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An effectiveness-implementation trial of home-based early hand therapy for young children with cerebral palsy

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ABSTRACT

Background: Early hand therapy is an effective approach for improving hand function in young children with cerebral palsy (CP), yet clinical implementation is limited. This trial assessed implementation and effectiveness of a high dose early hand therapy.
Methods: A home-based, caregiver-delivered intervention of 18-weeks with daily 30-minute practice (60 h total) of constraint-induced movement therapy and bimanual therapy. A coaching approach was used to support caregivers, with weekly coaching sessions provided in-person or virtually. Implementation strategies included training, educational materials, and dedicated clinician time. The primary effectiveness outcome was achievement of individualized hand function goals, assessed via the Canadian Occupational Performance Measure (COPM) pre/post/8-weeks post-intervention. The primary implementation outcome was satisfaction assessed by caregivers and clinicians post-intervention. A repeated measures ANOVA assessed change in COPM scores, with Bonferroni correction of post hoc pairwise comparisons (paired t-tests). Mean values and standard deviations (SD) were calculated for satisfaction scores.
Results: Eighteen participants completed the protocol, aged 4–22 months (mean 13, SD 6 months). COPM scores significantly improved from pre- to post-intervention ($p < 0.001$) and pre- to 8-weeks post-intervention ($p < 0.001$). Mean satisfaction scores indicated a large to very large extent of satisfaction for caregivers (4.9/5.0, SD 0.3) and for clinicians (4.5/5.0, SD 0.6).
Conclusions: Implementation of a caregiver-delivered home-based early hand therapy was highly satisfactory and effective for achievement of individualized hand function goals. Resources are available to support implementation spread.

1. Introduction

Early hand therapy is increasingly recognized as critical for optimizing hand function outcomes for infants and toddlers with

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asymmetric hand use due to cerebral palsy (CP), (Boyd et al., 2025; Morgan et al., 2021; Novak et al., 2020) yet clinical implementation is limited. Home-based therapy is attractive for potential benefits such as higher therapy doses at lower cost, increased accessibility for families, and caregiver empowerment (Beckers et al., 2020). In a home-based model, trained therapists coach caregivers in therapy delivery. Within one Canadian province, caregivers, researchers, clinicians, and healthcare administrators formed a research team to integrate recent evidence with feedback from caregivers and clinicians to optimize effectiveness and implementation of home-based early hand therapy.

Implementation is most commonly guided by a 2014 protocol for baby-constraint induced movement therapy (CIMT), including in the Canadian province of Alberta (Eliasson et al., 2014). The protocol involves constraining a baby's preferred arm for 30 min daily for 12 weeks, with a six-week break in the middle of treatment. Caregivers complete daily home-practice and weekly therapy sessions with an occupational therapist. Fidelity to the original protocol varies in clinical settings, and more recent evidence calls for changes to optimize gains and support implementation (Boyd et al., 2025).

Current evidence and feedback from clinicians and caregivers were integrated to identify three modifications to the baby-CIMT protocol. First, a bridge integrating gains from CIMT to daily life is lacking in a pure CIMT model, which may limit potential for long-term changes. Bimanual practice may encourage carry-over into everyday activities and recent evidence supports use of CIMT or bimanual therapy (Boyd et al., 2025). As coordinated bimanual movements emerge throughout the first years of life, a concentrated focus on bimanual practice may not be suitable for young infants (Greaves et al., 2012). Splitting therapy time between CIMT and bimanual training may be an appropriate and feasible solution (Palomo-Carrión et al., 2024, 2025). Second, the six-week treatment break in the baby-CIMT protocol can create discontinuity in progression and is not evidence-based. Caregivers have not reported treatment fatigue at 12 weeks and a greater treatment dose is optimal (Jackman et al., 2020; Merino-Andrés et al., 2024). An 18-week intervention with daily 30 min practice has an intervention dose of $>$ 60 h, may be both feasible and effective for meaningful improvements (Merino-Andrés et al., 2024). Third, advances in telehealth create the opportunity for an option of in-person and/or virtual (phone or video call) delivery of weekly therapy sessions. Offering some flexibility for the caregiver and/or therapist to choose the delivery mode may increase adherence and feasibility (Verhaegh et al., 2025).

To facilitate clinical implementation of these protocol changes, implementation science methods are necessary. Implementation science is the study of methods and strategies that support clinical uptake (Nilsen, 2015). Process models, like the Ottawa Model of Research Use (OMRU), (Logan & Graham, 1998) are applied in implementation science to guide the translation of research into practice (Nilsen, 2015). The OMRU is not a sequential model but does provide a guide for steps in implementation, which were followed in this study. The OMRU is particularly well-suited to guide the implementation in this study because it has an interdisciplinary focus and prioritizes involvement of patients, which encompasses caregivers. Engaging occupational therapists and caregivers is critical for successful implementation of home-based early hand therapy.

This study aimed to assess implementation of a home-based early hand therapy intervention, with a specific focus on acceptability in terms of caregiver and therapist satisfaction. The secondary aim was to evaluate effectiveness in terms of changes in achievement of caregiver-identified goals for child hand/arm function.

2. Methods

2.1. Study design

This hybrid type 2 effectiveness-implementation study (Curran et al., 2012) was a single-arm prospective trial with pragmatic intentions (Loudon et al., 2015). The study was embedded as a clinical program at one tertiary centre (Edmonton, Canada) and one community rehabilitation program (Calgary, Canada). Caregivers who had previously completed a rehabilitation program with their infant/toddler were actively engaged as patient partners on the research team throughout all research stages, including developing study-specific measures. The contribution of caregiver partners was recognized by annual honoraria, and all are listed as co-authors (SRA, RP, CT, ST). Other knowledge user research team members included occupational therapists (MH, KO), a therapist assistant (CD), and a clinical practice lead (EH).

The study was registered at ClinicalTrials.gov (NCT05346887) on April 19, 2022, before participant enrolment. Ethics approval was obtained from the University of Calgary (REB21–1981) on April 26, 2022, and from the University of Alberta (REB21–1981; pSite00000059) on June 13, 2022. Written informed consent was obtained from the participants' parent or legal guardian prior to participating. Reporting follows StaRI (for implementation studies), (Pinnock et al., 2017) STROBE (for observational studies), (von Elm et al., 2007) TIDieR (intervention elements), (Hoffmann et al., 2014) and the GRIPP2 (Staniszewska et al., 2017) (for patient engagement).

2.2. Participants & sample size

A target sample of minimum twenty participants was recruited over a one-year period, based on clinical estimates from previous year. This sample size was appropriate to ensure resources were responsibly used and to answer the primary research questions. Eligible children: (i) were aged three to 24 months (corrected, if premature); (ii) had a clinician-identified hand asymmetry due to suspected/confirmed CP (hemiplegia or triplegia), identified following expert recommendations on clinical features of: hand preference, persistent unilateral hand fisting, and/or asymmetry between hands in quality or speed of movements; (Boychuck et al., 2020) and (iii) were willing to withhold other formal upper limb focussed treatment during the study intervention. Exclusion criteria included participation in formal CIMT or botulinum toxin A injections within the last six months, and/or any other neurological or

upper limb condition unrelated to CP. Rolling participant enrolment provided opportunity for on-going assessment and monitoring of implementation. Potentially eligible children identified through clinical triaging at each site were directly referred to trained occupational therapists.

2.3. Implementation methods & strategies

Implementation methods followed the six steps of the OMRU, with steps 1–4 detailed here and steps 5–6 of monitoring and evaluation detailed in Section 2.6. The first two steps of the OMRU involve setting the stage by identifying key players and resources and then specifying the innovation (detailed below in 2.4). Of the two sites, the tertiary hospital had been offering baby CIMT while the community rehabilitation program was newly receiving referrals for eligible children. Representatives from both sites were included in the multidisciplinary research team. During these steps, the study design was assessed using PRECIS-2 (Loudon et al., 2015) to optimize pragmatic intentions by mirroring current clinical practices as closely as possible.

In the third step, the multidisciplinary research team assessed the intervention, potential adopters (caregivers and clinicians), and the environment (clinical program sites) for barriers and facilitators to implementation through a series of informal methods: conversations, joining clinical team meetings, and holding debrief conversations after group meetings. Barriers identified that were specific to clinicians included lack of training on a coaching approach and CIMT, and limited time that prohibited weekly sessions for 18-weeks. Identified barriers for caregivers included feeling overwhelmed, having limited time, not understanding the importance of early hand therapy for lifelong outcomes, not feeling supported, and lack of resources. Aspects of the therapy protocol were identified as facilitators by clinicians and caregivers: option for virtual sessions, home-based delivery, and evidence for improved hand/arm function. Facilitators specific to clinicians included their interest in gaining coaching and CIMT skills and support from leadership. Main facilitators for caregivers included the desire to access the best therapy for their child, feeling a connection with the therapy team, and observing improvements in their child's hand function.

In the fourth step of the OMRU, implementation strategies were identified to address barriers and leverage facilitators: training for clinicians, education and training for caregivers, and dedicated clinician time for intervention delivery and caregiver support. The multidisciplinary research team, defined above, co-designed the strategies. Prior to starting the intervention, caregivers and clinicians completed training. Caregivers were provided with an online module with general information like identifying behavioural cues and adjusting the task challenge level. The same caregiver(s) were requested to complete the training and attend every session to promote consistency and progression. Clinicians, specifically occupational therapists (OTs) and therapist assistants (TAs), completed a two-hour asynchronous online course on the Applied Coaching Tool (Teitelbaum et al., 2025) and then intentionally practiced coaching with mentorship for one month. An online module trained OTs and TAs on the therapy protocol. Clinicians who had less than one-year experience with CIMT young children received additional training and on-going mentorship with an experienced clinician (i.e., >3 years' experience).

Ongoing educational support was offered through an educational website (https://cumming.ucalgary.ca/research/early-hand-therapy-4-cp) and downloadable manuals for caregivers and clinicians. This website was under continuous development as we collected caregiver and clinician feedback. The clinician manual detailed evidence for the therapy protocol, outlined the intervention schedule and content, provided activity suggestions, and detailed administration of outcome measures. The caregiver manual went beyond intervention purpose and implementation to include information such as positive caregiver-infant interactions and child development (Harniess et al., 2022; Lord et al., 2018). A section of the manual explained the importance of early hand therapy for lifelong outcomes in lay terms.

Lastly, healthcare administration at each site approved dedicated clinician time blocks for training, study participant sessions, and for ad hoc participant communication. The baseline assessment included time to problem-solve around how to fit therapy into each family's unique context. Weekly sessions with the therapy team and caregivers included celebrating successes, adjusting the intervention plan, modelling new activities, and/or problem-solving any challenges that caregivers experienced.

2.4. Intervention

The home-based caregiver-delivered intervention involved 18 weeks of daily 30-minute home-practice with one weekly session with an OT or TA. One OT and one TA were assigned to each child as the treatment team. Each weekly session could be delivered virtually (phone or video call) or in-person at the local rehabilitation centre, as determined by the caregiver and clinician. Home practice time was distributed across the day as necessary to facilitate integration into daily routines. Caregivers completed a diary to document time and reflect on practice, which was reviewed at the weekly session. Concurrent gross motor practice was permitted to support child development, but upper limb-focused training outside of the study was not permitted to avoid co-intervention bias.

The first 13 weeks of the intervention were exclusively CIMT. Weeks 14–18 were tailored to the child's age and develop of manual skills as follows: 4 to $<$ 9months: exclusive CIMT; 9 to $<$ 18months: 20 min of CIMT + 10 min bimanual training; 18–24 months: 10 min of CIMT + 20 min bimanual training. For CIMT, use of the affected hand was encouraged through restraint of the preferred arm using a mitt or other method acceptable to the child. The restraint was not worn outside of the prescribed CIMT time. For bimanual training, activities focused on involvement of both hands. Children practiced in a supported position. Intervention content was individualized based on child age, ability, interests, and caregiver-identified goals using the Canadian Occupational Performance Measure (COPM) (Law et al., 1990). Content was grounded in motor learning principles, namely repetition, progressive challenge, and a variety of activities in a real-life setting.

2.5. Effectiveness outcome measures

Outcome measures were administered by a non-treating OT at three timepoints: pre-intervention, post-intervention, and follow-up (8-weeks post-intervention). The primary effectiveness outcome measure was the COPM, specifically the Performance score. The COPM is not age-specific, supporting longitudinal data collection and evaluation of change as children age. Using the COPM, three to five individualized goals were identified by caregivers in collaboration with the treating OT. Goals were scored by the caregiver on a scale of 1–10 for both Performance (how well the goal is performed) and Satisfaction (how satisfied caregivers are with goal performance, a secondary outcome) (Law et al., 1990). The mean of the goals was calculated for each participant for Performance and Satisfaction. A score change of ≥ 2 is considered clinically meaningful on the COPM.

Other secondary outcomes assessed goal achievement, child hand function, and caregiver well-being. For goal achievement, the treating OT transformed the COPM goals into objectively measurable goal attainment scaling (GAS) goals that could be targeted by the intervention. GAS goals were scored post-intervention and then change scores were transformed into a T-score with mean 50.0 (SD 10.0) (King et al., 1999). One of three hand assessments was used based on child age at assessments: the Hand Assessment for Infants (HAI) (Krumlinde-Sundholm et al., 2017) was used for children aged 4 to $\leq$ 8 months, the mini-Assisting Hand Assessment (AHA) (Greaves et al., 2013) for children aged $\geq$ 8 to $\leq$ 18 months, and the AHA for children aged $\geq$ 18 months (Holmefur & Krumlinde-Sundholm, 2016). These three assessments examine hand function in a video-recorded play-based session lasting 10–15 min. A non-treating certified OT scored hand assessments from the videos. The scorer was not informed of assessment timing and videos were scored in random order. Raw scores were converted into a 0–100 logit-based scale, and mini-AHA scores were converted to AHA scores (Greaves et al., 2025). Change scores of $\geq$ 3 on the HAI (Ullenhag et al., 2021) and $\geq$ 5 on the AHA are considered the minimal detectable change.

Caregiver-report questionnaires of well-being included the Hospital Anxiety Depression Scale (HADS), (Bjelland et al., 2002) the Perceived Stress Scale (PSS), (Lessenberry & Rehfeldt, 2004) and the Parenting Sense of Competence scale (PSOC) (Karp et al., 2015). HADS scores were separated into Anxiety and Depression, and categorized as Normal (0−7), Borderline (8−10), and Abnormal (11−21). PSS scores were also categorized as Low (0−13), Moderate (14−26), and High (27−40).

Certain measures were collected at baseline only to characterize participants. Caregivers completed a study-built demographic

Table 1
Implementation Outcomes.

Category	Outcome	Indicator	Criteria	Results
Efficiency	Recruitment	Time to recruit n=20	≤24 months	12 months
Safety	Adverse events	# Minor/moderate/severe AE	0	0
Cost	Clinician time	# Sessions >45min	0 per participant	n=3: 2 sessions 45-60min n=2: 1 session 45-60min
Acceptability	Perceived preparedness	Caregiver questionnaire (study-built)	Mean item score ≥4 ("large extent")	4.3 (SD 0.8) pre-intervention 4.5 (SD 0.5) post-intervention
	Perceived satisfaction	**Caregiver/therapist questionnaire** (adapted from GS-PEQ)	**Mean item score ≥4 ("large extent")**	**4.9 (SD 0.3) Caregiver** **4.5 (SD 0.6) Clinician**
	Session format	# In-person sessions per participant	<13 sessions	0-12 in-person sessions
Appropriateness	Treatment response	Main effect of time for COPM, AHA	$p<0.05$	Maximum $p=0.009$
	Treatment effect	COPM-P, COPM-S AHA	d≥0.80 r≥0.80	d=2.28 (P); d=2.81 (S) r=0.96
Reach	Recruitment	# Decline participation	<10%	7% (2/28)
	Attrition	Withdrawals	≤10%	10% (2/20)
		Reasons for withdrawing	<10% study-related	0%
	Participation	Geographic location of participants	<30% same neighbourhood ∇	10.5% (2/19)
Feasibility	Attendance	Attendance logs	≤2 missed sessions	n=2: missed 5 sessions n=1: missed 3 sessions n=1: missed 9 sessions
	Missing data	Missed assessments	None	n=2: missed 1 assessment
	Accessibility	# Families needing devices/data	<10%	0%
	Technology	# Sessions interrupted/canceled	≤2 sessions with issues	n=4: 4 sessions with issues n=1: 3 sessions with issues
		Time spent troubleshooting per session	<5min	<5min
Fidelity	Fidelity	FIRM[39] from one filmed session	All items ≥2 "acceptable"	98.8% ≥ 2
		Caregiver diaries	≤1 week incomplete	n=4: 18 weeks incomplete n=1: 2 weeks incomplete n=1: 3 weeks incomplete
		Intervention modifications	FRAME documentation	1 documented
Sustainability	Continued implementation	Agreement by healthcare administrators to continue implementation	n/a	Interventions continuing with modifications

Legend: Green shading: criteria met; red shading: criteria not met; bold test: primary implementation outcome; AE: adverse events; min: minutes; Ax: assessment; Pre: pre-intervention; Post: post-intervention; GS-PEQ: Generic Short Patient Experiences Questionnaire; COPM: Canadian Occupational Performance Measure; P: performance; S: satisfaction; GAS: Goal Attainment Scaling; AHA: Assisting Hand Assessment; ∇: neighbourhood based on first three characters of Canadian postal code; FIRM: Fidelity of Implementation Measure; FRAME: Framework for Reporting Adaptations and Modifications-Expanded (Wiltsey Stirman et. al 2019).

questionnaire and the Ages and Stages Questionnaire-3 (ASQ-3) (Squires & Bricker, 2009). ASQ-3 scores for each area were compared to cutoffs and categorized as above, close to, or below cutoff. For children > 12 months old, the Mini Manual Ability Classification System (MACS) (Eliasson et al., 2017) classified manual ability from level I (highest function) to V. Clinical MRI scans, if available, were reviewed by a pediatric neurologist (AK) to report brain injury and birth timing.

Table 2
Baseline Participant Characteristics.

Outcome	
Child age (corrected)	Mean 13 (SD 5) months, range 4–22 months
Sex	n = 8 female
Diagnosis of CP at study entry	n = 11
Laterality of impairment	n = 7 Right
	n = 13 Left
MRI & birth history	n = 6 Arterial ischemic stroke, term birth
	n = 5 Periventricular hemorrhagic infarction, premature
	n = 2 Posthemorrhagic hydrocephalus, premature
	n = 2 Premature white matter injury, premature
	n = 2 Structural
	n = 1 Normal MRI
	n = 2 No MRI available
Mini-MACS Level	n = 1 I
	n = 8 II
	n = 2 III
	n = 2 V
	n = 7 < 12months at baseline
ASQ-3 Fine Motor (n = 16)	n = 5 Above cut-off
	n = 1 Close to cut-off
	n = 10 Below cut-off
ASQ-3 Gross Motor (n = 16)	n = 3 Above cut-off
	n = 1 Close to cut-off
	n = 12 Below cut-off
ASQ-3 Communication (n = 16)	n = 6 Above cut-off
	n = 4 Close to cut-off
	n = 6 Below cut-off
ASQ-3 Problem solving (n = 15)	n = 5 Above cut-off
	n = 1 Close to cut-off
	n = 9 Below cut-off
ASQ-3 Personal social (n = 15)	n = 3 Above cut-off
	n = 4 Close to cut-off
	n = 8 Below cut-off
Caregiver age (mean, SD)	31 (SD 4) years
Household income (CAD)	n = 1 < $30,000
	n = 6 $30,000 to $70,000
	n = 7 $71,000 to $110,000
	n = 3 $111,000 to $150,000
	n = 2 > $151,000
	n = 1 Not reported
Number of children	n = 9 One child
	n = 7 Two children
	n = 3 Three children
	n = 1 Not reported
Caregiver status	n = 13 Co-caregiver
	n = 2 Lone caregiver
	n = 1 Grandparent
	n = 2 Not reported
Biological Parent 1 race	n = 14 Caucasian
	n = 2 Black
	n = 2 East Indian/South Asian
	n = 1 Indigenous
	n = 1 Not reported
Biological Parent 2 race	n = 14 Caucasian
	n = 1 Caucasian, Indigenous
	n = 2 Black
	n = 2 East Indian/South Asian
	n = 1 Not reported

Legend: Values for all children enrolled (n = 20) presented unless otherwise specified. CP: cerebral palsy; MRI: magnetic resonance imaging; MACS: Manual Ability Classification System; ASQ: Ages & Stages Questionnaire.

2.6. Implementation outcomes

The fifth and sixth step of the OMRU outlines assessment, monitoring, and evaluation as a dynamic and iterative process, thus implementation outcomes were monitored during the 12-month implementation to assess whether strategies were effective, needed to be changed, or new strategies needed to be added. A taxonomy of implementation outcomes (Alberta SPOR Support Unit LHST, 2020; Proctor et al., 2011) was used to organize indicators and ensure a comprehensive approach to assessment (see Table 1).

The primary implementation outcome was perceived satisfaction of caregivers and occupational therapists for each child, assessed post-intervention via study-built questionnaires with adapted from the Generic Short Patient Experiences Questionnaire (GS-PEQ) (Kjærandsen et al., 2021). The questionnaire had a five-point response scale: 1 = 'Not at all', 2 = 'To a small extent', 3 = 'To a moderate extent', 4 = 'To a large extent', and 5 = 'To a very large extent'. Four additional yes/no questions asked about whether they liked the frequency of therapy sessions, hybrid in-person/virtual delivery of sessions, intervention length, and duration of daily practice. As listed in Table 1, most secondary implementation outcomes were metrics tracked by research team members. Three outcome measures were also used. A study-built questionnaire about caregiver's Perceived Preparedness to deliver the intervention included five questions scored on the same five-point response options as the satisfaction scale. Two questions asked specifically about the manual and introductory webinar. The Framework for Reporting Adaptations and Modifications-Expanded (FRAME) (Wiltsey Stirman et al., 2019) was used to report intervention adaptations/modifications and the Fidelity of Implementation Measure (FIRM) (Ramey et al., 2019) was scored from one filmed session mid-intervention.

2.7. Statistical analysis

Participants and outcomes were described using the appropriate descriptive statistics. Implementation outcomes were compared to pre-set criteria as appropriate. For effectiveness outcomes, per-protocol scores at the three time points (pre, post, follow-up) were compared using repeated measures ANOVAs (COPM, HADS, PSOC, PSS) or Friedman's tests (AHA) with Bonferroni correction of post hoc pairwise comparisons (paired *t*-tests or Durbin-Conover tests). Changes in HAI scores were analysed descriptively based on sample size (n = 2). Estimates of effect size were based on pre- to post-intervention change using Cohen's d statistic (COPM) or rank-biserial correlation (AHA). For outcomes with established minimal detectable change or minimal clinically important difference values (i.e., COPM, AHA, HAI), the number of participants with change at/above the minimal value were summarized based on intention-to-treat data. Similarly, for outcomes with severity categories (i.e., HADS, PSS, PSOC), the number of participants in each category were summarized. Significance was set at $p < 0.05$ for all analyses. Analyses were conducted using Jamovi (version 2.3.28.0).

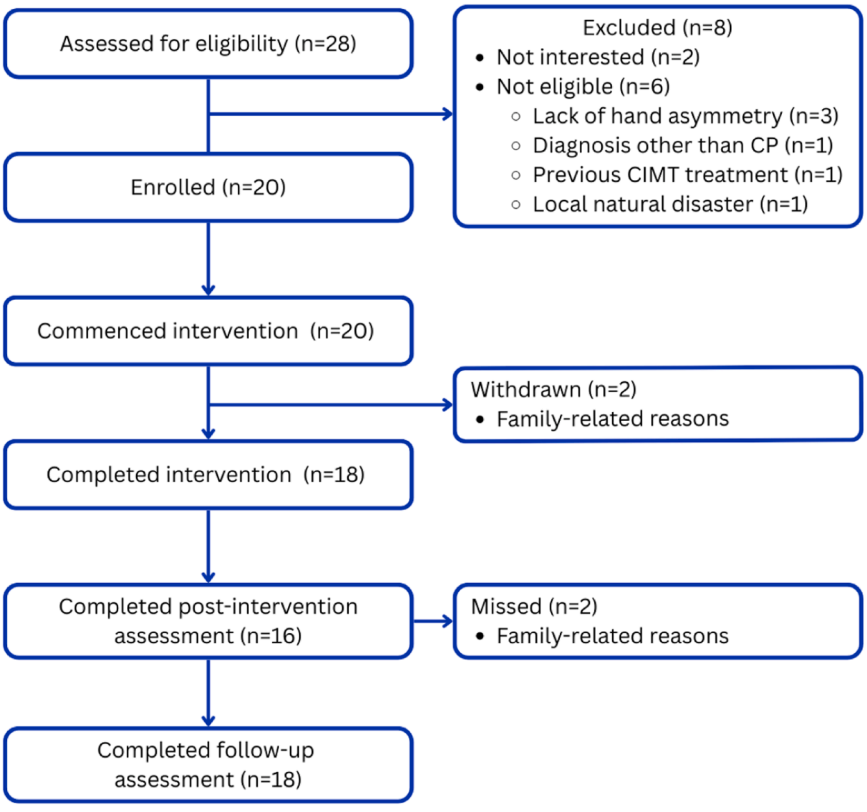

Fig. 1. Study flow. Legend: CP: cerebral palsy; CIMT: constraint induced movement therapy.

3. Results

3.1. Participants

In a 12-month period at each site, 20 participants were enrolled. Mean age was 13 (SD 5) months, with a range from 4 to 22 months. The left side was more affected for thirteen children, and eleven children had a CP diagnosis at study entry. Baseline characteristics are detailed in Table 2, with the study flow depicted in Fig. 1.

3.2. Effectiveness Outcomes

For the primary effectiveness outcome of COPM Performance, scores significantly improved over time ($p < 0.001$, n = 16). Improvements were maintained from post-intervention to follow-up ($p = 0.972$), as seen in Fig. 2 and detailed in Table 3. From pre- to post-intervention, mean change was 4.3 (SD 1.9) and 14 of 16 participants had change ≥ 2 (87.5%). From pre-intervention to follow-up, mean change was 3.7 (SD 2.2) and 15 of 18 participants had change ≥ 2 (83.3%). A large effect was observed pre/post-intervention (d=2.28).

For secondary outcomes, COPM Satisfaction scores significantly improved over time ($p < 0.001$, n = 16), and were maintained post-intervention to follow-up (Satisfaction: $p = 1.000$). All participants had change ≥ 2 from pre- to post-intervention (100%) with mean change of 5.1 (SD 1.8). From pre-intervention to follow-up, 17 of 18 participants had change ≥ 2 (94.4%) with overall mean change of 4.6 (SD 2.4). Pre/post-intervention effect size for COPM Satisfaction was large (d=2.81). The mean GAS score was 59.54 (SD 13.13), indicating that most participants met or exceeded expectations for goal achievement.

Significant change was also observed over time in AHA (including converted mini-AHA) scores ($p = 0.009$, n = 13). There were significant changes from baseline to post-intervention ($p = 0.013$) and from baseline to follow-up ($p = 0.002$). Scores were maintained from post-intervention to follow-up ($p = 0.404$). From pre-to post-intervention, seven of 13 participants changed ≥ 5 points (54.8%).

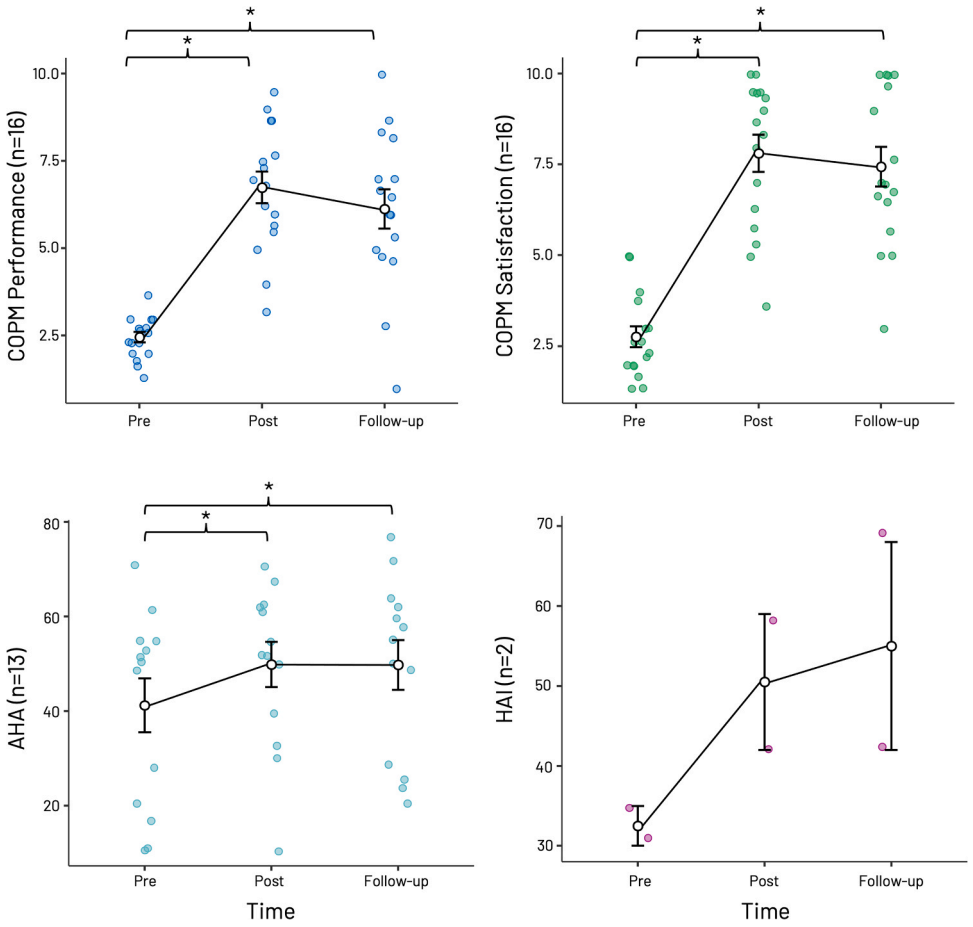

Fig. 2. Change in Individualized Goals and Hand Function. Legend: Coloured data points are observed scores while black circles show mean values with standard error bars; *p < 0.05; COPM: Canadian Occupational Performance Measure; AHA: Assisting Hand Assessment, including converted scores from the mini-AHA; HAI: Hand Assessment for Infants. p-values were not calculated for the HAI based on the sample size.

Table 3
Change in Outcome Scores.

Outcome	Analysis	Pre	Post	Change Pre to Post	Follow-up	Change Pre to Follow-up
COPM-P	PP	2.45 (0.60) n = 16	6.74 (1.80) n = 16	***p*< 0.001**	6.12 (2.24) n = 16	***p*< 0.001**
	ITT	2.25 (0.69) n = 20			6.05 (2.29) n = 18	
COPM-S	PP	2.75 (1.15) n = 16	7.80 (2.03) n = 16	***p*< 0.001**	7.44 (2.17) n = 16	***p*< 0.001**
	ITT	2.48 (1.18) n = 20			7.22 (2.30) n = 18	
AHA	PP	41.23 (20.63) n = 13	49.85 (17.18) n = 13	***p*= 0.013**	49.77 (18.88) n = 13	***p*= 0.002**
	ITT	42.71 (22.60) n = 17			44.81 (21.59) n = 16	
HAI	PP	32.50 (3.54) n = 2	50.50 (12.02) n = 2	—	55.00 (18.39) n = 2	—
	ITT	31.67 (2.89) n = 3				
PSOC	PP	79.99 (6.65) n = 12	78.67 (8.88) n = 12	$p = 1.000$	78.17 (11.72) n = 12	$p = 1.000$
	ITT	78.84 (7.14) n = 19	79.07, SD 9.22, n = 15		79.19 (11.29) n = 16	
HADS Anxiety	PP	9.00 (4.85) n = 13	8.00 (4.24) n = 13	$p = 0.884$	9.23 (5.18) n = 13	$p = 1.000$
	ITT	8.26 (4.59) n = 19	7.60 (SD 4.33) n = 15		7.94 (5.21) n = 17	
		57.9% Normal	40.0% Normal		47.1% Normal	
		15.8% Borderline	33.3% Borderline		23.5% Borderline	
		26.3% Abnormal	26.7% Abnormal		29.4% Abnormal	
HADS Depression	PP	5.77 (4.28) n = 13	4.54 (3.23) n = 13	$p = 0.868$	5.62 (4.27) n = 13	$p = 1.000$
	ITT	5.16 (3.99) n = 19	4.40, SD 3.07, n = 15		5.06 (3.99) n = 17	
		78.9% Normal	80.0% Normal:		70.6% Normal	
		10.5% Borderline	13.3% Borderline		17.6% Borderline	
		10.5% Abnormal	6.7% Abnormal		11.8% Abnormal	
PSS	PP	15.92 (5.20) n = 13	18.15 (8.83) n = 13	$p = 0.807$	15.85 (8.92) n = 13	$p = 1.000$
	ITT	15.32 (5.06) n = 19	17.47 (8.59) n = 15		15.00 (8.34) n = 17	
		31.6% Low	40.0% Low		58.8% Low	
		68.4% Moderate	46.7% Moderate		23.5% Moderate	
		0.0% High	13.3% High		17.6% High	

Legend: Mean values (SD) presented; PP: per-protocol data; ITT: intention-to-treat data; bold text indicates $p < 0.05$ (Bonferroni corrected); COPM: Canadian Occupational Performance Measure; P: Performance; S: Satisfaction; AHA; Assisting Hand Assessments; HAI: Hand Assessment for Infants; PSOC: Parenting Sense of Competence Scale; HADS: Hospital Anxiety and Depression Scale; PSS: Perceived Stress Scale.

From pre-intervention to follow-up, 10 of 15 participants changed ≥ 5 points (66.7%). The effect size pre/post-intervention was large (r = 0.96). Two children were assessed using the HAI at all three timepoints. Changes scores from pre- to post-intervention were + 7 and + 29, and scores were either maintained (change 0) or improved (change +9) from post-intervention to follow-up. Change over time was not possible to calculate for one child who completed the HAI at baseline and the mini-AHA at subsequent assessments. Post-intervention scores were unobtainable for one other child due to technical difficulties with the video recording.

There were no significant changes over time in scores for Anxiety, Depression, PSOC, or PSS (minimum $p = 0.364$ for the main effect of time). For Anxiety and Depression, scores were most frequently categorized as "Normal" at all time points. For the PSS, scores were most frequently categorized as "Moderate" at pre- and post-intervention, and as "Low" at follow-up. See Table 3 for details.

3.3. Implementation outcomes

For the primary implementation outcome of acceptability, mean caregiver satisfaction scores were 4.9 (SD 0.3) and mean clinician scores were 4.5 (SD 0.6) on a 1–5 scale. Daily practice and the 18-week intervention duration were liked by 89% caregivers. OTs deemed daily practice to be appropriate for 94% participants, while the intervention duration was deemed appropriate for 72%. Weekly sessions were liked by 83% of caregivers and 89% of OTs. The choice of virtual or in-person weekly sessions was preferred by 94% caregivers and all OTs.

Pre-set criteria were met for secondary implementation indicated in categories of Efficiency, Safety, Acceptability, Appropriateness, Reach, and Sustainability, but not for Cost, Feasibility, and Fidelity (detailed in Table 1). For Cost, sessions were all completed in < 60 min, but not under the target of < 45 min. Within Feasibility, four participants missed more than two weekly sessions. Two families often forgot about appointments, while two other families had troubles attending due to health issues with their child. Two post-intervention assessments were missed for family-related reasons that caused scheduling difficulties. Completion of primary outcomes was prioritized, and secondary outcomes were not always completed, as outlined in Table 3. Technical issues interrupted or cancelled weekly sessions for four sessions for four different participants. Within Fidelity, caregiver diaries were not completed by four participants. Two other participants did not complete diaries for 2–3 weeks. Finally, FIRM item scores were ≥ 2 for 98.8% of items, slightly below the criteria of all items.

Within categories where pre-set criteria were met, additional details are provided here to supplement Table 1. Attrition met the criteria of ≤ 10% with two participant withdrawals. These were not study-related, but rather due to health issues of the child or a family member. Intervention modifications were documented as part of Fidelity. One child refused the constraint and began exclusively bimanual therapy at Week 10. This decision was made by clinicians and researchers as a reactive adaptation at the individual level to improve fit with the recipient (Wiltsey Stirman et al., 2019). As per the FRAME, (Wiltsey Stirman et al., 2019) this was a fidelity consistent adaptation (core elements of dose and weekly coaching conserved). Caregiver perceptions of preparedness met criteria, and mean scores were > 4.00 ("large extent") for specific questions about the helpfulness of the manual (4.22, SD 1.11) and the

introductory webinar (4.16, SD 1.07). Regarding Sustainability, implementation continued at the two sites following study completion. Both sites continued to offer hybrid weekly sessions (in-person or virtual) using a coaching model. One site followed the reported protocol and used the COPM for evaluation. The second site piloted a modified protocol of 12-weeks. Bimanual therapy was introduced earlier in the intervention, based on age as outlined in the study protocol. The appropriate hand assessment and COPM were used for evaluation.

4. Discussion

This study demonstrated successful implementation of an early hand therapy intervention for young children with CP that was effective for achieving individualized hand function goals. To our knowledge, this is the first study to use implementation science methods to support and evaluate clinical implementation of home-based early hand therapy. A key outcome from our study is a road map for clinical roll-out, including publicly available caregiver education materials and an intervention manual for therapists on our website: https://cumming.ucalgary.ca/research/early-hand-therapy-4-cp.

There is often a disconnect between explanatory rehabilitation trials and clinical reality. Our synergistic approach to trial design and execution capitalized on knowledge of researchers, clinicians, healthcare administrators, and caregivers to provide the pragmatism that is required for rapid clinical transfer. A type 2 effectiveness-implementation trial was appropriate to simultaneously examine effectiveness and implementation, (Curran et al., 2012) as a novel therapy protocol emerged in the implementation planning processes. The overall success of the intervention was evidenced by the high satisfaction of caregivers and therapists with the therapy, improvement in individualized goals and child hand function, and sustainable implementation.

Novel components of the therapy included introducing bimanual therapy to CIMT in a staged, age-based approach. Combining CIMT with bimanual therapy has recently shown greater improvements than CIMT or bimanual alone (Palomo-Carrión et al., 2025). However, benefits may be seen regardless of the approach, which emphasizes the need for flexibility and family-centredness. In our study, one family moved to exclusively bimanual therapy as the child refused constraint. This improved therapy fit, and the family completed the intervention. Therapy dose and active caregiver involvement, rather than therapy approach, may be the priority ingredients for early hand therapy (Palomo-Carrión et al., 2025).

The option for virtual or in-person delivery of weekly coaching sessions was also novel and pragmatic for families and clinicians. The COVID-19 pandemic increased use of telerehabilitation, which should not be eliminated based on results of our study. The choice of virtual or in-person weekly sessions was preferred by almost all caregivers and occupational therapists (94%). Virtually delivered therapy can also increase reach. In fact, only two participants lived in the same neighbourhood in our study. Evidence for telerehabilitation in early therapy will increase as on-going studies are completed (e.g., NCT04997109).

The implementation strategies applied in this study, specifically education and training, resulted in high fidelity, preparedness, and satisfaction. Training and education were designed to support caregiver involvement in therapy delivery and decision-making, which is increasingly recognized as imperative for early intervention success (Harniess et al., 2022). Success of caregiver-delivered early interventions may be contingent upon effectively supporting and empowering caregivers, (Lord et al., 2018) which requires therapists to move away from traditional directive relationships with caregivers (Teitelbaum et al., 2025; Akhbari Ziegler & Hadders-Algra, 2020). The therapist education on coaching strategies provided in this study may be necessary to support the practice shift, both for families and therapists. A coaching approach fosters equal partnership and collaboration, (Ogourtsova et al., 2019) which is especially important for goal setting and treatment planning in the home environment (Harniess et al., 2022; Lord et al., 2018; Palomo-Carrión et al., 2021).

Caregiver well-being didn't increase with the home-based intervention, but it also didn't decrease with the additional education and support. It is possible that the education and support mitigated any stressors introduced by the intervention (Roldán-Pérez et al., 2024; Verhage et al., 2025). Caregiver partners on our research team highlighted that their child's CP is one component of their lives, and overall well-being is multifaceted (Swift et al., 2023). Finances, employment, competing demands, and other persistent challenges may have greater influence over caregiver well-being than home-based intervention (Swift et al., 2023).

Challenges with session attendance and intervention completion arose due to health issues in some cases. The reduced therapy dose may have influenced outcomes for these children. It is important for children's health to be stable in order to prioritize therapy, and for the family to be ready to commit to a high dose, multi-week intervention. For some families, a lower dose could be more feasible and may still be beneficial. We did not conduct interim assessments to evaluate minimum dose, which is a needed next step in early hand therapy research.

Limitations include adherence to at-home practice. Methods to monitor at-home practice were in place, including diaries and questions at weekly sessions. However, diaries were not completed by all families which may have been due to low adherence and/or noncompletion. Learning family preferences for documenting practice is necessary to improve adherence tracking and support validity of investigations of any dose-response relationships. Technology issues with virtual sessions occurred but were quickly resolved.

This study was not powered for subgroup analyses (e.g., diagnosis, age) which may have influenced outcomes (Boyd et al., 2025). The sample size was determined by recruitment feasibility rather than calculated a priori to ensure the study was appropriately powered. Without a control group, it is not possible to determine how developmental changes may have contributed to improvements in hand function. The small sample size, lack of control group, correlation between pre/post scores, and possibility of non-random error could have contributed to the large effect sizes, which should therefore be cautiously interpreted (Gorard, 2013). Further, the pre/post effect sizes should not be included in future meta-analyses (Cuijpers et al., 2017).

While we identified hand asymmetry based on expert recommendations of clinical features, (Boychuck et al., 2020) simple, accessible, and validated methods for early identification continue to emerge that will improve screening processes (Kembe et al.,

2025). Finally, as the HAI and mini-AHA/AHA scores cannot be combined, change in hand function over time was not calculated for one participant. Selecting a primary outcome that is not age-specific, like the COPM, remains necessary for studies that cross age spans for hand assessments.

5. Conclusions

This study demonstrated successful clinical implementation of an effective high dose early hand therapy for young children with CP. Comprehensive implementation outcomes and publicly available materials are shared to support implementation spread. Continued efforts are needed to ensure successful and widespread clinical implementation of early hand therapy to optimize hand function outcomes for children with CP.

CRediT authorship contribution statement

Hilderley A.: Conceptualization, Methodology, Investigation, Project administration, Formal analysis, Visualization, Writing – original draft, Funding acquisition. **K. O'Grady:** Methodology, Project administration, Investigation, Writing – review & editing. **M. Herrero:** Conceptualization, Methodology, Writing – review & editing. **E. Heptonstall:** Methodology, Writing – review & editing. **S. Reist-Asencio:** Conceptualization, Writing – review & editing. **R. Pynn:** Conceptualization, Writing – review & editing. **C. Tao:** Conceptualization, Writing – review & editing. **S. Tao:** Conceptualization, Writing – review & editing. **C. Diot:** Conceptualization, Methodology, Writing – review & editing. **J. Andersen:** Conceptualization, Methodology, Writing – review & editing. **A. Kirton:** Conceptualization, Methodology, Writing – review & editing, Supervision, Funding acquisition.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request and with ethical approval.

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