**ABSTRACT**

**Purpose:** This study aimed to investigate the benefit to upper limb function of a home-based version of pediatric constraint-induced movement therapy which was delivered over a two month period. **Methods:** Nine children [mean age: 6 years, 9 months] with hemiplegic cerebral palsy participated in this A1-B-C-A2 design, where A1 and A2 were non-intervention phases. In phases B and C participants wore a splint on their unaffected hand. In phase C, motivating feedback through a computer game was added. **Results:** The Melbourne Assessment of Unilateral Upper Limb Function and the Quality of Upper Extremity Skills Test (QUEST) scores were significantly higher at the end of phases B (95% CI, p=.037 & p=.006, respectively) and C (p=.001 & p=.001). Melbourne scores remained higher at the end of phase A2 (p=.001). **Conclusions:** A non-intensive form of home based CIMT was found to be effective. Improvements were larger after the second month of intervention.

**Keywords:**  upper limb, home-based, cerebral palsy, constraint-induced therapy, modified

**Introduction and Purpose**

Constraint-induced movement therapy (CIMT), in which use of a neurologically impaired limb is encouraged by restraint of the contralateral unimpaired limb, grew out of research with non-human primates in which somatosensory de-afferentation of the dorsal root of the spinal nerve innervating one of the upper extremities had been performed. ‘Learned non-use’, a behavioral phenomenon linked to the clinical picture of hemiplegia in these primates, has been hypothesized to occur also in humans and is an important concept underpinning the rationale for the use of CIMT.

Constraint-induced movement therapy is a therapeutic intervention involving restraint of the uninvolved upper limb and intensive practice with the affected limb. The amount of practice and restraint time may not be appropriate for children and their families, who may have difficulty with adhering fully to such a regimen. In a randomized controlled study1 of the use of a bi-valved cast with six hours of exercise daily for a three week period, improvements were reported in the Quality of Upper Extremity Skills Test (QUEST). The authors encouraged future researchers to investigate whether a more child-friendly regimen with reduced treatment hours could also prove effective. Thus, researchers have attempted to develop modified, less intensive protocols of CIMT by reducing either the amount of practice or the daily restraint time or both.2-7

Home-based programs of CIMT may increase the adherence of children and their caregivers to the therapeutic program and may enhance family and child participation in activities that use the child’s own toys and take place in their natural environment. Chen and colleagues8 reported better motor control changes induced by a home based CIMT program compared to a dose-matched clinic-based traditional therapy, which included neurodevelopmental treatment techniques and unilateral and bilateral activity-oriented training. A randomized controlled trial9, investigated the same modified regimen of CIMT in two groups. The only differences arose from the randomization to either home-based therapeutic environment, where the children had the opportunity to engage in real-life conditions using their own toys, or the clinic-based environment. The findings revealed greater improvements in the home-based group. Wallen et al3 did not find statistically significant differences between a modified type of constraint-induced therapy and intensive occupational therapy. The authors however provided very little information on the content of the therapeutic program, the activities used and whether these were tailored to each child’s needs. A similar design was used by Lin et al4 who reported that modified CIMT was more beneficial than dose matched classic occupational therapy. The CIMT program in this study was based on principles of shaping and relied on repetitive practice of activities of daily living skills when children were not in therapy sessions. Similarly, Al Oraibi & Eliasson9 reported superior outcomes compared to Neurodevelopmental therapy not matched for intensity of the intervention with a modified home-based program of CIMT adhering to basic principles, such as individualization of treatment, positive feedback, parental education as well as basic education of therapists providing the CIMT regimen. Research on home-based CIMT in children with cerebral palsy remains sparse and the topic needs further investigation.11

The limitations to the practicability of clinic based, intensive programs of CIMT in children with hemiplegia led us to develop a low intensity home based CIMT protocol12. The aim of the present study was to examine the feasibility and the effectiveness of this protocol and to test if a second intervention period would yield additional improvements.

**Methods**

**Design and setting:** This was an uncontrolled clinical trial, An A1 – B – C – A2 design was used, which is considered the most appropriate design for participants with motor disorders in childhood.13 A1 and A2 were the baseline and follow-up periods, respectively and B and C were intervention phases. The screening process and all the assessments took place at the (*anonymized*) [institution]. The therapist responsible for the assessments was not involved in the treatment. The study received approval by the (*anonymized*) ethics committee (REC reference: 06/Q1702/74).

**Study sample:** Participants were recruited from three research sites (*anonymized*) via their pediatricians based at Child Development Centers. All children continued with their routine ‘standard of care’ therapy.

Inclusion criteria were : (1) age 5-11 years; (2) diagnosis of congenital spastic hemiplegic cerebral palsy (CP); (3) performance above the 10th percentile on the Raven’s Coloured Progressive Matrices (RCPM), a measure of non-verbal cognitive abilities that is relatively independent of motor skills14 (4) normally able to use the affected upper extremity for gross function in bilateral tasks, as determined by observation and from discussion with the child’s occupational therapist and pediatrician; (5) willing to take part in the study including both informed child assent and informed parental consent. Exclusion criteria were: (1) fixed contractures that would limit the movement of the affected upper extremity by more than one quarter of the normal range and/or (2) behavioral problems that might interfere with the child’s ability to comply with the protocol (as determined by the child’s therapist).

**Intervention:** The intervention took place at children’s homes. Parents were given specific instructions in order to engage their children daily in some of the activities selected from the list they were given. Children were encouraged to wear the splint for as long as they could cooperate. The researcher and parents had frequent communication (once or twice within a week) to discuss any problems or concerns.

The four phases of the study (A1-B-C-A2) each had a four-week duration. During both phases B and C, parents were instructed to apply a custom-made splint covering the child’s less affected hand and arm just below the elbow12 (Figure 1) at home for two hours a day, which could be divided into sessions to increase adherence and practicality. While wearing the constraint, children were required to participate in some of the activities from the list, ensuring that daily living activities such as dressing up were included, as well as playing activities every day.

Children participated in functional activities during the intervention phases B and C. The activities were decided upon after consulting individually with the parents of each child to ensure that they would be interesting, motivating and appropriate for each child. Parents listed all the everyday activities that their child would normally take part in, including dressing up, cleaning teeth, helping mother to prepare meals etc, as well as turning pages to read a book, playing games with siblings, playing ball and other activities in which the child preferred to engage in on their free time. Out of this list of activities, the researcher and parents decided upon those that could be practised using only one hand. This process ended up with a list for each child that contained both everyday and play activities.

In phase C, constraint wearing and activity participation remained the same as in phase B but time playing a personal computer (PC) game was added. This game resembled ‘Pac-Man’ and required unilateral manipulation of a joystick, movement of which was recorded as a measure of activity, while wearing the splint. The game lasted 20 minutes, which was targeted as an appropriate extra duration of exercising and feedback at the end of the day. At the end of the game, a coloured bar was displayed on the screen providing feedback by showing to the child on how much they had moved their affected hand, along with motivational cues to encourage them to ‘keep trying’. This may be characterized as ‘augmented feedback’14 combined with extra practice for the upper limb.

*Insert Figure 1 about here*

**Outcome measures:**

Parents recorded on a daily log the total amount of time for which the splint was worn and the activities in which the children participated. The Melbourne Assessment of Unilateral Upper Limb Function (hereinafter referred to as ‘Melbourne’) and the Quality of Upper Extremity Skills Test (QUEST) were used as the main measures of the effects of the interventions on the functional use of both upper limbs, especially the affected one. Both Melbourne and QUEST assessments were applied at the start and finish of the baseline period (A1) and at the ends of phases B and C and the follow up period (A2). There were thus five sets of scores (labeled as T1-T5 in Table 3), separated by four intervals of one month. Tests were administered and recorded on video for subsequent scoring by an assistant occupational therapist, blind to the phase of the study to which the video applied. A detailed description of the design and timing of the assessments can be found in Table 1.

*Insert Table 1 about here*

The Melbourne has been designed for children with CP, validated for the ages 5-15 years and provides a standardized means of scoring the affected limb’s ability to perform unilateral functional tasks. Sixteen items involving reach, grasp, release and manipulation are scored on three, four and five point scales and summed to provide a total score, which is converted to a percentage score.16 The QUEST has been specifically developed and validated for children with CP and is suitable for children 18 months or older17. It includes items specifically related to hand function but also assesses movement of the adjacent joints. The test consists of four domains; dissociated movement, grasp, weight bearing and protective extension scored on a YES/ NO scale and summed to provide a percentage score. The QUEST was applied according to the manual to assess the function of both upper limbs.

**Statistical Analysis:** The mean score of assessments 1 and 2 was taken as the baseline score with which scores at assessments 3 and 4 (phase B and phase C,respectively) were compared. Persistence of benefit, four weeks after cessation of the intervention was measured at assessment 5. Repeated measures ANOVA was used to test for the statistical significance of changes in Melbourne and QUEST scores between assessments at a level of *p*< 0.05 for two-sided testing. Friedman and Wilcoxon’s non-parametric tests were performed in addition to the parametric tests. Change in the personal computer game score over time was assessed for each participant during phase C. Content analysis was used for the daily logs.

**Results**

Nine children (6 boys and 3 girls) with a mean age of 6 years and 9 months (range: 5 yrs, 1 mo to 11 yrs) were included in the study. The frequency of their routine care therapy sessions and their baseline Melbourne and QUEST scores are shown in Table 2.

*Insert Table 2 about here*

Analysis of the daily logs revealed that the splint was worn for 39 hours and 32 minutes on average over phase B, while during phase C the time increased slightly to reach 40 hours and 28 minutes. Only one child wore the splint for all 30 days during either phase. The other eight children wore the splint over a range of 8 to 29 days. Children participated in similar activities during both phases B and C, except for the personal computer game, which was only available in phase C. In both B and C, the activities performed most commonly were brushing teeth/ hair, eating finger food, getting dressed and playing with toys or computer games. The game was played in phase C by eight of the nine children, the exception being child 5 who did not have access to a computer. During phase C all the children gradually increased their scores on the personal computer game except for child 4, who used the game on only nine days, fewer than any other participant.

All scores showed an approximately normal distribution in the scatterplots designed justifying the use of parametric repeated measures ANOVA tests. The corresponding (Friedman’s & Wilcoxon) non-parametric tests showed statistically significant changes in all instances for which that was the case on ANOVA tests. Scores on the QUEST and the Melbourne Assessment were similar at the beginning and the end of the baseline period (Table 2) suggesting stable function for the group. Compared to baseline scores, the group mean scores on both QUEST and the Melbourne Assessment increased significantly after phase B (constraint + practice) and C (constraint + practice + motivating feedback). Changes in the group mean scores remained statistically significant at the end of the follow-up period (T5) only for the Melbourne Assessment (Table 3). Every participant individually had an increase in their individual outcome scores over the intervention periods.

*Insert Table 3 about here*

On the Melbourne Assessment seven out of nine participants reached the accepted threshold18 for a clinically important (12%) change in score between baseline and T4 and/ or T5. Child 2 and child 4 were the most severely impaired and Child 3 the least impaired as determined by observation supported by the baseline scores of Melbourne (42, 48 and 92 respectively) and QUEST (57, 53 and 89 respectively). These three children made small or moderate improvements.

**Discussion**

Every individual participant in this small study showed improvement on scores obtained on objective measures of upper limb function with CIMT. The group mean increase in score was statistically significant and was also a clinically important change in most participants individually. An increase in the benefit to function during the second month of intervention was most clearly evident in the Melbourne assessment, the primary outcome measure, and in 7 out of 9 participants remained a clinically important change one month after completing the intervention.

The QUEST data set was reduced by the fact that one child did not cooperate for the final measurement thus reducing the power to detect differences on that measure. Quality of Upper Extremity Skills Test, which assesses the whole arm and range of movement did not show persistent benefit one month after cessation of the intervention in contrast to the Melbourne Assessment, which is more focused on hand function and showed retention of improvements at the follow-up. The majority of the everyday activities and games that the children practiced at home predominantly required hand function, which is probably why despite temporary improvements in large movements, persistent effect was noticed only on functional skills.

All but one participant showed an increase in the scores (representing the amount of hand movement) obtained at the end of each game session. The computer game was the only additional activity during the second month of intervention (phase C) but the study does not allow us to distinguish between the effect on these scores resulting from a learning effect of continued CIMT over time and that resulting from an increase in motivation and feedback. A controlled study would be needed to test the potential increase of motivation when feedback games are included in a CIMT program.

Although consistency of the benefit of each intervention period (phase B and phase C) is apparent from the fact that it was observed in every participant, variability between participants with respect to functional outcome was observed, as reported in other studies.7,19 Our findings on the functional improvement of children with severe or minor impairments support the observation of Gordon et al20 that low or very high functioning patients do not benefit from CIMT as much as those functioning at an intermediate level. Other studies19,7 have, however, found that response to treatment was better in children with an initially lower ability. Eliasson et al7 suggested that these differences might be related to the outcome measures used and explained that the Assisting Hand Assessment (AHA ), which was used in their study, measures a large range of skills, even very low abilities, making it possible to detect changes other than those related to grasping. Eliasson et al21 reported significant individual variation in improvements with no clear relationship to the hours of training, age or children’s mastery of behavior. Thus, there remain some variation in the findings in published reports, highlighting the need for large multi-center trials to investigate which individual characteristics at baseline predict the greatest benefit from CIMT.

The fact that the hours of use were less than 60% of those specified in the protocol and that only one child wore the splint for all 30 days in any month of intervention highlights the difficulties in adherence to a home-based intervention with limited therapist participation. Similarly, large variability in time spent wearing the constraint was observed in the study of Klingels et al19: an 80% compliance level of 40 hours was reported in only a small number of participants. Similar difficulties have been reported by other researchers that tested home-based CIMT protocols.7,10 All participants completed the program of Hsin et al11 but the intervention was carried out by a therapist at children’s homes, thus extra attention and support was given. In other studies,22,11 compliance was reported to be close to the target as suggested by the 3.5 hours of daily constraint use. However, in these studies children only participated in practice sessions at 2 days per week and therefore, it is not possible to know if the constraint time had been combined with functional use of the hemiplegic hand for the remaining days.

The Melbourne Assessment was also used by Gordon and her associates6 (2007) to assess the results of 2-hour daily therapy for 4 weeks. The lack of statistically significant improvements in that report could be due to a Type 2 error attributable to the small sample size (n=6) or due to the low functional status of the participants, as evident from the group mean Melbourne score of 52 at baseline. The functional gains found in the present study were larger than those observed in three other studies in which only moderate changes were found.5,19,23 The interventions tested were different in that the first of those studies used a group type of therapy for children, with activities not individually tailored for each child and neither study followed a home-based protocol. Klingels et al19 reported on two groups of which one received constraint without specific training. The other group followed a practice regimen that was distributed over 10 weeks, while training was taking place by a therapist over three 45-min weekly sessions. In the study of Sakzewski et al23, variability of the functional status of the sample was large, which might account for the small changes in the Melbourne Assessment. Similar improvements in QUEST score to those observed in the present study were reported by Choudhary et al2. DeLuca et al1 used a cast as the constraint on the better functioning arm and an intensive regimen of 6 hours of CIMT daily for 21 days. Improvements on QUEST were moderate compared to the present study suggesting that a less intensive and more prolonged application of home-based CIMT comprising approximately 1,5 hours of daily constraint and training (that was the actual restraint time, according to the results) over one or two-months time might be as effective as an intensive intervention, confirming the findings of other researchers.7,4,11,22

Strengths of the present study include use of constraints that had been shown in a previous study to be the most acceptable and effective12 and the use of objective measures by an assessor blinded to whether the participant was in baseline or intervention periods. The precision of the estimated treatment effect can be increased when the child acts as its own control.24. A non-intervention comparison period was provided by each participant and represented by the difference between the scores at the commencement and completion of the four week baseline period during which there was no statistically significant alteration in group mean score. The addition of an extra month of intervention revealed that improvements may be larger when applying a low intensity program over a period of two months. A limitation of the study was the small number of participants (n=9), while the generalisability of the findings is limited by the exclusion of those with potentially significant co-morbidities: a larger study would be needed to determine whether similar benefits are apparent in a broader range of participants. An adequately powered, pragmatic randomized controlled trial would be an appropriate next step to test the effectiveness of the suggested protocol and the potential added benefit that the inclusion of feedback might offer.

**Conclusion**

Our observations suggest that an intervention applied in a natural environment, combined with custom-made activities in order to increase motivation, may be effective in facilitation of the motor learning acquired with CIMT. An intervention of 1-2 hours of daily constraint use and practice may be more effective if applied in a two month therapy program rather than one month..

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**FIGURE LEGENDS**

Figure 1. The splint

Table 1. The procedure and timing of assessments of the study

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening process** | **Constraint build** | **Week**  **0** |  | **Week 4** |  | **Week 8** |  | **Week 12** |  | **Week 16** |
| **Assessment 1**  **(Melbourne & QUEST)** | A1  No Intervention | **Assessment 2**  **(Melbourne & QUEST)** | B  Splint  + functional activities | **Assessment 3**  **(Melbourne & QUEST)** | C  Splint  + functional activities + PC game | **Assessment 4**  **(Melbourne & QUEST)** | A2  No Intervention | **Assessment 5**  **(Melbourne & QUEST)** |
|  | Daily log | Daily log |  |