study to explore a pediatric occupational therapist's perceptions who had an awareness of CIMT as an intervention method. Eight pediatric occupational therapists were interviewed, focusing on the participants' knowledge of CIMT, implantation practices, and current perceptions of CIMT in pediatrics (Chakraborty et al., 2019). Results showed three emerging themes from the data: perceived benefits of CIMT, varying comfort levels with the intervention's delivery, and differing methods of implementation (Chakraborty et al., 2019). All eight participants perceived CIMT to be a beneficial intervention for children with hemiparesis, making comments regarding children's increase in the use of affected upper extremity in daily activities and play (Chakraborty et al., 2019). Concerns were raised from implantation, where the participants described different implementation methods when using CIMT; there was no consistent protocol reported among the participants (Chakraborty et al., 2019). Chakraborty et al. (2019) outlined the need for a standardized

protocol for CIMT and further research into occupational therapist perceptions of CIMT to help identify any perceived barriers for carryover of this treatment method into clinical practice.

Previous literature has shown the benefits of PCIMT in randomized controlled trials (Boyd et al., 2017; DeLuca et al., 2003; Pidcock et al., 2009; Reidy et al., 2012; Taub et al., 2011). However, there continues to be a gap into transitioning PCIMT into clinic-based settings with minimal research that shows the impact of CIMT in clinic-based environments (Reidy et al., 2012 & DeLuca et al., 2017). Understanding the benefits of clinic based PCIMT will significantly impact PCIMT programs' importance and overall benefits to children with unilateral upper extremity limitations. This projects aims to answer the following questions: (1) Is there a significant difference in upper extremity function as measured by the PMAL before and after a three-week clinic-based PCIMT intervention, (a) is there a significant difference following clinic-based CIMT treatment in upper extremity function based on upper extremity classification (MACs or Mini-MACs), (2) Is there a significant difference in upper extremity movement quality measured by the Melbourne-2 before and after a three-week clinic-based PCIMT intervention, and (a) is there a significant difference following clinic-based CIMT treatment in upper extremity movement quality based on upper extremity classification (MACs or Mini-MACs)? The purpose of this project is to demonstrate the impact of a clinic based PCIMT program on children with unilateral hemiparesis.

Method

Study Type and Design

This is a retrospective study completed to examine records associated with participants between 2.5 and 8 years of age who underwent a clinical 3-week PCIMT program for the treatment of hemiparesis. Prior to data collection, the study was approved by both Texas Children's Hospital and University of Indianapolis institutional review boards.

Participants

Participants were identified through a query of the electronic medical records at Texas Children's Hospital based on the following criteria: participants successfully completed the PCIMT program at Texas Children's Hospital between January 2019 and May 2021; were between 2.5 years to 8 years at the time they completed PCIMT; and had a diagnosis of unilateral hemiparesis. Sample size was estimated using G*Power 3.1.9.7 software (Faul et al., 2007) based on conducting a paired *t* test to determine if there was a difference in PMAL scores before and after participating in the PCIMT program. The following parameters were set for the calculation: two-tailed test, effect size of 0.50, and power of 0.80. There are no similar study results published to allow for the calculation of effect size; therefore, a medium effect size of .50 was used. The minimum sample size through calculations was 34. To participate in the PCIMT program patients met the following inclusion and exclusion criteria:

Inclusion Criteria

1. Patient must have not missed more than 1 day of the program.
2. Patient must have obtained a MACS/Mini-MACS score of 1-5 during their initial pre-intervention assessment

3. Patient must have been between the ages of 2.5 years and 8 years of age at the start of the PCIMT program.

Exclusion Criteria

1. Patient with uncontrolled seizures
2. Patient with contractures greater than 10 degrees in their involved upper extremity
3. Patient who had recently received Botox injections (6 months prior to participating in the program) in their hand or upper extremity
4. Children who were unable to follow verbal directions or who had uncontrolled aggressive behaviors.

Data

Extracted data from the electronic medical record (EMR) at Texas Children's Hospital included participant demographics: age, diagnosis, MACS or Mini-MACS score and gender; as well as treatment parameters (e.g. time participated in the program in months, and number of sessions attended), and treatment outcome data used to measure upper extremity function. These measures include the PMAL and MAUL-2 scores.

Instruments

Pediatric Motor Activity Log

The PMAL is a parental rating assessment in which parents rate their child's use of their effective upper extremity on a 5-point Likert-like scale (0 = no use, 5 = normal use) in comparison to the unaffected limb (DeLuca et al., 2003). The PMAL is used for children 2-8 years of age. Parents complete the log assessing their children on 22 arm-hand functional tasks in terms of how often and how well they use the affected upper extremity when compared to the unaffected upper extremity (DeLuca et al., 2017). After administering the PMAL, mean PMAL

scores are calculated for the two sections of how well and how often by adding the range of possible total scores. PMAL has been shown to have high internal consistency (Cronbach's α = .93) and test-retest reliability (r = .89) (Uswatte et al., 2012). Convergent validity was also supported by a moderate correlation between changes in the PMAL scores and affected arm use during play, $r(53) = .50$, $p < .001$ (Uswatte et al., 2012).

Melbourne Assessment of Unilateral Upper Limb Function (MAUL)-2

The MAUL-2 is a standardized measure that assesses the range of movement, the fluidity of movement, accuracy, dexterity, and object manipulation through a series of unilateral activities (Reidy et al., 2012). The MAUL-2 is administered by a licensed Occupational Therapist. The test is comprised of 14 test items which require a child to reach, grasp, and manipulate simple items. Each of these items are video recorded for subsequent scoring. The MAUL-2 provides a standardized tool for administering the assessment with a standardized measure for camera location to provide the assessor with the best angle for scoring (Reidy et al., 2012). From there, a percentage score is calculated to determine the quality of movement of a child's more involved upper extremity (Randall et al., 2001).

Standardized scores are available for children age 2.5 years to 15 years of age. Randall et al. (2014) found the final modified version (MAUL-2) of each subscale demonstrated good internal consistency, with high population stability index (PSI) values ranging form .81 and .92. Randall et al. (2012) found the MAUL-2 could also be used for individuals with a variety of neurological and physical impairments and help to establish criteria for determining severity level of upper limb impairment. There was strong evidence of differences in children's percentage scores on MAUL-2 for the three clinical levels of upper limb impairment, $F(2, 27) = 67.8$, $p = .001$ (Randall et al., 2012). Post-hoc comparisons using Tukey's HSD test found

evidence that the mean score for children classified as 'mildly' impaired was 83.7 (8.0) which was different from the mean score for 'moderately' impaired children of 58.9 (7.2); p = .02 (Randall et al., 2012). There was also evidence which found a difference between classification of moderate and severe, given that the mean score for the children classified as 'severely' impaired was 38.1 (SD 12.1); p = .01 (Randall et al., 2012).

The Melbourne Assessment was found to have good reliability on a sample of 20 children with varying types and degrees of cerebral palsy (Randall et al., 2001). Randall et al. (2001) found very high internal consistence of test items ($\alpha = 0.96$), moderate to high agreement for both within and between raters for all test items (intraclass correlation coefficient [ICC] of at least .70) apart from item 16 (hand to mouth and down), and high interrater reliability ($\alpha = 0.95$) and intrarater reliability ($\alpha = 0.95$) for total test scores. The assessment was given to the same children by the same therapist after a two-week interval (Randall et al., 2001). Per Randall et al. (2001) the assessment is useful to monitor a child's individual change in their performance over time. Additionally, the assessment can also be used to compare performance of tasks between same aged children which makes the assessment a useful tool for assessing pre-intervention and post-intervention research studies (Randall et al., 2001).

The Manual Ability Classification Scale or the Mini Manual Ability Classification Scale

The MACS is a five-level, ordinal classification system which describes the manual ability of children aged 4 to 18 years of age (Burgess et al., 2018). The Mini MACS is a five-level, ordinal classification system which describes the manual ability of children age 1 to 4 years of age (Burgess et al., 2018). The five-level MACS/Mini-MACS scale is ordinal, which means that the differences between levels are not necessarily equal, nor are children's manual abilities equally distributed across the five levels.

The MACS level is determined by a licensed therapist or physician. Level is determined based on observation of the child and their ability to handle objects. The purpose of the MACS is to categorize a child's ability to handle objects in daily life skills (Burgess et al., 2018). Level one on the MACS represents the highest level of ability where the child is able to handle objects easily and without difficulty (Burgess et al., 2018). Level five is considered total assist and the child is unable to handle any objects (Burgess et al., 2018). The MACS/Mini-MACS provides written examples to allow therapist/healthcare professionals to determine the category for a child's current level of function (Eliasson et al., 2013). The authors also provide examples to help determine the difference between levels to help guide the categorization of function (Eliasson et al., 2013).

Eliasson et al. (2006) used a one-way random effects model, Intraclass correlation coefficient (ICC) (1), due to different raters were assessing the children. Reliability was tested between pairs of therapists for 168 children, 70 females and 98 males with hemiplegia (n = 52), diplegia (n = 70), tetraplegia (n = 19), ataxia (n = 6), dyskinesia (n = 19), and unspecified CP (n = 2) between the ages of 4 and 18 years and between 25 parents and their children's therapist. The results demonstrated that MACS has good validity and reliability. Based on a 95% confidence interval, the ICC between therapists was .97, and between parents and therapist was .96, indicating excellent agreement.

Procedures

Data Collection

Data of children who participated in the CIMT program between January 2019 and May 2021 was extracted from the electronic medical record (EMR). From these participants, those who met the inclusion criteria were deidentified and organized into an Excel spreadsheet. Each

chart was thoroughly reviewed by the primary researcher (R. S.) to determine if patients met the eligible criteria to be included in the study design. No data was collected from records where children did not meet inclusion criteria. Once a list of participants was finalized, data from each of the assessments was transferred to a separate Excel spreadsheet for coding prior to being transferred to software for analyzing. All identifiers were removed, and children were given a study identification number. Children were categorized by level of motor involvement using their MACS/Mini-MACS scores level 1-5. Any missing data was reported and categorized in final report of document. Children were excluded if MACS level was not identified in either evaluation or re-evaluation.

Data Management

All data files were kept under a dual inscription software to maintain HIPAA compliance and protect medical records. No patient identifiers were kept. Once patients were included/excluded they were each given a non-identifiable study number. The Microsoft Excel, Version 16.57 (Saxton, 2021). file with study identification numbers was inspected and cleaned to prepare it to be exported for data analysis. The Excel sheet was housed on Texas Children's Hospital's server and was only accessed through this controlled server.

Statistical Analysis

Data analyses were completed using IBM SPSS Statistics for Macintosh, Version 27.0 (Armonk, NY: IBM Corp.). All statistical tests were two-tailed with a significance level set at .05. Normality of the data were assessed by visual inspection of histograms and Q-Q plots and use of the Shapiro-Wilk test. Nominal data was presented as frequency and percentage while interval and ratio data was reported as mean and standard deviation or median and interquartile range, depending on normality of data. To determine if there was a difference between pre-

intervention and post-intervention a paired *t* test were used since the data was normally distributed. Ordinal logistic regression was used to determine if the MACS (Mini-MACS) significantly predicts the post-PMAL scores and change scores. Similarly, ordinal logistic regression was used to determine if the MACS (Mini-MACS) significantly predicted the post-Melbourne-2 scores and change scores. In both cases, ordinal logistic regression was conducted due to the ordinal nature of the outcome variables.

Results

Total number of participants who met the inclusion and exclusion criteria was *N*=31 for the PMAL and *N*=27 for the MAUL-2. All 31 participants were given a Mini-MACs or MACs classification level. The age range was between 2 years 6 months (30 months) and 8 years 4 months (100 months). The participants' age demographics are presented in Table 1 for the 31 participants. The participants' Mini-MACs and MACs classification variables are presented in Table 2 for the 31 participants.

Table 1

Age Demographics

Classification Variables	*n*	%
Under 3	4	12.9%
3:0-3:11	9	29.0%
4:0-4:11	4	12.9%
5:0-5:11	4	12.9%
6:0-6:11	7	22.6%
7:0-7:11	2	6.5%
8:0-8:11	1	3.2%

Table 2

Classification Variables of Mini-MACs and MAC

Classification Variables	*n*	%
Mini-MACS		
II	5	16.1%
III	6	19.4%
IV	3	9.7%
MACS		
II	8	25.8%
III	7	22.6%
IV	2	6.6%

Planned data analyses included paired samples t-tests to look at pre- to post-treatment changes for each outcome measure. Paired samples testing was chosen to statistically account for the known relationship between pre- and post-treatment samples. The mean PMAL How Well rating pre-treatment was 1.78 (SD. =0.80) with a post-treatment mean of 3.09 (SD. = 0.80) with a resulting $t = 12.02$, $p < 0.0001$. The mean PMAL How Often rating pre-treatment was 1.63 (SD. = 0.78) with a post- treatment mean of 3.17 (SD. = 0.86); $t = 10.84$, $p < 0.0001$ indicating that the two times differed statistically in both how often and how well at an alpha 0.05 level. This indicates a 3-week intensive PCIMT clinic-based program significantly improved how often a child uses their affected upper extremity in daily tasks as well as how well they use their affected upper extremity to complete the same task. Figure 1 illustrates the difference in raw scores between pre- and post- PMAL in the how often category for all 31 participants, and figure 2 shows the difference in raw scores between pre- and post- PMAL in the how well category for all 31 participants following the 3-week intensive intervention. Figure 3 illustrates the difference between times in both how often and how well categories of the PMAL. Effect sizes can be found on table 2.

Figure 1

PMAL How Often Raw Score Difference Pre and Post Intervention

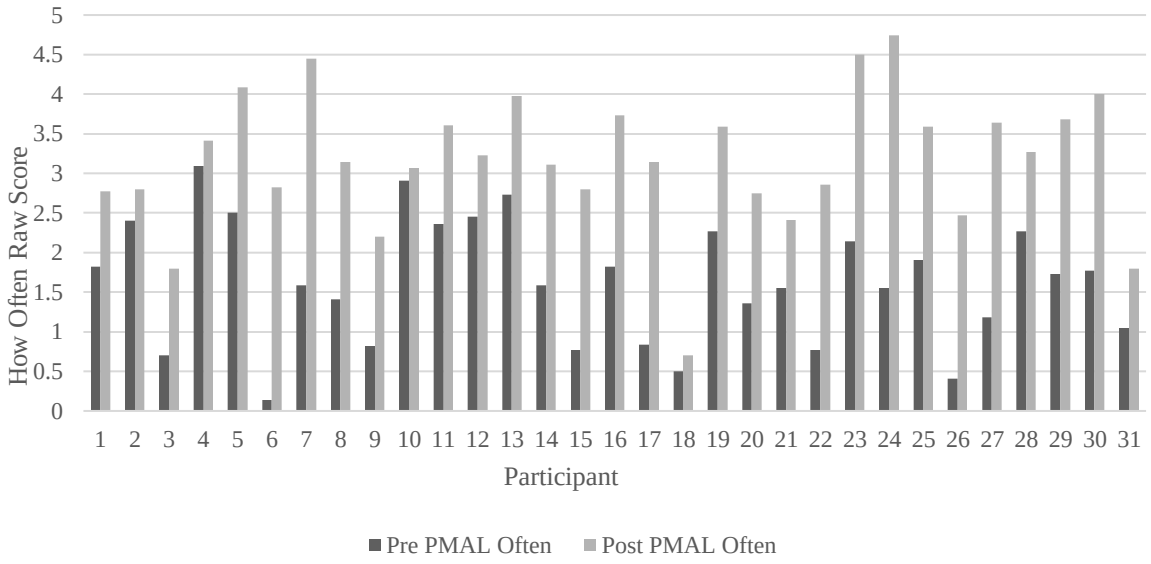


Figure 2

PMAL How Well Raw Score Difference Pre and Post Intervention

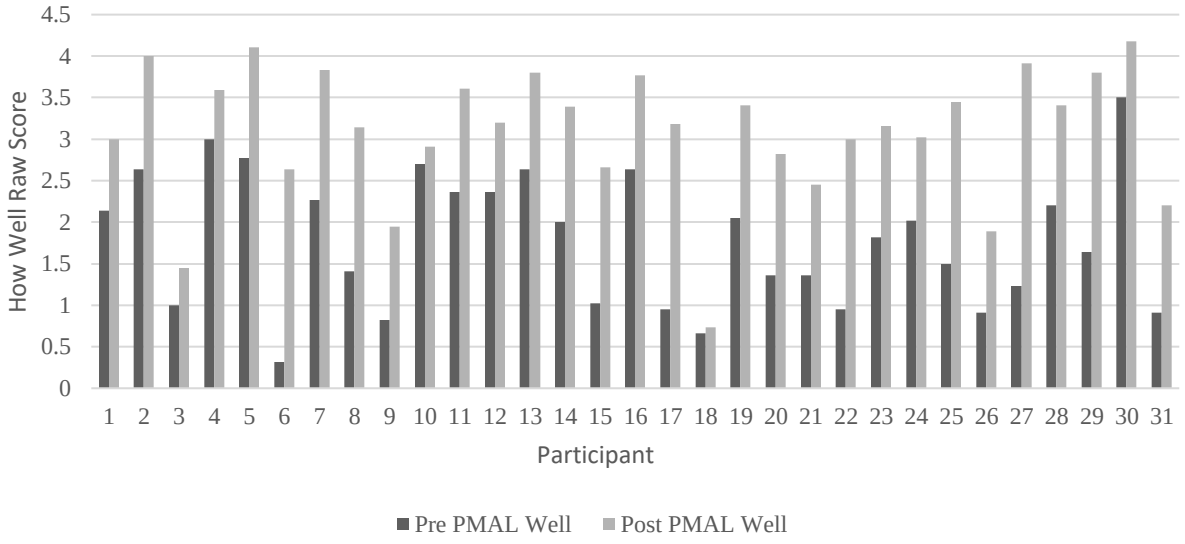
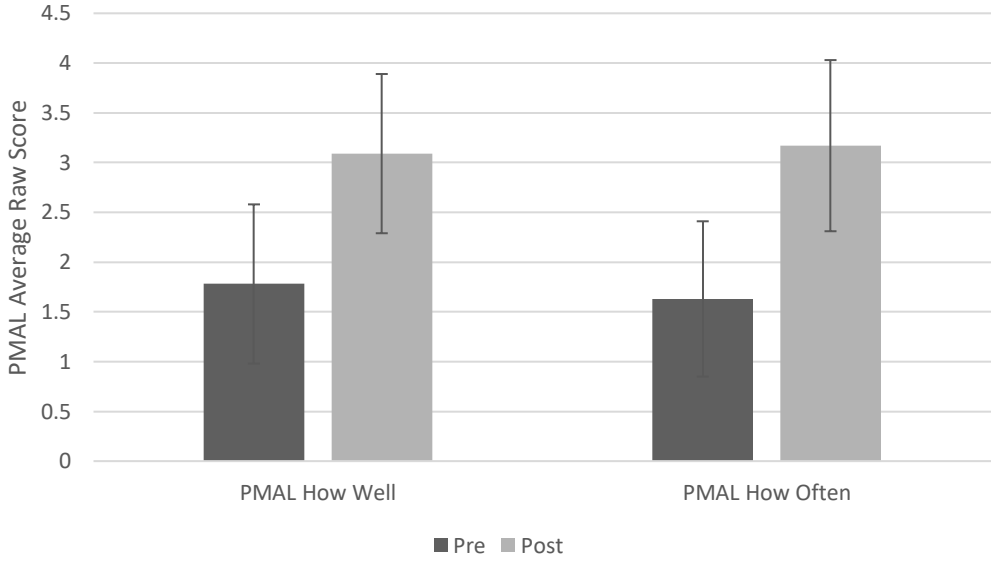


Figure 3

PMAL Average Score Over Time



The mean MAUL-2 ROM raw score was 15.00 (SD = 4.77) with a post-treatment mean of 17.7 (SD = 4.83) with a resulting $t = 4.176$, $p \leq 0.0001$. The mean MAUL-2 accuracy raw score was 16.25 (SD = 5.48) with a post-treatment mean of 18.85 (SD = 4.45) with a resulting $t = 4.84$, $p \leq 0.0001$. The mean MAUL-2 dexterity raw score was 7.07 (SD = 3.40) with a post-treatment mean of 8.81 (SD =3.14) with a resulting $t = 3.73$, $p = 0.001$. The mean MAUL-2 Fluency raw score was 10.96 (SD = 3.95) with a post-treatment mean of 13.59 (SD = 2.97) with a resulting $t = 2.36$, $p = .026$ indicating that the two time periods differed statistically in all four subtests of the Melbourne 2 at an alpha .05 level. Therefore, a 3-week intensive PCIMT clinic-based program increased ROM, accuracy, dexterity, and fluency of movement. Figure 4 shows the mean difference between pre and post MAUL-2 scores for range of motion, Figure 5 shows the mean difference between pre and post MAUL-2 scores for accuracy, Figure 6 shows the mean difference between pre and post MAUL-2 scores for dexterity, and Figure 7 shows the mean difference between pre and post MAUL-2 scores for fluency following 3-week intensive intervention. Effect sizes are found on Table 2.

Figure 4

Melbourne 2 Average Range of Motion Over Time

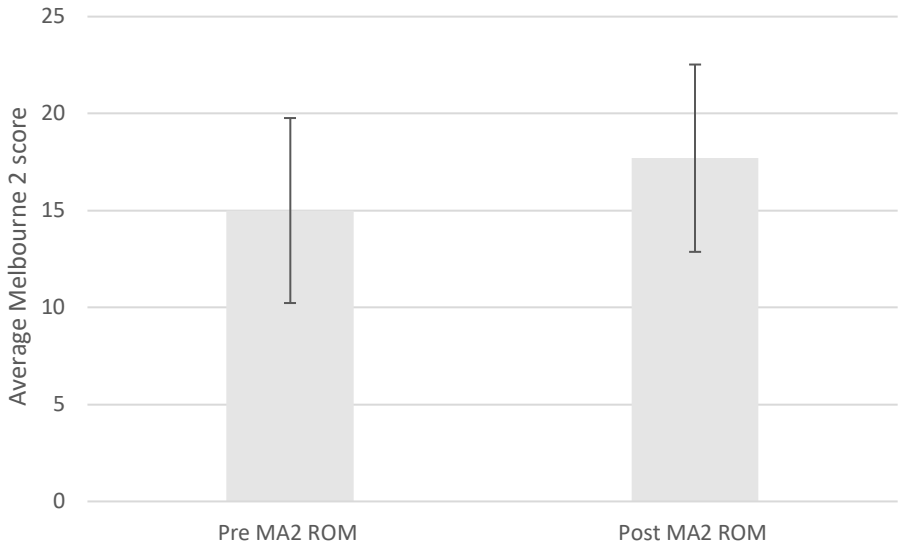


Figure 5

Melbourne 2 Average Accuracy Over Time

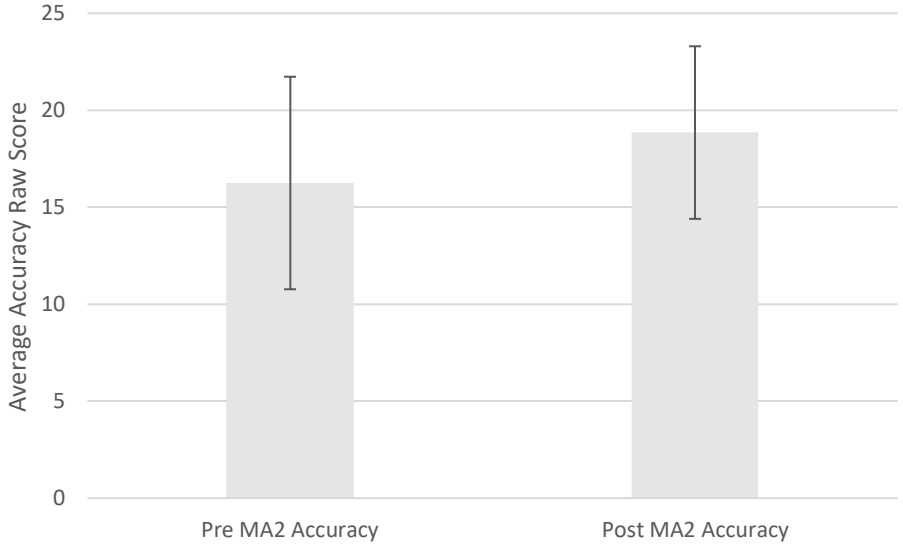


Figure 6

Melbourne 2 Average Dexterity Over Time

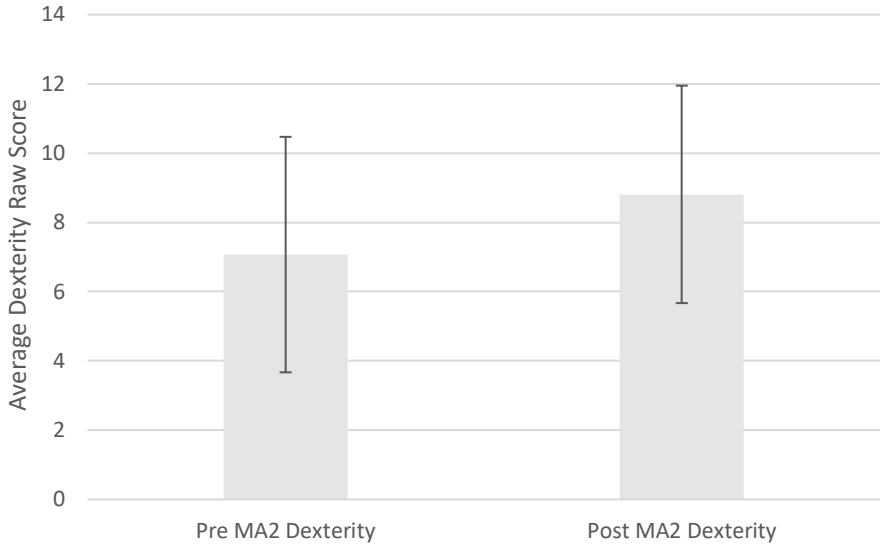


Figure 7

Melbourne 2 Average Fluency Over Time

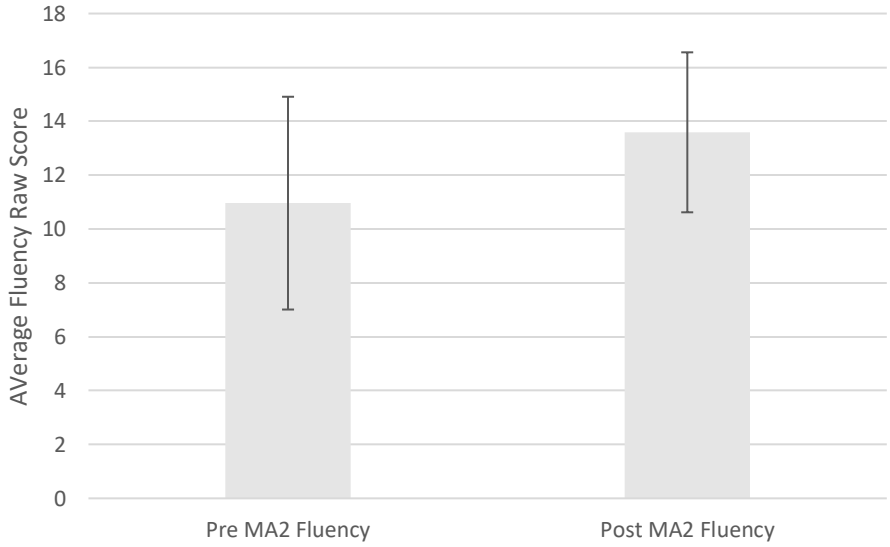


Table 2

Cohen's Effect Size (differences over time)

Subtest	*d*	Classification
PMAL How Well	1.63	Very Large
PMAL How Often	1.88	Very Large
MAUL-2 ROM	0.56	Medium
MAUL-2 Accuracy	0.52	Medium
MAUL-2 Dexterity	0.53	Medium
MAUL-2 Fluency	0.76	Large

Next, this study determined if the MACS/Mini-MACS (entered together as one variable) level significantly predicted change on the PMAL following clinic-based CIMT treatment in upper extremity function based on MACs or Mini-MACs classification as recorded prior to treatment. For these analyses linear regression techniques were utilized. MACs and Mini-MACs were not significant predictors of post PMAL how often change scores at $F(1, 29)=.005$, $p=.944$. The relationship between these variables was $r=-.013$, therefore 0% of the variance was shared between variables. This indicates that using Mini-MACs/MACs levels alone cannot predict PMAL How Often change after a 3-week intensive clinic-based PCIMT. In addition, MACs and Mini-MACs were not significant predictors of post PMAL how well change scores at $F(1, 29)=.007$, $p=.934$. The relationship between these variables was $r=.015$, therefore 0% of the variance was shared between variables. This indicates that using Mini-MACs/MACS levels alone cannot predict PMAL How Well change after a 3-week intensive clinic-based PCIMT.

Lastly, this study determined if the MACS or Mini-MACS (entered together as one variable) level predicted change on the Melbourne-2 (the four domains: ROM, Accuracy, Dexterity, and Fluency) following clinic-based CIMT treatment in upper extremity movement quality based on MACs/Mini-MACS classification as recorded prior to treatment. For these

analyses linear regressions were utilized. MACs/Mini-MACs were not significant predictors of ROM change at F(1, 24)=.000, p=1.000. The relationship between these variables was r=0, therefore 0 of the variance was shared between variables. MACs/ Mini-MACs were significant predictors of accuracy change at F(1, 24)=5.543, p=.027. The relationship between these variables was r=.433, therefore 18.8% of the variance was shared between variables. To estimate a participants' post Melbourne raw change score the following equation can be used: post Melbourne raw change score = -1.420+1.312(MACS or Mini-MACs score). For example: if a patient has a MACs score of 3 than we can predict with 18.8% assurance the child will achieve a post MAUL-2 raw accuracy change score of 2.516.

MACs/Mini-MACs were not significant predictors of dexterity change at F(1, 24)=1.800, p=.192. The relationship between these variables was r=.264, therefore 7% of the variance was shared between variables. MACs/ Mini-MACs were not significant predictors of fluency change at F(1, 24)=.008, p=.924. The relationship between these variables was r=.019, therefore 0% of the variance was shared between variables. These scores indicate that using the Mini-MACs or MACs level alone cannot be a significant predictor of post MAUL-2 raw change scores for ROM, dexterity and fluency. However, we can predict with 18.8% certainty post MAUL-2 raw accuracy score based on a child's Mini-MACs or MACs level.

Discussion

The purpose of this study was to determine the effectiveness of a clinic-based constraint induced movement therapy program for children age 18 months to eight years of age utilizing three different variables for measurement. For the purpose of classification, the Mini-MAC and MACs levels were used. For pre and post intervention scores, the parent questionnaire of PMA and therapist scored measure of MAUL-2 were utilized. This study was a retrospective design

examining participant data from January 2019 to May 2021. There were 31 participants who met the inclusion and exclusion criteria whose results were used for the data entry. All 31 participants had pre and post PMAL scores and Mini MACs/MACs levels. However, only 27 participants had both pre and post MAUL-2 scores available for data comparison causing for a smaller sample size for the MAUL-2 results.

Analysis of this study yielded interesting findings for both assessment variables, for pre and post assessment for PMAL, the results showed a significant difference in scores in both subtests of how well and how often. Showing improvements in both frequency of use and quality of movement, the affected upper extremity statistically improved following the 3-week intensive program. The results of the current study were comparative to DeLuca et al., (2017) where the mean PMAL quality of movement rating (How Well) pretreatment was 1.44 (s.d. = 1.01) with a post-treatment mean of 2.94 (s.d. = 0.94) with a resulting $t = 13.40$ $p < 0.0001$. The mean PMAL frequency of use rating (How Often) pre-treatment was 1.10 (s.d. = 0.78) with a post-treatment mean of 3.05 (s.d. = 0.96); $t = 16.14$, $p < 0.0001$. This study further adds to the research demonstrating significant change in pre and post clinic-based intervention for PCIMT. The MAUL-2 scores also made statistically significant gains in all four sub-tests. This change demonstrates that a clinic-based pediatric constraint induced movement therapy program can yield results producing valuable change in pre and post intervention scores. While this study examined separate subtests, Reidy et al. (2012), results found that total mean score for MAUL-2 improved significantly with p=.002.

For this study, the Mini-MACs and MACs were used as one variable. When using the Mini-MACs or MACs classification system, theses scores were not significant predictors of five of the six subtest examined in this study (PMAL how often, PMAL how well, MAUL-2 ROM,

MAUL-2 dexterity, and MAUL-2 fluency), meaning, using only a child's Mini-MACs or MACs classification system, we were unable to predict the post RAW score of these five specific variables following the 3-week intensive intervention. However, linear regression shows a predictability of 18.8% in post MAUL-2 accuracy scores, meaning, with the use of Mini-MACs or MACs score, there is a possibility to predict the post RAW score for accuracy in the MAUL-2 assessment variable. This can be a useful tool to show perspective parents and insurance companies for outcome prediction from a 3-week intensive PCIMT program.

Study limitations

This study had limitations. One limitation was missing data points in the MAUL-2 assessment which caused for a decreased sample size for MAUL-2 results (N=27) compared to the sample size for PMAL (N=31). There are few studies of clinic-based constraint induced movement therapy for this specific age range, which limits our ability to compare to various populations in other clinic-based settings. This study did not examine any specific population or diagnosis and only utilized Mini-MACS/MACs scores for classification. As this study is unique to this population, type of treatment, specific age range, and particular variables it is difficult to generalize to other populations. Minimum sample size through calculation with medium effect size of .50 was 34. However, only 31 participants met all the inclusion and exclusion criteria for the study, and of the 31, only 27 had all data points for both the PMAL and MAUL-2 assessments.

An additional limitation was age range of the sample. Due to the assessments that were chosen, the age range had to be limited to 2.5 years to 8 which further limited the sample size selection. Lastly, for the purpose of this study, specific diagnoses were not considered when determining the sample size which led to a lack of a homogeneity.

Conclusion

Understanding the benefits of clinic-based PCIMT will significantly impact PCIMT programs importance and overall benefits to children with unilateral upper extremity limitations. The research questions aimed to (1) determine if a three-week PCIMT program will change the upper extremity function measured by the PMAL in children 30 months to eight years old, (2) to determine if a three-week PCIMT program will change upper extremity movement quality measured by the Melbourne-2 in children 30 months to eight-years-old. (3) to determine MACS or Mini-MACs, affects upper extremity function measured by the PMAL when children 30 months to eight years old receive a three-week clinic-based PCIMT intervention and (4) to determine measured by MACS or Mini-MACs, affects upper extremity movement quality measured by the Melbourne-2 when children 30 months to eight-years-old receive a three-week clinic-based PCIMT intervention. These questions led us to an examination of 31 participants (N=31 for PMAL and N=27 for MAUL-2). Our results indicate a clinic-based PCIMT program can significantly improve upper extremity functional use, quality of movement, ROM, dexterity, accuracy, and fluency when comparing pre and post 3-week intervention. Limitations of this study were sample size, age range, heterogeneity of the sample, and missing data. These results are important to clinical practice because, at the time of this study, there has been limited research to show clinical application of PCIMT programs. It is important to show results can be significant regardless of setting. Clinic-based outcomes can produce significant improvements equivalent to randomized controlled trials.

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