Effectiveness of Modified Constraint-Induced Movement Therapy Compared With Bimanual Therapy Home Programs for Infants With Hemiplegia: A Randomized Controlled Trial

Rena Chamudot, Shula Parush, Amihai Rigbi, Roni Horovitz, Varda Gross-Tsur

OBJECTIVE. We examined the effectiveness of modified constraint-induced movement therapy (mCIMT) in treating infants with hemiplegic cerebral palsy and compared therapy outcomes with a nonconstraining bimanual therapy (BIM) of equal intensity.

METHOD. In a single-blinded randomized controlled trial, 33 infants with hemiplegia (mean corrected age = 11.1 mo, standard deviation = 2.2) received either mCIMT (n = 17) or BIM (n = 16). Both interventions included home programs encouraging the use of the affected hand during daily 1-hr play sessions for 8 wk. Outcome measures were administered pre- and posttreatment and included the Mini-Assisting Hand Assessment for babies and the Functional Inventory. At baseline, parents also filled out the Dimensions of Mastery Questionnaire.

RESULTS. Both groups demonstrated a significantly large and equal improvement in hand and gross motor function posttreatment (p < .001) and high treatment compliance.

CONCLUSION. mCIMT and BIM are equally effective methods for treating infants with hemiplegia.

Chamudot, R., Parush, S., Rigbi, A., Horovitz, R., & Gross-Tsur, V. (2018). Effectiveness of modified constraint-induced movement therapy compared with bimanual therapy home programs for infants with hemiplegia: A randomized controlled trial. *American Journal of Occupational Therapy, 72,* 7206205010. https://doi.org/10.5014/ajot.2018. 025981

emiplegia accounts for approximately 25% of all children diagnosed with cerebral palsy (CP; Shevell et al., 2003) and affects one side of the body. Characteristically, one hand functions well and the other is impaired (Steenbergen et al., 2007). In addition to the core impairments of the affected hand, a mechanism of negative feedback from the difficulty in using the affected hand leads the child to further reduce the use of the affected hand. This phenomenon is

known as learned nonuse, or developmental disregard (Deluca et al., 2006).

Constraint-induced movement therapy (CIMT) and its modified version (mCIMT) refer to the practice of restricting the functional hand while training the affected hand. The core concept underlying CIMT is to increase opportunities to use the affected hand and thereby improve its performance (Eliasson et al., 2005; Gordon et al., 2005). According to a recent systematic review, a large body of evidence supports the effectiveness of CIMT and mCIMT in treating children over age 2 yr (Chen et al., 2014). However, despite the consensus among researchers that treatment during the very early years is crucially important (Guralnick, 1997), the literature focusing on improving hand function in infancy is sparse. To date, only a small number of case studies (Coker et al., 2009; Cope et al., 2008; DeLuca et al., 2003; Fergus et al., 2008),

Rena Chamudot, PhD, OT, is Lecturer, School of Occupational Therapy, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel, and Occupational Therapy Director, Dvorah Agmon Pre-School Development Center, Jerusalem, Israel. At the time of the study, she was Doctoral Student, School of Occupational Therapy, Faculty of Medicine, Hebrew University of Jerusalem, Israel; chamudot@012.net.il

Shula Parush, PhD, OT, is Professor Emeritus, School of Occupational Therapy, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel.

Amihai Rigbi, PhD, is Senior Lecturer, Faculty of Education, and Research Authority, Beit Berl Academic College, Kfar-Sava, Israel.

Roni Horovitz, MSc, OTR/L, is OTD Candidate, Boston University, Boston, MA. At the time of the study, she was Graduate Student, School of Occupational Therapy, Faculty of Medicine, Hebrew University of Jerusalem, Israel.

Varda Gross-Tsur, PhD, MD, is Professor of Pediatrics, Neuropediatric Unit, Department of Pediatrics, Shaare Zedek Medical Center, Jerusalem, Israel, and the Hebrew University of Jerusalem, Jerusalem, Israel. one pilot study (Lowes et al., 2014), and two protocols (Chorna et al., 2015; Eliasson et al., 2014) have been published on the use of CIMT and mCIMT in infants.

Substantial reasons support the importance of starting treatment as early as possible: the brain has increased plasticity at a younger age, the development of the corticospinal tract is highly dependent on the quality of activity during the first 2 yr of life (Holt & Mikati, 2011), and learned nonuse has less time to become ingrained if training starts early (Basu, 2014). However, treating infants raises extra challenges because of their limited attention span, motivation, and understanding. In addition, there is a lack of outcome measures that take into account infants' swift natural development (Basu et al., 2015). Another reason for the absence of research on infants may be concern regarding the neural developmental consequences of fully restraining the functional hand over time, as is performed in classical CIMT (Basu & Eyre, 2012).

The primary objective of this study was to examine, in a randomized controlled trial for the first time, the efficacy of mCIMT in treating infants younger than 18 mo diagnosed with spastic hemiplegic CP by comparing it with a conventional nonconstraining bimanual treatment of equal intensity and to assess the relationship between the outcomes of these treatments with demographic, medical, and motivational variables.

Method

Research Design and Procedure

Before participating in the research, parents signed an institutional review board (IRB) consent form from Shaare Zedek Medical Center (Jerusalem, Israel). Participants were assigned randomly, by an external agent using a block design, to either the mCIMT experimental group or to the bimanual therapy (BIM) control group. After randomization, baseline assessments of outcome measures regarding hand and general function were performed. Posttreatment assessments were performed at the conclusion of the 8-wk intervention. Assessments were conducted by a trained and certified Mini-Assisting Hand Assessment (Mini-AHA; Greaves et al., 2013) assessor (R. Chamudot) not blinded to group allocation. Before the treatment, parents filled out questionnaires about the child's demographic background and motivation. To control for expectation bias, the primary outcome measure was videotaped and scored in a random order by an independent trained and certified rater, blinded to group allocation.

Participants

Participants were recruited by health professionals (pediatric neurologists, occupational therapists, and physiotherapists) through public health services. Inclusion criteria were formal diagnosis with spastic hemiplegic CP by a physician; ages 8–16 mo (18 mo at the conclusion of the treatment), which is the age range of the Mini–AHA; ability to follow simple age-appropriate instructions; and parental agreement to participate and a signed IRB consent form. Exclusion criteria were additional medical issues, such as respiratory problems and intractable epilepsy, and no difference in the function of both hands, indicated by a perfect or nearly perfect score on the main outcome measure.

Thirty-eight infants were recruited for the purpose of this research. Two infants did not meet inclusion criteria for randomization and were excluded. The 36 remaining infants were randomly assigned to either the mCIMT or the BIM group, 18 in each group. After randomization and primary evaluation, 2 infants were excluded from the BIM group because they performed almost perfectly on the primary outcome measure (Mini–AHA). After 2 wk of intervention, 1 infant dropped out of the mCIMT program because of family circumstances, which resulted in 33 infants who fully participated in this study (Figure 1).

Instruments

Primary Outcome Measure. The Mini-AHA, the infant version of the Assisting Hand Assessment (AHA; Krumlinde-Sundholm & Eliasson, 2003), was used to assess the treatment's impact on hand function (Greaves & Krumlinde-Sundholm, 2013). The Mini-AHA is a reliable and validated observation-based criterion reference test that measures how effectively infants ages 8-18 mo with hemiplegia use their affected hand. The test is conducted by observing the infant play with specific toys that encourage bimanual hand use; it discriminates between different levels of ability to evaluate change over time (Greaves et al., 2013). The raw scores range from 20 to 80 and are converted into standard-unit scores. A higher score indicates better performance. Scores are not influenced by age. Within the age range of the test, typically developing infants perform perfectly, and among infants with hemiplegia, no correlation exists between age and performance (Greaves et al., 2013). In the current study, the Mini-AHA presented high internal consistency on the initial score (Cronbach's $\alpha = .95$) and on the posttreatment score (Cronbach's $\alpha = .98$).

Secondary Outcome Measures. The Functional Inventory (FI) was developed specifically for this study

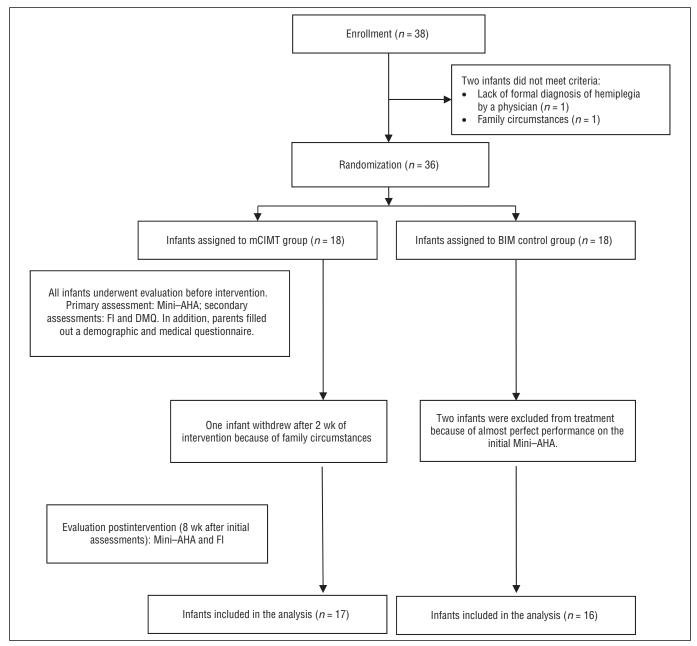


Figure 1. Flow diagram of trial participants using CONSORT guidelines (Moher et al., 2001).

Note. BIM = bimanual therapy; DMQ = Dimensions of Mastery Questionnaire; FI = Functional Inventory; Mini-AHA = Mini-Assisting Hand Assessment; mCIMT = modified constraint-induced movement therapy.

because of the paucity of outcome measures available for this population. It was designed to assess the impact of the treatment program on gross motor and hand function of infants ages 7–18 mo. The 31 FI items encompass activities expected of typical age-matched infants. Items are divided into three categories: Gross Motor Skills (GMS; 12 items; e.g., creeps on tummy, sits independently), Unilateral Hand Use (UHU; 12 items; e.g., pulls hand into sleeve, points), and Bilateral Hand Use (BHU; 7 items; e.g., claps hands, reaches out to be held).

The FI is completed by the parents with the occupational therapist. Scoring of each category is a summation of all the items that the infant is able to perform divided by the number of items included in the category (meaning that the range of scores in each category is 0-1).

The knowledge base used to formulate these items was derived from two different sources: a review of accepted developmental assessments of gross and fine motor functions in general (Folio & Fewell, 2000; Haley et al., 1992), and hand function in particular (Wallen et al., 2009), and data from interviews conducted with three parents who participated in a pilot mCIMT home program. These data informed us about the parents' perspectives of their child's function before and after intervention. After the FI items were determined, four experienced occupational therapists administered the

inventory in clinical settings and found that it was user friendly and provided a useful profile for treatment planning.

To test the reliability of the FI (Crist, 2014), internal consistency analysis of the composite scales was performed on our study group. High internal consistency in the initial total FI score (Cronbach's $\alpha=.91$) and the posttreatment total FI score (Cronbach $\alpha=.86$) were found. High consistency was found also in the each of the three categories, ranging between .76 and .93 before treatment and between .71 and .77 after treatment.

Additional Assessments. At baseline, parents filled out a demographic and medical questionnaire regarding pregnancy and labor (Table 1). In addition, because motivation is considered to be an important factor in motor learning (Smith & Wrisberg, 2008) and has been found to be correlated with treatment outcomes in children with CP (Miller et al., 2014), we used the Dimensions of Mastery Questionnaire (DMQ; Morgan et al., 2009) to assess the possible relationship between motivation and treatment outcome.

The DMQ was completed by the parents before the intervention. The infant version of the DMQ is standardized for ages 6–18 mo. The DMQ measures infants' mastery of motivation by having parents rate the typical behavior of the child on 45 items using a 5-level rating scale. The items are divided into seven subscales: Object-Oriented Persistence (OOP), Gross Motor Persistence,

Social Persistence With Adults (SPA), Social Persistence With Children, Mastery Pleasure (MP), Negative Reactions to Failure (NRF), and General Competence. A higher score on all subscales except NRF indicate a higher level of motivation. The DMQ has shown to be a reliable test with good internal consistency on all subscales (Cronbach α s ranging between .69 and .84). In our study, reliability was satisfactory for most subscales (Cronbach α s ranging between .75 and .86). SPA and MP yielded low reliability coefficients (Cronbach α = .43 and .56, respectively).

Interventions

Infants in both intervention groups received a home program designed to encourage the use of the affected hand. The program was chosen on the basis of clinical experience treating infants and successful protocols performed on older children (Eliasson et al., 2005) and was individualized for each infant on the basis of initial Mini–AHA results. It involved a 1-hr daily play session with parents 7 days a week for a period of 8 wk. The parents could divide the daily session into two.

The treatment was performed in a sitting position, on the floor or in a high chair, with trunk support provided when needed. All infants had adequate head control. Infants in the mCIMT group were required to wear a soft custommade mitt throughout the play session. The mitt restrained the functional hand by preventing the ability to grasp

Table	1 Da	rticinant	Domogram	hic and	Recoling	Characteristics
rabie	I. Pai	rucivani	Demourat	JIIIC anu	i baseiine	Characteristics

	mCIMT Group $(n = 17)$		BIM Group $(n = 16)$		All Participants ($N = 33$)		$\chi^2(df)$ or	
Characteristic	n (%) or M (SD; range)	Mdn	n (%) or M (SD; range)	Mdn	n (%) or M (SD; range)	Mdn	t(df)	р
Gender							$\chi^2(1) = 0.68$.50
Female	9 (53)	_	5 (31)	_	14 (42)	_		
Male	8 (47)	_	11 (69)	_	19 (58)	_		
Corrected age,a mo	11.4 (2.2; 8–15)	12	10.9 (2.3; 8–16)	11	11.1 (2.2; 8–16)	11	t(31) = 1.6	.21
Gestational age, wk	33.4 (5.7; 25-41)	36	37.8 (3.4; 32-42)	39	35.5 (5.1; 25-42)	37	t(26) = -2.7	.01
Birth weight, g	1,939.1 (957.7; 645–3,38	0) 2,040	2,758.9 (754.7; 1,385–3,888)	2,850	2,336.5 (948.0; 645–3,888)	2,490	t(31) = -2.7	.01
Apgar score at 1 min	7.9 (1.8; 4–10)	9	8.3 (1.4; 5–9)	9	8.1 (1.6; 4–10)	9	t(28) = 0.6	.57
Apgar score at 5 min	8.9 (1.6; 4-10)	9	9.3 (1.0; 7–10)	10	9.1 (1.3; 4–10)	9.5	t(28) = 0.7	.49
Treatment, hr	48.4 (9.5; 30-60)	50	45.0 (10.2; 30-60)	47	46.7 (9.9; 30-60)	50	t(31) = 1.0	.34
Hemiplegia side							$\chi^2(1) = 3.0$.14
Right	9 (53)	_	13 (81)	_	22 (67)	_		
Left	8 (47)	_	3 (19)	_	11 (33)	_		
Mini-AHA (logit- based 0-100 score)	28.6 (19.5; 0–57)	31.5	23.3 (19.2; 0–48)	23	26.0 (19.2; 0–57)	30	t(29) = 0.8	.46
FI-GMS	0.6 (0.3; 0-1)	0.6	0.5 (0.3; 0.17-1)	0.5	0.6 (0.3; 0-1)	0.6	t(31) = 0.7	.48
FI-UHU (95% CI)	0.1 (0.3; [0, 0.92])	0	0.1 (0.3; [0, 0.92])	0	0.1 (0.3; 0-0.92)	0	t(31) = 0.2	.86
FI-BHU (95% CI)	0.2 (0.3; [0, 0.86])	0	0.2 (0.2; [0, 0.83])	0.2	0.2 (0.3; [0, 0.86])	0.1	t(31) = -0.4	.70

Note. Boldface indicates a significant p value. BHU = Bilateral Hand Use; BIM = bimanual therapy; CI = confidence interval; df = degrees of freedom; FI = Functional Inventory; GMS = Gross Motor Skills; M = mean; mCIMT = modified constraint-induced movement therapy; Mdn = median; Mini-AHA = Mini-Assisting Hand Assessment; UHU = Unilateral Hand Use.

^aAge was adjusted for preterm birth by subtracting the number of weeks born preterm from the chronological age.

objects. The activities during the session were designed to encourage unilateral hand use (e.g., eat biscuit, knock down tower of blocks with involved hand). In the BIM group, the activities were designed to encourage the use of both hands symmetrically (e.g., shake pair of rattles, play xylophone with two hands) and asymmetrically (e.g., pull beads off stick, take blocks out of container). The activities in both groups were designed to be as similar as possible regarding the toys used, the content, and the level of play.

Parents received professional guidance once a week at home from one of two experienced occupational therapists on how to encourage the use of the affected hand during the play sessions. One therapist had more than 20 yr of experience, and the other had more than 4 yr of experience treating infants and children with hemiplegia. To avoid therapist identity bias, the two therapists treated an even number of infants from both groups. In addition, the treatment was free of charge.

Therapist guidance was based on principles of motor learning and included highly motivating activities, specific task practices, and repetitive practices, all of which were developmentally appropriate for the child (Smith & Wrisberg, 2008). The visits included monitoring the infant's current hand use and precise guidance on which activities to perform in the upcoming week. When necessary, the therapists supplied the parents with appropriate toys for the activities. The parents were guided on which actions to encourage while making sure that the infant received positive reinforcement from the action (e.g., toys with sensory feedback, planning the activity in a manner that ensured success, parental praise). It was important that the activity would lead to further motivation for practice. In addition, parents were required to keep a daily log in which they recorded the infant's compliance with the program, the activities performed during the play session, the infant's emotional reaction to the treatment, and the parents' observations of any improvement or change in the infant's function.

Statistical Analyses

Sample size calculation was based on Eliasson et al.'s (2005) study, which tested the effectiveness of constrained therapy compared with a control group using the AHA–Kids assessment as the main outcome measure. Eliasson et al. reported a significant improvement of 1.23 AHA logits score within the experimental group after 2 mo of treatment. This improvement is considered above the smallest detectable difference (i.e., 0.97 logits, as suggested by Krumlinde-Sundholm [2012]) and yielded a large effect size of d = 1.16. On the basis of this finding, a sample size of 8 in the experimental

group would be required for a two-tailed study to achieve an effect size of the same magnitude, under $\alpha = .05$ and estimated power of .80. The current study included 17 infants in the mCIMT group and 16 in the BIM group, thus reaching an adequate sample size.

For baseline comparison, continuous variables were compared using two-sided t tests; categorical variables were compared by using Pearson's χ^2 test or Fisher's exact test, as appropriate. Correlations between continuous variables were calculated using Pearson's r correlation coefficient. A mixed-design analysis of variance (ANOVA), which refers to a repeated-measures ANOVA that also included a between-group factor, was used to determine the effect of treatment on the outcome measures. All models included the time of assessment (before or after treatment) as the within-group independent variable, the treatment group (mCIMT or BIM) as the between-group independent variable, and their interaction (Time × Treatment). Effect sizes for significant effects were calculated by converting the F ratio to r and were interpreted as small (r = .1), medium (r = .3), or large (r = .5; Field, 2009). Analyses were done using IBM SPSS Statistics (Version 20; IBM Corp., Armonk, NY). A $p \le .05$ was considered statistically significant.

Results

Baseline Comparisons

Table 1 presents demographic and clinical characteristics of the entire study sample and of the mCIMT and BIM groups separately. The sample consisted of 33 infants (19 boys and 14 girls; mean corrected age = 11.1 mo, standard deviation [SD] = 2.2, range = 8–16). The experimental group (mCIMT) and the control group (BIM) included 17 and 16 infants, respectively. No baseline differences between the two groups were found except gestational age and birth weight: The mCIMT group's gestational age was significantly younger, t(26) = -2.7, p = .01, and their birth weight was significantly lower, t(31) = -2.7, p = .01. However, both gestational age and birth weight were not correlated with the baseline levels of the primary outcome measure, Mini-AHA, r = -.06, p = .73, and r = -.10, p = .58, respectively. In addition, they were not correlated with the baseline levels of the secondary outcome measures, FI-GMS, r = .28, p = .11, and r = .26, p = .15; FI-UHU, r = .24, p = .18, and r = .21, p = .23; and FI-BHU, r = .06, p = .74, and r = .00, p = .97, respectively.

The average treatment time for the whole group was 46.7 hr (SD = 9.9) out of a total of 60 hr (78% compliance).

In the mCIMT group, the average was 48.4 hr (SD = 9.5; 81% compliance); in the BIM group, it was 45.0 hr (SD = 10.2; 75% compliance).

Outcome Measures

Table 2 presents the analysis of the effect of treatment on the Mini–AHA score and on the three FI scales. The analysis revealed significant main effects of time for all outcome measures, with large effect sizes (Mini–AHA, r=.83; FI–GMS, r=.72; FI–UHU, r=.86; FI–BHU, r=.88), indicating greater scores in both groups after treatment, regardless of treatment type (either mCIMT or BIM). Effects of treatment and of the Treatment \times Time interaction were insignificant for all outcome measures.

Analysis of Factors Related to Improvement

To investigate the possible role of the infants' motivation in the experimental treatments, semipartial correlations were calculated between the seven subscale scores of the DMQ and the Mini-AHA difference score¹ (calculated as the after score minus the before score; Table 3). The analysis revealed that the only DMQ subscale that differentiated between the groups was OOP. In the BIM group, the association was of small size (r = .10) and insignificant (p = .73); however, in the mCIMT group, the association was of medium size (r = -.50) and significant (p = .05), indicating greater improvement for infants manifesting low levels of OOP. In addition, the same analysis of semipartial correlations was calculated between the variables of corrected age, gestational age, birth weight, Apgar score at 1 and 5 min, and the Mini-AHA difference score, but none of them differentiated between the groups. Finally, the Mini-AHA difference score was not correlated with the Mini-AHA baseline score in both groups (CIMT, r = .29, p = .28; BIM, r =.11, p = .70), indicating that improvement was not related to the infants' baseline assessment.

Discussion

This study examined whether mCIMT is an effective method for treating infants with hemiplegia and the extent to which constraining the functional hand is essential to the success of treatment by comparing mCIMT with BIM of equal intensity. To our knowledge, this is the first ran-

domized controlled study of mCIMT or CIMT performed on infants under age 18 mo. We found high compliance with both treatment programs, and infants in the mCIMT group showed good tolerance to wearing the restraint. The high feasibility of the treatments is worthy of interest because of the difficulties in treating such young children. The results showed a significantly large and equal improvement in hand function in both groups as documented by the scores of the Mini–AHA for babies and the FI. The FI also revealed a significant and equal improvement in gross motor function in both groups.

At present, little research exists on CIMT in infants despite the accepted advantage of early intervention. The lack of empirical intervention studies in infants may be due to the difficulties in treating this population because of their limited understanding, cooperation, and motivation and, until recently, the lack of a standardized ageappropriate assessment tool. We overcame these challenges by implementing a modified and feasible protocol of mCIMT and administering a new standardized evaluation for infants (i.e., the Mini-AHA) and the FI. By comparing mCIMT with an equal-intensity BIM, we were able to assess the contribution of restraining the functional hand during the treatment. Note that in most of the early research on CIMT and mCIMT, control groups did not receive treatment of equivalent intensity. This deficiency has been addressed only in more recent studies (Dong et al., 2013).

Although the results of our study show equal gains in both groups, variability among participants within each group was found. In addition, as opposed to several studies on CIMT and mCIMT in older children (Charles et al., 2006), this study did not exclude infants with low-level hand function. These factors raise the question of whether it is possible to find predictors that enable clinicians to determine the preferred therapy for each individual infant.

Improvement on the Mini–AHA was not predicted by Apgar scores, gestational age, birth weight, age, hours of treatment, or Mini–AHA baseline scores. In addition, no correlation was found between degree of improvement and six out of seven motivational subscales of the DMQ. However, within the mCIMT group, a negative correlation was found between the OOP subscale and the degree of improvement on the Mini–AHA. OOP measures the intrinsic psychological force that stimulates a person to persist and master a challenging manual task (Morgan et al., 2009). Infants who had a low score on this aspect of motivation showed greater improvement on the Mini–AHA than did the children who received a high motivation score. No such correlation was found in the BIM group. This negative correlation with the OOP is thought

¹The semipartial correlations were calculated by correlating each DMQ factor score with the residual score of the Mini–AHA difference in each treatment group separately. The residual score was produced by regressing the Mini–AHA difference score against the Mini–AHA baseline score. This procedure enabled us to assess the association between each DMQ factor and improvement, as assessed by Mini–AHA, which was not accounted for by Mini–AHA baseline performance.

Table 2. Analysis of the Effect of Treatment and Time on Outcome Measures

mCIMT		BIM					
Measure and Time	M (SE)	95% CI	M (SE)	95% CI	Treatment Effect	Time Effect	$\textit{Treatment} \times \textit{Time Effect}$
Mini–AHA					F(1, 29) = 0.2, p = .68	F(1, 29) = 68.3, p < .001	F(1, 29) = 1.0, p = .32
Before treatment	28.6 (4.8)	[18.7, 38.4]	23.3 (4.5)	[13.1, 33.5]			
After treatment	43.1 (6.1)	[30.8, 55.5]	42.0 (6.2)	[29.2, 54.8]			
FI-GMS					F(1, 30) = 2.4, p = .13	F(1, 30) = 31.5, p < .001	F(1, 30) = 0.0, p = .86
Before treatment	0.6 (0.06)	[0.5, 0.7]	0.5 (0.06)	[0.4, 0.6]			
After treatment	0.9 (0.06)	[0.8, 1.0]	0.8 (0.06)	[0.6, 0.9]			
FI-UHU					F(1, 30) = 1.1, p = .31	F(1, 30) = 85.6, p < .001	F(1, 30) = 0.7, p = .40
Before treatment	0.2 (0.07)	[0.0, 0.3]	0.1 (0.07)	[-0.1, 0.3]			
After treatment	0.8 (0.08)	[0.7, 1.0]	0.8 (0.08)	[0.5, 0.8]			
FI-BHU					F(1, 30) = 0.0, p = .97	F(1, 30) = 107.2, p < .001	F(1, 30) = 0.2, p = .65
Before treatment	0.2 (0.07)	[0.0, 0.4]	0.2 (0.07)	[0.1, 0.4]			
After treatment	0.7 (0.07)	[0.6, 0.9]	0.7 (0.07)	[0.6, 0.9]			

Note. **Boldface** indicates significant p values. BHU = Bilateral Hand Use; BIM = bimanual therapy; CI = confidence interval; FI = Functional Inventory; GMS = Gross Motor Skills; M = mean; mCIMT = modified constraint-induced movement therapy; Mini-AHA = Mini-Assisting Hand Assessment; SE = standard error; UHU = Unilateral Hand Use.

provoking because, according to motor learning principles, optimal persistence and practice are likely to lead to better motor control (Smith & Wrisberg, 2008).

We hypothesized that infants with low OOP fail to use the full functional capacity of their affected hand because of the relative difficulty of using this hand.

Table 3. Semipartial Correlations Between the Seven DMQ Subscale Scores and the Mini-AHA Difference Score

Subscale	r	р
00P		
mCIMT	503*	.047
BIM	.096	.733
GMP		
mCIMT	387	.139
BIM	.093	.742
SPC		
mCIMT	.190	.480
BIM	084	.766
SPA		
mCIMT	.203	.452
BIM	226	.418
MP		
mCIMT	.109	.687
BIM	152	.589
NRF		
mCIMT	.197	.463
BIM	260	.349
GC		
mCIMT	083	.760
BIM	.224	.423

Note. BIM = bimanual therapy; DMQ = Dimensions of Mastery Questionnaire; GC = General Competence; GMP = Gross Motor Persistence; mCIMT = modified constraint-induced movement therapy; Mini–AHA = Mini–Assisting Hand Assessment; MP = Mastery of Pleasure; NRF = Negative Reactions to Failure; OOP = Object-Oriented Persistence; SPA = Social Persistence With Adults; SPC = Social Persistence With Children. *p = .05.

Therefore, the lower the OOP, the greater the gap between the potential and actual hand function. Restraining the functional hand increases the necessity for using the affected hand, thereby leading the infants to use more of their potential. In older children, Miller et al. (2014) found that higher initial scores correlated with higher participation outcomes posttreatment. The difference between our finding and theirs can be explained by the fact that their mCIMT treatment was combined with BIM and the age difference for study participants.

The use of a home program in this study had several advantages. First, the guidance given to the parents enabled them to integrate ongoing practice with the infants into the family's daily activities. This type of practice, within the natural environment of the infant, is considered essential for achieving motor skill acquisition (Smith & Wrisberg, 2008). Second, the flexibility of a home program allowed the parents to schedule the treatment according to the optimal levels of arousal and cooperation of the infants. Third, having parents serve as primary treatment providers served to empower them. Finally, this treatment model allows for greater cost-effectiveness. However, the fact that the parents were the main treatment providers may have led to differences in the way that treatment was performed because of obvious differences between families.

Limitations and Future Research

The main outcome measure used in this study, the Mini–AHA, is independent of the age of the infant being evaluated (Greaves et al., 2013). Therefore, it is reasonable to assume that the posttreatment improvement seen in both groups was due to the intervention and not to the infants'

maturation and development. Nevertheless, note that a weakness of this study is that it did not include a non-intervention control group. However, creating such a control group raises ethical concerns. According to the rationale of early intervention, denying treatment from infants even for a period of a few months may have negative long-term effects (Friel et al., 2012).

Because the FI was developed specifically for this research, there is room for further psychometric testing. Therefore, the results presented should be perceived with caution. Another issue is the difference between the two groups in gestational age and birth weight. To overcome these differences, we correlated these factors with the baseline performance on the outcome measures and found that there was no correlation. As mentioned previously, there was no correlation between birth weight and birth week and the degree of improvement on the Mini–AHA.

Larger studies with long-term effects of the treatments are needed. Because of the advantage of treating such young infants, it may be expected that the treatment could have long-term benefits.

Implications for Occupational Therapy Practice

The results of this study have the following implications for clinical practice:

- mCIMT and BIM home programs are effective treatments for improving hand function and gross motor function in infants younger than 18 mo diagnosed with hemiplegia.
- The family, together with the occupational therapist, should choose the treatment method with which they feel more comfortable, because the study showed equal gains overall for both types of interventions.
- Our findings suggest that among infants treated with mCIMT, those with lower motivation to persist in mastering manual tasks will have relatively greater gains.

Conclusion

The main conclusion of this study is that mCIMT and BIM therapy are both effective methods for treating infants with hemiplegia. This conclusion is based on the significantly large and equal improvement in hand function, gross motor function, and high treatment compliance demonstrated in both groups posttreatment.

Acknowledgments

We sincerely thank the families who participated in this study. We also thank Vardit Kindler, the occupational therapist, for independently scoring the Mini–AHA. We extend our thanks to Associate Professor Lena Krumlinde-Sundholm and Susan Greaves for their guidance and special assistance in implementing the Mini–AHA. The study was approved by the institutional review board at Shaare Zedek Medical Center (Jerusalem, Israel) and is registered as NCT01214902 in ClinicalTrials.gov.

References

- Basu, A. P. (2014). Early intervention after perinatal stroke: Opportunities and challenges. *Developmental Medicine and Child Neurology*, *56*, 516–521. https://doi.org/10.1111/dmcn.12407
- Basu, A., & Eyre, J. (2012). A plea for consideration of the less affected hand in therapeutic approaches to hemiplegia. *Developmental Medicine and Child Neurology*, 54, 380, author reply 381–382. https://doi.org/10.1111/j.1469-8749.2012.04242.x
- Basu, A. P., Pearse, J., Kelly, S., Wisher, V., & Kisler, J. (2015). Early intervention to improve hand function in hemiplegic cerebral palsy. *Frontiers in Neurology*, *5*, 281. https://doi.org/10.3389/fneur.2014.00281
- Charles, J. R., Wolf, S. L., Schneider, J. A., & Gordon, A. M. (2006). Efficacy of a child-friendly form of constraint-induced movement therapy in hemiplegic cerebral palsy: A randomized control trial. *Developmental Medicine and Child Neurology*, 48, 635–642. https://doi.org/10.1017/S0012162206001356
- Chen, Y. P., Pope, S., Tyler, D., & Warren, G. L. (2014). Effectiveness of constraint-induced movement therapy on upper-extremity function in children with cerebral palsy: A systematic review and meta-analysis of randomized controlled trials. *Clinical Rehabilitation*, 28, 939–953. https://doi.org/10.1177/0269215514544982
- Chorna, O., Heathcock, J., Key, A., Noritz, G., Carey, H., Hamm, E., . . . Maitre, N. L. (2015). Early childhood constraint therapy for sensory/motor impairment in cerebral palsy: A randomised clinical trial protocol. *BMJ Open, 5*, e010212. https://doi.org/10.1136/bmjopen-2015-010212
- Coker, P., Lebkicher, C., Harris, L., & Snape, J. (2009). The effects of constraint-induced movement therapy for a child less than one year of age. *NeuroRehabilitation*, 24, 199–208.
- Cope, S. M., Forst, H. C., Bibis, D., & Liu, X. C. (2008). Modified constraint-induced movement therapy for a 12-month-old child with hemiplegia: A case report. *American Journal of Occupational Therapy*, 62, 430–437. https://doi.org/10.5014/ajot.62.4.430
- Crist, P. (2014). Reliability and validity, the psychometrics of standardized assessments. In J. Hinojosa, P. Kramer, & P. Crist (Eds.), *Evaluation obtaining and interpreting data* (4th ed.). Bethesda, MD: AOTA Press.
- Deluca, S. C., Echols, K., Law, C. R., & Ramey, S. L. (2006). Intensive pediatric constraint-induced therapy for children

- with cerebral palsy: Randomized, controlled, crossover trial. *Journal of Child Neurology*, 21, 931–938. https://doi.org/10.1177/08830738060210110401
- DeLuca, S. C., Echols, K., Ramey, S. L., & Taub, E. (2003). Pediatric constraint-induced movement therapy for a young child with cerebral palsy: Two episodes of care. *Physical Therapy*, 83, 1003–1013.
- Dong, V. A., Tung, I. H.-H., Siu, H. W.-Y., & Fong, K. N.-K. (2013). Studies comparing the efficacy of constraint-induced movement therapy and bimanual training in children with unilateral cerebral palsy: A systematic review. *Developmental Neurorehabilitation*, 16, 133–143. https://doi.org/10.3109/17518423.2012.702136
- Eliasson, A. C., Krumlinde-Sundholm, L., Shaw, K., & Wang, C. (2005). Effects of constraint-induced movement therapy in young children with hemiplegic cerebral palsy: An adapted model. *Developmental Medicine and Child Neurology*, 47, 266–275. https://doi.org/10.1017/S0012162205000502
- Eliasson, A. C., Sjöstrand, L., Ek, L., Krumlinde-Sundholm, L., & Tedroff, K. (2014). Efficacy of baby–CIMT: Study protocol for a randomised controlled trial on infants below age 12 months, with clinical signs of unilateral CP. *BioMed Center Pediatrics*, 14, 141–152. https://doi.org/10.1186/1471-2431-14-141
- Fergus, A., Buckler, J., Farrell, J., Isley, M., McFarland, M., & Riley, B. (2008). Constraint-induced movement therapy for a child with hemiparesis: A case report. *Pediatric Physical Therapy*, 20, 271–283. https://doi.org/10.1097/PEP.0b013e318181e569
- Field, A. (2009). *Discovering statistics using SPSS*. London: Sage.
- Folio, M. R., & Fewell, R. R. (2000). *Peabody Developmental Motor Scales* (2nd ed.). Austin, TX: Pro-Ed.
- Friel, K., Chakrabarty, S., Kuo, H. C., & Martin, J. (2012). Using motor behavior during an early critical period to restore skilled limb movement after damage to the corticospinal system during development. *Journal of Neuroscience*, 32, 9265–9276. https://doi.org/10.1523/JNEUROSCI.1198-12.2012
- Gordon, A. M., Charles, J., & Wolf, S. L. (2005). Methods of constraint-induced movement therapy for children with hemiplegic cerebral palsy: Development of a child-friendly intervention for improving upper-extremity function. *Archives of Physical Medicine and Rehabilitation*, 86, 837–844. https://doi.org/10.1016/j.apmr.2004.10.008
- Greaves, S., Imms, C., Dodd, K., & Krumlinde-Sundholm, L. (2013). Development of the Mini-Assisting Hand Assessment: Evidence for content and internal scale validity. Developmental Medicine and Child Neurology, 55, 1030–1037. https://doi.org/10.1111/dmcn.12212
- Greaves, S., & Krumlinde-Sundholm, L. (2013). *Mini–Assisting Hand Assessment (AHA), English version*. Melbournel Stockholm: Cerebral Palsy Alliance.
- Guralnick, M. J. (1997). The effectiveness of early intervention. Baltimore: Brookes.

- Haley, S., Coster, W., Ludlow, L., Haltiwanger, J., & Andrellos, P. (1992). *Pediatric Evaluation of Disability (PEDI)*. Boston: New England Center Hospitals, PEDI Research Group.
- Holt, R. L., & Mikati, M. A. (2011). Care for child development: Basic science rationale and effects of interventions. *Pediatric Neurology*, *44*, 239–253. https://doi.org/10.1016/j.pediatrneurol.2010.11.009
- Krumlinde-Sundholm, L. (2012). Reporting outcomes of the Assisting Hand Assessment: What scale should be used? *Developmental Medicine and Child Neurology*, 54, 807–808. https://doi.org/10.1111/j.1469-8749.2012.04361.x
- Krumlinde-Sundholm, L., & Eliasson, A. (2003). Development of the Assisting Hand Assessment, a Rasch built measure intended for children with unilateral upper limb impairments. *Scandinavian Journal of Occupational Therapy, 10,* 16–26.
- Lowes, L. P., Mayhan, M., Orr, T., Batterson, N., Tonneman, J. A., Meyer, A., . . . Case-Smith, J. (2014). Pilot study of the efficacy of constraint-induced movement therapy for infants and toddlers with cerebral palsy. *Physical and Occupational Therapy in Pediatrics*, 34, 4–21. https://doi.org/10.3109/01942638.2013.810186
- Miller, L., Ziviani, J., Ware, R. S., & Boyd, R. N. (2014). Mastery motivation in children with congenital hemiplegia: Individual and environmental associations. *Develop*mental Medicine and Child Neurology, 56, 267–274. https://doi.org/10.1111/dmcn.12356
- Moher, D., Schulz, K. F., & Altman, D. G. (2001). The CONSORT Statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. *Annals of Internal Medicine*, 134, 657–662. https://doi.org/10.7326/0003-4819-134-8-200104170-00011
- Morgan, G. A., Busch-Rossnagel, N. A., Barret, K. C., & Wang, J. (2009). *The Dimensions of Mastery Questionnaire (DMQ): A manual about its development, psychometrics, and use.* Fort Collins: Colorado State University, Human Development and Family Studies Department.
- Shevell, M. I., Majnemer, A., & Morin, I. (2003). Etiologic yield of cerebral palsy: A contemporary case series. *Pediatric Neurology*, 28, 352–359.
- Smith, R. A., & Wrisberg, C. A. (2008). *Motor learning and performance: A situation based learning approach* (4th ed.). Baltimore: Human Kinetics.
- Steenbergen, B., Verrel, J., & Gordon, A. M. (2007). Motor planning in congenital hemiplegia. *Disability and Rehabilitation*, 29, 13–23. https://doi.org/10.1080/09638280600947591
- Wallen, M., Bundy, A., Pont, K., & Ziviani, J. (2009). Psychometric properties of the Pediatric Motor Activity Log used for children with cerebral palsy. *Developmental Medicine and Child Neurology*, 51, 200–208. https://doi.org/10.1111/j.1469-8749.2008.03157.x