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# Effectiveness of Modified Constraint-Induced Movement Therapy in Children With Unilateral Spastic Cerebral Palsy: A Randomized Controlled Trial

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## Abstract

**Background.** In children with unilateral spastic cerebral palsy (CP), there is only limited evidence for the effectiveness of modified constraint-induced movement therapy (mCIMT). **Objective.** To investigate whether 6 weeks of mCIMT followed by 2 weeks of bimanual task-specific training (mCIMT-BiT) in children with unilateral spastic CP improves the spontaneous use of the affected limb in both qualitative and quantitative terms more than usual care (UC) of the same duration. **Methods.** Children with unilateral spastic CP with Manual Ability Classification System (MACS) scores I, II, or III and aged 2.5 to 8 years were recruited and randomly allocated to either the mCIMT-BiT group (three 3-hour sessions per week: 6 weeks of mCIMT, followed by 2 weeks of task-specific training in goal-directed bimanual play and self-care activities) or to 1.5 hours of more general physical or occupational weekly plus encouragement to use the affected hand for the UC group. Primary outcome measures were the Assisting Hand Assessment and the ABILHAND-Kids. Secondary outcomes were the Melbourne Assessment of Unilateral Upper Limb Function, the Canadian Occupational Performance Measure, and the Goal Attainment Scale. **Results.** Twenty-eight children were allocated to mCIMT-BiT and 24 to UC. Except for the Melbourne, all primary and secondary outcome measures demonstrated significant improvements in the mCIMT-BiT group. **Conclusion.** mCIMT followed by task-specific training of goal-directed bimanual play and self-care activities is an effective intervention to improve the spontaneous use of the more affected upper limb in children with relatively good baseline upper extremity function.

## Keywords

randomized control trial, modified constraint-induced movement therapy, cerebral palsy, upper limb, rehabilitation, bimanual training

## Introduction

Cerebral palsy (CP) is the most frequent cause of physical disability in children.<sup>1</sup> Particularly in hemiparetic children, the focus of treatment is to improve the functional use of the affected arm and leg. In the rehabilitation of the upper limb, according to a Cochrane review,<sup>2</sup> therapists working with these children try to encourage movements of the affected arm and hand using either bimanual or repeated unilateral activities. However, intensive verbal and physical prompting is often required to “force” children to properly execute the training tasks. This need for external stimulation is frustrating for both the child and the therapist and frequently results in unsuccessful and incomplete task execution. Indeed, children with unilateral spastic CP often

display a form of learned disuse because in daily life they experience too little incentive to use their affected upper limb during functional tasks, in particular during bilateral activities. Gordon’s Hand-Arm Bimanual Intensive Training<sup>3,4</sup> encourages the use of the affected arm and hand, but in children with learned disuse, it is still difficult to achieve adequate bimanual coordination.

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Constraint induced movement therapy (CIMT)<sup>5</sup> is a promising approach for rehabilitation of the upper limb in hemiparetic children with CP. This therapy is based on 2 principles: (a) constraint of the least affected arm and hand and (b) intensive and frequent training of activities with the affected arm and hand. According to a recent Cochrane review,<sup>2</sup> CIMT and modified CIMT (mCIMT) should be distinguished from forced use therapy (FUT), which merely imposes a restraint on the unaffected upper limb. In the past few years, an increasing number of studies have indicated positive (m)CIMT effects on the potential of the affected arm to assist the unaffected arm during bimanual activities,<sup>6,7</sup> as well as on the quality, speed, and dexterity of upper limb function,<sup>7-15</sup> the spontaneous use of the affected arm,<sup>8,9,11</sup> and the level of independence in self-care.<sup>7-9,12-14</sup> However, the restraint method for the affected arm varied greatly (sling, splint, glove, cast), as well as the intensity and length of the restraint (from 8 hours daily during 2-3 weeks to 2 hours daily for 8 weeks).

Clinical evidence supporting (m)CIMT is limited to 3 controlled trials that found beneficial effects on the speed and dexterity of upper limb movement,<sup>9</sup> on functional use measures,<sup>8,9,12</sup> and on the effectiveness of the assisting hand.<sup>6</sup> However, the strength of evidence from 2 randomized control trials (RCTs)<sup>9,12</sup> was limited due to small sample sizes (22 and 18 subjects,<sup>9,12</sup> respectively) and the fact that the control group received considerably less or even no treatment. As a result, the observed outcomes may have been related to differences in the intensity of therapy rather than the specificity of CIMT. A potential confounding factor in the third study<sup>6</sup> was the nonrandomized design in which the experimental group was recruited from 13 centers for pediatric services in the region of Stockholm, whereas the control group was mainly recruited from other regions in Sweden. Evidence of the efficacy of FUT is limited to 2 RCTs that included 25<sup>14</sup> and 31 children.<sup>13</sup> In both studies, problems with including a comparable control group affected the internal validity. In light of these findings, a Cochrane review<sup>2</sup> concluded that, although these results are encouraging they are still inconclusive and that the effectiveness of (m)CIMT or FUT should be revealed in future trials to obtain stronger evidence. A further recommendation was that these studies should be appropriately powered and should use uniform, objective, and valid outcome measures.

Considering the variety in the currently proposed therapeutic (m)CIMT approaches and the limited evidence for their clinical efficacy, it remains a challenge to construct an age-appropriate and appealing program for young children with unilateral spastic CP to encourage them to use their affected arm and hand and to teach them new skills. In addition, such a program should incorporate the parents' needs. To achieve the best results in children with unilateral spastic CP, we assumed that training should (a) be focused

on children with unilateral CP, (b) take place in a challenging environment, (c) be sufficiently intensive and given in a relatively short period, (d) preferably take place among peers, (e) focus on meaningful activities, (f) start with unilateral training feasible for young children (mCIMT), and (g) end with goal-directed,<sup>16,17</sup> task-specific<sup>18</sup> bimanual training (BiT) to integrate the activated upper limb functions in age-appropriate skills. The objective of this study was, therefore, to investigate whether 6 weeks of mCIMT followed by 2 weeks of bimanual training (mCIMT-BiT) in children with unilateral spastic CP improves the spontaneous use of the affected limb in both qualitative and quantitative terms more than usual care (UC) of the same duration.

## Methods

### Participants

Children with unilateral spastic CP were recruited from 8 rehabilitation centers in the Netherlands. The children and their parents were first approached and informed by their treating pediatric physiatrist or occupational therapist. A screening was performed by 2 occupational therapists from the recruiting rehabilitation center. Inclusion criteria were (a) CP with a unilateral or severely asymmetric, bilateral spastic movement impairment; (b) age 2.5 to 8 years; and (c) Manual Ability Classification System (MACS)<sup>19</sup> scores I, II, or III. Exclusion criteria were (a) intellectual disability such that simple tasks could not be understood or executed (ie, developmental age less than 2 years), (b) inability to combine the study protocol with the regular school program, and (c) inability to walk independently without a walking aid.

### Study Design

Thirty-six participants (18 per group) were required to obtain a power of 90% to detect at least a moderate treatment effect (Cohen's  $d^{20}$  value  $>.5$ ) on the Assisting Hand Assessment (AHA; standard deviation [SD] = 12.22) and/or ABILHAND-Kids (SD = 5.28) using a 2-sided significance level of .05. The SDs were derived from earlier pilot observations in the same target group. Taking into account a maximum attrition rate of 30% (due to the intensity of the program), 52 subjects needed to be randomized. Within 48 hours after inclusion, each participant was randomized to the mCIMT-BiT or UC group by throwing a dice with equal probabilities. Before the start of the intervention period (week 0), all children underwent a comprehensive upper limb evaluation that was repeated at the end of the intervention period (week 9) and again after 8 weeks (follow-up in week 17). At the end of the study protocol (week 17), the children who had been allocated to the UC group were also offered the opportunity to participate in an mCIMT-BiT

group. The study was approved by the regional Medical Ethical Committee for Research Involving Human Subjects. Oral and written informed consent was obtained from all parents or caregivers.

### Interventions

**mCIMT-BiT group.** In the mCIMT-BiT group, also named the “Pirate group,” functional training was given during 3-hour afternoon sessions, 3 days per week for 8 weeks, at the primary rehabilitation center (Sint Maartenskliniek; total therapy time: 9 hours/week). During the first 6 weeks, restraint of the unaffected arm and hand was applied. Children were told that they were pirates and that their best arm was injured and had to be kept in a sling. Their affected arm had to be used for all activities, especially to handle a sword (see Figure 1). In all of these therapy sessions, the principles of shaping and repetitive task practice<sup>8,21</sup> were applied. Immediate feedback on task performance and results was given. During the last 2 weeks, the emphasis was on task-specific exercises in goal-directed bimanual play and self-care activities without restraint. These 2 weeks were used to train individual goals that were set by the parents, using Goal Attainment Scaling.<sup>22</sup>

Each mCIMT-therapy session during the first 6 weeks started with 30 minutes of group activities including dressing up as a pirate, which was followed by making targeted movements<sup>21</sup> (shoulder abduction, shoulder external rotation, wrist extension) with the sword while singing pirate songs. During the following 60 minutes, individual therapy was given in groups of 6 children by 4 occupational therapists, 1 physical therapist, and 1 therapy assistant using shaping and repetitive task practice. Afterward, the children collectively participated in 30 minutes of eating and drinking activities during which the principles of repetitive task practice were maintained as much as possible. After a brief sanitary break, the children participated in activities<sup>21</sup> such as board games, card games, puzzles, and arts and crafts during 45 minutes in small groups (2-3 children). At the end of each session, during 15 minutes, the children changed into their own clothes and prepared for going home. In addition to these therapy sessions, parents were asked to stimulate their child to use the affected arm and hand at home as much as possible and to register the duration of specific periods of stimulation on the child’s daily record form.

**UC group.** In the UC group, children received a regular rehabilitation program in one of the participating rehabilitation centers. For 8 weeks, the program included individual occupational therapy (OT) and/or physical therapy (PT) given twice a week in 0.5- to 1-hour sessions (total therapy time: 1.5 hours/week). During each OT or PT session, the child was engaged in exercises to stretch the affected arm, to improve its weight-bearing capacity, and to use the affected



**Figure 1.** Pirate wearing a sling and waving the sword with the affected arm

arm and hand as a good assist. In addition, parents and teachers were instructed to stimulate the children at least 7.5 hours a week to use the affected arm and hand as an assist in daily activities. Parents and teachers received oral and written instructions about activities they were expected to train at home or at (pre)school. Parents and teachers were asked to register the duration of specific periods of stimulation on the child’s daily record form.

Due to the nature of both interventions, it was impossible to blind either subjects or therapists with regard to treatment allocation.

### Outcome Assessments

The primary outcomes were the AHA and the ABILHAND-Kids. The AHA aims to evaluate the spontaneous use of the

assisting hand during activities that require bimanual handling in children in the age range of 18 months to 12 years.<sup>23,24</sup> Interrater and intrarater reliability of the AHA<sup>25</sup> have high intraclass correlation coefficients for sum scores (.98 for 2-rater design and .97 for 20-rater design; intrarater = .97). We used scaled scores to compare performances between different weeks. The ABILHAND-Kids is a questionnaire about manual skills in children with upper limb impairments.<sup>26,27</sup> This scale consists of 21 mostly bimanual items rated by the parents. Its range and measurement precision are appropriate for clinical practice (reliability:  $R = .94$ ; reproducibility over time:  $R = .91$ ). Whereas the AHA is primarily focused on play activities, the ABILHAND-Kids is an instrument to investigate manual ability in self-care activities.

Secondary outcomes consisted of the Melbourne Assessment of Unilateral Upper Limb Function (Melbourne),<sup>28</sup> the Canadian Occupational Performance Measure (COPM),<sup>29</sup> and Goal Attainment Scaling (GAS).<sup>30</sup> The Melbourne aims to assess the quality of upper limb movements in children with neurological impairment in the age range of 5 to 15 years. The modified Melbourne Assessment of Unilateral Upper Limb Function<sup>31</sup> for children in the age range of 2 to 5 years has recently been developed. In the present study, this modified Melbourne was used for this age-group, whereas the original Melbourne was used for the older children. In both versions of the Melbourne, 16 different tasks are scored from a video tape on range of motion, accuracy, and fluency of movement.<sup>32</sup> The COPM is a family-centered tool that lists the problems experienced in daily life through a semistructured interview.<sup>29</sup> Five of the most important areas are selected and then scored by the parents at 2 levels: (a) perception of current performance (COPM-P) and (b) satisfaction with current performance (COPM-S). The COPM ratings are on a 10-point scale; scores closer to 10 indicate better performance and increased satisfaction. By means of the COPM, individual training goals were set by the parents. With the GAS, the most important functional goal for the affected arm and hand was broken down into attainable subgoals during the preintervention assessment with the parents.<sup>30,33</sup> In this study, the perceived outcome was scaled from -3 to +2. A score of -3 indicated a level lower than the initial performance level, -2 indicated an unchanged level of performance, -1 indicated a level lower than the desired outcome, 0 indicated the desired outcome level had been achieved, +1 indicated somewhat more improvement than expected, and +2 indicated much more improvement than expected (a total of 6 levels of performance). Parents scored their children at each measurement by selecting the appropriate performance level. All selected outcome measures are valid and reliable, and most of them have been recommended in the literature to evaluate the effects of (m)CIMT.<sup>2,7</sup>

All assessments were conducted by the same occupational therapist at the primary rehabilitation center, who was unaware of the individual study phase of any particular child, blinded for group allocation, and not involved in any other aspect of the study. Both the AHA and the Melbourne tapes were scored by a certified occupational therapist who was blinded for group allocation and test session.

### Statistical Analysis

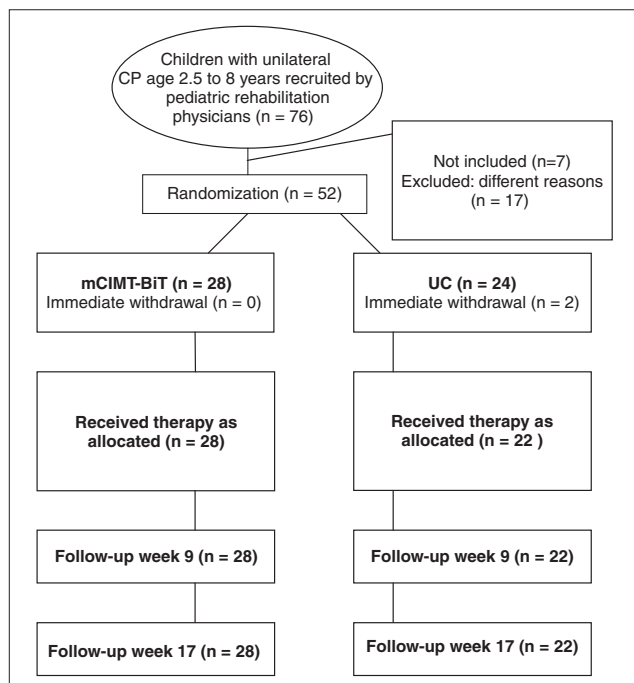
Student *t* tests (for unrelated samples) were used to determine comparability at baseline with regard to sociodemographic characteristics (age, distance between residence and the primary rehabilitation center, as well as all outcome measures except the GAS). For the AHA, ABILHAND-Kids, Melbourne, COPM-P, and COPM-S, the 2 groups were compared posttreatment (week 9) with ANCOVA in which differences at baseline, even when “insignificant,” were used as covariates. Cohen’s *d* values<sup>20</sup> were calculated to obtain a pre–post intervention effect size. The ratings of the GAS were dichotomized as either “improved” (increase of 2 points or more) or “not improved” (less than 2 points increase or any decrease); the percentages of children who improved were analyzed by intervention group. To find out if possible effects remained constant over time, Student *t* tests (paired samples) were used to compare the results between week 9 (postintervention) and week 17 (8-week follow up). All data handling and analyses were carried out by an independent statistician who was blinded for group allocation. SPSS version 17.0 was used for computerized analysis (SPSS, Inc, Chicago, IL).

## Results

### Patient Flow

Information pertaining to the patient flow through the trial is presented in Figure 2.

In total, 76 children were screened for eligibility. Seven children could not be included because their MACS scores were too high. Seventeen children were excluded: 8 children because of mental retardation, 7 children because they could not combine the training with their school program, and 2 children because they could not walk independently. As a result, 52 children with unilateral spastic CP were definitively included. Of these children, 28 children were randomly allocated to the mCIMT-BiT group and 24 to the UC group. Immediately after randomization, 2 children withdrew from the UC group due to family circumstances. Thereafter, no subjects were lost to follow-up or changed group allocation. Hence, the data of 22 subjects in the UC group will be presented.



**Figure 2.** Patient flow diagram

Abbreviations: mCIMT-BiT, modified constraint-induced movement therapy combined with bimanual training; UC, usual care.

### Control of Bias

The mCIMT-BiT group ( $n = 28$ ) and the UC group ( $n = 22$ ) had similar baseline sociodemographic characteristics (see Table 1). In addition, no significant differences between groups were found for the baseline scores on the AHA, ABILHAND-Kids, Melbourne, COPM-P, or COPM-S. According to the children's daily record forms, the mCIMT-BiT group received on average 9 hours per week therapy and 3.3 hours additional stimulation at home (total stimulation time =  $12.3 \pm 1.9$  hours). The UC group received on average 1.5 hours per week therapy and 11.2 hours additional stimulation at home or at school (total stimulation time =  $12.7 \pm 2.1$  hours). Blinding of the assessor was tested afterward by asking the occupational therapist to indicate for each child whether she thought the child had participated in the mCIMT-BiT group or in the UC group. Comparable with the actual distribution of the children, the OT assessor made a correct guess in 48% of all cases.

### Primary Outcomes

Table 2 presents the results for the primary outcome measures. The mCIMT-BiT group showed significantly more improvement after 9 weeks when compared with the UC group.

**Table 1.** Baseline Characteristics of Both Groups<sup>a</sup>

Characteristics	mCIMT-BiT (N = 28)	UC (N = 22)
Sex		
Male	14 (50)	14 (64)
Female	14 (50)	8 (36)
Age (mean $\pm$ SD in years)	4.8 $\pm$ 1.3	5.1 $\pm$ 1.7
Distance <sup>b</sup> (mean $\pm$ SD in km)	55.0 $\pm$ 35.9	45.2 $\pm$ 30.2
1-29	8 (29)	8 (36)
30-68	10 (36)	8 (36)
69-152	10 (36)	6 (27)
Hemiparetic side		
Left	14 (50)	14 (64)
Right	14 (50)	8 (36)
GMFCS		
I	27	21
II	1	1
MACS		
I	9	7
II	12	10
III	7	5

Abbreviations: mCIMT, modified constraint-induced movement therapy; UC, usual care; GMFCS, Gross Motor Function Classification System; MACS, Manual Ability Classification System.

<sup>a</sup>Values are the number (percentages) unless otherwise indicated.

<sup>b</sup>Distance = number of kilometers between Sint Maartenskliniek and home address of the child.

Compared to baseline (week 0), the children of the mCIMT-BiT group showed a 13% improvement on the AHA as well as a 36% improvement on the ABILHAND-Kids at the end of the intervention (week 9). These improvements were 2.5 and 7 times greater than the respective scores of the UC group: 5% and 5%. The effect size was small for the AHA (Cohen's  $d = .43$ ) and large for the ABILHAND-Kids (Cohen's  $d = 1.01$ ).

At follow-up (week 17), the observed improvements were maintained in the mCIMT-BiT group; compared with week 9 the AHA decreased by 1%, whereas the ABILHAND-Kids increased by 2%. The improvements of the UC group decreased slightly on the AHA by 2% and increased slightly on the ABILHAND-Kids by 3%. Within either group, there were no significant differences between the scores on the AHA and ABILHAND-Kids between week 9 and week 17.

### Secondary Outcomes

The results for the secondary outcome measures are presented in Table 3. Overall, the pattern of change was the same as for the primary outcome measures: the mCIMT-BiT group showed significantly greater improvements than

**Table 2.** Primary Outcome Measures for Both Groups

Outcome Measures	mCIMT-BiT	$\Delta$ mCIMT-BiT	UC	$\Delta$ UC	Mean Difference (95% CI) <sup>a</sup>	Effect Size <sup>b</sup>	mCIMT-BiT t Value	mCIMT-BiT P Value	UC t Value	UC P Value
AHA (range 0-100)										
Baseline, mean $\pm$ SD	53.3 $\pm$ 14.6		50.6 $\pm$ 22.5							
Week 9	60.1 $\pm$ 15.3	6.8 $\pm$ 8.2	53.1 $\pm$ 22.2	2.5 $\pm$ 6.3	4.5 (0.26-8.77)	.43				
Week 17	59.7 $\pm$ 13.5	6.4 $\pm$ 5.7	52.3 $\pm$ 21.4	1.7 $\pm$ 5.5			.306	.762	.764	.453
ABILHAND (range 0-42)										
Baseline, mean $\pm$ SD	20.9 $\pm$ 5.1		22.6 $\pm$ 6.9							
Week 9	28.4 $\pm$ 5.9	7.5 $\pm$ 4.0	23.7 $\pm$ 6.0	1.1 $\pm$ 4.8	5.9 (3.55-8.29)	1.01				
Week 17	28.9 $\pm$ 5.2	8.0 $\pm$ 3.9	24.4 $\pm$ 6.6	1.8 $\pm$ 3.8			-.817	.421	-.816	.424

Abbreviations: mCIMT-BiT, modified constraint-induced movement therapy combined with bimanual training; UC, usual care; CI, confidence interval; AHA, Assisting Hand Assessment; ABILHAND, ABILHAND-Kids.

<sup>a</sup>Mean group difference (95% CI) (differences at baseline were used as covariates).

<sup>b</sup>Effect size (Cohen's *d*): "small" = .2 < *d* < .5; "moderate" = .5 < *d* < .8; and "large" = *d* > .8.

**Table 3.** Secondary Outcome Measures for Both Groups

Outcome Measures	mCMT-BiT	$\Delta$ mCMT-BiT	UC	$\Delta$ UC	Mean Difference (95% CI) <sup>a</sup>	Effect Size <sup>b</sup>	mCMT-BiT t Value	mCMT-BiT P Value	UC t Value	UC P Value
COPM-S (range 0-10)										
Baseline, mean $\pm$ SD	3.7 $\pm$ 1.1		3.9 $\pm$ 1.1							
Week 9	7.4 $\pm$ 1.2	3.7 $\pm$ 1.6	5.3 $\pm$ 1.2	1.4 $\pm$ 1.1	2.2 (1.51-2.86)	1.32				
Week 17	7.3 $\pm$ 1.2	3.6 $\pm$ 1.6	5.5 $\pm$ 1.2	1.6 $\pm$ 1.3			.288	.776	-.949	.535
COPM-P (range 0-10)										
Baseline, mean $\pm$ SD	3.0 $\pm$ 1.0		3.4 $\pm$ 1.1							
Week 9	6.5 $\pm$ 1.0	3.5 $\pm$ 1.3	4.6 $\pm$ 1.4	1.2 $\pm$ 1.1	2.1 (1.43-2.72)	1.31				
Week 17	6.5 $\pm$ 0.9	3.5 $\pm$ 1.3	4.7 $\pm$ 1.4	1.3 $\pm$ 1.2			-.503	.619	-.527	.604
Melb. (range 0-100)										
Baseline, mean $\pm$ SD	63.9 $\pm$ 12.6		62.1 $\pm$ 16.2							
Week 9	68.8 $\pm$ 11.6	5.0 $\pm$ 7.6	63.5 $\pm$ 16.7	1.4 $\pm$ 6.2	3.8 (-0.06 to 7.73)	0.40				
Week 17	69.1 $\pm$ 12.0	5.3 $\pm$ 5.8	65.1 $\pm$ 14.3	3.0 $\pm$ 6.0			-.318	.753	-1.410	.173
GAS, goals (%)										
Week 9	82 <sup>c</sup>		23 <sup>c</sup>							
Week 17	86 <sup>c</sup>		36 <sup>c</sup>							

Abbreviations: mCMT-BiT, modified constraint-induced movement therapy combined with bimanual training; UC, usual care; CI, confidence interval; COPM-S, Canadian Occupational Performance Measure-Satisfaction; COPM-P, Canadian Occupational Performance Measure-Perception; Melb., Melbourne Assessment of Unilateral Upper Limb Function; GAS, Goal Attainment Scaling.

<sup>a</sup>Mean group difference (95% CI) (differences at baseline were used as covariates).

<sup>b</sup>Effect size (Cohen's *d*): "small" = .2 < *d* < .5; "moderate" = .5 < *d* < .8; and "large" = *d* > .8.

<sup>c</sup>Percentage of children that showed an increase of 2 points or more compared with baseline.

the UC group on all secondary outcomes, except for the Melbourne, which merely showed a positive trend in favor of the mCIMT-BiT group. After 9 weeks, the mCIMT-BiT group showed improvements on the COPM-P and the COPM-S with respect to baseline of 117% and 100%, respectively. The UC group showed much lower percentages of change, 35% and 36%, respectively. The effect sizes were large for both the COPM-P and the COPM-S (Cohen's  $d = 1.32$  and  $1.31$ , respectively). Improvements on the Melbourne were 8% and 2% compared with baseline for the mCIMT-BiT group and the UC group, respectively. This group effect was small (Cohen's  $d = 0.4$ ). The dichotomized GAS scores showed improvement (increase of 2 points or more) in 82% of the mCIMT-BiT participants, whereas only 23% of the UC group showed improvement on the GAS.

At follow-up (week 17), the improvements of the mCIMT-BiT group when compared with posttreatment (week 9) increased by 3% for the COPM-P and decreased by 3% for the COPM-S. The improvements of the UC group increased by 3% and 8% for the COPM-P and the COPM-S, respectively. The improvements on the Melbourne remained stable for the mCIMT-BiT group and increased by 2% for the UC group. As for the GAS, 86% of the mCIMT-BiT and 36% of the UC participants still showed improvement compared with baseline. Within either group, there were no significant differences between the scores on the COPM-P, COPM-S, or the Melbourne between week 9 and week 17.

## Discussion

We investigated whether 8 weeks of mCIMT-BiT in young children with CP improves the spontaneous use of the upper limb in both qualitative and quantitative terms more than UC of the same duration. All primary and secondary outcome measures demonstrated significantly greater improvement in the mCIMT-BiT group than in the control group; the Melbourne showed at most a positive trend in favor of mCIMT-BiT. In comparison with UC, mCIMT-BiT improved the effectiveness of the assisting hand (AHA) and also demonstrated higher scores for bimanual performance during self-care and leisure tasks (the ABILHAND-Kids). All effects were maintained at 8 weeks follow-up, which implies a clinically meaningful effect even after the therapy had finished.

A strength of this study is that the Pirate group provided a meaningful and challenging environment for the children, who enjoyed the playlike treatment and the provocative activities with peers. Parents reported that the children liked the therapy in the Pirate group much more than the individual therapy they had received before they started in the Pirate group. In addition, parents were very much engaged in the family-centered process of selecting goals for their child. They often commented that their participation in stimulating the use of the pirate hand at home kept them focused

on the intervention and improved the child's compliance with the therapy. In contrast to other studies,<sup>9,11</sup> no child dropped out from the mCIMT-BiT group and none of the children deviated substantially from the study protocol.

The results of this study corroborate the findings of previous studies showing significant improvement in upper limb function through (m)CIMT or FUT in children with CP. However, an essential difference is that in this study improvements were achieved by using a combination of 6 weeks mCIMT and 2 weeks of goal-directed and task-specific bimanual training, each during 3 hours per afternoon and 3 times per week, whereas some other studies have employed much longer periods of physical restraint (6-8 hours per day<sup>4,12</sup>). With 50 participants, this study was appropriately powered, and the randomization procedure created comparable groups at baseline with regard to sociodemographic characteristics and outcome measures. Total stimulation time was comparable between the mCIMT-BiT and the UC groups, and the OT assessor was blinded successfully. The principles of mCIMT-BiT as described by Taub et al<sup>34</sup> were used and involved 3 main elements: (a) intensive training of the more affected extremity, (b) prolonged restraint of the less affected extremity, and (c) a "package of techniques" to induce behavioral change in daily life activities.

As suggested by Hoare et al,<sup>2</sup> valid and reliable outcomes that measure the use of the most affected upper limb in bimanual tasks (eg, the AHA) and its use in relation to individual client and family goals (eg, the COPM and GAS) were selected. The greatest changes from baseline to post-treatment were found for the COPM-P and COPM-S, which is in contrast with the mCIMT feasibility study by Wallen et al,<sup>7</sup> in which only a trend for COPM improvement was found. One explanation for this difference is that this study incorporated 2 weeks of task-specific bimanual training for the mCIMT-BiT group to optimize transfer of upper limb skills to daily life activities. The mCIMT-BiT group showed relatively large improvements on the ABILHAND-Kids as well, which might be related to the same period of "transfer training." In this study, all COPM, GAS, and ABILHAND-Kids forms were filled in together with the same OT assessor to overcome the problem mentioned by others that the scoring only by parents may be biased by their subjectivity.<sup>7</sup> Although it showed a positive trend, the improvements of the mCIMT-BiT group on the capacities measured by the Melbourne were small. As in the study by Wallen et al,<sup>7</sup> the changes in the Melbourne did not reach the 12% value to be considered clinically significant. It may well be that the Melbourne is less sensitive to the applied mCIMT-BiT intervention, because it focuses on upper limb capacity rather than spontaneous use of the upper extremity during "natural" activities. This could also mean that the children might have needed a longer period of restraint and training to reach a significant result on the Melbourne.

Although this is the largest RCT of (m)CIMT in children with CP, the number of participants is still moderate. In addition, most of the children that were included had relatively good arm–hand capacity, that is, 73.6% had an MACS score of I or II. Both of these aspects limit the generalizability of the results of this study. Another limitation is the possible difference in “quality of stimulation” between both groups. Although the total duration of therapy plus stimulation was the same, the mCIMT-BiT group was mostly trained by dedicated therapists, whereas the UC group received therapeutic attention from parents and teachers. Last, the follow-up of 8 weeks was relatively short to judge long-term effects, whereas the loss to follow-up of 2 participants in the UC group immediately after randomization prevented a true intention-to-treat analysis.

In conclusion, mCIMT-BiT is an effective intervention to increase the spontaneous use of the more affected arm and hand in children with CP, aged 2.5 to 8 years, with MACS scores I, II, or III. Future research might be focused on the preventive effect of mCIMT-BiT in even younger children as well as on the therapeutic effects in children with less arm–hand capacity. In addition, the optimal frequency and intensity of mCIMT-BiT in young children with CP should be determined in relation to the size and duration of its effects, including the need for “booster” sessions in case of functional relapse.

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