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RESEARCH ARTICLE

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Evaluation of Effectiveness of Modified Pediatric Constraint-Induced Movement Therapy Performed on Children with Cerebral Palsy by a Home-Treatment Program

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ABSTRACT

A series of pediatric Constraint-induced Movement Therapy (CIMT) sessions were conducted online on ten children with unilateral cerebral palsy (CP) under a home treatment program. The intervention effectiveness of the therapy was evaluated by employing Peabody Developmental Motor Scales (PDMS), Pediatric Evaluation of Disability Inventory (PEDI), and Pediatric Motor Activity Log PMAL) as indices. The home practice CIMT protocols included the constraining of the non-paralyzed hand (by wearing safety mittens on it), MAL management by mothers, and intensive practices by shaping performed at home with mothers. Notably, all ten participants completed the program. Scores of PDMS, PEDI, and PMAL exhibited significant improvements during the intervention, whose effects lasted until the follow-up evaluation three months after it. The results of this study demonstrate that pediatric-CIMT (P-CIMT) at home, involving the constraining of the non-paralyzed hand by wearing safety mittens on it, could exhibit the same level of treatment effects as the P-CIMT conducted on patients visiting the outpatient department of medical facilities.

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Introduction

Cerebral palsy (CP) is a neurodevelopmental disorder characterized by motor and postural deficits; it consists of two-thirds of all cases of pediatric motor disabilities [1]. The types of CP by body parts include quadriplegia, triplegia, diplegia, and unilateral CP. Cases with unilateral CP consist of 30% of all CP cases, and it is the most frequent type of CP in full-term infants, with a prevalence of 0.6 per 1,000 newborns [2]. Many unilateral CP cases exhibit problems in hand motor coordination, affecting negatively on the independent performance of activities of daily living (ADL) and quality of life (QOL) of the children [3,4]. Importantly, this situation often leads to a condition known as learned non-use, because those with unilateral CP tend to "learn" to use only the non-paralyzed-side extremities in performing ADLs [5]. Constraint-induced movement therapy (CIMT) is one of the intervention treatment methods aiming to overcome the condition of learned non-use [6,7]. Taub et al. of the University of Alabama developed a CIMT applicable to children with unilateral CP, called pediatric-CIMT (P-CIMT), in 2004, whose efficacy has already been reviewed in several studies [8-12]. Many studies of P-CIMT employ the following four protocols: 1) intensive training with progressively increasing difficulty levels (shaping); 2) fitting the participants with a fiberglass cast on their non-paralyzed upper extremity for two weeks (constraining); 3) therapists and mothers attending face-to-face interview sessions daily to confirm how often children use their paralyzed hands in ADLs (pediatric motor activity log (PMAL) administration); and 4) administering daily home practice (HP). However, the protocol has two problems. First, mothers have to visit care facilities with children everyday, increasing their stress levels and leading to their exhaustion. Numerous studies have reported depression or exhaustion among mothers of children with CP, demonstrating that daily commuting to and from care facilities would increase mothers' stress levels [13-15]. Another problem is the injury risk of the children from falling when the movement of the non-paralyzed-side extremities was completely restrained. Several studies have reported that the falling risk of children with CP is higher than that of ordinary children, with 35% of them falling everyday and 30% of them falling every week and every month [16,17]. Considering this high falling risk, wearing a fiberglass cast can be dangerous and performing all ADLs with constraints is extremely challenging. Therefore, the number of papers discussing P-CIMT is relatively less, suggesting that the successful completion of the P-CIMT program is not an easy task. To attend to these problems, the program was implemented online in this study without participants' commuting to and from medical facilities, by providing a spasm reducing treatment device for in-home use and online intervention by therapists, thereby supporting the participants to conduct intensive practice at home. In addition, the home pediatric CIMT (HP-CIMT) of this study, in which the constraining equipment fitted to the non-paralyzed-side extremities was changed from a fiberglass cast to safety mittens to enable the participants to use their hand to prevent from falling, was evaluated of its effectiveness, with mothers not commuting daily with their children with unilateral CP to clinics.

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Methods

Participants were recruited by contacting multiple associations of families with CP patients and social networking services. The inclusive criteria for the study were set as follows: 1) children aged six to eight years and were diagnosed with unilateral CP; 2) children who were categorized under level II or III according to the manual ability classification system (MACS) scores [18]; 3) children who exhibited evident paralysis in their paralyzed-side upper extremities; and 4) children for whom the consent of family was obtained to participate in the intervention program that includes the intensive use of the paralyzed-side upper extremities. The exclusive criteria were also set as follows: 1) children with medical problems unrelated to CP; 2) children who exhibited severe tension in relevant muscles (with modified Ashworth scale score > 3.5), and 3) children who had received or planned to receive botulinum toxin treatment within the past six months of or during the research period.

The first author of this paper explained the details of the HP-CIMT program to ten candidates among 14 applicants, from whom a written consent was obtained ahead of their participation in the program. This study was conducted with the approval of the Research Ethics Committee of Tokyo Metropolitan Fuchu Medical Center for the Disabled and the Shonan University of Medical Sciences, and informed consent was obtained from the participants and their guardians.

Evaluation

All participating children and their mothers had visited the care center to which the second author of this paper belongs, at the following times: three months before, one day before, on the final day of, and three months after the program period for the intervention effectiveness evaluation. The second author of this paper is a physical therapist, who has completed the P-CIMT training course at the University of Alabama and was responsible for the evaluation of all participants.

For the participants' physical function assessment, two subscales of the Peabody developmental motor scales - Second Edition (PDMS-2) [19], namely, 26 items of PDMS-G with a total score of 52 points and 72 items of PDMS-V with a total score of 144 points (for the evaluation of visual-motor integration) were employed in this study. Each of the item in the two subscales was evaluated against a three-point scale with 0 point for being unable or unwilling to move, 1 point for being able to move but not at the standard level of movement, and 2 points for being able to move at the standard level of movement.

The evaluation using the pediatric evaluation of disability inventory (PEDI) [20] was also conducted to assess the participants' ADL performance. Notably, PEDI is a set of scales that determine the level of independence in ADLs. First, the functional skills scale (FS scale) samples the meaningful sub-tasks of a set of complex functional activities. In addition, a caregiver assistance scale (CA scale) is a measure of the extent of help the caregiver provides in typical daily situations. Notably, Part I of the scales (FS scale) evaluates the children's functional abilities in the areas of self-care (73 items), mobility (59 items), and social function (65 items). The scores for this evaluation are set as follows. A score of 1 is assigned if the child performs the assessed item, and a score of 0 is assigned if the child cannot perform it. Likewise, Part II of the scales (CA scale) aims to determine the level of the child's need for assistance from a caregiver for performing 20 items in the same areas evaluated in the first part. The scores for this evaluation are set as follows. A score of 5 for being independent, 4 for needing supervision, 3 for needing minimum assistance, 2 for needing moderate assistance, 1 for needing maximum assistance, and 0 for needing total assistance. In addition to the above task-performance evaluations, a series of structured interviews using the pediatric motor activity log (PMAL) [21] were conducted to confirm how often the participants had used the paralyzed upper extremity (How Often scale or HO scale) and how well they performed these tasks (How Well scale or HW scale) in terms of 22 ADL items conducted outside of the clinic. A six-point scale, ranging from 0 to 5, was used to give a score to each ADL item. The higher the HO scores, the more often the participant had used a paralyzed hand, and higher HW scores led to better movement quality. The total score of each scale was calculated using the items' mean scores.

Intervention

All ten participants were elementary school students and participated in the program for 15 consecutive days during a summer vacation. The program protocols employed in this study included: 1) intensive training to the participants with progressively increasing difficulty levels (shaping); 2) wearing safety mittens on the non-paralyzed-side hand everyday during waking time except for the final two days of the program (constraining the non-paralyzed-side hand); 3) online daily interview sessions between the therapists and mothers (to confirm how often children use their paralyzed hands in ADLs: PMAL administration); and 4) administration of HP. Participants were allowed to remove safety mittens on the final two days of the program to induce the use of paralyzed-side hand during bilateral movement training. Participants wore safety mittens on the non-paralyzed-side hand during shaping and repeatedly practiced movement tasks required in ADLs, such as playing with toys or eating snacks, by using their paralyzed-side hand. Muscle tone in the participants' fingers would increase at each trial and require a therapist's treatment for spasm reduction in conventional CIMT programs. In this study, a spasm reduction treatment device was provided to each participant for use in their homes and the mothers performed spasm reduction treatment using the device. Notably, the piston device for finger (PDF; Figure 1) developed by Nagoya Institute of Technology was employed as the spasm reduction device. A study reported the effectiveness of PDF in spasm reduction and stretching of contracted muscles by moving the finger joints of the paralyzed-side hand at a frequency of 5Hz and above [22]. For the constraining of the non-paralyzed-side hands, Safe Mitten III for Child manufactured by a Japanese medical equipment manufacturer, Taketora Co., Ltd., was employed in this study. The wearers of this mitten cannot perform pinching or grasping movement by the wearing hands but they can press, clap, and hold items using palms of both hands. It also allows the wearers to regain balance by putting their hands on the floor during falling. In addition, the participants wearing the mittens could perform several gross motor movements using non-paralyzed upper extremities during this program, and we intentionally

allowed them in this study. Mothers were allowed to let the children remove the mittens when they were unwilling to wear them and instructed to record the time without mittens. They were also instructed to record HW scale alone in terms of PMAL management so that the daily improvement in the score would motivate them to encourage their children to use paralyzed hands. Regarding HPs, mothers and participants were instructed to select multiple tasks from a list of various toy-play activities associated with ADLs and performed the tasks repeatedly for the day, so that they could enjoy the program activities at home without pressure. The first author of this paper attended daily online interview sessions with mothers of all ten participants using an internet meeting service provided by Zoom Video Communications, Inc. Three topics, 1) duration of mitten wearing; 2) HW scale score in PMAL; and 3) HP performance status, were primarily discussed in these interviews, in addition to attending to mothers' questions and counseling requests. The participants had removed the mittens and performed bilateral movement training with their mothers on Days 14 and 15. All ten participants had visited the care center to which the second author of this paper belongs, three months before the program, and received explanation of the HP-CIMT program outline and precautions in program participation from the first author.

Data Analysis

A matched pair test of Wilcoxon was employed for the statistical analysis of the data obtained on the day before and the final day of the program to clarify changes in scales. The test was also used to compare the results obtained immediately after the program and those obtained in the follow-up evaluation to confirm if the intervention effects would endure. The levels of intervention effectiveness was determined using Cohen's formula, in which the levels were set as follows. A score of 0.8 and above was deemed to correspond to a "large effect", 0.5 and above was deemed to denote an "intermediate effect", and 0.2 and above was deemed to signify a "small effect" [23].

Results

All ten participants (six boys and four girls, mean age of 7.52 years, and a standard deviation of 0.94 years) completed the HP-CIMT program, with no program withdrawal, including all relevant protocol practices and evaluation sessions. Table 1 shows the participants' baseline data. The average duration in which participants wore the safety mittens during the wakening time was 5.78 hours (7.2 hours was the longest duration, and 4.8 hours was the shortest).

Table 1: Clinical characteristics at baseline (n = 10).

Child	Affected side	Gender	Age, Yr.Mo	MACS
1	Left	Male	7.6	II
2	Right	Female	6.2	II
3	Right	Male	7.5	III
4	Right	Male	6.8	III
5	Left	Female	8.9	II
6	Right	Male	6.3	II
7	Left	Male	8.8	III
8	Right	Male	7.2	III
9	Left	Female	8.3	II
10	Left	Female	7.6	II

Table 2 indicates the score fluctuation in PDMS, PEDI, and PMAL obtained at pre-, post-, and follow-up of the intervention. PDMS-G, evaluating the skill activities of the paralyzed-side hand, showed significant improvements during the intervention, exhibiting p=0.01 in the comparison between pre-and post-interventions, along with a score of 0.61 in Cohen's d at p=0.01. In contrast, no significant difference was observed between post-intervention and three-month follow-up evaluation. The PDMS-V results also showed a significant improvement during the intervention with the score of 0.99 in Cohen's d at p=0.01 in the comparison between pre-and post-interventions. It also exhibited no significant difference between post-intervention and three-month follow-up evaluation, as seen in the results

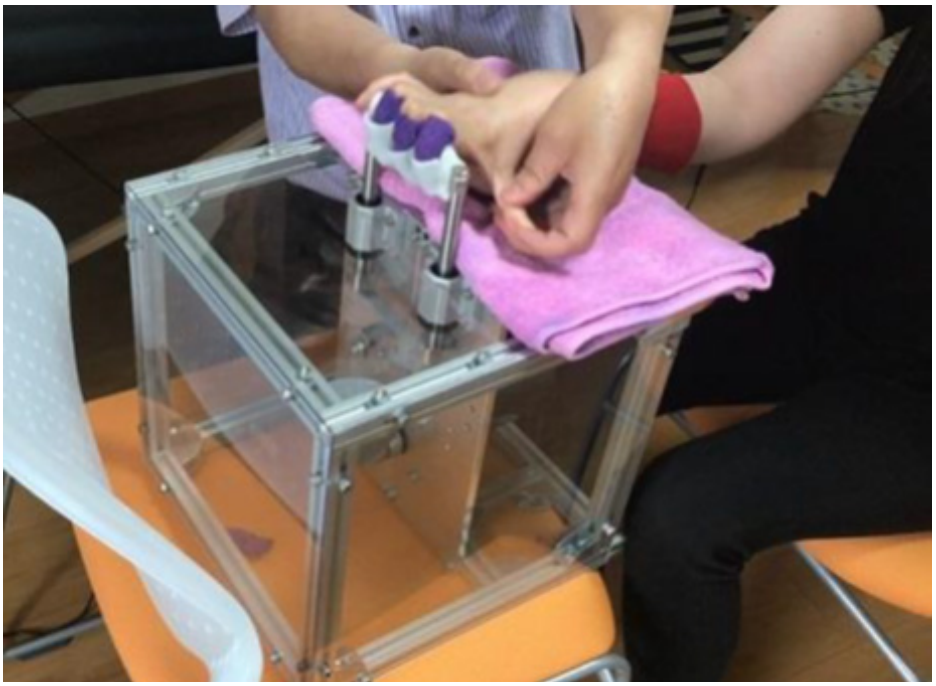

Figure 1: A child with unilateral cerebral palsy (CP) participating in the HP-CIMT program using a piston device for finger (PDF).

Outcome Measure		Pre	Post	*p*	Cohen's d Pre-Post	1-Mo Follow-Up
PDMS	Grasping	36.34 (1.59)	40.93 (1.97)	0.01	0.61	39.25 (1.94)
	Visual	86.73 (10.41)	100.54 (13.91)	0.01	0.99	96.72 (13.45)
PEDI	FS	49.04 (1.90)	53.16 (1.84)	0.01	2.24	51.47 (1.78)
	CA	50.74 (2.07)	58.49 (2.60)	0.01	2.98	56.55 (3.83)
PMAL	HO	0.76 (0.43)	2.40 (0.41)	0.01	4.00	2.09 (0.41)
	HW	2.54 (0.44)	2.97 (0.31)	0.01	1.39	2.74 (0.39)

Note: Values indicated in pre-, post-, and 3-Mo Follow-up are average scores (standard deviations). Grasping tasks were evaluated using the Peabody developmental motor scales – Second Edition (PDMS-2) and its sub-scale, PDMS-G. PDMS-V is another PDMS sub-scale integrating the evaluation of visual and physical movements. A subscale of PEDI called PEDI-FS is used to assess functional skills. PEDI-CA is another sub-scale of PEDI to evaluate CA.

of the other subscale. Regarding the PEDI self-care items, the participants' functional skills (FS) exhibited intermediate improvement, indicating a score of 2.24 in Cohen's d at p=0.01. However, a significant difference was observed between post-intervention and three-month follow-up evaluation in this scale, showing that the effect did not endure. The caregiver assistance scale (CA scale) score exhibited a substantial improvement in the comparison between pre-and post-interventions, showing a score of 2.98 in Cohen's d at p=0.01, whereas no significant improvement was observed between post-and three month after the intervention. In addition, the HO scale in PMAL showed an improvement with a score of 4.00 in Cohen's d at p=0.02 in the comparison between pre-and post-interventions. No significant difference was confirmed between post- and three month after the intervention. The HW scale showed a significant improvement with a score of 1.39 in Cohen's d at p=0.01 in the comparison between pre and post-interventions. At the same time, the comparison between post- and three month after the intervention did not indicate a significant difference.

Discussions

In this study, ten children with unilateral CP had participated in a unique modified P-CIMT program (HP-CIMT) where treatment sessions were implemented not onsite at clinics but online at home. In addition, the program introduced safety mittens for the constraining of the non-paralyzed hand instead of a fiberglass cast and evaluated their effectiveness. All participants successfully completed the program without any dropouts. Meanwhile, a study in the business field reported that remote work would increase workers' productivity and enhance their work-life balance [24]. Another study demonstrated that workers who employ this newly emerged working style exhibit better work performance and satisfaction, improving learning accomplishments as well [25]. According to the above study results, the online sessions can also be applicable to physical therapy, and the HP-CIMT program of this study could be completed without any setbacks.

The PDMS, PEDI, and PMAL results exhibited significant improvements during the intervention, whose effects endured up to the three-month follow-up in all scales except for the PEDI-FS. This suggests a possibility that the attempts to use the paralyzed upper extremities successfully led to the habituation because the practice was not conducted at medical facilities but at home, where the practice could easily be associated with ADLs. Regarding the task assignment, Page et al. reported that therapists often struggle to organize practice tasks that participants feel attractive [26]. In this study, participants' mothers, who know their children's preferences in plays and daily activities better than anyone else, assisted them in using the paralyzed upper extremities instead of therapists. Mothers' assistance at home would likely achieve the same degree of benefits as the tasks that are practiced with therapist's assistance. The average duration of wearing the safety mitten during the awakening time was 5.78 hours in this study. This suggests that the mitten-wearing duration was relatively more extended in this study than in previous studies using a fiberglass cast; one of which also reported that the participants did not wear casts at home [27].

Using safety mittens to restrain the non-paralyzed-side hand is superior in terms of safety compared to wearing fiberglass casts. However, the former allows more freedom in movement than the latter, and although the safety mittens restrained movements that require precision, participants could use the non-paralyzed-side hand in gross motor movements using both hands or in one-handed movements. The study results were significant in the point that a sufficient level of motor function improvement and an increase of frequency in the use of paralyzed-side hand were observed in the constraining condition using safety mittens. An experimental study subjecting participants with unilateral CP reported that repeated practice of the movement to grasp items using both hands improved the ability to manipulate the fingers of the paralyzed hand [28]. The protocols employed in this study aimed at guiding participants to use the paralyzed hand in precision-requiring movements while allowing the use of both hands. The study results suggested that such protocols could also be effective in motor function improvement of the paralyzed hand and the habituation of its use in ADLs. A study reported that removing the constraint on the paralyzed hand at the end of the P-CIMT program often led to a result where the use of paralyzed hand in ADL were not habitualized [29]. In this study, participants performed practices using both hands without a constraint in the final two days of the program. Performing various trainings using both hands and upper extremities after the training of the paralyzed hand probably resulted in a similar achievement of studies that reported the promotion of frequent use of a paralyzed hand in situations where one could use both hands [30,31].

A support style introduced in this study to implement programs at home should be a promising option that can be widely applicable to the CIMT practices aimed at habituating subjects to use their paralyzed upper extremities in ADLs.

Study Limitations

No control group was set and the sample size was too small in this study to collect enough data to test the effectiveness of the study. The effect of introducing a home practice instead of visiting medical facilities was not evaluated for whether it had contributed to reducing the mothers' mental/physical stress and exhaustion. The effect of introducing safety mittens instead of fiberglass casts in constraining the non-paralyzed hand was not evaluated. In other words, the study did not analyze which of these modified factors contributed to the results. Further investigation is necessary with a larger sample size and control groups to compare the effectiveness in terms of practice site and constraining equipment.

Conclusion

An in-home CIMT program, HP-CIMT using online session, was conducted on ten participants capable of voluntary movements in paralyzed-side upper extremities. Intervention effects were evaluated using PDMS, PEDI, and PMAL as standards. The HP-CIMT protocols included the constraining of the non-paralyzed hand (with safety mittens to avoid falling risks), MAL administration by mothers, and intensive practices of shaping at home by mothers. All participants successfully finished all protocols and evaluation sessions to complete the program. The PDMS, PEDI, and PMAL scores exhibited significant improvements during the intervention, whose effects endured up to the three-month follow-up evaluation. The study results suggested that the P-CIMT program conducted at home with protocols including the constraining of the non-paralyzed hand using safety mittens could achieve a similar level of effects of the P-CIMT conducted at medical facilities as one-on-one sessions with therapists.

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