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Protocol and Feasibility-Randomized Trial of Telehealth Delivery for a Multicomponent Upper Extremity Intervention in Infants With Asymmetric Cerebral Palsy

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Abstract

Background: Past work showed that an *in-person*, therapist-guided, parent-implemented multicomponent intervention increased the motor functioning of the more affected upper extremity (UE) in infants with asymmetric cerebral palsy. The authors document treatment fidelity and provide initial testing of *telehealth* intervention delivery in a new subject sample. **Methods:** The authors adapted the intervention manual used in the previous trial for telehealth. Infants (6-24 months) were randomly assigned to intervention (n = 7) or waitlist (n = 6). The intervention prescribed soft-constraint wear on the less affected UE for 6 hours, 5 d/wk, and exercises. After an initial in-person training session, three 15- to 45-minute telehealth sessions were performed. **Results:** Median weekly constraint wear was 21 hours (interquartile range = 10.3-29.7); average parent-treatment fidelity was 95.7% (SD 11.2). A significant large (Cohen $d = 0.92$) between-group differences occurred on fine motor functioning of more affected UEs. **Conclusion:** The telehealth intervention was feasible and potentially effective, but a larger trial is needed to evaluate efficacy.

Keywords

cerebral palsy, infant, neurodevelopment, rehabilitation, treatment

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Even before the access crisis resulting from the SARS-CoV-2 pandemic, decreased access to health care was a widespread problem in the United States and significantly affected health outcomes.[1,2] Those living in rural areas, or with lower socioeconomic status, are still at particular risk of inadequate access to health care. In rural areas, which are more likely to be medically underserved, disparities exist in both the scope of available care and the quality of this care.[3] For patients with specialized medical needs, this means decreased access to medical specialties and subspecialties, including high-quality rehabilitative care, new and experimental treatments, and research trials.

Barriers to access for caregivers of children with specialized medical needs can be geographical (due to lack of proximity to centers providing specialized care) or socioeconomic (due to lower insurance coverage, access to paid time off, and transportation).[4] Children with developmental disabilities living in rural areas are less likely to have seen a therapist or have a well-child checkup in the past year compared to those in urban areas.[5] Telehealth in pediatric primary care has the potential to address some of these barriers and is gaining popularity, with high parent satisfaction reported.[1,4] Various models have been explored in

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providing rehabilitation services (physical, occupational, and speech therapies) via telehealth, but protocols and evidence for their efficacy are limited.[6]

Cerebral palsy (CP) is a common cause of childhood disability, with a prevalence of 2.11 per 1000 live births.[7] Children from economically disadvantaged families, and those living in rural areas, are more likely to be diagnosed with developmental disabilities, including CP.[5,8] Children with CP benefit from specialized care initiated early to improve functional outcomes.[9] Rehabilitative telehealth delivered by skilled therapists with access to the latest evidence base could potentially expand access to care, decrease costs to families, and empower caregivers to take an active role in their child's treatment. This model of intervention delivery, which incorporates coaching and parent participation, is consistent with the World Health Organization's International Classification of Function, Health, and Disability model for CP[10] as it acknowledges environmental limitations while supporting participation.

In the current study with a new sample of participants, we sought to accomplish 3 goals. First, we describe the treatment, which was initially manualized for the larger National Institutes of Health–funded randomized controlled trial (RCT) that found it to be efficacious and safe when guided by *in-person* therapists.[11] This was adapted so that it could be used as a telehealth protocol. Second, we implemented a small pilot RCT (ie, a proof-of-concept) of the efficacy of the intervention when delivered via telehealth in reach smoothness and fine motor skill development of the most affected upper extremity (UE). Finally, we documented parents' actual adherence to the treatment protocol.

Methods

Part A: Telehealth Intervention Protocol

The intervention lasts 28 days (Figure 1).

The first session involves an in-person assessment followed by therapist demonstration and teaching of parents. At each of the 3 subsequent sessions delivered through video conferencing, the following sequence is followed:

1. Assessment of parent fidelity of treatment;
2. Demonstration of advancement of tasks and toys, if appropriate; and
3. Demonstration of parent understanding of new procedure, if appropriate.

Each telehealth session lasts 15 to 45 minutes, depending on the level of the child and the level of parental understanding. The fourth and final assessment of parent fidelity of treatment is performed in-person on the post-intervention assessment day.

Intervention Components

For the intervention group, participants wear a loose and soft-constraint harness[12] (C-Mitt) on the less affected arm to encourage the use of the more affected arm. The C-Mitt allows sensory feedback, a full range of arm motion, and use of the less affected hand as an assist or for gross motor skills such as crawling. The main restriction imposed by the C-Mitt is on fine manipulation and grasping in the less affected hand.

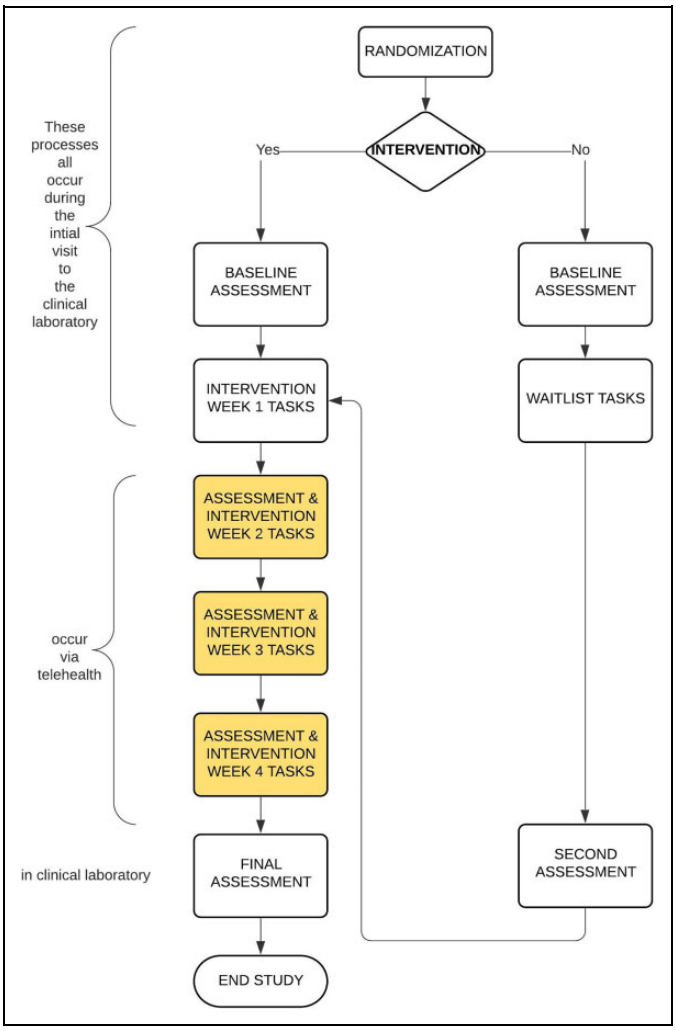

Figure 1. Training flow algorithm to determine the starting level of the intervention.

Other intervention components are listed in Table 1. Children in the waitlist group are only provided activities designed to elicit bimanual play (ie, intervention component 1 in the table). A video version of the treatment manual demonstrating each of the components of the intervention, with an explanation of the training steps and principles is available on a secure online video channel to parents and therapists throughout the intervention.

For components 3 and 4, children with less sensory-motor experience or more functional difficulties can have difficulties initiating a movement on their own upon request. In this case, a prescribed sequence of encouragement-to-demonstration, which is modified from published protocols,[14–16] and mirroring-to-parallel actions is followed by the parent (Supplemental Table 1). It is based on initiating sensory awareness of a limb (often decreased in children with perinatal brain insults),[17] followed by mirror action observation,[18–20] and only as a final step parallel movement demonstration.

Positive Parenting

Before starting the demonstration of various functional tasks, parents are educated for 20 to 30 minutes on key components of positive parenting[21–23] modified from Centers for Disease Control and Prevention

Table 1. Intervention Components.

	Intervention component	Duration
1[a]	Bimanual play with provided therapist training and suggested/provided toys	20 min/d
2	Soft-constraint harness (C-Mitt) on less affected upper extremity	6 h/d
3	Sensory-motor exploration with the non-constrained hand for provided small toys in bins with 2 sensory environments[b] ***SAFETY NOTE*:** Supervision by caregiver and removal of bins after play is critical to prevent mouthing or eating of sensory materials	10-20 min/d
4	Reaching with a mitten made "sticky" with Velcro[13] on the more affected extremity at 75% full-reach distance (shoulder level) on an adjustable tray ***NOTE*:** Objects of increased weight and size challenge incorporated for sensory reinforcement	10-20 min/d
5	Education of parents on principles of positive parenting psychology	20-30 min[c]

[a]Children in the waitlist group are only provided intervention component (1).
[b]Large fava beans provide an even warm temperature, smooth texture, and large particle size. Specialty sand in bins at a depth ~7 to 8 cm to allow small toys to be buried provides a cooler temperature, fine particle size with a sticky feel.
[c]Prior to demonstration of functional tasks.

Table 2. Study Inclusion and Exclusion Criteria.

	Criteria or methodology
Participant	
Inclusion criteria	Diagnosis of hemiplegic or asymmetric quadriplegic CP using published algorithms and neurological examination 6 to 24 months corrected age 2 years
	Asymmetric CP using Hammersmith Infant Neurological Examination Asymmetry Score >6
Exclusion criteria	Congenital brain malformations
	Receipt of botulinum toxin to the affected extremity within 3 months of study entry
	Any prior long-term hard constraint programs
Caregiver	
Inclusion criteria	Access to internet connectivity, video conferencing means in order to use platform[a]

Abbreviation: CP, cerebral palsy.
[a]Parents lacking a smartphone or internet connectivity were provided with an internet hotspot and iPad with earbuds.

guidelines.[24] In addition to what they currently do with their child that is consistent with the approach, parents were given opportunities to practice new skills. The concept of parents being central to infant's development, sense of self-confidence, and progression is emphasized. From there, the importance of consistent positive reinforcement with praise, touch, and facial expression is explained as a natural result of parents being most important in their infant's worldview. Structure is discussed with an emphasis on routines, consistency, and appropriate developmental expectations for the treatment. To help with calibrating expectations, parents are shown the importance of regular weekly reassessments with the therapist via telehealth to support them in finding a "just-right challenge" (ie, activities that allow for initial failures quickly progressing to more success with parental support).[25,26] Finally, expectations of age-appropriate attention span,[27] endurance, and limits in interest and exercise time are reviewed.

Overview of Evaluation of Starting Level and Graduated Progression of the Intervention

Prior to the start of the intervention, each child is evaluated to determine the level at which they will start the tasks. Initial completion of the fine and gross motor sections of the Bayley Scales of Infant and Toddler Development, Third Edition (Bayley)[28] enables therapists to determine the child's developmental skill level (see Supplemental Table 2). Also, at baseline, the child's skill level is observed with each toy used during intervention. Using principles in Supplemental Table 3, the sequence of a toy selection and level of assistance the child needs are decided on. Examples of each type of task are given in the next section. Throughout the treatment, the principles in Supplemental Table 3 are used to adjust expectations and assistance level as the child progresses during telehealth check-ins.

Application of Developmental Evaluation with Sensory-Motor Reaching Task

Baseline developmental reach skill (Supplemental Table 2) is assessed by demonstrating a reach with positive reinforcement (Yay, I did it!) to encourage the child to reach for an easy to grasp object (eg, a brightly colored rattle not requiring a mature grasp pattern) partially buried-in beans. The child's ability to initiate purposeful reach toward the object is noted. If child is unable to independently contact the object with their hand, the intervention is instead initiated at the *basic level* with larger, visually attractive objects (eg, large colorful infant easy to grasp balls or light-up toys). If successful with reaching, the child is assessed for the ability to independently grasp the toy. Maturity of grasp pattern as compared to a sequence for age in typically developing children[29–31] is noted (Supplemental Table 2). If the child is unable to grasp or demonstrates an immature or ineffective grasp pattern, the intervention is initiated at the *basic level* with a variety of toys selected to encourage increased maturity and variety of grasps (appropriate to the child's corrected age), while allowing for successful completion of the task. For children who are already consistently

Table 3. Participant Characteristics.

	N	Immediate	Waitlist	*P*
Distance, median [IQR], kilometers	13	150 [13-312]	152 [146-190]	.65[a]
Corrected age at intervention, median [IQR], completed months	13	12 [10-15]	10 [9-11]	14[a]
GMFCS at baseline	13			.42[b]
Level I		1	0	
Level II		0	2	
Level III		2	3	
Level IV		4	1	
MACS at baseline	13			.85[c]
Level I		2	0	
Level II		0	2	
Level III		2	3	
Level IV		3	1	
HINE AS, median [IQR]	13	10 [7.5-13.5]	11 [9.5-11.75]	.65[a]
HINE Total, median [IQR]	13	45 [33.5-53.5]	46 [40.5-48.5]	.85[a]

Abbreviations: GA, gestational age; GMFCS, Gross Motor Function Classification System, HINE, Hammersmith Infant Neurological Exam; IQR, interquartile range; MACS, Manual Abilities Classification Scale; N, number of non-missing values.
[a] One-way group-level analysis of variance.
[b] Chi-squared.
[c] Chi-squared performed between I/II and III/IV.

Table 4. Baseline Upper Extremity Assessments.[a]

Dependent variables	N	Immediate M (SD)	Waitlist control M (SD)	*P*
Movement units: kinematic measure of reach smoothness	10	6.7 (3.9)	5.1 (2.3)	.43
Bayley measure of fine motor capacity	13	6.9 (5.9)	6.7 (4.6)	.95
Bayley measure of bimanual fine motor capacity	13	2.7 (1.6)	2.8 (1.0)	.88
Bayley measure of gross motor capacity	13	27.4 (9.1)	25.5 (5.4)	.66

[a] Group-level analysis of variance.

reaching and grasping partially buried toys, the intervention is initiated at the *advanced level*. In general, children with a 3-5 month grasp maturity start at basic levels, while those at a 6 months and above start at the advanced level.

Sensory-motor exploration sessions (1 session/day: 12-15 attempts per container)

A. Box with sand: The goal of this activity is to teach the child how to reach through a dense, gritty, and cool material, helping the child to be aware of their hand.
B. Container with beans: The goal of this activity is to teach the child how to reach through a warm, smooth, and shifting material, also helping the child to be aware of their hand.

Procedure

1. At the first training session (occurring in-person), the therapist demonstrates *Activity A* (box with sand) and *Activity B* (container with beans) (Supplemental Table 4). The caregiver is advised to start with whichever container the child preferred after being verbally offered a choice: "Would you like the sand first or the beans first?" and given the opportunity to indicate a preference.
2. Caregiver places the box/container in front of the child (close to body and below elbow height), either on the child's lap or on table/tray in front of child, with the caregiver facing the child.
3. After the therapist demonstrates each task, the caregiver is asked to practice performing the task under supervision until the caregiver is consistent with the protocol (even if the child was not).
4. Progression to more advanced task: When the child can consistently (ie, 8 out of 10 trials) and independently grasp and remove toys from bin, the caregiver is instructed to progress to the advanced reaching task level (Supplemental Table 4).

Application of Developmental Evaluation With Sticky Mitten Task

Child's baseline skill level is evaluated by placing a large and light object with Velcro on it (eg, large plastic ball or bath toy animal) on a block at shoulder level at 75% full-reach. If child is unable to start at the *basic level* at *shoulder-level height*, the object is placed on the tray at midline, approximately at *elbow level*. If the child is successful, but difficulty with the task is observed (in particular, difficulty with elbow extension and forearm supination), the activity is started at the *basic level*. If the child is successful at shoulder level and the task appears easy with good fluency, the activity is started with more difficult to hold

Table 5. Post-Intervention Outcomes.[a]

Dependent variables	N	Immediate M (SD)	Waitlist control M (SD)	*F*	*df*,*df*	*P*
Movement units[b] (reach smoothness)	10	3.6 (0.6)	4.9 (0.5)	2.1	1,7	.19
Bayley unimanual fine motor	13	9.6 (1.0)	5.2 (1.1)	8.2	1,10	**.02**
Bayley bimanual fine motor	13	3.5 (0.4)	2.6 (0.4)	2.4	1,10	.15
Bayley gross motor	13	29.5 (0.8)	28.4 (0.8)	0.8	1,10	.38

[a]Pretest-adjusted immediate posttest means, SDs, tests of significance, and *P* values for between-group differences. Adjusted means, *F*, and *P* for groups of dependent variable outcomes post-intervention.
[b]For movement units, a lesser number indicates a smoother reach, as a perfectly smooth reach would have only 1 to 2 movement units. *P* value from analysis of covariance.
Bold *P* values were significant ($P < .05$).

and *heavier* objects (eg, baseball) and with objects placed approximately *10 degrees above shoulder level* (*advanced level*).

Sticky mitten sessions (1 session/day, 12-15 attempts). The goal of this activity (Supplemental Table 5) is to allow the child to mimic "grasping" in a way that allows them to be successful. This experience of successful reach and grasp is designed to encourage the child to attempt to reach for toys more independently.

Procedure

1. Provided tray is placed in front of the child on their highchair/toddler seat tray or table.
2. With C-Mitt donned, the sticky mitten is placed on the child's unrestrained hand, with outside-facing Velcro oriented toward the palm side of their hand. Caregiver ensures that the mitten is snug so as not to sag or fall off as the child reached.

Bimanual Task/Two-Handed Play Sessions (1 session/day, 12-15 attempts). The goal of this activity (Supplemental Table 6) is to develop bimanual (two-handed) skills. The C-Mitt is removed for this task and the child is allowed to use both hands. Toys that require two hands for successful play are selected.

Part B: Feasibility Pilot

Trial Design

This was a prospective between-group experiment involving random assignment of parent–child dyads to either intervention or waitlist control groups (see Figure 2).

This was a convenience sample that represented 20% of the initial large RCT-powered sample. Participants were randomly assigned to groups with a 1:1 allocation using permuted blocks of random sizes. Allocation concealment was implemented by using unidentifiable study numbers. Parents could not be masked to allocation due to the waitlist design, but dependent variables were not derived from parent reports or parent–child interaction sessions. The authors controlled for assessment bias by using examiners who were unaware of children's treatment group assignment. For example, Bayley examiners at posttest were different from treating therapists.

Infant participants were selected on the basis of 6 to 24 months corrected age and the presence of asymmetrical CP. Other child and caregiver inclusion and exclusion criteria are listed in Table 2. Infants were screened for eligibility in the electronic medical record of outpatient clinical therapy notes, and the Neurology/Stroke and High-Risk Infant Follow-up clinics at Nationwide Children's Hospital.

The first participant was enrolled on December 5, 2018, and the last participant completed the intervention on May 16, 2019. Relevant to the geographic access to care issue, the median one-way distance to the hospital was 150 km (94 miles) interquartile range (IQR) = 125-312 km (78-195 miles), range 8-1709 km (5-1068 miles). All data, including assessments and review of the clinical neuroimaging record to ensure that the primary insult is consistent with a diagnosis of CP (encephalopathy of prematurity with white matter injury, neonatal encephalopathy, and perinatal infarct/thrombosis), were collected at Nationwide Children's Hospital and were recorded in REDCap[32] (Research Electronic Data Capture). Children with congenital brain malformations were excluded because many are associated with genetic conditions[33] and do not respond to treatments in the same way.[34] Ethical approval (IRB15-00547) was obtained from institutional review board (IRB) of Nationwide Children's Hospital on June 18, 2015. Written informed consent was obtained for each subject per protocols approved by the hospital's IRB.

Monitoring of compliance with the intervention was accomplished using 2 procedures. First, we inserted a movement sensor (Fitbit One; Fitbit) in the soft constraint to measure wear time. Coordinator input login and password information into the Fitbit smartphone app that corresponded with the corresponding Fitbit used during intervention. Fitbit data were downloaded on a weekly basis through the Fitbit application. If the caregiver did not have a smartphone, a dongle (Dongle Dangler; Smart Tech Innovations, LLC) was provided for data download through USB. Second, during weekly video conferences, 2 independent raters scored parents' fidelity of the intervention each week during the intervention using a checklist that addressed all 5 components of the intervention while parents demonstrated how they administered the intervention at home.

Overview of Dependent Variables

Two *a priori* primary motor outcome measures were chosen: (1) Smoothness of reach of the more-affected UE, which was

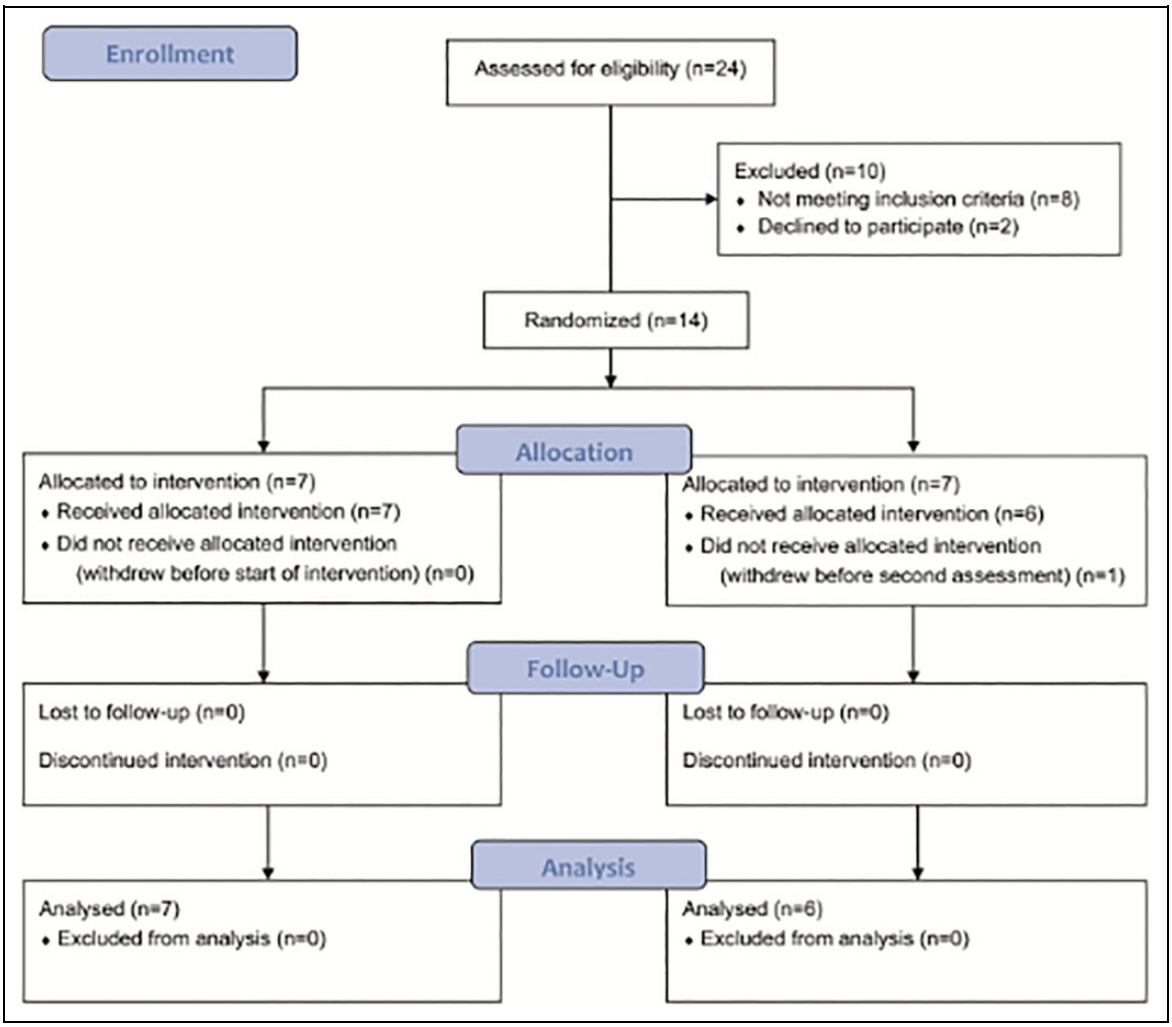

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

considered a proximal motor outcome, and was measured using the number of movement units derived from a kinematic analysis during a standardized paradigm, and (2) fine motor skill in the more-affected hand, which was considered a distal motor outcome, and was measured using the Bayley unimanual raw score.

Although deemed less likely to change due to the intervention, we also examined the following secondary outcomes: Bayley gross motor raw scores and bimanual Bayley raw scores.

Assessment Procedures

Kinematic measures of reach. Infants were seated in a fixed high-chair with a model tray to ensure objects were placed at 75% full-reach, shoulder level, and midline. Blind examiners followed a scripted algorithm of toy presentation to elicit reach. Video-recorded trials and written data regarding trial details were maintained separately. Videotaped movements were analyzed with Vicon X system (Vicon Motion Systems Ltd) software and data were extracted using published MATLAB algorithms.[35] Smoothness of reach, quantified as the number of movement units, has high validity and reliability as an outcome measure for UE intervention trials in children with CP.[36] In the current study, the average number of movement units was calculated from the velocity peaks. Variables were extracted during the first 3 trials in which infants had hand-toy contact with a small ball; trials without hand-toy contact were eliminated as un-codable. Positional data were extracted, and kinematic parameters were calculated in MATLAB software by off-site analytic staff blind to the intervention group.

Bayley measures of motor skill level. Bayley Gross Motor and Fine Motor subscales were administered using standard and published protocols.[28,37] Assessment reliability among testers was established to achieve >90% by a central examiner, who is the site gold standard for Neonatal Research Network[38] Bayley testing, and is recertified annually. In addition to gross motor subscale raw scores, we determined raw scores for unimanual fine motor items for both less- and more-affected UE (and

bimanual fine motor items). Mild restraint of the less-affected extremity was administered, as necessary, when testing the more-affected UE.[37]

Statistical Analysis

The analysis followed intent-to-treat principles, regardless of wear time of the C-Mitt or parent-implemented intervention fidelity. Treatment effects were tested using analysis of covariance to test for between-group differences on immediate posttest scores controlling for the pretest of the dependent variable. To most accurately estimate treatment effect size, we calculated the pretest adjusted immediate posttest standardized means between the intervention and waitlisted groups. SPSS Statistics v. 26.0 (IBM) was used for analyses.

Results

At pretest, infants had a median age of 11 months corrected age (IQR = 9-12 months). The 2 randomized groups did not differ statistically in any demographic or CP characteristics, although the numbers were small in each group (Table 3). In addition, there were no pretest differences between intervention and waitlist groups on any dependent variables (Table 4; unadjusted *P* values .43 to .95).

Infants in the intervention group had median C-Mitt wear time of 21 h/wk (IQR = 10.3-29.7), equivalent to 3 h/d for the 28 days of the intervention. Average parent intervention fidelity was as follows: week 1 = 93.3% SD = 12.4, week 2 = 100%, week 3 = 94.6% SD = 14.3, and week 4 = 95.0% SD = 13.3.

All infants in this pilot completed the intervention, but one did not complete the waitlist, resulting in 7 infants in the intervention and 6 in the waitlist group.

Treatment Effects

Table 5 provides the pretest-adjusted immediate posttest means and SDs for the dependent variables by group. There were no significant between-group differences on smoothness of reach, fine or gross motor scores; SDs were large. There was a significant between-group difference on unimanual function of the most affected UE as measured with the Bayley unimanual fine motor raw score, with an adjusted effect size of Cohen $d = 0.92$, $P < .05$.

Discussion

This study demonstrates the feasibility of a telehealth-based, parent-administered UE intervention for infants with asymmetric forms of CP. With initial in-person training and ongoing coaching by experienced therapists, parents were able to deliver a targeted intervention with good fidelity. The intervention group showing a significant improvement in unimanual fine motor skills compared to the waitlist control group, but this result should be interpreted with caution due to the small sample size and preliminary nature of this study. Large randomized controlled studies would be necessary to confirm effectiveness of the intervention delivered through telehealth. It is also likely that more than 4 weeks of intervention would be necessary for this new format, as a dosage of early developmental interventions is much debated in the CP literature.[39–41]

Current practice often involves using therapist-implemented outpatient UE therapy in a clinical setting, sometimes with limited hands-on participation from parents. These programs can be difficult to access due to geographic, economic, or social constraints. At a general level, the cost of administration of telehealth for our intervention was comparatively low due to fuel costs and potential loss of parent work hours. At a specific level, travel costs per intervention session in the current study were difficult to estimate as the combination of fixed and variable travel expenses requires in-depth analysis of vehicular characteristics. However, using the Internal Revenue Service[42] rate for 2020, an annually reevaluated metric, the median cost of a round trip to the specialized therapists at our tertiary care center is $109.25 (US) per session. Lost wages which include travel time and session time are also difficult to evaluate as the parents in our cohort ranged from stay-at-home mothers to employed graduate professionals. Based on the published average professional salaries for the region,[43] approximate lost wages per session ranged from US$0 (and 1.45 hours) for the former to US$349 (and 6 hours) for the latter. Another consideration for state Early Intervention programs involves the costs of therapist wages and productivity. A study of cost-effectiveness comparing telehealth to outpatient early intervention or in-home early intervention therapist treatment demonstrates that the respective models' per-session-costs averaged US$54.02, US$138.63, and US$142.64.[44] While this study considered wages, drive time, fuel, and vehicular costs from 2015 data, a telehealth was approximately one-third the cost of an in-person session. Annualized costs supported this calculation. At the time, no carbon-footprint calculators were easily available, but current concerns about global warming can also be considered in future calculations. Finally, our telehealth intervention model allows for rapid response to health crises such as viral pandemics, when those individuals with disabilities are a high risk of no longer receiving needed services and assistance.[44,45]

Studies of telehealth in state Early Intervention programs for autism spectrum disorders demonstrated that parents had high acceptability and satisfaction levels for this mode of service provision. Conversely, challenges in implementing telehealth for early intervention identified in a large provider survey in Colorado included:[46] lack of specialized provider training in adapting to telehealth, lack of protocols, possible problems with access to technology/internet, and finally attitudinal barriers that reflected concerns of connecting with parents. The current protocol, with its targeted intervention, protocolized approach, adaptability to remote settings without existing technology, and strong parent-coaching component addresses many of these concerns. Enhancements that would allow telehealth protocols to be used even more widely including providing connectivity for those families who do not have internet access, usage of high-speed intuitive platforms, and if necessary, supporting

caregivers with appropriate technology (tablets and listening devices) for communication, remote training, and assessment.

The SARS-CoV-2 pandemic crisis with resultant social distancing highlights the need for effective, evidence-based interventions to be adapted to a telehealth model, to ensure continuity of care for children at risk of delays. Even outside the context of a global health crisis, this model has the potential to expand the reach of specialized rehabilitative care to underserved populations, without compromising the quality of care or outcomes.

Future evaluations using RCTs are necessary to determine whether this highly protocolized approach to upper-extremity intervention can be effective in multiple settings with varied challenges, such as those disclosed by institutions in a clinical network of institutions that implemented early diagnosis of CP guidelines.[47]

Authors' Note

Trial Registration: NCT02567630, registered October 5, 2015, ClinicalTrials.gov.

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Author Contributions

LP contributed to design contributed to acquisition and interpretation, drafted manuscript, critically revised manuscript, gave final approval, and agrees to be accountable for all aspects of work ensuring integrity and accuracy. SB contributed to design contributed to acquisition and analysis, drafted manuscript, critically revised manuscript, gave final approval, and agrees to be accountable for all aspects of work ensuring integrity and accuracy. PJY contributed to conception, analysis, and interpretation; drafted manuscript; critically revised manuscript; gave final approval; and agrees to be accountable for all aspects of work ensuring integrity and accuracy. JH contributed to design, analysis, and interpretation; drafted manuscript; critically revised manuscript; gave final approval; and agrees to be accountable for all aspects of work ensuring integrity and accuracy. DJL contributed to design and interpretation, drafted manuscript, critically revised manuscript, gave final approval, and agrees to be accountable for all aspects of work ensuring integrity and accuracy. NLM contributed to conception and design, acquisition, analysis, and interpretation; drafted manuscript; critically revised manuscript; gave final approval; and agrees to be accountable for all aspects of work ensuring integrity and accuracy.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr Maitre reports USPTO 29/577,142 (C-MITT, Soft Constraint Harness for Infants 6-27 Months – for Filing Design Application), pending, freely available to the general public on the NCH website at https://www.nationwidechildrens.org/-/media/nch/research/documents/cmitt-design-patent.ashx.

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Ethical Approval

Ethical approval (IRB15-00547) was obtained from Nationwide Children's Hospital Institutional Review Board (IRB) June 18, 2015.

Supplemental Material

Supplemental material for this article is available online.

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