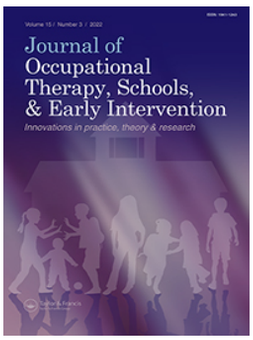

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Therapy together: A caregiver led constraint induced movement therapy program for preschool aged children utilizing a virtual environment due to COVID 19

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ABSTRACT

To pilot Therapy Together, an 8-week parent-led pediatric constraint induced movementtherapy (*P*-CIMT) program for preschool aged children with unilateral cerebral palsy (UCP). Five children with UCP and their caregivers participated in eight, 1 hour group sessions structured by the TEAM approach (topic, encourage, activity, and motivate). Three of the sessions were in person and 5 of the sessions were online due to COVID 19. Parent coaching and therapeutic activities for each weekly session aimed to improve a specific upper limb domain. The caregivers were asked to implement therapeutic activities 1 hour each day at home. The primary outcome measure was the Assisting Hand Assessment (AHA), scored by a blinded rater. The secondary outcome measure was the Canadian Occupational Performance Measure (COPM). Caregivers kept a log of hours completed at home, comments about implementing the program, and rated their child's unilateral and bilateral hand performance weekly. Participants demonstrated clinically significant changes in bimanual performance (AHA) with a large effect size, but statistical significance was not reached. Improvements in occupational performance and satisfaction (COPM) were clinically and statistically significant. Therapy Together is a promising *P*-CIMT intervention program for preschooler with UCP. The program incorporates caregiver education and coaching with caregiver-led home therapeutic activities to improve children's bimanual hand skills and occupational performance while addressing barriers to intervention access such as caregiver hesitancy in order to reduce health disparities in children with UCP.

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Unilateral cerebral palsy; constraint induced movement therapy; parent training

Introduction

Cerebral palsy (CP) is a non-progressive neurodevelopmental disorder caused by damage to the developing fetal or infant brain resulting in motor and sensory impairments and an increased risk of secondary conditions such as cognitive impairments and seizure disorders (Rosenbaum et al., 2007; Stanley et al., 2000). Unilateral cerebral palsy (UCP), also referred to as hemiplegia, in which one side of the body is affected, accounts for 36% of pediatric CP cases and affects children's ability to reach, grasp, manipulate objects, and use both hands

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together, limiting occupational participation and performance (Ropper et al., 2019; Rosenbaum et al., 2007). Infants and toddlers with UCP often adapt by performing activities one-handed with their unaffected limb or utilizing their weaker hand as the supporting hand less effectively than children without CP; this can lead to developmental disregard, or reduced awareness and use of their affected limb, further impairing performance of daily activities (DeLuca et al., 2012; Ramey et al., 2013; Zielinski et al., 2014). Because increased neural plasticity during the first two years of life may allow for re-organization of motor tracts in children with unilateral cerebral palsy, early implementation of evidence-based interventions is important for optimizing functional outcomes and combating or preventing developmental disregard (Hadders-Algra et al., 2014; Jaspers et al., 2016; Staudt, 2010; Tanner et al., 2020).

Research supports high-intensity upper-limb training such as pediatric constraint-induced movement therapy (*P*-CIMT) for children with UCP (Burkhardt et al.i, 2017; Huang et al., 2009; Novak et al., 2020). *P*-CIMT involves constraining the child's unaffected limb and providing high-dose, task-specific practice using their affected limb during which interventionists "shape" the child's movements to slowly increase movement difficulty and complexity. Considered a "green light," or evidence-based intervention, *P*-CIMT increases use of the affected limb in children with UCP (Hoare et al., 2019; Novak et al., 2020; Sakzewski et al., 2014a); however, there is inadequate access to early interventions such as *P*-CIMT, leading to significant health disparities for many children with UCP (Gmmash et al., 2020). The standard *P*-CIMT protocol typically involves continuous restraint of the upper limb alongside 3 or more hours of daily in-person therapy sessions in the child's natural environment with trained interventionists over 2 weeks (Hoare et al., 2019). This time commitment is unfeasible for many and may increase cancelations, reducing intervention efficacy (Ballantyne et al., 2019).

Research also supports modified CIMT protocols that maintain the core features of CIMT (constraint of the unaffected limb; intensive, repetitive use of the affected limb; and task shaping to create a "just-right" challenge) while deviating from the original protocol in constraint type and wearing schedule; frequency, intensity, and duration of the intervention program; and intervention setting (Ramey et al., 2013; Sakzewski et al., 2015). These modified protocols provide more flexibility in service implementation.

Despite increased flexibility of modified *P*-CIMT programs, barriers such as caregiver hesitancy and lack of service provider flexibility to accommodate scheduling needs still make such programs unobtainable for many (Ballantyne et al., 2019; Bass-Haugen, 2009; Gmmash et al., 2020; Sakzewski et al., 2014b). Caregiver participation is an important component of the family-centered approach to pediatric therapy, and recent research shows some effectiveness of caregiver-implemented CIMT (Zylstra & Sidhu, 2021). However, many caregivers struggle to participate in therapy due to uncertainty about their role in the therapy process, difficulty understanding CP and the interventions used, and limited access to toys and medical equipment (Gmmash et al., 2020). Because research supports modified, more-flexible *P*-CIMT protocols, a new program that combines the core features of *P*-CIMT with caregiver education, caregiver-led home therapeutic activities, and protocol modifications to reduce caregiver burden may improve intervention accessibility while maintaining intervention efficacy.

The purpose of this study was to develop and pilot "Therapy Together," an 8-week *P*-CIMT program for infants and toddlers modified to reduce time and scheduling demands and increase caregiver participation. The study had two aims:

(1) Develop a P-CIMT program with focus on caregiver training and education that can be implemented in a clinical setting

(2) Collect preliminary data on the intervention's effects on hand function and goal attainment

Methods

Study design and IRB approval

The study used a one-group pretest-posttest design; assessments were performed before the intervention, immediately after the intervention, and 2 months after the intervention. The study was approved by the Institutional Review Boards of the University of Texas Southwestern Medical Center and Texas Woman's University.

Participants and setting

Using volunteer sampling, participants were recruited from a tertiary center in the southwest United States. Qualifying participants were infants and children ages 3 months to 4 years 11 months who had been diagnosed with UCP or who presented with early asymmetric hand use and were at risk of developing CP. Other inclusion criteria were the ability to visually attend to objects, demonstrate an interest in objects, and attempt to reach for or grasp them with the impaired upper extremity. All ethnic and racial groups were eligible to participate. The study excluded children with uncontrolled epilepsy, significant visual impairments, severe behavioral problems, or an inability to complete the assessments.

Five participants (3 male) enrolled in the study. The age range was 33 to 43 months with a median age of 40 months. All participants presented with unilateral cerebral palsy (3 right hemiplegia) and a MACS level II (n = 4) or level III (n = 1). Legal guardians provided written informed consent. All services were free of charge for participants.

Pre-assessments and the first three group sessions were provided at Scottish Rite for Children in Dallas. Due to the COVID-19 pandemic, the last five group sessions were provided virtually. Post-intervention measures were conducted virtually and in-person. The primary outcomes measure, the Assisting Hand Assessment, was only valid in-person.

Outcome measures and data collection

The primary outcome for this pilot study was bimanual hand skill, measured with the Assisting Hand Assessment (AHA) using a blinded rater, and the secondary outcome measure was goal attainment related to occupational performance and satisfaction, measured with the Canadian Occupational Performance Measure (COPM). Two occupational therapists who were primary researchers in this study administered the AHA and COPM during the pre-assessment, post-assessment, and 2-month follow-up assessment.

The AHA is a valid and reliable 22-item measure that assesses the assisting or affected hand in carrying out bimanual activities. It has been validated for children with cerebral palsy or obstetric brachial plexus palsy aged 18 months to 12 years (Krumlinde-Sundholm & Eliasson, 2003). This test demonstrates high inter-rater and intra-rater reliability (Krumlinde-Sundholm et al., 2017). Raw scores were converted to 0 to 100 logit-based AHA Units. The smallest detectable difference (SDD) is 5 AHA units to reflect a true change and clinical difference in bimanual performance (Krumlinde-Sundholm, 2012).

The COPM (Law et al., 1990) is an individualized, client-centered outcome measure designed to detect change in a subject's self-perception of occupational performance over time. The COPM is a valid and reliable tool designed for use with participants with a variety of disabilities and across all developmental levels. The OTs interviewed the caregiver to identify up to five goals related to participating in the Therapy Together program. The caregiver then ranked his/her child's performance and satisfaction of each identified goal at baseline and at the conclusion of Therapy Together. A change score of 2 points or more represents a clinically significant change in the participant's performance and satisfaction (Cusick et al., 2007).

In addition, caregivers provided feedback about their perceptions of the program, and researchers used follow-up phone calls to gather feedback from families who did not complete the program.

Therapy together intervention

Materials

Researchers gave families a caregiver manual with dates, times, and location of the group sessions as well as information handouts for weekly topics related to cerebral palsy, including hand skill development, the definition of and functional classifications for cerebral palsy, and available resources. The manual outlined weekly home therapeutic activities, toy recommendations, and activity grading options depending on the child's functional abilities. During in-person group sessions, caregivers checked out toys from a toy library to use during home therapeutic activities. The Therapy Together manual can be found at https://twu.edu/media/documents/occupational-therapy/Therapy-Together-Parent-Manual-(motor)—accessible-web.pdf.

Procedures

Caregivers and children attended eight 1-hour weekly group sessions led by the interventionists. The first three sessions were in-person with occupational therapy students as interventionists. To prepare, the students attended a 1-day training that covered HIPAA requirements, the research protocol, implementation strategies, grading of upper limb domains, and a review of participants. The principal investigators led the last five group sessions due to the transition to a virtual format. Home therapeutic activities were 1 hour a day for 8 weeks, and caregivers logged hours and hand use. Interventionists provided 3 levels of difficulty for each activity so caregivers could match the activities to the child's current skill level. The first 7 weeks used CIMT to promote use of the affected hand, and week 8 focused on bimanual hand skills. Weekly group sessions used a "TEAM Approach"

Table 1. Weekly topics and upper limb domains.

Week	Topics	Upper limb domain
1	Caregiver manual Responding to child's cues Positioning Constraint Toy selection	Initiates use, contact with objects
2	Hand skill development part 1 Review child goals	Upper arm, reaches
3	Hand skill development part 2	Holds, grasps
4	Cognition and hand function	Holds, grasps
5	What is cerebral palsy?	Holds, grasps
6	Functional classification systems	Forearm, finger movement
7	Resources and websites	Release
8	"Green light" upper limb interventions	Involved side as assisting hand

- Topic: introduce the topic(s) for the session, including the upper limb domain(s) addressed and one other component of the Therapy Together program
- Encourage: sharing, processing, and support
- Activity: upper limb activity domain and caregiver coaching
- Motivate: how to implement what was learned at home, activity and toy recommendations, toy library, and feedback on progress made

Weekly topics and upper limb domains are listed in Table 1. The three graded levels for each upper limb domain are listed in Table 2.

Data analysis

Researchers analyzed quantitative data utilizing descriptive statistics and paired samples t-tests to examine if significant differences occurred from pre – to post-intervention in hand function (measured by AHA) and occupational performance and participation.

Table 2. Upper limb domains and grading levels.

Upper limb domain	Grading levels 1	2	3
Initiates use, contact with objects	Contact with physical prompt or assistance	Independent contact	Independent contact and grasp
Upper arm, reaches	Move arm toward object with assistance	Move arm toward object with prompting; [increase excepted movement]	Independently move arm toward object; increase accuracy
Holds and grasps	Pre-grasp Maintain hold Move held object	Grasp from easy position Increase frequency, precision Change orientation, object size	Grasp from a distance Change orientation Advanced grasp patterns Catch moving items
Forearm, finger movement	Explore items near hand Maintain item in hand palm-up	Open, close hand Grasp different sizes Move arm while holding object Promote supination	Refine grasp, isolate two sides of hand Supination
Release	Let go with intention	Release into large container	Release with refinement
Involved side as assisting hand	Stabilize with assisting hand	Hold item with assisting hand	Use assisting hand as typical non-dominant hand

Additionally, repeated measures ANOVA were conducted to examine the growth of participants across all three time points. With three available time points, linear growth (i.e., individuals growth trajectories are a

straight line such that they grow the same from T1 to T2 and T2 to T3) along with quadratic

growth (i.e., individuals growth are curved such that there could be minimal growth from T1 to

T2 with large growth from T2 to T3) were examined (Duncan & Duncan, 2009). Due to small sample size, effect sizes will be the focus of interpretation. Thematic analysis was used for caregiver feedback.

Results

Five children completed the pre-assessments and 8-week intervention. Of the five, three completed the post-assessments in-person using safety precautions such as masks, face shields, and social distancing. The other two completed the COPM post-assessment virtually. The AHA could not be administered virtually. Descriptive statistics can be seen in Table 3.

Bimanual hand skills

The paired samples t-test pre – to post-intervention for AHA was not statistically significant, $t(2) = 2.138$, $p = .166$, $d = .58$. However, this demonstrated a medium effect size (Cohen, 1988) where individuals on average gained 11.67 logits, a .58 standard deviation increase. Following this, a repeated measures ANOVA was conducted to examine growth of these individuals from pretest to the two month follow up. Results indicated that 61.4% of their change in AHA scores could be attributed to linear growth, $F(1,2) = 3.176$, $p = .217$, $\eta^2 = .614$, while 67.4% of change could be due to quadratic growth, $F(1,2) = 4.167$, $p = .179$, $\eta^2 = .674$, seen in Figure 1.

Table 3. Descriptive statistics (n = 5).

Variable	Mean (*SD*)	Range
Age	3.00 (0.71)	2.00
Hours Completed	63.35 (28.72)	68.75
Pre-Intervention		
AHA	47.66 (15.01)	30.00
COPM Performance	3.00 (1.07)	2.85
COPM Satisfaction	3.46 (1.62)	4.15
Post-Intervention		
AHA	59.33 (24.11)	48.00
COPM Performance	6.04 (1.62)	4.50
COPM Satisfaction	6.16 (1.66)	4.50
2 Month Follow Up		
AHA	53.33 (18.45)	36.00
COPM Performance	5.50 (1.80)	3.50
COPM Satisfaction	5.50 (1.80)	3.50

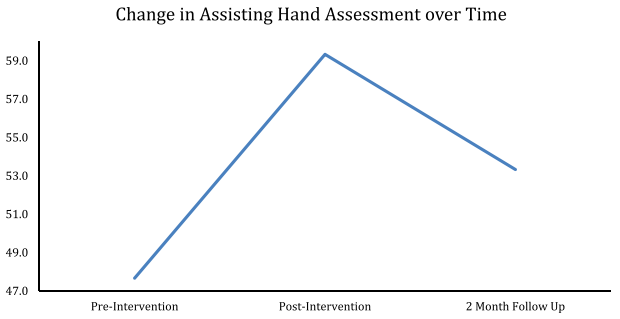

Figure 1. Assisting hand assessment over time.

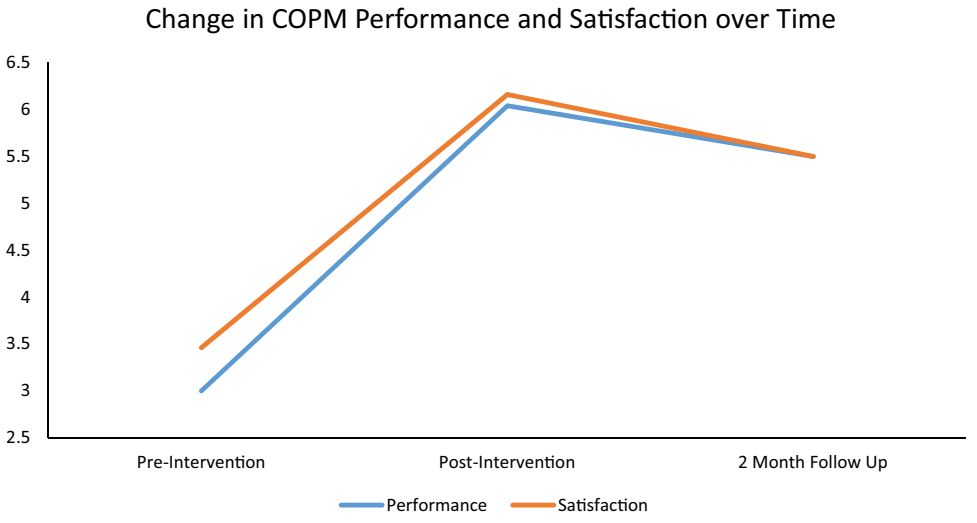

Figure 2. COPM over time.

Occupational performance and participation

The paired samples t-test for COPM Performance scores was statistically significant, t (4) = 5.026, p = .007, d = 2.18, and demonstrated a large effect size. Additionally, there was a large effect and statistically significant difference in COPM Satisfaction scores, t (4) = 3.878, p = .018, d = 1.65. Next, repeated measures ANOVAs were conducted. Results indicated that 76.9% of their change in COPM Performance (Figure 2) scores could be attributed to linear growth, F (1,2) = 6.654, p = .123, η^2 = .769, while 81.3% of change could be due to quadratic growth, F (1,2) = 8.692, p = .098, η^2 = .913. Examining COPM Satisfaction (Figure 2), results indicated that 69.0% of their change in satisfaction could be attributed to linear growth, F (1,2) = 4.454, p = .169, η^2 = .690, while 74.5% of change could be due to quadratic growth, F (1,2) = 5.841, p = .137, η^2 = .745.

Discussion

Bimanual hand skills and occupational performance and participation

Although no statistically significant change in hand function was measured by the AHA, likely due to the small sample size, a clinically significant improvement with a medium effect size and a mean change of 11.67 logits was found; a change of 5 logits for AHA is considered clinically significant (Krumlinde-Sundholm, 2012). Results from the COPM post-assessments show a statistically and clinically significant change in occupational performance and participation. The average changes in COPM Performance and Satisfaction scores were 3.04 and 2.7 respectively, which are greater than the 2-point increase required for clinical significance (Cusick et al., 2007).

Children in this study received an average of 63 hours over the 8-week intervention, including therapeutic activity in the home. Previous work by the research team demonstrates that the younger children participating in Therapy Together had a larger AHA mean change (11.67 AHA units) compared to school-age children (7 AHA units) receiving the same 60-hour dosage of *P*-CIMT (Roberts et al., 2021). This suggests that the neuroplasticity of younger children participating in *P*-CIMT is greater compared to older children potentially leading to greater gains, supporting the need for earlier intervention.

Caregiver feedback

All caregivers of the five participants who completed the 8-week intervention expressed a desire to repeat Therapy Together and provided qualitative feedback about their perceptions of the program. Five themes emerged: caregiver education and empowerment, child engagement and motivation, in-person versus virtual group sessions, program accessibility and resources, and combining Therapy Together with BoNT-A treatments.

Caregiver education and empowerment

Most caregivers who completed the intervention addressed the positive effects of group sessions, weekly goals, and demonstrations of therapeutic activities by interventionists. One caregiver noted that the goals and education from interventionists helped the family "build a sustainable therapy routine at home" and gave them new ideas for home therapeutic activities. The caregiver also said the group sessions provided "a network of other families to support each other and give each other ideas." Another caregiver described demonstrations as "motivating," while a third stated the goals and demonstrations "helped [the] family know what to do."

Child engagement and motivation

One caregiver said having weekly goals and new toys from the toy library helped motivate and engage the children. Two caregivers noted improvements in children's play skills, with one caregiver saying that their child "gained maturity [and] attention span to complete tasks as the program progressed." One caregiver stated that they needed to split up 1-hour home CIMT sessions because the child struggled to pay attention for an hour at a time.

In-person Vs. virtual group sessions

All three caregivers who provided feedback on group session formats said they preferred having group sessions in person. Two caregivers did not address this, but one of them highlighted the toy library and interaction with other caregivers as especially helpful, suggesting they benefited more from the in-person format. Caregiver preference for in-person sessions may reflect the importance of actively including caregivers in the therapy process. In person, interventionists could provide physical assistance as needed and model techniques for caregivers by working directly with the child. During virtual sessions, interventionists could only provide verbal and visual instruction and modeling. Lack of access to toys and other intervention materials is a common barrier cited in the literature; family feedback suggests that the toy library was an important aspect of Therapy Together and supports the idea that increasing access to toys improves caregiver participation.

Program accessibility and resources

Although caregivers preferred in-person group sessions, two caregivers stated they appreciated that the program was able to move to a virtual format instead of finishing early. Another caregiver highlighted the program's lack of financial commitment and the opportunity to check out toys during in-person group sessions.

Therapy together and BoNT-A

Two caregivers noticed little to no improvement in hand function after completing the 8-week intervention program, and both stated a desire to combine Therapy Together with BoNT-A treatments. BoNT-A injections reduce muscle spasticity, a common barrier to effective hand function in children with CP. Evidence supports the efficacy of occupational therapy after BoNT-A treatments in improving motor function and goal achievement for children with UCP (Novak et al., 2020); the children who showed little to no improvement may benefit from BoNT-A treatments before repeating Therapy Together. One child routinely received BoNT-A injections but lost access to the intervention due to pandemic shutdowns, negatively impacting success in home therapeutic activities.

Caregiver feedback supports conclusions by Gmmash et al. (2020) that instructing caregivers about their role in therapy, educating them about cerebral palsy and appropriate goals, and coaching them on how to implement interventions in the home decreases caregiver hesitancy and motivates caregivers to take a more active role in the therapy process. Therapy Together's emphasis on caregiver participation and education may reduce caregiver burden by empowering them with the skills they need to implement therapeutic activities in the home. Caregiver feedback about student interventionists was positive, but it is possible that using clinicians with more experience providing CIMT would improve outcomes.

Feedback also highlighted the importance of program flexibility, another barrier cited in the literature; one caregiver was able to individualize the intervention plan by reducing the length of intervention sessions, which would have been difficult to do with scheduled interventions. Indeed, due to flexibility in group session formats and reduced need for scheduling, Therapy Together was more accessible than BoNT-A treatments. Feedback regarding BoNT-A reflects the conclusion by Sakzewski et al. (2014b)that inconsistent or

inaccessible provision of needed interventions may limit a child's success and the efficacy of other interventions; caregivers attributed their child's lack of improvement to lack of access to BoNT-A and not to inefficacy of the Therapy Together protocol.

One caregiver saw an increase in their child's attention span, a cognitive skill important for motor learning. Cognitive impairments are common in children with UCP and limit occupational performance and participation (Goodman & Yude, 2000). Including interventions to support cognitive development may further improve outcomes of this protocol.

Study limitations

Study limitations include a small N size, limited age range of children participating, and program modifications due to COVID. Only five children completed the intervention, and although inclusion criteria allowed for children between the ages of 3 months and 4 years 11 months, all five children were between the ages of 2 and 4 years. The program protocol was modified after the study began, so outcomes reflect a modified Therapy Together program instead of the program as developed by principal investigators, limiting conclusions than may be drawn about the original program.

Implications for clinical practice

The program was developed to readily translate into clinical practice, and preliminary data show clinically significant improvements in bilateral hand function and occupational performance. The protocol is available for free online, and occupational therapy practitioners can easily implement the program in their own practice.

Conclusion

Therapy Together is a promising *P*-CIMT intervention program for infants and toddlers with UCP. The program incorporates caregiver education and coaching with caregiver-led home therapeutic activities to improve children's bimanual hand skills and occupational performance while addressing barriers to intervention access such as caregiver hesitancy in order to reduce health disparities in children with UCP. To further improve efficacy and accessibility of Therapy Together, future development of the program will include cognitive interventions and will address other barriers to accessing care such as low socioeconomic status and lack of transportation. Future studies will also examine intervention dosages to see if the large clinical gains seen in this study could be attained with fewer hours to further reduce the time commitment for this intervention.

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Disclosure statement

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