# Study to assess the effectiveness of modified constraint-induced movement therapy in stroke subjects: A randomized controlled trial

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#### **Abstract**

**Background and Purpose:** The purpose of this study was to assess the effectiveness of modified constraint induced movement therapy (m-CIMT) in stroke subjects. **Materials and Methods:** A total of forty sub-acute stroke subjects were randomly assigned to either a m-CIMT (n = 20) or in a control group (n = 20). The m-CIMT group (14 men, 6 women; mean age = 55.2 years) consisted of structured 2 h therapy sessions emphasizing affected arm use, occurring 5 times/week for 2 weeks. A mitt was used to restrain the unaffected arm for 10 h/day for 2 week. The control group (11 men, 9 women; mean age = 56.4 years) consisted of conventional rehabilitation for time-matched exercise program. The outcome measures were evaluated at pre- and post-intervention by using the Wolf Motor Function Test (WMFT) and Fugl-Meyer assessment (FMA) of motor recovery after stroke. **Results:** After intervention significant effects were observed in m-CIMT group on WMFT (pre-test and post-test score was  $28.04 \pm 6.58$ ,  $13.59 \pm 2.86$ ; P = 0.003). Similarly on FMA (pre- and post-test score was  $31.15 \pm 6.37$ ,  $55.7 \pm 6.4$ ; P = 0.00). **Conclusion:** There is a significant improvement in upper extremity function so it indicates that m-CIMT is effective in improving the motor function of the affected arm in stroke subjects. However, its long-term effect has not proved since there was no follow-up after intervention.

#### **Key Words**

Constraint induced movement therapy, exercise, rehabilitation, stroke

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### Introduction

Stroke presents one of the most disabling neurological disorders. For many subjects, the impact of stroke symptoms on activities of daily living is important. <sup>[1]</sup> Substantial efforts to develop rehabilitation protocols that minimize brain damage and improve outcomes in subjects with ischemic stroke are currently being pursued. Subjects with stroke often fail to develop full functional use of the affected upper extremity due to residual muscle weakness, spasticity and decrease in bone strength. <sup>[2]</sup>

Constraint induced movement therapy (CIMT) is a technique used in physical rehabilitation to treat individuals with decreased upper extremity function. Early research on CIMT

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was initiated by Dr. Edward Taub on monkeys'.[3] CIMT is based on the theory of "learned non-use," which develops, during the early stages following a stroke as the subjects begins to compensate for difficulty using the impaired limb by increased reliance on the intact limbs. [4] This compensation has been shown to hinder recovery of the function in the impaired limb. It is also based on neuro-plasticity and cortical reorganization. Nudo and Milliken describe the cortical representation shrinking after lesion or sensory or motor deprivation. Changes in representational areas were prevented or reversed by focused motor training in primates with concurrent improvements in motor function.<sup>[5-7]</sup> In addition, functional imaging studies in humans with stroke have found recovery to be associated with shifts of activation during motor tasks involving the affected hand to ipsilateral secondary and tertiary motor areas and to contra lateral homologous motor areas.[8]

CIMT encourages, the use of the affected upper extremity with the goal of maximizing or restoring motor function, a technique known as "shaping". [9] It is a form of operant or instrumental conditioning (associating a reward with a correct response as a basis for reinforcing the correct response) characterized by repetitions of a defined movement, such as picking up blocks and moving them toward a pail, in a series of trials. The

objective of shaping is to alter motor behaviors by repetitive use of basic movement tasks, the difficulties of which are progressively increased. The subject should be motivated to perform even more optimally on the basis of the progressive improvement over trials.<sup>[10]</sup>

Although, efficacious, findings from survey<sup>[11]</sup> measuring subjects' and therapists' opinions of CIMT suggest that its clinical implementation is limited. Specifically, when CIMT was described in an excerpt from case report<sup>[12]</sup> (1) 68% of the subjects with stroke said that they would not want to participate in the protocol; (2) two-thirds of the subjects who said that they would participate in CIMT conceded that they were somewhat or extremely unlikely to adhere to the CIMT protocol; (3) more than 80% of the patients felt that, if the protocol lasted for more weeks, with shorter physical therapy sessions and/or fewer hours wearing the restrictive devices, they would participate. Among therapists surveyed, more than 60% felt that subjects were extremely unlikely to adhere to such a protocol, with the primary reasons being the amount of time wearing the restrictive device and the number of practice hours.<sup>[12]</sup>

So Page et al,[13,14] modified the CIMT, which combines structured, 30 min, functional practice sessions using more-affected arm, with restriction of the less-affected arm 5 days/week for 5 h/day. Modified Constraint induced movement therapy (m-CIMT) has been shown to increase affected arm use and function in case studies,[15] and randomized controlled pilot studies enrolling subjects with acute stroke, [16] sub-acute stroke, [9,13] and chronic stroke.[17] Besides its reimbursement within existing current procedural terminology codes, CIMT and m-CIMT effects appear to be comparable.<sup>[18]</sup> Other data suggest that cortical reorganizations, brought about by increased arm use during m-CIMT, are responsible for the motor changes. [19] Long duration in the past studies poses great hindrance in practical application of this result oriented intervention. It is practically not possible for the therapist to treat single subject for 6-7 h and hence the present study aims to determine the effect of m-CIMT in improving the upper extremity function of stroke subjects in 2 h.

#### **Materials and Methods**

Stroke subjects were recruited from Central Referral Hospital and STNM Hospital in Sikkim, India by simple random sampling method. Institutional ethics committee approved the study. The subjects who fulfilled the following inclusion criteria were selected: (1) Ischemic or hemorrhagic first ever sub-acute stroke subjects referred by physician between 2 weeks and 4 weeks after the onset, (2) both genders of any age, (3) having at least 10° of active extension of each metacarpophalengeal joints, inter-phalengeal joints of all the digits and 10° wrist extension of the affected limb, (4) spasticity grade ≥1 according to Modified Ashworth Scale, (5) Mini Mental State Examination ≥17. We also applied the following exclusion criteria: Subjects with severe aphasia, severe shoulder pain affecting therapy or any comorbid condition that could limit upper extremity function. The baseline measures were collected after informed consent was obtained. Subjects were individually randomized into intervention and control groups by using lottery method. There was total number of 20 subjects in each group. Since no follow-up and less time was kept for restraint of the unaffected upper extremity so no drop out during the study. The baseline data regarding name, age, sex, hospital number, post stroke duration, and the side of involvement were taken for all subjects.

The WMF and Fugl-Meyer assessment (FMA) were administered as an outcome measure for the both groups and the scores were documented by the tester. The subjects in both groups were made to sit in comfortable position in a calm and well-ventilated room before treatment.

#### m-CIMT group

In intervention group, a mitt was used to restrain the unaffected arm which prevented the use of unaffected limb. It was made of cotton material which was extending till the forearm. The subjects were encouraged to wear a mitt during treatment and post treatment as 10 h/day for 2 weeks except for activities like toileting, washing etc., The mitt allowed the unaffected upper extremity to assist in transfers and ambulation, but it prevented use of the unaffected fingers to manipulate objects and necessitated use of the affected hand to perform daily activities. The total duration for mitt was recorded by subjects in the log book, which was provided by the therapist.

The shaping technique for m-CIMT was given for 2 h/day for 2 weeks at the frequency of 5 days a week. "Shaping" is a commonly used operant conditioning method in which a behavioral objective (in this case, movement) is approached in small steps of progressively increasing difficulty. The participant is rewarded with enthusiastic approval for improvement, but never blamed or punished for failure. Tasks were individually selected according to motor ability, to ensure successful experience, and prevent frustration leading to learned non-use. Task difficulty was progressively increased using behavioral techniques of shaping and successive approximation.

#### **Control group**

The control group received standard physical therapy treatment that included compensatory technique for ADLs (all daily living activity), upper extremity strength, and range of motion and traditional positioning for affected arm. To equalize treatment intensity, the same number of therapy sessions was provided to both groups. No restraint was used and subjects were free to use either hand for daily activities.

#### **Outcome measure**

Wolf Motor Function Test (WMFT) is a 17 item instrument consisting of 15 timed and 2 strength task. Tasks 1-6 of the WMFT involve timed joint segment movement and tasks 7-15 consisted of timed integrated functional movements. FMA is a cumulative numerical scoring system for measurement of motor recovery, balance, sensation, and joint range of motion in subjects who have sustained stroke. The functions of wrist and hand were assessed separately. Pre-intervention and at the end of 2<sup>nd</sup> week outcome measures, WMFT and FMA were taken for both the group for determination of motor function.

#### Data analysis

Data analysis was performed using SPSS Windows, version 16. Comparisons of differences within each group before and after therapy sessions in items WMFT and FMA were performed by using the paired *t*-test.

#### Results

Total 40 subjects were recruited, out of which 20 were in intervention group and 20 in control group. Mean age in intervention group was  $55.2 \pm 9.27$  and in control group, it was  $56.4 \pm 11.4$ . Out of 20 subjects in intervention group, 14 were males and 6 were females. In control group, 11 were males and 9 were females. Baseline characteristics of all subjects are given in Table 1.

Table 2 shows the pre- and post-test score of WMFT and FMA in intervention and control group. The pre-test score for WMFT in intervention group was  $28.04 \pm 6.58$  and post-test score was  $13.59 \pm 2.86$  (P = 0.003). In control group, the pre-test score was  $29.59 \pm 5.84$  and after 2 weeks of conventional therapy, it was  $22 \pm 4.68$  (P = 0.00). In intervention group, the pre-test score of FMA was  $31.15 \pm 6.37$  and after 2 weeks of intervention it was  $55.7 \pm 6.4$  (P = 0.0). In control group, pre-test score was  $29.3 \pm 6.10$  and post-test score was  $39.1 \pm 6.4$  after 2 weeks (P = 0.0).

Pre- and post-test difference of WMFT and FMA in intervention and control group has shown in Table 3. The difference of WMFT in intervention group was  $14.75 \pm 4.83$  and in control group it was  $7.21 \pm 2.01$ . In intervention group, the difference of FMA was  $24.95 \pm 3.74$  and in control group it was  $9.5 \pm 2.7$ .

#### **Discussion**

The outcome measures in this study showed improvements, after 2 week training period in stroke subjects. So, the results indicate that m-CIMT is improving the function of the affected upper extremity in stroke subjects. According to Fritz *et al*,<sup>[20]</sup> and Wolf *et al*.<sup>[13]</sup> WMFT was used as an outcome measure to determine the motor function of the upper extremity of the affected side. FMA upper extremity portion was also used to measure the motor function of upper extremity.

The pre-test score for WMFT in intervention group was  $28.04 \pm 6.58$  and post-test score was  $13.59 \pm 2.86$  (P = 0.003). In control group, the pre-test score was  $29.59 \pm 5.84$  and after 2 weeks

Table 1: Subjects baseline characteristics of subjects in intervention and control group

Variables	Interventio	n group	Control group			
	Mean±SD	Range	Mean±SD	Range		
Age	55.2±9.27	34-67	56.4±11.40	30-71		
Post stroke duration	18.3±3.31	14-28	19.60±3.85	14-28		
MMSE	25.15±2.3	21-29	24.80±2.11	22-29		
MAS	1.25±0.44	1-2	1.15±0.36	1-2		

MMSE= Mini mental state examination, MAS= Modified ashworth scale

of conventional therapy, it was  $22\pm4.68$  (P=0.00). In intervention group, the pre-test score of FMA was  $31.15\pm6.37$  and after 2 weeks of intervention it was  $55.7\pm6.4$  (P=0.0) and in control group, pre-test score was  $29.3\pm6.10$  and post-test score was  $39.1\pm6.4$  after 2 weeks (P=0.0). This shows that there is a significant improvement in upper extremity function and thus, it indicates that m-CIMT is effective in improving the motor function of the affected arm in stroke subjects.

Findings of our study are in correlation with the findings of Wolf et al,[21,22] and Taub et al,[23] showed improvements in motor skills and the use of the affected arm and hand in daily activities after CIMT. Prior studies carried out by Wolf et al, [24] and Morris et al, [25] reported that WMFT is an useful measure to examine and measure the effectiveness of CIMT for stroke survivors and Page et al, [13] saw considerable changes among CIMT subjects between pre-test and post-test sessions on the WMFT, both in terms of rating of arm use, and in terms of time taken to complete the task. Subjects in CIMT group showed especially, strong improvements on "shaping" tasks on WMFT. The greater improvement in the scores of FMA was seen in m-CIMT group than traditional rehabilitation group corresponded with those of previous studies carried out by Page  $\it et\,al.^{[13,17]}$  The substantial improvement pattern reflected by FMA, in the m-CIMT group suggested that m-CIMT reversed impairments rather than simply helped patients to adapt to residual impairments.

In-line with a previous report, statistically significant improvements in hand function after CIMT was observed. Furthermore, analysis showed that more of the subjects scored relatively higher for hand improvement. Several possibilities may account for this. First is an inclusion criterion. In-line with methodologies described in previous CIMT studies, only subjects capable of at least 10° extension at the finger joints were enrolled. This inclusion criterion is further supported by a recent article, which suggests that finger extension ability predicts the effects of CIMT. Another influence is the "shaping" tasks that the subjects practiced during CIMT. In this study, graded shaping programs were used and the neural mechanism underlying the effects of CIMT is also likely to affect results. The motor learning literature suggests that massed practice has only a neutral or negative effect on the learning of continuous tasks and a variable effect on the learning of discrete tasks. However, CI Therapy employs massed practice to increase the tendency of patients to use their more-impaired limb, and thereby induces a use-dependent functional reorganization of brain structures.<sup>[26]</sup>

Recent studies using brain imaging and transcranial magnetic stimulation techniques show that after CIMT there is reorganization in the motor representations of upper

Table 2: Pre- and post-score of Wolf motor function test and Fugl-Meyer assessment in intervention and control group

Outcome measures	Intervention group				Control group					
	Pre-test		Post-test		P	Pre-test		Post-test		P
	Mean±SD	SE	Mean±SD	SE		Mean±SD	SE	Mean±SD	SE	
WMFT	28±6.58	1.4	13.6±2.86	0.64	0.003	29.59±5.84	1.3	22.27±4.6	1.04	0.00
FMA	31.15±6.37	1.4	55.7±6.43	1.43	0.00	29.35±6.1	1.3	30.1±6.46	1.44	0.00

WMFT= Wolf motor function test, FMA= Fugl-Meyer assessment

Table 3: Pre- and post-difference of Wolf motor function test and Fugl-Meyer assessment in intervention and control group

Group	WMFT	FMA	SE	
Intervention group	14.75±4.83	24.95±3.74	1.08	
Control group	7.21±2.01	9.5±2.7	0.45	

WMFT= Wolf motor function test, FMA= Fugl-Meyer assessment

extremities. Penfield's brain mapping shows that the motor areas for the hands are much larger than for shoulder, elbow, and forearm. Correspondingly, cortical reorganization induced by intensive training involving the upper extremity has been reported most frequently for the hand representation areas within the primary motor cortex. The consequent increase in more affected arm use, involving sustained and repeated practice of functional arm movements, induces expansion of the contralateral cortical area controlling movement of the more-affected arm and recruitment of new ipsilateral areas. This use-dependent cortical reorganization may serve as the neural basis for the permanent increase in use of the affected arm. This kind of evidence suggests that body elements with the most extensive cortical representation areas are more likely to show training-induced neural changes.

It is believed that stroke subjects express greater motor disability on their more affected sides than that which actually exists. Over time, this movement suppression or learned non-use becomes so habitual that subjects use the less affected side for most ADLs. Data from this study provide further support for contention that learned non-use after stroke can be overcome by m-CIMT.<sup>[13,15]</sup> Furthermore, WMFT and FMA data support the contention that m-CIMT participation can elicit functional changes.

Our study and previous ones demonstrate that implementation of m-CIMT during early stoke rehabilitation is safe and feasible. No significant adverse events occurred during the intervention period, and no loss of motor function caused by restraint of unaffected arm could be detected. Therefore, available evidence in human stroke subjects undergoing m-CIMT does not bear out the potential adverse consequences of early overutilization of the affected limb as seen in animal studies. Given that, the previous CIMT studies reported use dependent cortical reorganizations<sup>[27]</sup> and given that remarkably short training protocols have induced cortical and functional changes<sup>[28]</sup> increases in affected limb use that we observe are believed to have caused cortical reorganization that resulted in functional improvement. The m-CIMT protocol emphasizes intensive practice and use of functional tasks to train the affected arm. Intensive practice of the affected arm might provide sufficient proprioceptive and visual feedback to develop the internal models for feed forward control of movement. Thus, subjects are able to preplan motor patterns more efficiently after m-CIMT. However, m-CIMT did not improve efficiency of movement execution (normalized movement time) or movement smoothness (normalized movement units) as it happens in conventional rehabilitation.[29]

The original CIMT protocol advocates restriction of the unaffected upper extremity for 90% of waking hours for 2 week.<sup>[30]</sup> This original protocol however, is mentally

challenging and often results in poor compliance. In this study, to promote clinical compliance, modified version of CIMT was employed in which the duration of restraint was combined total of 10 h/day and intermission was freely allowed on request. Moreover, results of previous study suggest that, while at least 3 h of restraint per day is effective, it is less effective than 6 h.[31] To clarify this issue, further studies are needed. There are few limitations of our study like: Small sample size due to limited stroke subjects, the rater who was not blinded to the study. Another limitation could be no follow-up after the intervention and hence the improvement of upper extremity function in two groups could not be better compared.

#### Conclusion

Authors conclude that m-CIMT is effective in improving function and use of the affected upper extremity in stroke subjects.

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