


The Effect of Occupation-Based Modified Constraint-Induced Movement Therapy on the Participation of Children with Cerebral Palsy: A Single-Blind Randomized Controlled Trial

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Abstract

Objective

This study investigates the impact of modified constraint-induced movement therapy (m-CIMT), accompanied by occupation-based and activity analysis, on the participation of children with hemiplegia.

Materials & Methods

Twenty-three participants were randomly assigned to the intervention and control groups. The intervention group received occupation-based m-CIMT (m-CIMT along with occupation-based and activity analysis), while the control group received m-CIMT without occupation-based and activity analysis. The intervention was conducted one hour per day, three days a week, for four weeks.

Results

The primary outcomes revealed no significant differences between groups in promoting the participation of children with hemiplegia in the activities of daily living (ADL). However, scores were higher in the intervention group with a medium to large effect size (Canadian occupational performance measure: $F_{(1,19)}=2.14$, $P=0.160$, $\eta^2_p=0.101$, Canadian occupational performance measure-satisfaction: $F_{(1,19)}=1.53$, $P=0.231$, $\eta^2_p=0.075$, Goal attainment scaling: $F_{(1,19)}=5.55$, $P=0.029$, $\eta^2_p=0.226$). This effect remained during the follow-up period. The secondary outcomes indicated no significant differences between groups in improving the manual ability of the children. However, scores were higher in the intervention group with a medium to large effect size (ABILHAND-Kids: $F_{(1,19)}=0.64$, $P=0.434$, $\eta^2_p=0.033$, pediatric motor activity log- how long: $F_{(1,19)}=3.53$, $P=0.076$, $\eta^2_p=0.157$, pediatric motor activity log- how well: $F_{(1,19)}=2.59$, $P=0.124$, $\eta^2_p=0.120$). This

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effect was sustainable during the follow-up period.

Conclusion

m-CIMT accompanied by occupation-based and activity analysis and the client-centered paradigm substantially enhances the manual ability of children with hemiplegia and their participation in the ADL.

Keywords: Occupation; Cerebral palsy, m-CIMT; Upper extremity; Hemiplegia; Parent empowerment.

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Introduction

Cerebral palsy (CP) refers to a series of motor disorders caused by non-progressive damage to the brain during infancy or the embryonic period. This motor disorder persists throughout a person's lifetime and adversely affects movements, posture, and tone (1). In other words, CP restricts activity performance and participation in different activities (2). The overall prevalence of this disorder is 2.11 per 1000 live births (2), and 29% of them are diagnosed with hemiplegia. In these children, one side of the body is affected more than the other, and the upper extremity is usually involved more severely than the lower extremity (3). Therefore, they have difficulty playing with toys and performing activities of daily living (ADL) (1). Most of these children are intelligent and study at regular schools (4). However, due to their inability to use the upper extremity of one side of their body, they are limited in education and leisure, consequently significantly influencing their social functioning and participation in daily living skills (5). Due to the poor function of their upper extremity, children with hemiplegia tend to use the less affected side of their body while performing their occupations, such as the ADL (3). This phenomenon is called "learned non-use," in

which the affected hand is used less than the non-affected hand or is not used at all (3).

Modified constraint-induced movement therapy (m-CIMT) is employed to overcome the learned non-use phenomenon during the treatment process. m-CIMT is the modified version of signature pediatric constraint-induced movement therapy (P-CIMT), meaning that m-CIMT has all components of P-CIMT, but the dosage of m-CIMT is less than P-CIMT (6). m-CIMT is comprised of three major components: 1) Restricting the non-affected upper extremity, 2) Encouraging repetitive and intensive movement exercises using the affected upper extremity, and 3) Dividing the desired performance movements into smaller ones, offering a reward when the favorable outcomes are approximately reached, and helping children to transfer the exercises to the ADL in their natural environment (7). This approach aims to assist children in voluntarily using the affected upper extremity by limiting the non-affected upper extremity and giving them no choice but to use the affected one (8). m-CIMT benefits children by compelling them to find solutions for their movement restrictions (3).

Occupational therapists are experts at occupation-based and activity analysis (OB/AA), so they can

use their skills in such analysis during treatment. The occupation-based analysis is performed to determine the client's specific conditions and the occupations they want or need to do in the natural environment and is carried out based on the client's goals. In contrast, activity analysis is conducted to identify how the activity is performed. Both types of analysis are used to detect performance patterns and skills and client factors to improve the preferred performance (9). Both analyses are necessary to evaluate performance and design treatment plans. The client-centered approach is a way to actively involve clients and caregivers in the treatment process, emphasizing the client's knowledge and experience, ability to choose, and autonomy (9). To design interventions for clients based on the client-centered paradigm, therapists need to amass important information. In other words, they should know what clients want and need to do. This valuable information helps therapists set treatment priorities based on clients' wants and requirements. In this regard, the client-centered approach necessitates occupation-based and activity analysis (9). Based on previous studies, constraint-induced movement therapy effectively improves upper extremity performance at the activity level. It plays a significant role in children's participation in occupational performance (3,6). However, no study has examined the effect of using m-CIMT along with occupation-based and activity analysis on the participation of children with hemiplegia. This study aims to investigate the effect of m-CIMT using occupation-based and activity analysis on the participation of children with hemiplegia as an essential and integral part of the client-centered intervention. Additionally, the present study examines the transferability of the learned skills to the ADL. Every child was treated individually using

the client-centered paradigm during occupational therapy, and the treatment goals were determined based on the needs and wants of the child and his/her parents.

Materials & Methods

Participants

In this study, as a single-blind clinical trial, the assessor and the families were unaware of the group they were assigned.

The inclusion criteria were as follows: 1) The child was diagnosed with hemiplegic CP by a neurologist, 2) The child was classified in manual ability scale levels I to III, 3) The child could actively extend the wrist of the affected hand 20 degrees, 4) The child could actively extend the fingers of the affected hand 10 degrees, 5) The child scored above 44 on the pediatric balance scale (10), 6) The child had no vision problems, 7) The child had no behavioral problems, so he/she could withstand the applied restriction, 8) The child's IQ score was higher than 70, and 9) The child had undergone no upper extremity surgeries nor had botulinum toxin injections over the last six months before the intervention and was not going to have them during the intervention.

The exclusion criteria included: 1) The child's comorbidity along with CP and 2) Seizure.

Twenty individuals with CP participated in this study. The sample size was calculated based on the results of Ahmadi Kahjoogh et al.'s study using the COPM score as a primary outcome measure (11) which showed that there should be 11 people in each group, with 80% power and significance level of 0.05. Unfortunately, due to excluding three participants due to the coronavirus outbreak, ten participants remained in each group.

Stratified randomization was performed to assign

the children to the groups. A random number table included two categories, MACS levels of I and II and a MACS level of III. The assignments were enclosed into sequentially numbered, opaque sealed envelopes (SNOSE) that the therapist kept.

Procedure

After the initial registration, children who met the inclusion criteria were selected as the current study participants. Two weeks before the intervention, an assessor evaluated the manual ability of these participants through the Pediatric/Tween Motor Activity Log (PMAL/TMAL) and ABILHAND-Kids instruments in the clinic. After that, the client and his/her family's wants and needs were determined using Canadian Occupational Performance Measure (COPM). Eventually, with the cooperation of the child and family, therapeutic goals related to ADLs were selected and set. Furthermore, various steps to achieving these goals were identified based on the information obtained from the COPM and the Goal Attainment scaling (GAS). All of these data were collected by an assessor who was unaware of the allocation of the participants to the groups before randomization. The family completed the COPM and GAS instruments for 5-to-9-year-old children, while these instruments were filled out for the 10-to-12-year-old children by both the child and the family. In the same session, the children's hand size was measured for building orthoses.

Based on the principles of the family-centered program (FCP) and occupational therapy home program (OTHP), the parents performed the intervention at home one hour per day, three days a week for four weeks, under the full supervision of the researcher (an occupational therapist). During the intervention, the non-affected upper extremity was restricted by an orthosis. After the one-hour

direct intervention by parents, the non-affected upper extremity was restricted by the orthosis for another three hours. The principles used for the intervention were based on the five principles of the OTHP to empower the parents.

After the orthoses were constructed (figure 2), therapist started treating both groups. He visited the participants at home and taught the child and family the principles of m-CIMT, the nature of this intervention, and how it should be implemented. For instance, the therapist explained how to shape, grade, and repeat activities and reward the child for being encouraged to cooperate, use the affected hand during exercises, and continue his/her cooperation. The therapist also provided examples of exercises considering the group to which they belonged. For the 5-to-9-year-old children, just the family received the training mentioned above, while these instruments were filled out for the 10-to-12-year-old children by both the child and the family. The therapist was an individual who was an expert in m-CIMT and pediatric occupational therapy, especially with CP, and the assessor was an individual who was an expert in pediatric occupational therapy, especially with CP. Both of them had at least five years of work experience and were explained the purpose and nature of the study by the researcher in three two-hour sessions to maintain the study's veracity. In addition, the therapist has not been a research team member.

Intervention Group

In this group, the therapist first analyzed the ADL tasks (activity analysis), determined from COPM, and what the child and family want and need. Then he went to the participants' homes and asked the child to perform the activities. After that, the therapist assessed the child based on the items of performance skills in Occupational Therapy

Framework Practice (OTPF) (fourth edition) and detected the motor deficits, including reaching, grasping, manipulating, and releasing of the child in performing the activities (occupation-based analysis). Then, the movements required to perform each skill were evaluated and analyzed to determine the movement the child could not do. Thus, both types of analysis were used to design treatment plans and therapeutic activities for the participants in this group. Then the child and the family were taught exercises and activities that only required performing the ineffective movements; for example, supination movements to take a spoon to the mouth and wrist extensions in holding a glass. Activities and exercises for each client differed from the others based on his/her condition, and the exercises did not include all the movements required for the skills mentioned. Worth mentioning that the exercises were chosen and done based on the principles of m-CIMT. They also were asked to use these activities under the full supervision of the therapist. At the end of each session, the parents sent the therapist short videos of the performed exercises on WhatsApp. They also reported the duration of each activity and the number of repetitions.

Regarding the purpose of the study (the implementation of m-CIMT using occupation-based and activity analysis), the therapist provided the required feedback to the family. Therefore, if parents did what the therapist had taught them incorrectly, the therapist warned them to do it correctly. In addition, if the parents had made any mistakes, the therapist informed them about their mistakes. The therapist also answered any questions they had.

Control Group

In this group, the therapist went to the participants'

homes and taught the family and the child practices, including reaching, pinching/grasping, releasing, in-hand manipulating, and weight-bearing, without using occupation-based and activity analysis they practiced these activities in the ordinary way of m-CIMT. In other words, none of the analysis were used to design treatment plans and activities for the participants in this group. At the end of the session, the therapist asked the parents to send short videos of the exercises on WhatsApp. The duration of each exercise and the number of repetitions were also reported to the therapist. If parents did what the therapist had taught them incorrectly, the therapist warned them to do it correctly, and when they asked any questions, he answered them.

One week after the completion of the intervention, the COPM, ABILHAND-Kids, and PMAL/TMAL instruments were filled out by the family to compare these data with the baseline assessments performed before the intervention and identify the outcomes of the intervention. The GAS was also completed to determine the child's progress toward the predetermined goals. All of the assessments were performed in the clinic environment. Two months after the second assessment, each child was reevaluated via the abovementioned instruments to follow up on the treatment.

Notably, this study was accepted by the Ethics Committee (ethical code: IR.IUMS.REC.1399.299, IRCT ID: IRCT20191109045376N1) of the Iran University of Medical Sciences. After the final registration and before the assessment process, the families signed the written informed consent.

Outcome measurement

Primary outcome

Canadian Occupational Performance Measure (COPM)

The COPM is a client-centered assessment tool

whose focus is on clients. COPM evaluates the child in self-care, leisure, and productivity. In this instrument, the child and the parents initially detect the occupations the child has difficulty performing and then prioritize three or five occupations to improve his/her self-care, leisure, and productivity. The child and the parents rate the performance and the level of satisfaction in each area from one to ten. Test-retest reliability of the performance and satisfaction scores were 0.84 and 0.87, respectively (12). This tool's minimal detectable clinical change was 2 (13).

Goal Attainment Scale (GAS)

The score of this instrument is in the range of -2 to +2. At the end of the treatment sessions, a score of zero is expected to be a desirable goal. If the child develops more than the determined goal, the score is +1, and if he/she develops much more than the determined goal, he/she receives a score of +2. Similarly, if the child progresses less than the identified goal, he/she receives a score of -1, and if he/she progresses much less than the identified goal, he/she receives a score of -2. In the present study, all goals were weighted 1, and the children's performance scores were -2 at the beginning of the intervention. Because of the validity and reliability of this tool, every attempt was made to coordinate the assessor, the therapist, and the researcher in terms of the purpose of the study, goal setting, and the scoring procedure. In each assessment phase, the child's score was calculated based on the following formula:

$$T \text{ score} = 50 + \frac{10 \sum(w_i x_i)}{\sqrt{(0.7 \sum w_i^2 + 0.3(\sum w_i)^2)}}$$

Manual Ability Classification System (MACS)

MACS is a system for classifying the manual

ability of children with CP aged four to 18 in five levels based on the ability to manipulate objects, the amount of help, and the adaptation needed to perform daily manual activities (14). In this classification system, each hand is not classified separately, but the use of both hands is classified simultaneously (14). In level I, the child can use his/her hand quickly, and objects are handled successfully. Level II is the same as level I, but speed and performance quality is reduced. In level III, the child needs help, and the activity should be modified. In level IV, the child needs more support and assistive devices and is restricted from performing some movements. Finally, in level V child's hand is severely affected, meaning that he/she cannot do even simple actions and needs total assistance (15). The more the child's level of MACS is low, the better the child's manual abilities. This system was just used for inclusion criteria, and randomization and MACS are no longer used for post-test and follow-ups.

Secondary

Pediatric/Tween Motor Activity Log (PMAL/TMAL)

The PMAL/TMAL score children's motor ability between seven months to eight years (PMAL) and those aged nine to 14 years (TMAL). The PMAL/TMAL includes twenty-two activities that require using arms and hands. It is designed to assess the spontaneous use of the affected hand during uni/bilateral gross/fine motor activities using the modified versions of the MAL. It includes two significant scales: the "how often" scale and the "how well" scale. The "How often" scale is the degree to which the affected hand is used and is scored from 0 (not used) to 5 (always used). The "How well" scale is the quality of using the affected hand rated from 0 (not used at all) to 5

(commonly used). These two scales of the PMAL have high intra-class correlation coefficients (HO: ICC=0.94; HW: ICC=0.93) (16) by children with hemiplegic cerebral palsy (CP). In the current study, the minimal detectable clinical change was 0.78 for PMAL-HO and 0.79 for PMAL-HW (17).

ABILHAND-Kids

The ABILHAND-Kids is a tool that is scored by parents and includes twenty-one items of bilateral ADL. Parents rate the items based on their perception of the difficulty of each item for the child on a three-level scale: impossible (0), difficult (1), and easy (2). The test-retest correlation coefficient for item difficulty and children's measures was 0.96 and 0.70, respectively (18). The minimal detectable change of this tool was 31.07% (3.21 logits, a raw score of 6.13).

Statistical analysis

In the present study, continuous variables were expressed as mean, standard deviation (SD), and categorical variables as frequency (percentage). Analysis of covariance (ANCOVA) was used to compare the groups after controlling for pretest scores. The effect size was reported in partial eta squared (η^2_p); η^2_p values of 0.01-0.06, 0.06-0.14, and >0.14 were considered as small, medium, and large effect sizes, respectively (19). Statistical analysis was undertaken using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). A $P < 0.05$ was considered statistically significant.

Results

Participants' characteristics

The flow of participants through the trial is illustrated in Figure 1. Thirty-six children were screened, and twenty-three underwent randomization. The first patient underwent

randomization on July 23, 2020, and the last on February 3, 2021. Of these, follow-up data were available for twenty children (86.9%) to be included in the intention-to-treat analysis (Figure 1). The demographic and clinical characteristics of the children are presented in Table 1. The mean age of the children was 7.73 (SD=2.43) years. Of the children, 54.5% were male, 36.4% had a left-sided unilateral CP, and 45.5% had a MACS III level. Demographics and clinical characteristics were well balanced between m-CIMT and m-CIMT+OB/AA groups.

Primary outcomes

As presented in Table 2, the m-CIMT+OB/AA group revealed higher COMP-P scores compared with the m-CIMT group at both post-test and follow-up measurements. However, these differences were not statistically significant ($F_{(1,19)}=2.14$, $P=0.160$, $\eta^2_p=0.101$, and $F_{(1,19)}=3.92$, $P=0.062$, $\eta^2_p=0.171$, respectively). The effect sizes, calculated using partial eta squared, were 0.101 and 0.171, considered medium and large, respectively. The same results were also obtained for COMP-S scores at post-test ($F_{(1,19)}=1.53$, $P=0.231$, $\eta^2_p=0.075$) and follow-up ($F_{(1,19)}=2.11$, $P=0.162$, $\eta^2_p=0.100$). After adjusting for pretest scores, patients in the m-CIMT+OB/AA group scored, on average, 13.6 (95% CI: 1.5-25.6) points higher on the GAS than patients in the m-CIMT group at the post-test measurement ($F_{(1,19)}=5.55$, $P=0.029$, $\eta^2_p=0.226$). The same result was obtained at the follow-up measurement ($F_{(1,19)}=4.88$, $P=0.040$, $\eta^2_p=0.205$).

Secondary outcomes

At the post-test measurement, there was no statistically significant difference in ABILHAND-Kids between m-CIMT and m-CIMT+OB/AA groups ($F_{(1,19)}=0.64$, $P=0.434$, $\eta^2_p=0.033$). At the follow-up, the ABILHAND-Kids scores in the

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m-CIMT+OB/AA group were higher than that in the m-CIMT group, although this difference was not statistically significant ($F_{(1,19)}=2.90$, $P=0.105$, $\eta^2_p=0.133$).

Results of the ANCOVA showed a higher PMAL-HO score for the m-CIMT+OB/AA group compared to the m-CIMT group at both post-test and follow-up measurements. However, these differences were not statistically significant ($F_{(1,19)}=3.53$, $P=0.076$, $\eta^2_p=0.157$, and $F_{(1,19)}=3.72$, $P=0.069$, $\eta^2_p=0.164$). The effect sizes were 0.157 and 0.164, respectively, which are considered significant.

At both post-test and follow-up measurements, the m-CIMT+OB/AA group showed higher PMAL-HW scores when compared with the m-CIMT group. However, these differences also were not statistically significant ($F_{(1,19)}=2.59$, $P=0.124$, $\eta^2_p=0.120$, and $F_{(1,19)}=2.53$, $P=0.128$, $\eta^2_p=0.117$). The effect sizes were 0.120 and 0.117, respectively, considered medium.

Table 1. Baseline characteristics of study participants.

	Total (n=22)	Group	
		m-CIMT (n=12)	m-CIMT+OB/AA (n=10)
Age (years), mean (SD)	7.73 (2.43)	7.58 (2.43)	7.90 (2.56)
Gender, n (%)			
Male	12 (54.5)	6 (50.0)	6 (60.0)
Female	10 (45.5)	6 (50.0)	4 (40.0)
Affect side, n (%)			
Left	8 (36.4)	4 (33.3)	4 (40.0)
Right	14 (63.6)	8 (66.7)	6 (60.0)
MACS level, n (%)			
I and II	12 (54.5)	7 (58.3)	5 (50.0)
III	10 (45.5)	5 (41.7)	5 (50.0)

Abbreviations. SD: Standard Deviation; MACS: Manual Ability Classification System; m-CIMT: Modified- Constraint Induced Movement Therapy; OB/AA: Occupation-Based and Activity Analysis.

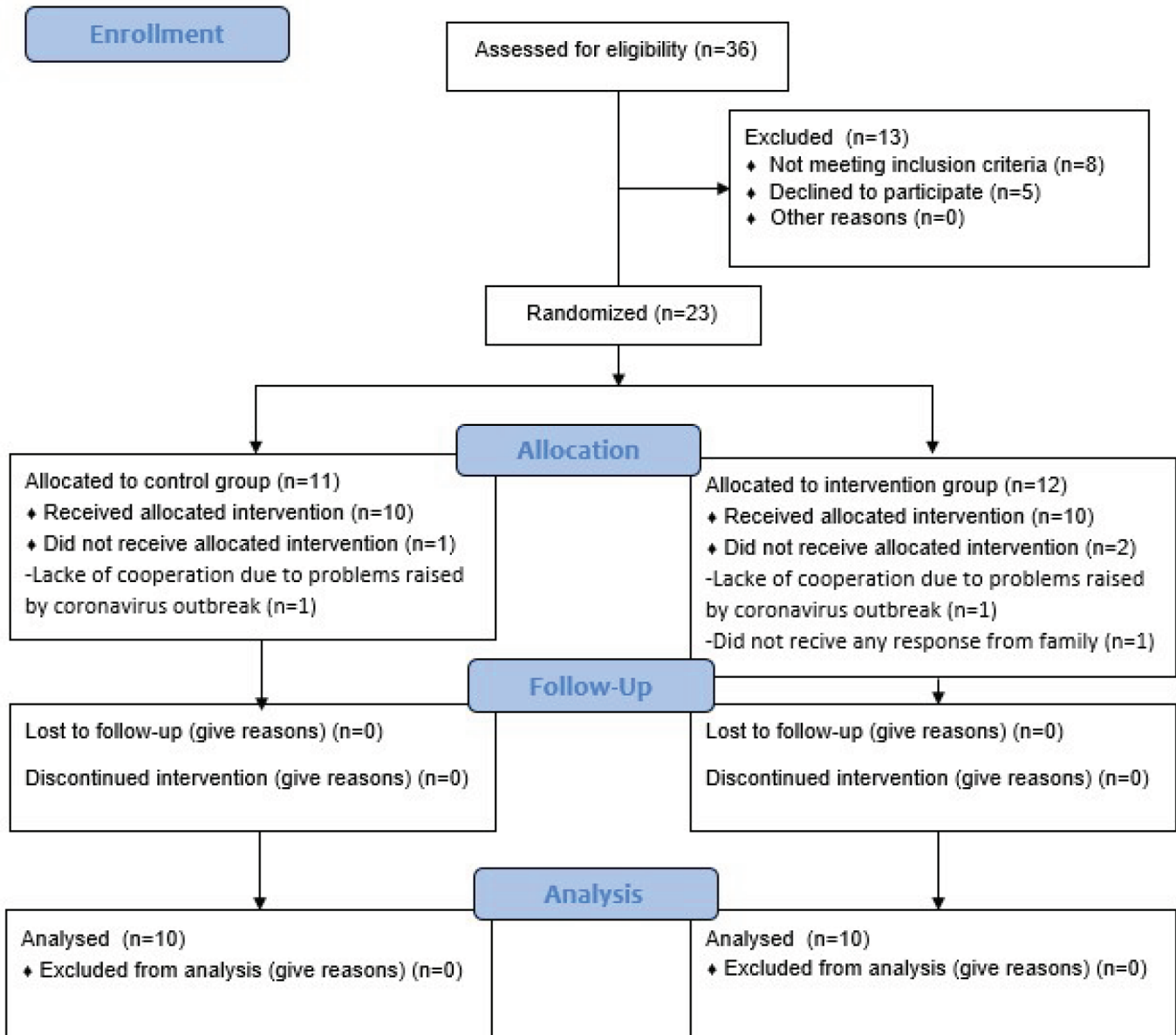


Figure 1. Consort 2010 flow diagram



Figure 2. A participants while wearing An orthosis

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Table 2. Results of ANCOVA examining group effect on post-intervention scores of the outcome variables

	m-CIMT	m-CIMT+OB-AA	Adjusted mean difference (95% CI) ^a	F _(1,19)	P	η ² _p
COMP-P						
Pretest	3.18 (1.87)	3.76 (2.27)				
Posttest	4.80 (2.07)	6.28 (2.96)	0.87 (-0.37 to 2.10)	2.14	0.160	0.101
Follow-up	4.83 (2.06)	6.75 (3.14)	1.31 (-0.07 to 2.70)	3.92	0.062	0.171
COMP-S						
Pretest	3.64 (2.61)	3.50 (2.06)				
Posttest	5.26 (2.62)	5.95 (2.84)	0.82 (-0.57 to 2.21)	1.53	0.231	0.075
Follow-up	5.30 (2.69)	6.26 (2.98)	1.09 (-0.48 to 2.66)	2.11	0.162	0.100
GAS						
Pretest	25.6 (2.3)	26.4 (3.9)				
Posttest	42.0 (13.8)	55.0 (12.3)	13.6 (1.5 to 25.6)	5.55	0.029	0.226
Follow-up	45.4 (14.5)	58.1 (14.0)	13.6 (0.7 to 26.5)	4.88	0.040	0.205
ABILHAND-Kids						
Pretest	19.2 (7.4)	20.3 (11.3)				
Posttest	26.5 (6.4)	29.1 (10.3)	1.9 (-3.0 to 6.8)	0.64	0.434	0.033
Follow-up	26.2 (5.7)	30.5 (9.9)	3.5 (-0.8 to 7.9)	2.90	0.105	0.133
PMAL-HO						
Pretest	1.70 (1.29)	1.19 (0.83)				
Posttest	2.36 (1.07)	2.58 (0.86)	0.56 (-0.06 to 1.18)	3.53	0.076	0.157
Follow-up	2.46 (1.14)	2.76 (0.88)	0.64 (-0.05 to 1.34)	3.72	0.069	0.164
PMAL-HW						
Pretest	1.64 (1.21)	1.46 (0.96)				
Posttest	2.22 (1.09)	2.54 (1.00)	0.45 (-0.14 to 1.04)	2.59	0.124	0.120
Follow-up	2.32 (1.10)	2.71 (1.05)	0.51 (-0.16 to 1.19)	2.53	0.128	0.117

Data are mean (SD), unless otherwise specified.

^aAdjusted for pretest scores.

η²_p values of 0.01-0.06, 0.06-0.14, and >0.14 were considered as small, medium, and large effect size, respectively.

Abbreviations. M-CIMT: Modified-Constraint Induced Movement Therapy; OB/AA: Occupation-Based and Activity Analysis; CI: Confidence Interval; COPM-P: Canadian Occupational Performance Measure–Performance; COPM-S, Canadian Occupational Performance Measure–Satisfaction; GAS: Goal Attainment Scaling; PMAL-HO: Pediatric Motor Activity Log-How Often; PMAL-HW: Pediatric Motor Activity Log-How Well.

Discussion

m-CIMT leads to increased participation and manual abilities in children with hemiplegia (3,20–22), which is seen in both groups of present study. According to the results of this study, occupation-based m-CIMT accompanied by occupation-based and activity analysis leads to further increased participation and improved manual abilities.

According to the results of the study done by Sakzewski et al. (23), although the results of Activity-based and goal-oriented CIMT have a significant difference, it has little effect on participation. However, according to the results of the present study, occupation-based m-CIMT (m-CIMT+OB/AA) leads to a significant increase in participation, and its effect remains during follow-up.

In another study by Sakzewski et al., although therapeutic goals were determined with the cooperation of the child and family like in our study, and there were significant results of the interventions, a slight difference in manual abilities was observed between the two groups receiving Hybrid-CIMT and the group receiving routine occupational therapy interventions (24). Due to the high effect size in the present study, it seems that using m-CIMT accompanied by occupation-based and activity analysis alone and with proper intervention duration can increase manual ability more.

Previous studies have suggested that more than thirty hours of direct intervention is advised for the m-CIMT to be effective and its effect remains for a long time (24,25), while the duration of interventions in the present study was 12 hours of direct intervention and another thirty-six hours non-affected hand was limited only. In addition, the follow-up period was two months. Because of

these and medium to large effect sizes in outcome measures, in future studies, it is necessary to perform m-CIMT accompanied by occupation-based and activity analysis with the suggested duration and longer follow-up time that may influence significance.

Even though there was a lack of significant difference between the results of the two groups, based on a study by Aarts et al. (26) and the present study results, the scores obtained from COPM-P and COPM-S, the participation in both groups has increased. However, participation in the m-CIMT+OB/AA group has increased more with medium to large effect size, and its effect remains to follow-up. The average scores of participation (COPM-P and COPM-S) in the m-CIMT+OB/AA group in the post-test to follow-up significantly increased compared to the control group. This issue is also seen in the scores obtained from ABILHAND-Kids, which leads to a significant improvement in manual abilities and bilateral activities in the post-test with medium to large effect size in m-CIMT+OB/AA group, and its improvement increases during the follow-up.

However, the scores obtained from GAS show a significant difference with the high effect size at the time of post-test and follow-up, which indicates the achievement of the client's desired goals and increased participation greater extent in the m-CIMT+OB/AA group.

Based on previous studies, it can be concluded that occupation-based m-CIM+OB/AA increases the transfer and generalization of motor skills which causes participation and manual abilities to promote after the post-test. It also leads to more client motivation and cooperation in the interventions (28) because changes in participation depend on the goals set by the child and the family

(23), which is a prerequisite for occupation-based interventions.

With this interpretation and what is said in OTPF4, occupation-based intervention like m-CIMT+OB/AA first requires occupational-based and activity analysis as an integral part of it.

One of the goals of m-CIMT is to reduce the learned non-use phenomenon (3,8,29–31). According to the results of this study, m-CIMT+OB/AA increased the use of the affected hand more and reduced developmental disregard compared with the control group, which remains its effect during follow-up. The scores of PMAL-HO showed this issue with a large effect size (post-test: 0.157, follow-up: 0.164), and its P-value is closer to 0.05 (post-test: 0.076, follow-up: 0.069) than other instruments.

As a result, based on the study of Rostami et al. (27) and the present study, it can be said that the content of the intervention and how to select and target treatment (m-CIMT+OB/AA) is essential in increasing participation and manual ability of these children, which increases the use of the affected hand.

Among the factors that may affect the effectiveness of the m-CIMT are the age and extent of the level of affected hand function (29,32). In the present study, the number of people with MACS levels of I, II, and III is almost equal (level I and II:55.5% and level III:45.5%), which can affect the results (P-value). As a result, it is suggested that in future RCTs, m-CIMT+OB/AA will be done with groups of level I, II, and III separately, which will assess the m-CIMT+OB/AA effect on each level of affected hand function. However, it is said that age is one of the variables affecting the m-CIMT. Nonetheless, Deppe et al. stated that age is not effective in m-CIMT (32), and the age range of

participants in our study is almost similar to Deppe et al. study.

As mentioned in the previous study, valid and reliable tools should be used in a study (33,34). Due to the recommendation of previous studies to use tools that assess functional skills (29), COPM and GAS were used to measure participation. However, in previous studies, GAS and COPM tools have been used to determine goals and goal setting (23,24,26,35). In this regard, proposedly, other tools, such as LIFE-H, AMPS, and WeeFIM, can be used to measure participation more accurately. Other tools should be used because participation is a subjective concept that affects individual, environmental, and family factors (23) and the significance level of the results. This issue might cause a difference in participation scores, but in the present study, the scores have not been significantly different, and other aspects should have been evaluated.

The present study has several limitations that should be considered when interpreting the findings. First, the prevalence of COVID-19 caused some parents to refuse to participate in the study before starting or during the intervention, leading to excluding the study. Second, the sample size was relatively small, which may have reduced the statistical power to detect differences between groups at post-test and follow-up. Third, some families did not have internet access. Therefore, they could not participate in our study.

Finally, according to the results of this study and the existing limitations, to ensure the generalizability of this study, it needs to be executed m-CIMT+OB/AA with a higher sample size in future RCTs to investigate the effect of occupation-based m-CIMT by using occupation-based and activity analysis in children's participation with hemiplegia in the

ADL and other occupational areas.

In Conclusion

Occupation-based and activity analysis, one of the critical parameters of OTPF, should be used by occupational therapists when they use m-CIMT because it leads to increased participation and quantity and quality of manual ability in daily living skills. In addition, another suggestion based on this study is that m-CIMT should be done at home by empowering and training parents under the supervision of a therapist based on FCP and OTHP principles. In addition, using occupation-based and activity analysis leads to more client-centered intervention, so it can increase the motivation of the child and parents to cooperate in intervention, which leads to more efficacy of m-CIMT.

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Author's contribution

Malek Amini: conceptualized the study, helped in writing and the final manuscript as submitted, helped in holding a briefing session for the therapist and assessor to familiarize with the purpose and nature of the study.

Ali ostadzadeh: conceptualized the study, wrote the manuscript, Communication with therapist and assessor to receive data and helped in holding

a briefing session for the therapist and assessor to familiarize with the purpose and nature of the study.

Afsoon Hassani mehraban: conceptualized the study, helped in writing and the final manuscript as submitted and contacting the officials of the clinics to introduce the participants.

Saman Maroufizadeh: helped in writing and the final manuscript as submitted.

Ata farajzadeh: Communication with therapist and assessor to receive data, helped in holding a briefing session for the therapist and assessor to familiarize with the purpose and nature of the study.

All the authors agreed not to interfere with personal interest in the writing of the study for the accuracy of the study results and to be accountable appropriately for all parts of the work.

Conflict of interest

The authors declare that they have no conflict of interest.

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