

ORIGINAL ARTICLE

A Randomized Controlled Trial of Modified Constraint-Induced Movement Therapy for Elderly Stroke Survivors: Changes in Motor Impairment, Daily Functioning, and Quality of Life

Ching-yi Wu, ScD, OTR, Chia-ling Chen, MD, PhD, Wen-chung Tsai, MD, PhD, Keh-chung Lin, ScD, OTR, Shih-han Chou, BS

ABSTRACT. Wu C-Y, Chen C-L, Tsai W-C, Lin K-C, Chou S-H. A randomized controlled trial of modified constraint-induced movement therapy for elderly stroke survivors: changes in motor impairment, daily functioning, and quality of life. *Arch Phys Med Rehabil* 2007;88:273-8.

Objective: To examine the benefits of modified constraint-induced movement therapy (mCIMT) on motor function, daily function, and health-related quality of life (HRQOL) in elderly stroke survivors.

Design: Two-group randomized controlled trial, with pre-treatment and post-treatment measures.

Setting: Rehabilitation clinics.

Participants: Twenty-six elderly stroke patients (mean age, 72y) with 0.5 to 31 months postonset of a first-ever cerebrovascular accident.

Interventions: Twenty-six patients received either mCIMT (restraint of the unaffected limb combined with intensive training of the affected limb) or traditional rehabilitation for a period of 3 weeks.

Main Outcome Measures: Outcome measures included the Fugl-Meyer Assessment (FMA), FIM instrument, Motor Activity Log (MAL), and Stroke Impact Scale (SIS). The FMA evaluated the severity of motor impairment; the FIM instrument and MAL reported daily function; and the SIS detected HRQOL.

Results: The mCIMT group exhibited significantly greater improvements in motor function, daily function, and the physical domain of HRQOL than the traditional rehabilitation group. Patients in the mCIMT group perceived significantly greater percent of recovery after treatment than patients in the traditional rehabilitation group.

Conclusions: These findings suggest mCIMT is a promising intervention for improving motor function, daily function, and physical aspects of HRQOL in elderly patients with stroke.

The mCIMT was well tolerated by the elderly patients even though it is a rigorous training program.

Key Words: Controlled clinical trials; Occupational therapy; Quality of life; Rehabilitation; Stroke.

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IT IS ESTIMATED THAT 75% of strokes occur in elderly patients.^{1,2} More than 50% of those 65 years and older who survive a stroke report persistent impairment of upper-extremity (UE) movement.³ They have been encouraged to use their unaffected UE to perform tasks and progressively avoid use of the affected UE during task performance. This behavior may result in learned nonuse phenomenon hindering a person's recovery of movement and function in the affected limb.⁴ One approach that has shown great promise for enhancing UE motor performance and functional use of the affected UE among patients with stroke is constraint-induced movement therapy (CIMT).⁵ The specific techniques of CIMT involve restraining the use of the unaffected UE (6–20h/d for 2–3wk) and intense motor training (eg, 6h/d on 10–15 consecutive weekdays) through the use of shaping movements of the affected limb.⁶ The shaping procedure involves individualized task selection, graduated task difficulty, verbal feedback, prompting, and physically assisting with movements and modeling.⁷

Although CIMT shows promise for improving motor deficits after stroke, converging data suggested that it may not be plausible in many environments. One possible reason is that intense and prolonged practice during CIMT may be less safe and more tiring particularly for elderly or deconditioned patients.⁸ To address the problems, Page et al⁸ devised a modified CIMT (mCIMT) with shorter training (eg, 2h/d on 10–15 consecutive weekdays) and restraint (eg, 6h/d for 2–3wk) time.⁹ The mCIMT program was shown to be applicable in chronic or subacute patients with a wide variety of motor disability⁹⁻¹⁴ and may be especially relevant for the elderly patients. However, no study has specifically examined the efficacy of mCIMT in elderly stroke survivors aged over 65.

A further gap in knowledge about the therapeutic benefits of mCIMT lies in the limited scope of outcome measures in prior research. Based on the *International Classification of Functioning, Disability and Health* framework¹⁵ measurements at the impairment, activity, and participation levels may reflect the full range of domains affected by stroke. Nevertheless, mCIMT studies in general tend to capture effects on impairment level measures and activity level measures without evaluating outcomes of activity participation (eg, health-related quality of life [HRQOL]). The impairment level measure involved measures of synergy patterns, muscle strength, or motor

From the Graduate Institute of Clinical Behavioral Science and Department of Occupational Therapy, Chang Gung University, Tao-yuan, Taiwan (Wu, Chou); Department of Physical Medicine and Rehabilitation, Chang Gung Memorial Hospital, Tao-yuan, Taiwan (Chen, Tsai); School of Occupational Therapy, College of Medicine, National Taiwan University, and Department of Physical Medicine and Rehabilitation, National Taiwan University Hospital, Taipei, Taiwan (Lin).

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Correspondence to Keh-chung Lin, ScD, OTR, Sch of Occupational Therapy, College of Medicine, National Taiwan University and Department of Physical Medicine and Rehabilitation, National Taiwan University Hospital, 17, F4, Xu Zhou Rd, Taipei, Taiwan 100, e-mail: kclin@ha.mc.ntu.edu.tw.

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efficiency such as Fugl-Meyer Assessment (FMA), maximum grip strength,^{9,16} Wolf Motor Function Test (WMFT), and Nine Hole Peg Test.^{9,11,12,14} The activity level (or the functional level) measure involved assessment of performance of daily activities including objective measures such as FIM instrument and patient-oriented measures (eg, self-reported Motor Activity Log [MAL]).^{9-12,14} Functional performance after stroke may not correlate with level of HRQOL.¹⁷

One recent study¹⁸ investigated the effects of the CIMT on motor function (grip force for strength, Modified Ashworth Scale [MAS] for spasticity), daily function (WMFT and MAL for function in daily living), and HRQOL (Stroke Impact Scale [SIS]). As stated by these researchers, this study lacked a control therapy and the operation of other nonspecific effects cannot be ruled out. Cumulative data on comprehensive outcome measures for intervention effects are essential for evidence-based clinical decision making, research, and appropriate clinical management of stroke survivors.¹⁹ To examine the benefits of mCIMT in different aspects of health in elderly stroke survivors, we used FMA to reflect the improvement of motor function, FIM and MAL to objectively and subjectively represent daily function, and SIS to reflect HRQOL. This research used a randomized controlled trial to overcome the previous concern regarding research methodology in the study of Dettmers et al.¹⁸ The hypothesis was that patients receiving 3 weeks of mCIMT would exhibit substantially better performance in their affected UEs reflected by these 4 measures than patients receiving traditional rehabilitation.

METHODS

Participants

We recruited 26 elderly stroke patients (15 men, 11 women; mean age, 71.69y; range, 65–87y) from the rehabilitation departments of 3 medical centers and obtained informed consent. The subjects were right-handed before stroke by self-report, and were 0.5 to 31 months post onset of a first-ever cerebrovascular accident (mean, 7.5mo). To be included, the subject had to reach Brunnstrom stage III²⁰ for the proximal part of UE or above. The other inclusion criteria were as follows: (1) no serious cognitive deficits (a score ≥ 63 on the modified Mini-Mental State Examination [MMSE]²¹); (2) considerable nonuse of the affected limb (an amount of use [AOU] score < 2.5 on the MAL²²); (3) no balance problems sufficient to compromise safety when wearing the project's constraint device; and (4) no excessive spasticity in any of the joints of the affected UE (shoulder, elbow, wrist, fingers) (MAS score ≤ 2 in any joint).²³ The institutional review board for human studies approved this protocol. All potential subjects received independent examinations by a physiatrist and an occupational therapist to determine their eligibility for inclusion.

Outcome Measures

We used FMA (maximum score, 66) to assess several dimensions of motor impairments by using a 3-point ordinal scale (0, cannot perform; 1, can perform partially; 2, can perform fully).²⁴ Test-retest reliability, interrater reliability, and construct validity have been well established.^{25,26}

The FIM instrument was used to objectively measure changes in activity performance through performance observation, and the MAL was used to subjectively measure changes in activity performance through self-report. The FIM instrument (maximum score, 126) consists of 18 items grouped into 6 subscales measuring self-care, sphincter control, transfers, locomotion, communication, and social cognition ability.²⁷ Each item is rated

with a score from 1 to 7 (1, complete assistance to perform basic activities of daily living [ADLs]; 2, maximal assistance; 3, moderate assistance; 4, minimal assistance; 5, supervision; 6, modified independence; 7, complete independence in performing basic ADLs). The FIM has established good interrater reliability.²⁸⁻³²

The MAL is a semistructured interview that obtained information about how patients use their affected limbs during 30 important ADLs. Patients used a 6-point AOU scale (score range, 0–5) to rate how much the arm is being used and a 6-point quality of movement (QOM) scale (score range, 0–5) to rate how well they are using their affected UEs.²²

The SIS is a comprehensive measure of health outcomes in stroke populations. The evaluation of SIS involves a person's participation in the activities that the person usually does in his/her life situation and relevant skills such as communication, memory, and mobility for participation in personal meaningful activities.³³ The SIS was, thus, appropriate to be used to measure changes in HRQOL and participation performance through self-report.

The SIS, version 2, is a 64-item self-report scale designed to assess 8 functional domains including strength, memory, emotions, communication, ADLs and instrumental ADLs (IADLs), mobility, hand function, and participation, with established reliability and validity.^{33,34} Patients responded to items in each domain using a 5-point rating scale. Aggregated scores in each domain were generated and scores for each domain were computed using procedures published previously.³³ A higher score means better performance.³³

One question for assessing the patient's global perception of percentage of recovery was included in the SIS. After patients finished the questions of the 8 domains, they were required to rate their percent recovery since their stroke on a visual analog scale of 0 to 100, with 0 indicating no recovery and 100 indicating full recovery.³³

Design and Intervention

We applied a randomized pretest and posttest control group design. Subjects were individually randomized into the mCIMT or the traditional rehabilitation group by using a table of random numbers (fig 1).³⁵ Before and after the 3-week intervention period, the tests were administered in random order by a blinded rater. Prior to administration of clinical measures (FMA, FIM), the blinded rater was trained to properly administer these 2 measures. This training included careful examination of written instructions and repeated practice. Rater competence was assessed by a senior certified occupational therapist.

For both groups, the study treatment occurred during the regularly scheduled occupational therapy (OT) session and all other routine interdisciplinary stroke rehabilitation proceeded as usual. When 2 or more study subjects were in the OT clinic at the same time, they were assigned to different treatment areas without opportunities to observe each other or rearranged to receive therapy at different times to prevent unintended crossover.

Each subject assigned to mCIMT participated in individualized, 2-hour therapy sessions, 5 times a week for 3 weeks. Shaping and adaptive and repetitive task practice techniques were used during the training sessions. Therapy concentrated on the affected limb use in functional tasks chosen by patients and the treating therapist, including turning on and off a light switch, reaching forward to move a jar from one place to another, picking up a cup and drinking from it, picking up a hairbrush and combing hair, and other activities similar to those performed on a daily basis. Approximately 15 minutes of

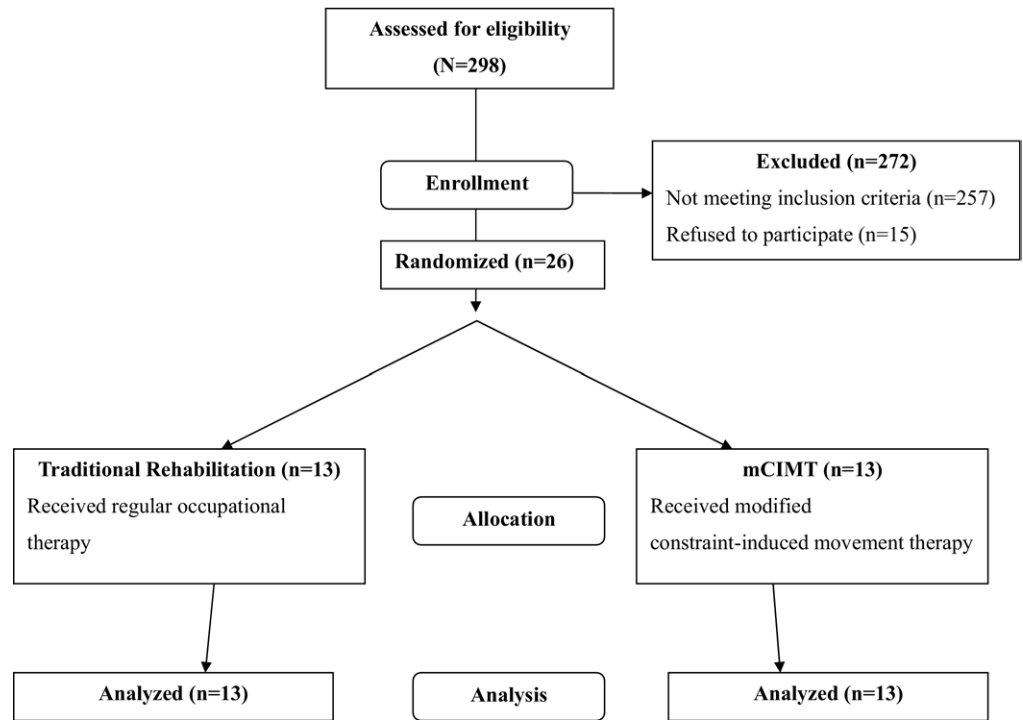


Fig 1. Flow diagram of the randomization procedure.

therapy was spent on normalization of muscle tone of the affected limb as needed. During the 3-week period, the patients' unaffected hands and wrists were placed in mitts with self-adhesive (Velcro) straps every weekday for 6 hours identified as a time of frequent arm use.

With equivalent time and intensity of treatment, patients in the traditional rehabilitation group received standard therapy. During a 2-hour therapy session, approximately 75% of traditional rehabilitation focused on neurodevelopmental techniques emphasizing functional task practice when possible, as well as stretching of the affected limb, weight bearing with the affected limb, and fine motor dexterity activities. Approximately 25% of traditional rehabilitation focused on compensatory techniques using the unaffected limb to perform functional tasks and assist the affected limb during task performance.

Statistical Analysis

For all variables, we used analyses of covariance (ANCOVAs)³⁶ to test whether, when controlling for pretreatment differences, the intervention improvement in the mCIMT group was greater than that in the traditional rehabilitation group. For each analysis, the pretest performance was the covariate, group was the independent variable, and posttest performance was the dependent variable. Effects sizes were calculated for each individual variable and indexed by using the effect size *r*.³⁷ According to Cohen, a large effect is represented by an *r* of at least .50, a moderate effect by .30, and a small effect by .10.³⁸

RESULTS

After being randomly assigned to 1 of the 2 groups, 13 subjects were included in the mCIMT group and 13 in the traditional rehabilitation group. The demographic and clinical characteristics of subjects in the 2 groups were comparable

(table 1). Because the natural recovery of stroke patients with onset less than 6 months might be a confounder for study effects,³⁹ we compared the onset time (mean onset: for mCIMT, 1.76mo; for traditional rehabilitation, 2.44mo) of patients whose onset was less than 6 months (mCIMT group, n=9; traditional rehabilitation group, n=8) between the 2 groups and found no significant differences (*P*=.385) between the groups.

Table 2 shows the descriptive statistics for each outcome measure. The SIS score (*P*=.039) and the scores of participation (*P*=.004) and perceived recovery (*P*=.012) domains of the SIS showed significant differences between the groups at pretreatment time point. No other outcome measures showed significant differences between the groups before treatment.

Table 1: Characteristics of Study Participants

Characteristics	mCIMT (n=13)	TR (n=13)	<i>P</i> *
Sex (male/female)	8/5	7/6	.691
Age (y)	71.44±6.42	71.94±6.79	.849
Side of lesion (right/left)	6/7	7/6	.695
Months after stroke	6.70±8.99	8.32±7.97	.616
Brunnstrom stage of proximal part of UE (median)	4.5	4.5	.312
Modified MMSE	82.92±11.21	83.08±11.41	.973
AOU MAL	0.80±1.38	1.37±1.71	.356
MAS	0.26±0.32	0.32±0.34	.588

NOTE. Values are mean ± standard deviation (SD) or as otherwise indicated.

Abbreviation: TR, traditional rehabilitation.

**P* associated with the chi-square test for categorical variables, with the independent *t* test for continuous variables, and with the Mann-Whitney *U* test for ordinal variables.

Table 2: Performance on the Outcome Measures From Pre- to Post-Treatment

Measures	Pretreatment		Post-Treatment	
	mCIMT (n=13)	TR (n=13)	mCIMT (n=13)	TR (n=13)
FMA (UE)	41.85±11.33	47.08±10.94	49.54±12.84	49.38±10.18
FIM	95.08±15.24	98.31±21.48	104.85±12.13	100.85±20.08
MAL				
AOU	0.80±1.38	1.37±1.71	1.78±1.28	1.57±1.76
QOM	0.79±1.29	1.35±1.64	1.99±1.31	1.49±1.58
SIS	53.13±8.95	63.70±14.95	62.22±8.71	63.64±15.18
Physical function				
Strength	35.58±17.19	48.56±18.78	51.92±17.00	44.71±16.31
Hand function	19.42±28.94	38.46±39.60	35.58±34.16	44.62±33.88
Mobility	61.35±25.85	70.77±29.64	70.96±14.91	68.27±28.84
ADLs/IADLs	52.59±18.07	62.00±22.23	63.74±17.40	59.74±27.15
Memory	77.91±14.06	76.44±20.04	79.58±11.61	79.57±17.57
Communication	88.05±20.28	90.93±15.47	91.81±13.72	88.46±18.45
Emotion	60.08±14.56	68.15±19.44	63.25±15.53	69.45±19.40
Participation	30.10±17.13	54.28±21.45	40.90±16.48	54.28±25.65
Stroke recovery	38.46±18.53	58.08±18.21	49.62±19.31	54.62±24.28

NOTE. Values are mean ± SD.

Table 3 shows the results of the ANCOVAs that tested the effects of mCIMT relative to traditional rehabilitation. The results showed significant and moderate-to-large effects in favor of the mCIMT group on FMA, FIM, and MAL. Patients in the mCIMT group reported greater improvements in AOU and in QOM of their affected limbs during daily activities. The mCIMT group reported using the affected UE for an average of 14 activities and the traditional rehabilitation group for an average of 16 activities before treatment, and the mCIMT for 24 and the traditional rehabilitation for 22 after treatment.

The results also showed significant and moderate effects of mCIMT on the overall SIS and some aspects of the SIS. These greater improvements were shown in a few QOL domains on the SIS including strength and ADLs and IADLs. There were small and nonsignificant differences between the 2 groups on hand function, the memory and thinking, emotion, communication, participation, and mobility domains. Finally, patients

reported significantly greater percent of recovery using the visual analog scale after treatment in the mCIMT group than in the traditional rehabilitation group.

DISCUSSION

This randomized controlled study supported in an elderly sample the effectiveness of mCIMT in stroke patients. Patients improved in different aspects of motor function, daily function, and participation as reflected by the UE movement patterns, independence in ADLs, and some aspects of QOL. There was no attrition and full protocol adherence, indicating that the mCIMT is well tolerated for the elderly stroke patients.

The greater improvement in the scores of the FMA and the FIM seen in the mCIMT group than in the traditional rehabilitation group corresponded with those of previous studies.^{9,11,12,14} The substantial improvement in the abnormal movement patterns, reflected by FMA, in the mCIMT group suggested that mCIMT reversed impairments rather than simply helped patients to adapt to residual impairments. Accordingly, largely improved daily function, reflected by FIM, in the mCIMT group may result from the reduced motor impairments rather than developing new compensatory strategies. The score changes in FIM were supported by the improvement reported for the ADL and IADL domain of the SIS.

Patients in the mCIMT group subjectively reported considerably larger improvements in the use and function of their affected UEs, as measured by the MAL, than those in the traditional rehabilitation group. These findings on MAL are consistent with previous findings.^{9,11,12,14} These MAL scores in the mCIMT group suggested that the learned nonuse phenomenon observed in the patients can be overcome through a modified intensive training and mitt wear schedule emphasizing repeated functional use.

As shown in the descriptive statistics (table 2), the mean scores of FMA, FIM, and MAL before treatment were slightly lower in the mCIMT group than in the traditional rehabilitation group, though nonsignificant differences were found. However, the mean scores of these 3 measures after treatment were higher in the mCIMT group than in the traditional rehabilitation group, demonstrating that patients receiving mCIMT exhibited improvements in reduced motor impairment and enhanced functional use of the affected UE in daily activities.

Table 3: Results of Inferential Statistics on the Outcome Measures

Measures	ANCOVA		
	F _{1,23}	P	Effect Size <i>r</i>
FMA (UE)	6.87	.008*	.48
FIM	4.94	.018*	.42
MAL			
AOU	9.75	.003*	.55
QOM	14.76	<.001*	.63
SIS	3.29	.042*	.35
Physical function			
Strength	5.33	.015*	.43
Hand function	0.71	.204	.17
Mobility	1.63	.107	.26
ADLs/IADLs	3.12	.045*	.35
Memory	0.02	.444	.03
Communication	0.59	.226	.16
Emotion	0.01	.464	.00
Participation	0.98	.167	.20
Stroke recovery	13.36	.001*	.59

**P*<.05.

The possible mechanisms responsible for improvement in motor function and daily function after such a short period of therapy can be speculated, based on the literature. First, reinforcement of using the affected limb and aversive consequences for its nonuse by constraining the unaffected hand may reduce the learned nonuse behavior. Second, repeated practice of functional tasks of ecologic significance to the patients may lead to increased reorganization of the brain after stroke. This use-dependent cortical reorganization may represent the neural basis of increased use of the affected UE.⁶ The natural recovery of stroke patients with onset less than 6 months might be a confounder for the explanation of the beneficial effects of mCIMT.³⁹ However, the numbers of subjects with onset less than 6 months between the 2 groups were similar and the difference in mean onset time was nonsignificant. Thus the observed effects in favor of mCIMT cannot be attributed to the confounding effect of natural recovery after stroke.

The mCIMT group appeared to obtain greater gains in HRQOL than traditional rehabilitation. These gains were mostly shown in the physical domains (ie, strength and ADLs and IADLs), which is partially consistent with the previous study.¹⁸ Because the mCIMT program targeted functional training of movement, patients should directly obtain gains in the physical performance and daily function. It should also be noted that the traditional rehabilitation group showed lower scores in some domains of HRQOL after treatment. The posttreatment differences between the study groups are due, in part, to the posttreatment declines in the traditional rehabilitation group.

Patients receiving mCIMT did not subjectively exhibit significantly greater improvements in hand function than those receiving traditional rehabilitation, inconsistent with the findings of the previous study.¹⁸ The possible reason is that hand dexterity and perceptual-motor adaptability decreases with age,^{40,41} especially after the age of 65 years. The potential for relearning hand function through rehabilitation training is, thus, limited and no further improvement was found in mCIMT. Ranganathan et al⁴² suggest that skilled finger movement exercise such as holding 2 metal balls in the palm of the hand and rotating the balls smoothly clockwise or counterclockwise improves hand function in elderly people. Future research may investigate whether incorporating intensive exercise of skilled finger movements into mCIMT may improve subjective perceptions of hand function.

Similar to the findings of previous research,¹⁸ patients in the mCIMT group did not perceive further improvement in mobility than those in the traditional rehabilitation group possibly because the training program did not involve transfer or mobility tasks. No significant differences after treatment between 2 groups on the memory and thinking, emotion, communication, and participation domains suggested that the effects of intensive physical training such as mCIMT on physical performance may not generalize into the effects on cognitive and psychosocial domains. Because mCIMT is an intensive training during 2 to 3 weeks, the interaction between therapists and patients is an important component of this treatment. To enhance the psychosocial well-being of individual patients, the therapist should consider patients' opinions regarding how the functioning gained from mCIMT applies to their social lives.⁴² mCIMT programs that link motor function to social activities may enhance social participation more effectively.^{43,44} Examples of such treatments are those that involve dyadic and group interaction on collaborative activities and practice on constituent tasks relevant for community function (eg, simulated activities of grocery shopping). Furthermore, home-based mCIMT⁴⁵ might also be appropriate for use in the elderly to

facilitate generalization of therapeutic gains in motor function and self-care skills to daily life and community function. Considerations of the practice context and activity parameters are especially relevant for mCIMT to be implemented with success in the aged populations. Future research may study whether mCIMT using client-valued activities for task-oriented practice in the home setting or domicile community would be more beneficial than hospital-based physical training for improving function and preventing disability in the elderly.

Study Limitations

A few limitations to this study warrant consideration. First, the treatment effects were measured immediately after treatment and the benefits of intervention may not be retained over time. Further study is underway that evaluates immediate and long-term effects of the treatment using broader functional outcomes. Second, individually randomizing study subjects into the mCIMT or the traditional rehabilitation group seemed to have resulted in nonequivalency in some of the outcome measures such as the participation and perceived recovery aspects of the SIS. To correct for this problem, ANCOVAs were used to control for the pretreatment differences between groups. Future research using stratified random sampling⁴⁶ (eg, matching groups on baseline characteristics) might serve to better control for the problem of pretreatment differences between groups. A final limitation pertains to a problem that is characteristic of all CIMT studies. Although all subjects received the same intensity and duration of treatment intervention, the CIMT group arguably received more "treatment" during restraint wear out of clinic. Future research may use a control group that receives traditional rehabilitation together with restraint wear out of clinic to address this potential bias.

Additional considerations for extended research include measurements of functional independence in various performance contexts (eg, hospital-based measures of self-care and mobility and evaluation for IADLs after hospital discharge). Future research may also study factors that may affect treatment outcomes (eg, stroke severity, side of hemiplegia, motivation for treatment participation). Such research may reveal prognostic factors relevant for outcome prediction and patient selection.

CONCLUSIONS

The unique contribution of this study is to investigate the feasibility and efficacy of mCIMT for improving affected limb use, daily function, and HRQOL in elderly stroke survivors. The findings suggest that mCIMT improves movement performance and ADL abilities as measured by clinical tests, whether subjective or objective. mCIMT improved physical aspects of QOL and was well tolerated by the elderly patients although it is a rigorous training program. Future clinical trials may enroll a larger sample for follow-up study to evaluate the long-term benefits of mCIMT in the elderly. More focused evaluation of rehabilitation practice that aims at improving aspects of HRQOL and functional domains at the activity level in the elderly is needed. This treatment evaluation will contribute to improved practice for elderly stroke survivors.

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