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Constraint-Induced Therapy Versus Dose-Matched Control Intervention to Improve Motor Ability, Basic/Extended Daily Functions, and Quality of Life in Stroke

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Background. Trials of constraint-induced movement therapy (CIT) to improve upper extremity function after stroke have usually not included an actively treated control group. **Objective.** This study compared a modified CIT intervention with a dose-matched control intervention that included restraint of the less affected hand and assessed for differences in motor and functional performance and health-related quality of life. **Methods.** This 2-group randomized controlled trial, using pretreatment and posttreatment measures, enrolled 32 patients within 6 to 40 months after onset of a first stroke (mean age, 55.7 years). They received either CIT (restraint of the less affected limb combined with intensive training of the affected limb for 2 hours daily 5 days per week for 3 weeks and restraint of the less affected hand for 5 hours outside of the rehabilitation training) or a conventional intervention with hand restraint for the same duration. Outcome measures were the Fugl-Meyer Assessment, Functional Independence Measure, Motor Activity Log, Nottingham Extended Activities of Daily Living Scale, and Stroke Impact Scale. **Results.** Compared with the control group, the CIT group exhibited significantly better performance in motor function, level of functional independence, mobility of extended activities during daily life, and health-related quality of life after treatment. **Conclusions.** The robust effects of this form of CIT were demonstrated in various aspects of outcome, including motor function, basic and extended functional ability, and quality of life.

Keywords: Rehabilitation; Stroke; Constraint-induced movement therapy; Instrumental activities of daily living; Quality of life

Constraint-induced therapy (CIT) and most of its derivatives are intensive, short-term treatments in which the less affected limb is restrained for an extended period and the affected limb repeatedly practices functional tasks.¹⁻⁴ One form of CIT, called modified CIT, has varied this intensive and short-term regimen to incorporate shorter periods of training over a longer intervention period.⁵ In previous studies, CIT and its derivatives involved training the affected limb by shaping for 0.5 to 6 hours for 3 to 5 times per week for 2 to 10 weeks while use of the less affected upper extremity was constrained for the most of the waking hours or 5 or 6 hours during this period to induce increased use of the affected limb.

Numerous studies of stroke patients have shown that CIT and its derivatives significantly improve motor ability and functional use of the affected limb compared with the improvements achieved with traditional or no active therapy.¹⁻⁵ A barrier in determining the efficacy of CIT is the lack of studies using a control group matched for dose of rehabilitative therapy together with restraint of the unaffected hand outside of the

therapy session.^{2,6} The CIT group arguably received more "treatment" when wearing a restraint outside of rehabilitation. To address this potential bias, this study used a control group that received conventional rehabilitation together with use of a restraint at home.

Because the primary goal of stroke rehabilitation is to improve quality of life (QOL) for patients experiencing daily living difficulties,⁷ the outcome measures for CIT efficacy should reflect a full range of domains affected by stroke, which has not been included in prior trials. To examine the benefits of CIT in different aspects of health in stroke survivors, we used comprehensive outcome measures of motor ability, perceived functional use of the affected limb, basic and extended performance of activities of daily living (ADL), and QOL.

The CIT and modified CIT programs have been shown to be applicable in patients with a wide variety of motor disabilities. In most studies,^{2,3,5,8-12} CIT was administered to patients who exhibited active extension in their affected wrists

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Table 1
Characteristics of Study Subjects

Variable	CIT (n = 16)	Control (n = 16)	P
Sex		>.99	
Males	11	11	
Females	5	5	
Age, mean (SD), years	54.14 (11)	57.38 (12.78)	.45
Side of stroke (R/L)			.73
Right	9	8	
Left	7	8	
Months after stroke, mean (SD)	16.93 (11.13)	13.23 (8.84)	.30
Brunnstrom stage of proximal part of UE, median (range)	4.75 (4.0-5.0)	4.50 (3.5-5.0)	.18
Mini Mental-State Exam scores, median (range)	27.25 (25-30)	28.56 (25-30)	.10
Daily restraint, mean (SD), hours	4.33 (1.04)	4.18 (1.12)	.70

Abbreviations: CIT, constraint-induced therapy; UE, upper extremity.

and fingers. Many patients, however, are not able to actively extend the wrist and fingers for 5° to 10°. Several studies^{4,13-18} comprised patients who had less motor function and still showed beneficial effects of CIT or modified CIT. For example, Bonifer and Anderson¹³ suggest motor improvement after CIT in patients who initially exhibited no isolated wrist movement. Some reports^{14,15,17} found salient changes in patients receiving CIT or modified CIT who initially were able “to lift a washrag or grasp a washcloth using any type of prehension and then release it.” Wu et al^{4,18} demonstrated that after CIT, significant improvements occurred in motor performance and motor control strategies in patients who initially could only place the hand behind their back, move the arm forward to a horizontal position, or perform pronation and supination with the elbow flexed at 90°. The motor criteria for patient recruitment in this study used this latter criterion for entry.

Methods

Subjects

After providing informed consent, 32 patients with a first stroke (22 men and 10 women) were recruited from rehabilitation departments at three teaching hospitals. The patients were a mean age of 55.7 years (range, 30-75 years), were right-hand dominant before their strokes (self-reported), and were a mean 15.1 months (range, 6-40 months) after onset (Table 1). Inclusion criteria were (1) Brunnstrom stage III or better for the proximal part of the affected upper limb,¹⁹ (2) considerable nonuse of the affected upper limb (amount-of-use score < 2.5 on the Motor Activity Log [MAL]),²⁰ (3) no serious cognitive deficits (score > 24 on the Mini Mental-State Exam),²¹ (4) no balance problems compromising safety when wearing the constraint device, and (5) no excessive spasticity (Modified Ashworth Scale ≤ 2 at any joint of the upper limb).²² All potential subjects underwent independent examinations by a physiatrist and occupational therapist to determine eligibility.

Outcome Measures

Outcome measures were the Fugl-Meyer Assessment,²³ Functional Independence Measure (FIM),²⁴ MAL,²⁰ Nottingham Extended Activities of Daily Living (NEADL) Scale,²⁵ and the Stroke Impact Scale.²⁶ The Fugl-Meyer Assessment was used to assess several dimensions of motor impairments and the MAL to assess self-perceived functional use of the affected limb. The FIM objectively measured changes in basic ADL function and NEADL in extended ADL performance. The Stroke Impact Scale is a comprehensive measure of health outcomes in stroke populations and assesses a person's participation in usual life activities and relevant skills. All measures demonstrate good reliability and validity with a higher score representing better performance than a lower score.²⁶⁻³⁸

Design and Intervention

The CIT and control groups were randomly assigned 16 patients each (Figure 1). Before and after the 3-week intervention, tests were administered by a rater blinded to group assignment. The blinded rater was trained to administer these measures properly, and rater competence was assessed by a senior certified occupational therapist. All subjects were blind to the study hypothesis.

For both groups, study treatment occurred during regularly scheduled occupational therapy sessions. All other routine interdisciplinary stroke rehabilitation proceeded as usual, and was delivered by a variety of treatment disciplines, including physical therapists and psychologists. When 2 or more study subjects received therapy at the same clinic and the same time, they were assigned to different treatment areas and had no opportunity to observe each other, or were rescheduled to receive therapy at different times to prevent unintended crossover.

Subjects in both groups received individualized, 2-hour therapy sessions, 5 times per week for 3 weeks. All subjects were required to place their less affected hand and wrist in

Figure 1
Flow Diagram of the Randomization Procedure

mitts with Velcro straps when not in therapy for a target of 5 hours per day, 5 days per week for 3 weeks. This training schedule was selected based on previous CIT trials^{4,18,39,40} that showed that the schedule was feasible and effective. In addition, this schedule was more feasible than other types of schedules within the confines of practice settings and payer restrictions in our study sites.

Patients were told to wear the mitt while they were active (eg, eating, using the toilet, and performing household activities). The mitt allowed the less affected upper extremity to assist in transfers and ambulation, but it prevented use of that hand to perform fine motor activities. If the subject was sedentary without need for hand movement, such as when watching television, the hours wearing the mitt were not counted. Subjects documented mitt compliance in daily logs. The only difference between these 2 groups was in the treatments applied during the 2-hour therapy session.

The CIT group focused on functional training of the affected limb. Shaping, adaptive, and repetitive practice of functional tasks were used during training sessions. Functional tasks selected by patients and therapists involved dialing a phone number, reaching forward to move a jar from one place to another, picking up a cup and drinking from it, and other activities similar to those performed on a daily basis. Approximately 15 minutes of therapy was spent on normalization of muscle tone of the affected limb as needed.

Conventional rehabilitation in the control group focused on neurodevelopmental techniques emphasizing functional task practice when possible, as well as weight bearing by the affected limb and fine motor dexterity activities. The intervention also included compensatory techniques using the less affected limb to perform functional tasks and assist the affected limb during task performance for about a half-hour during the 2-hour therapy session.

Statistical Analysis

For all variables, analysis of covariance (ANCOVA) was applied to examine the effects of CIT versus the control intervention. Pretest performance and restraint time per day were covariates, group was the independent variable, and posttest performance was the dependent variable. Restraint time was treated as a covariate because restraint time varied according to each subject's situation. Effect sizes were calculated for each individual variable and indexed using effect size r .⁴¹ According to Cohen,⁴² a large effect is represented by an r of at least .50, a moderate effect by .30, and a small effect by .10.

Results

Demographic and clinical characteristics of subjects in the 2 groups (16 subjects in each) were comparable (Table 1). Daily restraint varied from 3.5 to 7.6 hours, indicating that some patients may have encountered difficulties complying with the restraint requirement when performing activities outside rehabilitation.

Table 2 presents descriptive statistics and ANCOVA results for the effects of CIT relative to the control intervention. Experimental results showed significant and large effects favoring the CIT group on the Fugl-Meyer Assessment ($P < .001$) and FIM ($P < .001$). Significant and moderate-to-large effects existed for the 2 FIM domains of self-care ($P = .002$) and locomotion ($P < .001$), favoring the CIT group. Nonsignificant and trivial-to-small effects existed in subtests (amount-of-use and quality of movement) of the MAL. A significant and moderate effect existed on the NEADL, especially in the domain of mobility ($P = .007$), but not in other domains, favoring the CIT group. The Stroke Impact Scale results showed an overall significant and moderate effect ($P = .009$) in favor of the CIT group. The significant and large effects were demonstrated in 3 domains of the Stroke Impact Scale; that is, ADL ($P < .001$), mobility ($P = .0015$), and hand function ($P < .001$).

Discussion

Consistent in a large part with our hypothesis, the CIT program reduced motor impairment to a greater extent (measured by the Fugl-Meyer Assessment) and induced greater gains in functional capacity, especially for self-care,

Table 2
Descriptive and Inferential Statistics for Outcome Measures

	Pretreatment, Mean (SD)		Posttreatment, Mean (SD)		ANCOVA		
	CIT (n = 16)	Control (n = 16)	CIT (n=16)	Control (n = 16)	$F_{1,28}$	P	Effect Size r^a
FMA (UE)	46.56 (7.47)	49.13 (13.02)	53.13 (6.35)	51.88 (13.90)	16.53	<.001	0.57
FIM	118.19 (8.96)	117.88 (11.99)	122.13 (5.90)	118.19 (9.93)	24.33	<.001	0.67
Self-care	38.25 (4.91)	36.56 (8.07)	40.31 (2.55)	36.94 (7.65)	9.68	.002	0.49
Sphincter	13.88 (0.50)	13.94 (0.25)	13.81 (0.54)	13.81 (0.40)	0.15	.35	0.07
Transfer	20.00 (1.71)	20.31 (1.20)	20.81 (0.75)	20.63 (1.02)	1.18	.14	0.19
Locomotion	12.50 (1.26)	13.25 (2.05)	13.38 (0.72)	12.94 (2.02)	12.93	<.001	0.55
Communication	13.69 (1.01)	13.56 (1.09)	13.75 (1.00)	13.44 (1.15)	2.18	.075	0.26
Social cognition	19.88 (3.26)	20.25 (1.73)	20.06 (2.74)	20.44 (1.36)	0.84	.18	0.16
MAL							
AOU	0.83 (0.78)	1.09 (0.77)	1.63 (0.78)	1.78 (1.10)	.19	.33	0.07
QOM	0.78 (0.62)	1.35 (1.14)	1.80 (0.82)	2.05 (1.26)	2.54	.061	0.26
NEADL	28.31 (11.82)	26.69 (16.29)	30.88 (12.42)	25.94 (15.10)	3.18	.043	0.31
Mobility	12.31 (4.64)	11.50 (6.48)	14.25 (3.61)	11.19 (6.26)	6.85	.007	0.43
Kitchen	5.38 (4.00)	3.88 (3.40)	6.19 (4.18)	3.56 (3.50)	2.17	.076	0.26
Living	4.13 (3.24)	4.63 (4.77)	5.06 (3.99)	4.69 (4.38)	0.95	.17	0.18
Leisure	6.50 (2.94)	6.69 (3.91)	5.56 (3.69)	6.50 (3.65)	0.78	.19	0.16
SIS	538.12 (72.19)	543.39 (149.36)	598.08 (69.92)	559.05 (148.26)	6.38	.009	0.40
Strength, %	51.95 (22.33)	43.75 (27.29)	57.42 (22.62)	47.27 (18.54)	.72	.20	0.14
Memory, %	85.19 (16.98)	82.17 (26.81)	90.82 (13.97)	84.24 (26.52)	1.09	.15	0.18
Emotion, %	64.24 (24.63)	65.45 (15.91)	68.92 (15.62)	65.98 (20.92)	.37	.27	0.10
Communication, %	93.08 (16.47)	85.71 (25.35)	92.86 (17.15)	88.62 (22.22)	.53	.24	0.12
ADL/IADL, %	71.90 (16.71)	75.94 (22.59)	79.96 (12.14)	72.47 (23.95)	17.16	<.001	0.58
Mobility, %	83.65 (11.95)	81.45 (17.60)	92.50 (6.97)	79.90 (18.74)	10.62	.0015	0.49
Hand function, %	31.88 (27.13)	52.19 (35.02)	49.06 (23.82)	58.44 (31.82)	70.63	<.001	0.82
Participation, %	56.25 (26.38)	56.72 (26.60)	66.54 (23.40)	62.15 (24.76)	.47	.25	0.12

Abbreviations: ADL, activities of daily living; ANCOVA, analysis of covariance; AOU, amount of use; CIT, constraint-induced therapy; FIM, Functional Independence Measure; FMA, Fugl-Meyer Assessment; IADL, instrumental activities of daily living; MAL, Motor Activity Log; NEADL, Nottingham Extended Activities of Daily Living; QOM, quality of movement; SIS, Stroke Impact Scale; UE, upper extremity.

^aAccording to Cohen,⁴² a large effect is represented by an r of at least .50, a moderate effect by .30, and a small effect by .10. A positive value for effect size indicates that the effect is in the hypothesized direction and a negative value indicates that the effect is in the opposite direction of the hypothesized direction.

locomotion, and mobility (measured by the FIM and NEADL), than did the control intervention. Patients in the CIT group improved more in the physical aspects (ADL, mobility, and hand function) of QOL than those in the control group.

The experimental findings from the Fugl-Meyer Assessment and FIM are in agreement with those obtained by previous studies.^{1,4,5,13-15,39,40} Compared with previous research, this study provided more compelling evidence indicating that patients in the CIT group had better motor performance at the impairment level and basic ADL capacity, especially in self-care activities and locomotion, than those in the control group. Previous studies used a control group with equal treatment hours per week in a clinic as the CIT group, whereas this study required both groups to receive equal treatment hours in the clinic and restraint time outside rehabilitation treatment. The only difference between these 2 groups in this study is the 2-hour treatment program.

Although the CIT treatment program did not involve locomotor training, enhanced motor ability and problem-solving capacity may have motivated patients to explore functional activities involving locomotion.

In contrast to previous studies^{2-4,13-18,39,40} and our hypothesis, no significant differences were found in posttreatment MAL scores between the 2 groups. A possible reason is that both groups were required to restrain the less affected limb outside rehabilitation, which may have enhanced spontaneous use of the affected limb in both groups.⁴³ Significant differences existed between the 2 groups for overall NEADL scores. Specifically, the CIT group had significantly better posttreatment performance than the control group in the mobility domain of the NEADL. These improvements might result from enhanced performance of the upper limb, which is important for functional mobility (eg, opening and closing doors).

The CIT group obtained higher QOL scores after treatment than the control group. These gains were in physical domains such as ADL, mobility, and hand function; this finding is consistent with findings for objective measures of FIM and NEADL. The QOL results are partially consistent with those obtained by previous studies.^{3,4,8} The CIT patients may have perceived higher gains in physical performance and daily function because the CIT program targeted functional training of an affected limb. Patients receiving CIT did not perceive

significantly higher performance in strength than those receiving the control intervention; this finding is inconsistent with the findings obtained by previous studies.^{4,8} The likely reason is the lack of focus on muscle strengthening during treatment sessions for both groups. Future research may combine the CIT program with a muscle strengthening protocol to improve upper limb strength and function.⁴⁴

No significant differences after treatment existed between the 2 groups for memory and thinking, emotion, communication, and participation domains, suggesting that the effects of intensive physical training, such as the effect of CIT on physical performance, may not extend to the cognitive and psychosocial domains. One possibility is that the individuals recruited for this study showed good cognitive ability (at least 24 points in the Mini Mental-State Exam) before treatment. The room for improvement in the mental and psychosocial domains after the intervention was limited.

One study limitation warrants consideration. Some participants in both groups, despite encouragement, did not wear the constraint for 5 hours per day; that is, the time they wore the restraint varied markedly. This low level of compliance of some subjects may result from explicitly asking patients to wear mitts only when hand movement was required for study activities. However, no significant difference existed in mean time wearing the restraint between the 2 groups, and time wearing the restraint was treated as a covariate in statistical analyses. Study findings cannot be attributed to biased treatment in favor of either group. The variation in the time the participants wore the mitt suggests that appropriate restriction periods should be determined individually, on a case-by-case basis.⁴⁵

Conclusion

This study used a control group that received conventional rehabilitation together with wearing a restraint out of the clinic. Given the small differences between the 2 groups, experimental findings suggest that the robust effects of intensive training of an affected limb on various daily functions important for home and community living are significant. Future research may study the long-term benefits of CIT on extended ADL, work, and reintegration into a community, as well as stroke-related QOL. Furthermore, given the different life situations of individual stroke survivors living in a community, further research is needed to address the dose-response relationship between restraint duration and treatment outcomes in these patients.

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