# Efficacy of Modified Constraint-Induced Movement Therapy in Chronic Stroke: A Single-Blinded Randomized Controlled Trial

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ABSTRACT. Page SJ, Sisto SA, Levine P, McGrath RE. Efficacy of modified constraint-induced movement therapy in chronic stroke: a single-blinded randomized controlled trial. Arch Phys Med Rehabil 2004;85:14-8.

**Objective:** To determine efficacy of a modified constraint-induced movement therapy (mCIMT) protocol for patients with chronic stroke.

**Design:** Multiple-baseline, pre-post, single-blinded randomized controlled trial.

**Setting:** Outpatient clinic.

**Participants:** Seventeen patients who experienced stroke more than 1 year before study entry and who had upper-limb hemiparesis and learned nonuse.

**Intervention:** Seven patients participated in structured therapy sessions emphasizing more affected arm use in valued activities, 3 times a week for 10 weeks. Their less affected arms were also restrained 5d/wk for 5 hours (mCIMT). Four patients received regular therapy with similar contact time to mCIMT. Six patients received no therapy (control).

**Main Outcome Measures:** The Fugl-Meyer Assessment of Motor Recovery (FMA), Action Research Arm (ARA) Test, and Motor Activity Log (MAL).

**Results:** The mCIMT patients exhibited greater motor changes on the FMA and ARA (18.4, 11.4) than regular therapy (6.0, 7.1) or control (−2.9, −4.5). Statistical analyses showed significant differences in motor improvement on the FMA ($F_{2,12}=11.2$, $P=.002$) and the ARA ($F_{2,12}=14.0$, $P=.001$). Post hoc analyses showed that, when pretreatment motor differences are controlled, mCIMT resulted in substantially higher posttreatment FMA and ARA scores. Amount and quality of arm use, measured by the MAL, improved only in mCIMT patients.

**Conclusions:** mCIMT may be an efficacious method of improving function and use of the more affected arms of chronic stroke patients. Findings further affirm that repeated, task-specific practice is critical to reacquisition of function, whereas practice schedule intensity is less critical.

**Key Words:** Cerebrovascular accident; Exercise; Stroke; Rehabilitation.



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STROKE, THE LEADING CAUSE of disability in the United States,[1] causes a variety of impairments that compromise quality of life.[2] Upper-limb hemiparesis, a commonly seen impairment,[3] is particularly problematic given its impact on activities of daily living (ADLs). Despite millions of dollars being spent annually for stroke rehabilitation,[4] evidence that supports the efficacy of stroke motor rehabilitation is limited,[5,6] making interventions that reduce the impact of hemiparesis a priority.

It is commonly believed that motor recovery occurs only in the first 6 to 12 months after stroke.[7,8] Recently, though, improved use and function of the more affected upper limb were reported after chronic (>1y poststroke) stroke patients participated in constraint-induced movement therapy[9-12] (CIMT). CIMT emphasizes massed practice with the affected upper limb in 2 ways: (1) participants' less affected upper limbs are restricted during 90% of waking hours in a 2-week period; and (2) participants engage in 6-hour activity sessions in which they use their more affected limbs on the 10 weekdays of the same 2-week period.

Although efficacious, CIMT may be difficult to implement. Indeed, a recent CIMT case study reported that the patient "grew tired of wearing the mitt and had difficulty with full adherence . . . 'cheating' with the uninvolved hand was a frequent temptation."[13] This finding is corroborated by Schaumberg et al,[14] who reported 32% compliance with the CIMT restriction schedule, and by surveys in which we[15] reported that many stroke patients would not want to participate in CIMT, but would prefer a therapy protocol lasting for more weeks with shorter activity sessions and/or fewer hours of wearing the restrictive devices. More than 60% of responding therapists also speculated that patients were extremely unlikely to adhere to CIMT, and a majority of therapists believed that many facilities did not have available resources to execute CIMT. Additionally, both therapists and stroke patients expressed concerns over compromises in independent activities (eg, walking with a cane, driving) caused by the restrictive device schedule, and concerns about reimbursement for CIMT. Physical deconditioning,[16,17] as well as comorbidities associated with aging and availability of appropriate support, may also make participation in this intensive protocol difficult and/or unsafe.[18]

Although intense practice models, like CIMT, have been advocated,[19] researchers have also noted that "any technique that induces a patient to use an affected limb . . . should be considered therapeutically efficacious. This factor is likely to produce the use-dependent cortical reorganization. . .."[20] Consistent with this, short periods of concentrated, task-specific training have induced cortical reorganizations[21,22] and improved motor function.[23,24] Given these findings, and CIMT shortcomings, a less intense, modified CIMT (mCIMT) protocol has been developed that combines structured, ½-hour, functional practice sessions with restriction of the less affected upper limb 5d/wk for 5 hours, both during a 10-week period. In addition to being reimbursable within many managed care plans, mCIMT can be implemented on an outpatient basis and substantially improves affected limb use and function in subacute stroke patients.[25,26]

Given mCIMT's efficacy with subacute stroke patients, it is plausible that mCIMT could be efficacious for chronic stroke patients. The purpose of this study was to test the efficacy of mCIMT on chronic stroke patients' more affected upper-limb use and function by using a single-blinded, randomized controlled trial design. The primary study hypothesis was that after intervention, mCIMT would result in significantly greater improvements on the Fugl-Meyer Assessment of Motor Recovery (FMA) after stroke than either a 10-week regimen of traditional rehabilitation or no therapy (control). These changes would reflect a significant reduction in impairment of the more affected upper limb in patients receiving mCIMT. We also hypothesized that (1) after intervention, individuals who received mCIMT would exhibit greater improvements than individuals who received traditional rehabilitation or no therapy on the Action Research Arm (ARA) Test, and (2) individuals who received mCIMT would exhibit greater changes after intervention on the Motor Activity Log (MAL), on both the amount of use (AOU) and quality of use (QOU) scales.

## METHODS

### Power Analysis for Primary Outcome Measure and Proposed Study Sample

Before the study, we did a power analysis to determine appropriate sample size. Our main outcome measure was the FMA, and our main hypothesis was that mCIMT would enhance neurologic recovery at the impairment level, resulting in increased FMA scores. Therefore, a repeated-measures analysis of covariance (ANCOVA) design was entered into the PASS 2000 program.[27,a] Power calculations for the determination of changes in the upper-extremity scale of the FMA were based on mean anticipated differences for the 3 groups from pre- to postintervention observed in previous mCIMT studies.[26] To reach 80% power and an effect size of .36, using an F test to test the group by time interaction at a 5% significance level, 18 subjects were needed (6/group).

Given power analysis findings, volunteers were recruited through advertisements placed in therapy clinics and given to therapists in hospitals in the northeastern United States. A research team member screened volunteers by using the following inclusion criteria from previous research[25,26]: (1) ability to actively extend at least 10° at the metacarpophalangeal and interphalangeal joints and 20° at the wrist; (2) stroke experienced more than 1 year before the study; (3) a score of 70 or higher on the Modified Mini-Mental State Examination[28]; (4) no hemorrhagic lesions; (5) age between 18 and 95 years; (6) no excessive spasticity, defined as a score of 3 or higher on the Modified Ashworth Scale[29]; (7) no excessive pain in the affected upper limb, as measured by a score of 4 or higher on a 10-point visual analog scale; (8) discharged from all forms of physical rehabilitation; and (9) not participating in any experimental rehabilitation or drug studies. By using these criteria, 18 patients were found to be eligible and agreed to participate. However, 1 patient had received botulinum toxin type A in the more affected limb less than 3 months before the study and was excluded from analyses post hoc. Demographic data for the remaining 17 subjects (14 men; mean age, 59.2±12.0y; age range, 37–76y; mean time since stroke, 32.3mo; range, 14–74mo) are in table 1. Interpretation of informal interviews, MAL scores, and clinical judgments confirmed learned nonuse in all subjects.

**Table 1: Subject Characteristics**

| Gender | Age (y) | Months Since CVA | Side Affected | Group |
|---|---|---|---|---|
| M | 64 | 15 | R | mCIMT |
| F | 37 | 21 | L | mCIMT |
| F | 58 | 34 | R | mCIMT |
| M | 40 | 22 | R | mCIMT |
| M | 70 | 30 | R | mCIMT |
| M | 49 | 26 | L | mCIMT |
| M | 64 | 30 | R | mCIMT |
| M | 50 | 72 | R | TR |
| M | 72 | 34 | R | TR |
| M | 73 | 30 | L | TR |
| M | 48 | 16 | L | TR |
| M | 72 | 36 | L | CON |
| F | 69 | 62 | L | CON |
| M | 53 | 1 | L | CON |
| M | 56 | 74 | R | CON |
| M | 56 | 20 | R | CON |
| M | 76 | 14 | R | CON |

Abbreviations: CON, control therapy; CVA, cerebrovascular accident; F, female; L, left; M, male; R, right; TR, traditional rehabilitation.

### Instruments

Instruments used were applied previously in CIMT[12] and mCIMT[25,26] studies, and were shown to be responsive to changes in function after forced use.[30] They were the FMA, ARA Test, and MAL. The FMA is a 66-point, upper-extremity section of the FMA,[31] which assesses several impairment dimensions by using a 3-point ordinal scale (0, cannot perform; 1, can perform partially; 2, can perform fully). The FMA has impressive test-retest reliability (total range, .98–.99; subtests range, .87–1.00),[32] interrater reliability, and construct validity.[33] The ARA Test[34] is a 19-item test divided into 4 categories (grasp, grip, pinch, gross movement), with each item graded on a 4-point ordinal scale (0, can perform no part of the test; 1, performs test partially; 2, completes test but takes abnormally long time or has great difficulty; 3, performs test normally) for a total possible score of 57. The test is hierarchical in that, if the patient can perform the most difficult skill in each category, he/she will be able to perform the other items within the category and, thus, they need not be tested. The ARA has high intrarater ($r$=.99) and retest ($r$=.98) reliability and validity.[34,35] The MAL is a semistructured interview that measures how patients use their affected limbs for ADLs. In separate MAL interviews, patients and their caregivers independently rate how much and how well the patient has used the affected arm for 30 ADLs in the past week. Patients and caregivers use a 6-point AOU scale to rate how much they are using their affected arm and a 6-point QOU scale to rate how well the arm is being used.

### Testing and Intervention

A single-blinded, multiple baseline, randomized pretest and posttest control group design was applied. After subjects were screened and had signed consent forms approved by the local institutional review board, the FMA and ARA were administered on 2 occasions 1 week apart, and the MAL was administered once. After the second pretesting session, patients were randomly assigned to 1 of 3 condition groups with equal probability by using a computer-generated random numbers table. The conditions were: mCIMT, traditional rehabilitation, or no treatment.

**Table 2: Patient Scores on the FMA and ARA Before and After Intervention**

| | FMA | | | | ARA | | | |
|---|---|---|---|---|---|---|---|---|
| | Pre 1 | Pre 2 | Post | Change | Pre 1 | Pre 2 | Post | Change |
| mCIMT (n=7) | 31.3 | 30.4 | 49.2 | +18.4 | 26.2 | 26.6 | 37.8 | +11.4 |
| TR (n=4) | 29.3 | 29.8 | 35.5 | +6.0 | 18.0 | 22.8 | 27.5 | +7.1 |
| CON (n=6) | 31.8 | 33.3 | 29.7 | −2.9 | 29.0 | 27.7 | 23.8 | −4.5 |

NOTE. Pre 1 denotes the mean score obtained during first pretesting period. Pre 2 denotes the mean score obtained during second pretesting period. Post denotes the mean score obtained during posttest. Change refers to the mean change scores, which are computed using the formula: $\text{Post mean} = \left(\frac{\text{Pre 1} + \text{Pre 2}}{2}\right)$

### Modified Constraint-Induced Movement Therapy

As in previous studies,[25,26] mCIMT subjects participated in consecutive, ½-hour sessions of physical therapy (PT) and occupational therapy (OT) 3 times a week for 10 weeks. Approximately 20 to 25 minutes of OT concentrated on more affected limb use in functional tasks largely chosen by patients and their treating therapists, with some time (≈5min) spent on strengthening and/or compensatory techniques using the less affected arm as needed. During OT, shaping techniques (see Page et al[25,26] for a description) were used with 2 to 3 upper-limb activities chosen by the patients (eg, writing, using a fork and spoon, brushing teeth, combing hair). PT sessions largely concentrated on lower-limb activities (eg, dynamic stand and balance activities, gait training), but some time in each PT session was spent on upper-limb stretching to facilitate ADLs.

During the same 10-week period, the less affected upper limbs of subjects in the mCIMT group were restrained every weekday for 5 hours that were identified as a time of frequent arm use. Their arms were restrained with a cotton hemisling[b]; hands were placed in mesh, polystyrene-filled mitts with Velcro straps around the wrist.[b] Because patients were restricted at home, logs were kept to document device use time, as well as activities performed during restraint hours.

### Traditional Rehabilitation and Control Condition

Patients in traditional rehabilitation received ½-hour, consecutive PT and OT sessions, 3d/wk for 10 weeks. Approximately 80% of each PT and OT session (≈25min) focused on proprioceptive neuromuscular facilitation (PNF) techniques, with emphasis on functional tasks when possible, as well as stretching of the more affected limb and particularly in the more affected shoulder. Approximately 20% of traditional rehabilitation therapy (≈5min) focused on compensatory techniques using the less affected side (eg, performing functional tasks with the less affected arm, assisting the more affected arm during reaching tasks). The duration, frequency, and type of therapy provided to traditional rehabilitation subjects were consistent with that generally provided to stroke patients at this motor level in our clinics. Moreover, studies have not shown PNF is more effective than other therapies.[36] Therefore, this was an appropriate approximation of traditional rehabilitation. Patients assigned to the control condition received no therapy during the 10-week period. After 10 weeks, all patients returned to the laboratory, where they were again administered the FMA, ARA, and MAL by an examiner who was blinded in that he was unaware of the patients' randomized grouping.

## RESULTS

### Preliminary Analyses

Multiple baseline designs allow monitoring of subjects' motor levels over a prolonged period before the intervention. This is useful in discerning whether subjects are exhibiting motor changes before the intervention so that the changes can be accounted for when analyzing intervention results. In "eyeballing" pretest ARA and FMA scores, it appeared that scores were stable during pretesting, which suggests stable motor deficits (table 2). To further examine motor deficit stability, 2 paired samples *t* tests were performed. Neither the *t* test comparing the 2 pretest FMA scores ($t_{16}=.26$) nor the *t* test comparing the 2 ARA scores ($t_{16}=-.79$) showed significant differences, and effect sizes were small ($d=.06$, $d=.19$, respectively).[37] Because differences were unlikely to be clinically important, it was concluded that subjects were exhibiting stable motor deficits. Consequently, pretest scores for each scale were averaged to increase the reliability of the pretest measurement in subsequent analyses.

### Analysis of Change

After intervention, the mCIMT group displayed a mean improvement of 18.4 points on the FMA and 11.4 points on the ARA. Patients receiving traditional rehabilitation exhibited less improvement on the FMA (6.0) and ARA (7.1), whereas control patients exhibited negative changes on the FMA (−2.9) and ARA (−4.5). MAL scores, both in terms of AOU and QOU, also increased between pre- and posttesting sessions for the mCIMT group (AOU=2.38; QOU=2.28). Negligible MAL changes were observed among traditional rehabilitation and control subjects, both in terms of AOU (.33, .11, respectively) and QOU (.34, .008, respectively).

Two ANCOVAs were conducted to evaluate whether, when controlling for pretreatment, intergroup differences, groups significantly differed in their degree of motor improvement on the FMA and ARA. For each analysis, the average of the scores from the 2 pretest administrations was the covariate, group was the independent variable, and total posttest (FMA, ARA) score was the dependent variable. Omnibus tests for the 3 groups were significant for the FMA ($F_{2,12}=11.2$, $P=.002$) and the ARA ($F_{2,12}=14.0$, $P=.001$).

Pairwise differences were next examined by using *t* tests and scores adjusted for the covariate. On the FMA, mCIMT differed significantly from both traditional rehabilitation ($t_{12}=2.5$, $d=1.6$; 95% confidence interval [CI], 1.02–21.82) and control therapy ($t_{12}=4.7$, $d=2.7$; 95% CI, 10.52–28.48). The difference between traditional rehabilitation and control therapy was not significant ($t_{12}=1.7$, $d=1.1$; 95% CI, −2.55 to 18.71). On the ARA, subjects in both mCIMT ($t_{12}=5.3$, $d=3.1$; 95% CI, 9.75–23.93) and traditional rehabilitation ($t_{12}=3.1$, $d=2.0$; 95% CI, 2.68–19.42) exhibited significantly greater gains than did control subjects, but no difference was found between mCIMT and traditional rehabilitation subjects ($t_{12}=1.6$, $d=1.1$; 95% CI, −2.35 to 13.93). Adjusted least square means (table 3) indicated that, when controlling for pretreatment motor differ-

**Table 3: Results of *t* Test Comparisons Between Groups Using Adjusted Least Square Means**

| Group | Mean ± SE |
|---|---|
| FMA | |
| mCIMT | 48.6±2.8 |
| TR | 37.2±3.6 |
| Control therapy | 29.1±2.9 |
| ARA | |
| mCIMT | 37.6±2.2 |
| TR | 31.8±2.8 |
| Control therapy | 20.8±2.3 |

NOTE. These values are adjusted for the covariate pretest scores.
Abbreviation: SE, standard error.

ences, the mCIMT group showed substantially higher post-treatment mean scores on the FMA and ARA.

## DISCUSSION

For many stroke patients, participation in a traditional, more intense CIMT may be problematic, given the required practice intensity and the duration of the restraint schedule. Considerable evidence suggests that various practice schedules that emphasize repeated limb use can elicit cortical reorganization and subsequent functional improvement. In this study, we examined the efficacy of mCIMT in improving use and function of chronic stroke patients' more affected upper limbs.

Before intervention, MAL scores were below .55 for all subjects, which suggests that they never or only occasionally used their more affected arms for ADLs. Subjects confirmed that they were largely using their less affected limbs, or were having someone else perform their ADLs. These findings suggested learned nonuse of the more affected upper limb. After the intervention, subjects in the control therapy and traditional rehabilitation groups showed nominal MAL changes and reported use patterns similar to those that they reported before intervention. mCIMT subjects, however, displayed changes greater than 2.0 on both the AOU and QOU scales of the MAL, which suggests increased use of the more affected limb for ADLs, and confirms one of our secondary hypotheses. Although patients were not as deconditioned as reported in other CIMT studies,[13] the MAL changes, particularly in terms of AOU, were comparable. Interpersonally, mCIMT patients reported that they were attempting ADLs with the more affected limb that they had not attempted since before their strokes, including using the limb for writing, eating, and/or grooming. As the intervention period progressed, mCIMT patients realized that they were capable of doing more with their affected limbs than previously thought, and often attempted additional ADLs.

FMA and ARA change trends were similar to MAL trends. Before intervention, patients' motor deficits were relatively stable; patients' scores did not change substantially between pretesting periods (table 2), and *t* tests showed nonsignificant differences between the pretesting scores. Moreover, motor status scores had barely changed since discharge for many subjects. After the intervention, mCIMT patients displayed considerable increases on the FMA and ARA, traditional rehabilitation patients exhibited some increases, and control therapy subjects exhibited nominal changes. Least square means, as well as ANCOVAs, showed that individuals in mCIMT had the greatest gains, which was consistent with our original primary and secondary hypotheses. The greatest changes in mCIMT subjects were seen on the FMA wrist and hand items and on the ARA grip, grasp, and pinch scales, although these patients did not show significantly greater improvements on the ARA. Failure to find significance between mCIMT and traditional rehabilitation subjects on the ARA may have been because of inadequate power, because the sample effect size estimates between groups were quite large. Functionally, mCIMT patients reported better ability to perform valued ADLs that they could not previously perform, including gardening, cooking, writing, and grooming.

Overall, MAL, FMA, and ARA data trends were consistent with those observed in a previous mCIMT randomized controlled study with subacute stroke patients.[26] It is believed that most motor recovery occurs in the first 6 to 12 months after stroke.[7,8] Consistent with this, most patients in this sample had been told by their doctors and/or therapists that they had plateaued, and that additional motor recovery was doubtful. We submit that the functional outcomes of this and other recent studies[12,23] bring into question this precept.

It is believed that stroke patients express greater motor disability on their more affected sides than that which actually exists. Over time, this movement suppression, or learned nonuse, becomes so habitual that patients use the less affected side for most ADLs. Data from this study provide further support for the contention that learned nonuse after stroke can be overcome by mCIMT.[25,26] Furthermore, FMA and ARA data support the contention that mCIMT participation can elicit functional changes. Given that previous CIMT studies reported use-dependent cortical reorganizations,[38] and given that remarkably short training protocols have induced cortical and functional changes,[21-24] increases in affected limb use that we observed are believed to have caused cortical reorganizations that resulted in the functional improvements.

Most subjects in this sample had not recently engaged in therapeutic exercise programs, and it is likely that several were deconditioned.[17] Although mCIMT was the most potent therapeutic exercise regimen, traditional rehabilitation subjects displayed gains on the FMA and ARA. Data from both groups suggest that participation in late therapeutic exercise can be beneficial in some respects and further refute the notion that stroke patients can only exhibit gains up to 1 year poststroke.

## CONCLUSION

Practice conveys motor skill learning, yet many motor rehabilitation strategies (eg, Bobath, PNF) do not allow for direct repeated practice with the more affected arm and hand. Instead, "innervation is stimulated by cutaneous and proprioceptive as well as central facilitation techniques."[24] Based largely on CIMT findings, Taub[19] has suggested that intense practice models need to be clinically implemented. The results of this study and of several others,[21-26] however, have shown that cortical reorganizations and functional improvements can be realized following practice periods of lower durations but that still emphasize repeated, task-specific practice. Therefore, needed deviation from practice may not be implementation of intensive, massed practice. Rather, alteration of current practice sessions to allow for repeated, functional, task-specific practice of valued ADLs is needed, which would likely induce cortical reorganizations and meaningful functional improvements.

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## Suppliers

a. NCSS Statistical Software, 329 N 1000 E, Kaysville, UT 84037.
b. Mitts and slings; Sammons-Preston, PO Box 5071, Bolingbrook, IL 60440.