
Multicenter Randomized Controlled Trial of Pediatric Constraint-Induced Movement Therapy: 6-Month Follow-Up

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KEY WORDS

- cerebral palsy
- exercise movement techniques
- functional laterality
- motor skills
- pediatrics
- restraint, physical

OBJECTIVE. Pediatric constraint-induced movement therapy (CIMT) is a promising intervention for children with unilateral cerebral palsy (CP). This multisite randomized controlled trial (RCT) tested the hypothesis that 6 hr versus 3 hr per day for 21 days would produce larger maintenance of gains 6 mo posttreatment.

METHOD. Three sites recruited 18 children (6 per site) ages 3–6 yr with unilateral CP. Children were randomly assigned to 3 or 6 hr/day of CIMT for 21 days and wore a cast on the unaffected extremity the first 18 days. Occupational therapists applied a standardized pediatric CIMT protocol. Evaluators blinded to condition administered the Assisted Hand Assessment and the Quality of Upper Extremity Skills Test, and parents completed the Pediatric Motor Activity Log pre- and posttreatment (1 wk, 1 mo, and 6 mo).

RESULTS. Both CIMT dosage groups showed significant gains on all five assessments with no significant group differences at 6-mo follow-up. Effect sizes ($n = 15$) comparing preintervention to postintervention measures (partial η^2) ranged from .33 to .80.

CONCLUSION. This first multisite RCT of pediatric CIMT confirmed the maintenance of positive effects at 6 mo follow-up across multiple functional performance measures. The hypothesis that maintenance of effects would differ for children who received 6 versus 3 hr/day of CIMT (126 vs. 63 total hr) was not supported.

Case-Smith, J., DeLuca, S. C., Stevenson, R., & Ramey, S. L. (2012). Multicenter randomized controlled trial of pediatric constraint-induced movement therapy: 6-month follow-up. *American Journal of Occupational Therapy, 66*, 15–23. doi: 10.5014/ajot.2012.002386

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Children with unilateral cerebral palsy (CP) often demonstrate limited reach, grasp, and manipulation in the involved upper extremity. These limitations affect their functional activities, including object play, social play, self-care, and educational activities. Most children with unilateral CP learn to perform tasks primarily using their noninvolved arm with minimal to no use of the involved arm (a phenomenon termed *developmental disregard*; Deluca, Echols, Law, & Ramey, 2006).

Constraint-induced movement therapy (CIMT; Ostendorf & Wolf, 1981) is a short-term, intensive intervention that involves constraint of the non-involved arm and intensive movement practice of the involved arm. It was developed in the 1980s and has been successfully used with adults (Wolf, Lecraw, Barton, & Jann, 1989) and children (Charles, Wolf, Schneider, & Gordon, 2006; Deluca et al., 2006). Most pediatric protocols consider the child's age and interests, are specifically adapted to the child's type and level of impairment, and usually include an educational component for caregivers to encourage practice of newly gained skills.

Several CIMT trials with children have been published in the past decade (Aarts, Jongerium, Geerdink, van Limbeek, & Geurts, 2010, 2011; Charles et al., 2006; Deluca et al., 2006; Eliasson, Krumlinde-Sundholm, Shaw, &

Wang, 2005; Taub, Ramey, DeLuca, & Echols, 2004; Stearns, Burtner, Keenen, Qualls, & Phillips, 2009; Willis, Morello, Davie, Rice, & Bennett, 2002). Eliasson and colleagues (2005) conducted a controlled and blinded clinical trial of 41 children (ages 18 mo–4 yr) in Sweden in which 25 participants completed 2 mo of CIMT and 20 served as a control group. Constraint of the involved arm occurred 2 hr/day, 7 days/wk via a glove and a volar splint. Treatment was based on principles of motor learning. The CIMT group improved significantly more than the control group on the Assisting Hand Assessment (AHA; Krumlinde-Sundholm, 2003) at both posttest (effect size = 1.16) and 1-mo follow-up (effect size = 0.72).

Charles et al. (2006) completed a randomized, blinded trial of CIMT with 22 children (11 intervention, 11 control). The intervention schedule included 6 hr/day of treatment on 10 of 12 consecutive days during which the child wore a sling on the noninvolved arm. The CIMT group improved more on functional assessments of movement efficiency and dexterity immediately after treatment and at 6-mo follow-up.

In the largest trial to date, a team of Netherlands researchers (Aarts et al., 2011) investigated the effectiveness of modified CIMT (mCIMT) using a sample of 50 children with unilateral CP (28 in the mCIMT group and 22 in usual care). Children in the mCIMT group participated in a playful intervention while constrained using a sling for 6 wk; in the last 2 wk the restraint was removed and bimanual play was emphasized. The mCIMT group received 9 wk of 9 hr/wk of therapy. The usual-care group received 1.5 hr/wk of therapy. When the two groups were compared at 9 wk, the mCIMT group improved 2.5 times more on the AHA (Cohen's $d = 0.43$) and 7 times more on the ABILHAND-Kids (Arnould, Penta, Renders, & Thonnard, 2004; Cohen's $d = 1.01$) than the usual-care group. These scores were maintained at 17 wk.

Our study used a CIMT protocol developed by Deluca and colleagues (2006) in which the child wears a univalved cast 24 hr/day on the noninvolved arm while participating in an intensive intervention (6 hr/day for 21 treatment days). In this CIMT protocol, termed *ACQUIREc* (DeLuca, Echols, & Ramey, 2007), the child participates daily in 6 hr of therapy using motor learning and shaping. In shaping, the therapist designs activities that place increasing demands on the child to demonstrate more precision, strength, and coordination with the involved arm. The child is encouraged to attempt these more difficult tasks and to practice the movement patterns for repeated trials with reinforcement. The

intervention activities are administered in natural environments and use meaningful tasks (e.g., grooming a pet, making cookies, taking a bath) targeted to promote generalization and transfer of skills to the child's life situation. Using a randomized controlled crossover design with 18 children, Deluca et al. (2006) compared the performance of treatment and control groups using the Quality of Upper Extremity Skills Test (QUEST; DeMatteo et al., 1992), the Pediatric Motor Activity Log (PMAL; Deluca et al., 2006; Taub et al., 2004), and the Emerging Behaviors Scale (Taub et al., 2004). The children who received *ACQUIREc* improved significantly more than control participants on all measures. The researchers reported that all the children were positive responders, adapted well to the cast, had positive treatment experiences, and completed the treatment. Effects were maintained 6 mo later.

A Cochrane Review of pediatric CIMT (Hoare, Imms, Carey, & Wasiak, 2007) analyzed the findings of three randomized controlled trials (RCTs). Although each of the RCTs found significant improvement in the involved arm as measured by functional assessments, the effects were judged to be moderate and inconsistent. More recently, Huang, Fettes, Hale, and McBride (2009) completed a systematic review of CIMT trials for children with CP. They analyzed the validity and rigor of 21 trials and found that effect sizes (which could be computed for only four studies) ranged from medium to large ($ds = 0.6$ – 1.61). The researchers noted that both the type and the duration of constraint on the noninvolved upper extremity varied considerably across studies. In addition, the intervention duration and intensity (i.e., daily amount of therapy) varied from a minimum of 6 to a maximum of 126 total hours, without any compelling evidence about optimal duration or intensity. The conclusion from each of these major reviews was the same: Findings for CIMT are promising, but additional trials are critically needed. Although most trials use an intensive form (2–6 hr/day) of short-term therapy (10–21 days), consensus has not been reached on the differential effects of dosage (or intensity) of therapy or a minimum threshold to produce significant effects. Huang et al. (2009) specifically recommended further study of long-term effects of CIMT, particularly as these relate to different treatment dosage levels. The purpose of the multisite RCT described in this article, considered a Stage 2 clinical trial, was to better define intervention protocols, monitor safety and tolerability, and examine treatment dosage and efficacy (Dobkin, 2009) of the *ACQUIREc* method of CIMT. Details of this trial have been reported

elsewhere (DeLuca, Case-Smith, Stevenson, & Ramey, in press), and this article highlights functional outcomes at 6-mo follow-up.

Method

Research Design

Our team of interdisciplinary investigators designed this RCT on the basis of past clinical trials and critical reviews. Specifically, the intervention protocol included casting for continuous constraint during the intervention period and intensive intervention using motor learning and shaping techniques. Three of four collaborating universities—University of Alabama at Birmingham (UAB), Ohio State University (OSU), and University of Virginia (UVA)—recruited children and provided intervention. Georgetown University (GU) served as the Data Coordinating and Analysis Center (DCAC). The institutional review boards of all four universities approved the study, and we obtained informed consent from the parents or guardians of all participating children to be randomly assigned to one of two CIMT dosage conditions. The DCAC assigned children to treatment groups, and parents were informed shortly after enrolling. The study compared two dosage levels of CIMT: a 3 hr/day protocol and the previously tested 6 hr/day protocol (DeLuca et al., 2006, in revision).

Study Hypotheses

We tested two hypotheses:

1. Children with unilateral CP who receive 3 hr/day or 6 hr/day of CIMT for 21 days will show significant improvements in functional use of their upper extremity at 6-mo follow-up.
2. Children with unilateral CP who receive 6 hr/day of CIMT versus 3 hr/day for 21 days will show greater gains (higher levels of maintenance) at 6-mo follow-up.

Participants

Eighteen children ages 3–6 yr diagnosed with unilateral CP were recruited. All children had central nervous system lesions clinically judged to have occurred before 1 mo of age. Exclusion criteria included the use of botulinum toxin within the past 6 mo, previous participation in a formal CIMT program, the presence of major uncontrolled seizures or comorbid medical conditions, or the presence of visual impairment. After screening and enrollment, the DCAC randomized children to either the 3 hr/day or 6 hr/day treatment group by means of a computer-generated randomization table.

Measures

Participants' upper-extremity function was comprehensively assessed using two standardized assessments (producing three scores) and one parent report tool (producing two scores). Trained assessors who were blinded to group assignment administered the standardized measures within 1 wk before initiation of intervention and within 1 wk, at 1 mo, and at 6-mo follow-up.

The AHA is a standardized test for children with unilateral CP ages 18 mo–12 yr. The AHA measures the child's ability to use the affected hand to assist the unaffected hand in a variety of bimanual activities. The 15- to 20-min assessment session uses semistructured play with specific items. The session is videotaped and then scored on the basis of the child's displayed willingness and ability to use the weaker arm and hand. The AHA has 22 items each scored from 1 to 4. Using Rasch analysis, the developers demonstrated that the AHA can reliably separate and spread personal ability, is sensitive to change in performance, and represents a hierarchy of items ranging from easy to hard (Krumlinde-Sundholm, Holmefur, Kottorp, & Eliasson, 2007). Content validity was established during the initial development (Greaves, Imms, Dodd, & Krumlinde-Sundholm, 2010). For our study, a pediatric physical therapist certified in scoring the AHA by its developers and blinded to treatment group and testing period scored all AHA sessions. Scores were converted to logits (equal interval scores that account for item difficulty) using Rasch analysis–derived scores. We used the logit scores in our data analysis.

The QUEST measures upper-extremity movement patterns and hand function in children with CP ages 18 mo–8 yr. The test assesses upper-extremity dissociated movements, grasp, protective extension, and weight bearing. We used only the Dissociated Movement and Grasp/Release sections of the QUEST; the revised protocol used 27 of 36 items and took approximately 20 min to complete. The evaluating therapist scored items immediately after administration. Test–retest and interrater reliabilities of the QUEST are high, as is concurrent validity with the Peabody Developmental Motor Scale–Fine Motor (DeMatteo et al., 1992, 1993).

The PMAL is a parent-report tool of the child's frequency and quality of use of the affected upper extremity. Parents rate how often and how well their child performs 22 specific arm–hand functional tasks typical for young children ages 2–8 yr (e.g., holding a cup, eating finger foods, crawling on the floor, taking off shoes and socks). Items for both the How Often and How Well scales are rated from a low of 0 to a high of 5, with

specified descriptors for each numerical rating. Parents are instructed to use the past month as their frame of reference for judging how often and how well the child used his or her arms and hands. The PMAL was adapted from the adult Motor Activity Log, which demonstrated high internal consistency (Cronbach's α s = .88–.95) and high test–retest reliability ($r = .94, p < .01$; Taub, Uswatte, & Pidikiti, 1999).

Intervention

The CIMT protocol had three primary components: (1) casting the child's noninvolved arm for continuous constraint during the first 18 days of treatment; (2) administering an intensive, structured intervention protocol using motor learning and shaping principles to induce and refine many upper-extremity skills and movements; and (3) providing intervention in natural settings using individualized activities and objects that are motivating to the child and will continue to be part of the child's daily life after treatment ends.

After baseline assessment, a trained therapist casted the child's stronger or noninvolved arm from the axillary area to the end of the fingertips, with the elbow positioned in 90° flexion. She placed the child's wrist and fingers in a neutral position with the thumb abducted. Stockinette (Alba-Waldensian, Valdese, NC) and padding were applied under the cast. Immediately after casting, the therapist univalved the cast for easy removal and wrapped Coban (3M, St. Paul, MN) around the cast to form an outer layer that looked and felt continuous to the child. The therapist removed the cast once a week during the intervention period to check skin integrity and allow the child 15–20 min of active range of motion. No significant skin or range of motion problems occurred.

The 21 days of CIMT occurred over 4 wk. On each of the 21 intervention days, the therapists worked with the children for either 3 or 6 continuous hours, depending on group assignment. The therapist structured the practice of arm and hand movements into activities of daily living (e.g., dressing and undressing, eating, grooming) and play activities. The intervention incorporated the following principles of motor learning:

- Specificity of learning by means of particular tasks in the natural environment that required specific upper-extremity movements
- Blocked and random practice, with blocked practice used when a skill was first introduced and intermittent random practice after the skill was at least partially established
- Extrinsic and immediate feedback to reinforce the child's movement, improve motivation, and reduce error

- Transfer of learning to encourage the child to use the new movement patterns in a variety of settings and tasks (O'Brien & Williams, 2010; Schmidt & Wrisberg, 2000).

Intervention tasks included upper-extremity weight bearing and reaching, grasping, and manipulating objects. All tasks required the child to move his or her upper extremity repeatedly and intermittently. New or challenging movement patterns were also systematically introduced as movements and skills progressed, increasing the demands for more precision, strength, fluency, and automaticity—a technique labeled *successive approximations* (e.g., shaping; DeLuca et al., 2007; Stearns et al., 2009). Some therapy activities also focused on developing sensory awareness. The young children displayed enjoyment from natural reinforcement of effort (e.g., completion of puzzle, activation of toy). The therapists provided immediate and frequent rewards primarily in the form of verbal praise, smiles, and supportive gestures to encourage the children to sustain their efforts.

All children received intervention in natural settings (e.g., their home, temporary homelike accommodation, park, community setting). Theoretically, providing treatment in the natural environment promotes the child's comfort (Campbell, 2004); affords many natural opportunities for extending and practicing new skills (Humphry, 2002); allows the therapist many opportunities to model interactions for the parent (Dunst, Trivette, Humphries, Raab, & Roper, 2001); and promotes higher levels of generalization, transfer, and long-term maintenance than unfamiliar clinic or lab settings (Humphry & Wakeford, 2006). The therapist encouraged parents, siblings, and other relatives and friends to join in specific activities. All parents agreed in advance to attend at least 1 intervention day each week.

At the end of intervention Day 18, the therapist removed the cast and shifted the focus of the intervention for the final 3 days to bimanual activities. The therapist continued to use shaping and motor learning procedures with a strong emphasis on using new and improved skills in the child's daily life.

Intervention Fidelity

The therapists in the study videotaped their intervention activities 3 times each week (for a total of 12 sessions) to evaluate treatment fidelity. They also maintained systematic daily treatment logs that included the specific skills and activities practiced, frequency of administration, any behavioral or logistical challenges encountered, and daily progress observed. The experienced clinical research staff at UAB monitored fidelity by reviewing and analyzing the

videotapes and intervention logs using a fidelity checklist developed for the study.

Data Analysis

The investigators from each research site submitted assessment data to the Georgetown DCAC for data entry and analysis. We examined treatment dosage, site differences, and age and gender effects. We used repeated-measures analysis of variance to test for main effects of group and time and interaction effects related to group (i.e., dosage level), site (UAB, OSU, UVA), and assessment time (preintervention, postintervention, 1-mo follow-up, and 6-mo follow-up). We completed post hoc analyses for each time period using *t* tests. We used PASW/SPSS version 18 (SPSS, Inc., Chicago) to perform data analysis and compute effect sizes.

Results

All 18 children recruited into the study completed the intervention and were assessed within 1 wk and at 1 mo postintervention. Three of the 18 children (1 in the 3 hr/day condition and 2 in the 6 hr/day condition), however, did not complete the 6-mo follow-up assessment because of scheduling issues. Table 1 presents the gender, ages, and affected sides for study participants.

Effect of Intervention Across Time

Site differences across measures were not significant; therefore, participants were combined into two main groups (3 hr/day and 6 hr/day) for the remaining analyses. Table 2 presents results for the AHA and the QUEST at all four testing times. Children in both dosage groups showed significant improvement across time after receiving intervention. Specifically, the children's scores increased ($p \leq .01$ for the main effect of time) on both standardized assessments; effect sizes (η_p^2) ranged from .34 to .63.

Table 3 presents parent ratings on the PMAL. Parents' ratings of how well ($F[1, 14] = 14.71, p < .001$,

$\eta^2 = .71$) and how often ($F[1, 14] = 20.7, p = .001, \eta^2 = .78$) their children used their arm reflected significant improvement and high effects.

Differences Between Groups

The Time \times Group effect was not significant for any of the measures, indicating that a similar effect was achieved by both intervention groups. The 6 hr/day group demonstrated higher performance with the affected arm than the 3 hr/day group at baseline and remained higher at each measurement time.

Maintenance of Effects

The significant improvement in the children's performance during the intervention was maintained at 6 mo. Post hoc *t* tests revealed a significant difference for time from pre- to postintervention but not between any other postintervention periods. Although the participants appeared to lose a small amount of their posttreatment gains, the decline was not statistically significant. Table 4 presents the effect sizes (η^2) for pre- to postintervention scores and preintervention to 6-mo follow-up scores, demonstrating that the level of effect was maintained in all measures except QUEST Dissociated Movements. Because the general linear model analysis did not show any Group \times Time effects across all four measurement times, our hypothesis that the higher dosage group would show higher motor function at 6-mo follow-up was not supported.

Discussion

This Stage 2 multisite RCT examined intervention efficacy and dosage effects associated with the ACQUIREc protocol of pediatric CIMT. This protocol uses 24 hr/day casting, 21 days of intervention within a 1-mo period, and daily CIMT therapy sessions. Previous RCTs of ACQUIREc (Deluca et al., 2006; Taub et al., 2004) found moderate to strong effect sizes. This RCT examined whether a lower dosage (3 hr/day vs. 6 hr/day) of the

Table 1. Children's Characteristics, by Site

Characteristic	UAB	OSU	UVA	Total Sample
Age (mo), <i>M</i> (<i>SD</i>)	43.80 (9.50)	48.00 (14.70)	53.50 (12.19)	48.7 (12.19)
Gender, <i>n</i>				
Male	3	3	4	10
Female	3	3	2	8
Hemiparesis, <i>n</i>				
Right	3	1	3	7
Left	3	5	3	11

Note. *M* = mean; OSU = Ohio State University; *SD* = standard deviation; UAB = University of Alabama at Birmingham; UVA = University of Virginia.

Table 2. Children's Mean Scores on Standardized Functional Assessments, by Dosage Group and Assessment Period

Assessment and Dosage Group	Preintervention		Postintervention		1-Mo Follow-Up		6-Mo Follow-Up		Within-Subject Effects for Time ^a
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	
AHA									
3-hr group	-1.13	4.3	0.84	3.3	1.08	3.8	1.37	3.2	$F(1, 14) = 13.69, p < .001$
6-hr group	1.70	3.6	3.03	3.9	2.55	3.7	3.14	4.1	$\eta_p^2 = .63$
QUEST Grasp/Release									
3-hr group	4.50	2.6	4.50	2.6	5.25	3.1	6.13	2.9	$F(1, 14) = 4.6, p = .01$
6-hr group	4.14	2.6	5.0	2.6	5.73	3.0	5.86	3.6	$\eta_p^2 = .34$
QUEST Dissociated Movement									
3-hr group	15.38	5.9	22.13	6.0	22.25	6.3	19.9	5.5	$F(1, 14) = 7.6, p = .001$
6-hr group	19.43	9.0	21.86	9.1	23.22	8.5	22.6	7.2	$\eta_p^2 = .49$

Note. AHA = Assisting Hand Assessment; *M* = mean; QUEST = Quality of Upper Extremity Skills Test; *SD* = standard deviation.
^a η_p^2 = partial η^2 . Significance and effect sizes are from repeated-measures analysis of variance across the four testing occasions.

same protocol of CIMT could achieve similar results (DeLuca et al., in press), and this report focuses on 6-mo follow-up data. Our findings are consistent with the conclusion that a less intensive and, thus, less costly dosage level of CIMT can produce equivalent benefits for many young children and that the benefits are maintained at 6-mo follow-up. Intervention effect sizes in this study at 6-mo follow-up were moderate to strong ($\eta^2 = .33-.78$) using measures of bimanual performance, quality of movement, and parent report of typical daily use. On the performance measures, the children displayed the largest improvements on the AHA ($\eta^2 = .62$).

Several reasons may account for the finding that children made similar gains with 3 hr/day and 6 hr/day of occupational therapy intervention. First, children may reach maximum benefits with 3 hr/day of intervention, and the additional 3 hr may not result in additional learning or skill development. An alternative explanation is that the children who received 3 hr/day of intervention may have continued to practice the newly learned skills on their own or with parents during the remainder of the day, meaning that the amount of practice was similar between groups. Another possible influence is that young children ages 3–6 yr have limited attention spans; they thus may

be less engaged or even somewhat fatigued when they participate in intervention activities for 6 hr/day. Therapists' daily logs indicated a wide range of children's levels of engagement day by day.

One of the distinctive features of the ACQUIREc protocol is continuous, 24 hr/day casting of the unaffected extremity. The theory guiding the use of continuous constraint is that young children are far more motivated to attempt to use their involved upper extremity when they cannot rely on their more functional (i.e., less involved or uninvolved extremity) to play, explore, or complete everyday tasks. The children did not display any frustration or discomfort related to the continuous casting; in fact, most adapted quickly and showed no resistance when it was removed and replaced once a week to check skin integrity and range of movement. Anecdotally, treating therapists reported that the cast seemed to promote the children's increased regard for the more impaired upper extremity beginning almost immediately after casting. During this trial, no noteworthy problems were associated with either the casting process or adjustment to wearing the cast 24 hr/day. All children showed good adjustment during and after casting, and no important disruptions in children's sleep patterns, abrasions or

Table 3. Mean Scores on Parent-Report Assessments, by Dosage Group and Assessment Period

PMAL Scale and Dosage Group	Preintervention		Postintervention		1-Mo Follow-Up		6-Mo Follow-up		Within-Subject Effects for Time ^a
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	
How often (frequency of use)									
3-hr group	2.13	1.4	3.10	1.3	3.17	1.2	3.05	1.2	$F(1, 14) = 20.7, p = .001$
6-hr group	2.15	1.0	3.57	1.0	3.35	1.0	3.5	1.3	$\eta_p^2 = .78$
How well (quality of movement)									
3-hr group	2.02	1.1	3.40	1.4	3.04	1.1	3.14	1.2	$F(1, 14) = 14.7, p \leq .001$
6-hr group	2.63	1.1	3.43	0.8	3.65	1.1	3.61	1.4	$\eta_p^2 = .71$

Note. *M* = mean; PMAL = Pediatric Motor Activity Log; *SD* = standard deviation.
^a η_p^2 = partial η^2 . Significance and effect sizes are from repeated measures analysis of variance across the four testing occasions.

Table 4. Effect Sizes Pre- to Postintervention and Preintervention to 6-Mo Follow-up

Scale	Pre- to Postintervention Effect Size (η_p^2)	Preintervention to 6-mo Follow-Up Effect Size (η_p^2)
AHA	.59	.62
QUEST Grasp/Release	.48	.53
QUEST Dissociated Movements	.72	.33
PMAL How Often	.75	.69
PMAL How Well	.68	.80

Note. AHA = Assisting Hand Assessment; PMAL = Pediatric Motor Activity Log; QUEST = Quality of Upper Extremity Skills Test.

^a η_p^2 = partial η^2 .

irritations of the children's skin, or degradation in function of the children's involved arm and hand were reported. Ours is the fourth study to use 24 hr/day constraint with a cast (Deluca et al., 2006; Taub et al., 2004; Willis et al., 2002). Although all four studies used different measures, all produced large positive benefits that were maintained at 6 mo.

The total hours of intervention—63 for the 3 hr/day group and 126 for the 6 hr/day group—were similar to those in many CIMT trials. Charles et al. (2006) achieved medium to large effects on skill measures for the affected arm using 60 hr of intervention. Gordon, Charles, and Wolf (2006) also used 60 hr of intervention (6 hr/day for 10 days), achieving large effects on performance measures. Aarts et al. (2011) applied 72 hr of intervention (3 hr/day, 3 days/wk, for 8 wk), achieving a moderate effect on the AHA ($d = 0.43$) and a large effect on the ABILHAND-Kids ($d = 1.01$). When Eliasson et al. (2005) administered 120 hr of intervention, the effect size was large ($d = 1.16$) for AHA scores and was maintained at 6 mo ($d = 0.72$). These effect sizes are similar to our effect size for the AHA ($\eta^2 = .62$). Taken together, these findings suggest that moderate to large effect sizes can be achieved with intervention dosages of 60–126 hr and that 60–63 hr may be a sufficient and cost-effective dosage for children to benefit from CIMT.

This multisite RCT replicated earlier single-site intervention results and confirmed that this CIMT protocol, ACQUIREc, can be replicated successfully across sites. Children's performance on the AHA and QUEST indicated that at 6 mo post-CIMT, children demonstrated greater use and improved quality of movement in their involved arm and hand. The PMAL scores reflecting the frequency and quality of the child's use of the involved extremity affirmed that parents observed changes in the children's everyday activities. These results suggest that ACQUIREc therapy results in improvements in the specific movement patterns, amount of movement, spon-

aneous use, and functional skills of the child's involved upper extremity.

These results need to be interpreted in the context of the study's limitations. One limitation, the sample size, is particularly relevant because preintervention starting points for groups and sites were not equivalent. A sufficiently powered study with a larger sample size would decrease the likely effects of such variation. This study also examined a pediatric CIMT protocol in its entirety, focusing only on systematic variation in dosage level. We did not manipulate other components of the protocol, such as the use of 24 hr/day casting versus constraint only during the intervention sessions or the administration of intervention in natural settings versus a clinic or lab setting. Future research needs to address the effects of these and other features (e.g., types and amount of reinforcement, use of a prespecified set of activities versus individualized movement activities) of CIMT.

Implications for Occupational Therapy Practice

Our findings of significant gains in upper-extremity function with 3 or 6 hr of CIMT provide helpful clinical guidelines:

- CIMT is an intensive protocol that results in important gains in children's upper-extremity function as assessed by parents and practitioners.
- Key active ingredients appear to be the constraint of the unaffected arm, daily therapy sessions that focus on practice and challenges, immediate and specific reinforcement of performance, and transfer of learning into the child's natural environment.
- The children in our sample did not make significantly greater gains in performance with a 6 hr/day protocol than with a 3 hr/day protocol. Our results suggest that a 3 hr/day intervention is sufficient to achieve important effects and that >3 hr/day may not be more beneficial.

The findings recognize the limits to young children's performance, endurance, and attention within a day. Practitioners and families can expect retention of CIMT effects, and in our sample, effects were maintained 6 mo after the intervention. Because CIMT is an intensive program that requires extensive resources, retention of effects is an expected and important outcome. At 6 mo, the participants had maintained and, in some cases, further improved in two-hand functions.

Conclusion

This study adds to the literature indicating that pediatric CIMT is an efficacious intervention producing clinically significant improvements in upper-extremity function of

young children with unilateral CP. Although effects were slightly diminished at 6 mo compared with those immediately postintervention, the changes were not statistically significant, and moderate to high-level effects were sustained. Moreover, this study provides evidence that a specified pediatric CIMT protocol can be systematically implemented across sites. ▲

Acknowledgments

We acknowledge the contributions of the following colleagues to this study: Karen Echols, University of Alabama at Birmingham; Stephanie Lowenhaupt, University of Virginia; Linda Lowes, Ohio State University; and Nedaa Timraz, Georgetown University. We extend our deep appreciation to Whitney S. Fox and Daniel S. Goldberg for their generous funding support of this project. We also thank the Occupational Therapy Department, School of Health Professions, and Biomedical Research Support Fund at the University of Alabama at Birmingham and the Georgetown University Center on Health and Education. Finally, we thank the children and families who participated in this study to further knowledge about treatment and development of young children with unilateral CP.

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