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ORIGINAL ARTICLE

Constraint-Induced Movement Therapy for the Lower Extremities in Multiple Sclerosis: Case Series With 4-Year Follow-Up

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Abstract

Objective: To evaluate in a preliminary manner the feasibility, safety, and efficacy of Constraint-Induced Movement therapy (CIMT) of persons with impaired lower extremity use from multiple sclerosis (MS).

Design: Clinical trial with periodic follow-up for up to 4 years.

Setting: University-based rehabilitation research laboratory.

Participants: A referred sample of ambulatory adults with chronic MS (N=4) with at least moderate loss of lower extremity use (average item score ≤6.5/10 on the functional performance measure of the Lower Extremity Motor Activity Log [LE-MAL]).

Interventions: CIMT was administered for 52.5 hours over 3 consecutive weeks (15 consecutive weekdays) to each patient.

Main Outcome Measures: The primary outcome was the LE-MAL score at posttreatment. Secondary outcomes were posttreatment scores on laboratory assessments of maximal lower extremity movement ability.

Results: All the patients improved substantially at posttreatment on the LE-MAL, with smaller improvements on the laboratory motor measures. Scores on the LE-MAL continued to improve for 6 months afterward. By 1 year, patients remained on average at posttreatment levels. At 4 years, half of the patients remained above pretreatment levels. There were no adverse events, and fatigue ratings were not significantly changed by the end of treatment.

Conclusions: This initial trial of lower extremity CIMT for MS indicates that the treatment can be safely administered, is well tolerated, and produces substantially improved real-world lower extremity use for as long as 4 years afterward. Further trials are needed to determine the consistency of these findings.

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Impaired mobility is a major cause of reduced quality of life in patients with multiple sclerosis (MS).[1,2] Accordingly, over the past 30 years, nearly 100 peer-reviewed studies have investigated various forms of physical therapy involving the lower extremities for MS, including standard inpatient rehabilitation[3] and experimental outpatient approaches such as aerobic exercise,[4] progressive resistance strength training,[5] and robotic therapy.[6] Although such physical training can improve or maintain physical endurance, limb strength, cardiopulmonary fitness, or general well-being,[4,7-9] for the most part the studies to date have not evaluated whether the training benefits can transfer from the clinic or laboratory—where measurement is made primarily of maximal performance after prompting by the experimenter—to *spontaneous* use of the impaired limbs in the real world after return to the community.

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An additional important consideration is that experimental physical rehabilitation approaches to MS to date have only seldom used the type of methods to increase the relevance of therapies for activities in the life situation, of the sort used in various behavioral analysis programs for the control of obesity, smoking, or alcohol abuse.[10-12] Indeed, such approaches are not formally or systematically incorporated in physical rehabilitation for neurologic disorders in general. Nonetheless, a few recent studies have suggested that these techniques can bolster outcomes from physical rehabilitation. Studies on low back pain have shown that combining several techniques that are designed to increase the patients' adherence to the treatment (a treatment contract, emphasizing to patients their active participation in the treatment outcome, and maintaining a home diary) with exercise training can significantly improve self-rated disability over several years of follow-up relative to the same exercise training without such techniques.[13,14] More recent research has shown that upper extremity Constraint-Induced Movement therapy (CIMT) for poststroke hemiparesis that includes procedures to increase the relevance for everyday life of the training for the patient (see the Intervention section) can produce significant improvements in real-world upper extremity use, as assessed by the Motor Activity Log (MAL),[15] compared with task-oriented training without these procedures.[16] Moreover, this study showed that CIMT was associated with significant cortical gray matter increases over sensorimotor areas (as determined by voxel-based morphometry of brain magnetic resonance imaging scans), while there was no gray matter change after task-oriented training alone.

Numerous studies have shown that CIMT can successfully treat the reduction of spontaneous upper extremity use in the real world after stroke,[15-18] MS,[19] traumatic brain injury,[20] and cerebral palsy.[21] Moreover, specially adapted forms of CIMT have also successfully treated real-world lower extremity deficits after stroke[22-24] and spinal cord injury,[25] as well as verbal communication deficits in poststroke aphasia.[26-28] Regardless of the part of the body that is primarily affected, the goal of CIMT is to overcome either the reduced spontaneous use or the maladaptive use of the more-affected part of the body during functional activities. The term *Constraint-Induced Movement therapy* is considered appropriate to designate the upper extremity form of the treatment as well as the variation for the lower extremities, since the term *constraint* is meant to refer to either physical restraint of a less impaired extremity by a device or constraints imposed by behavioral procedures that limit use of compensatory strategies, or both.

Because of (1) the almost complete absence in MS rehabilitation research to date either of treatment techniques that are explicitly designed to transfer therapeutic gains achieved in the clinic to the real world or of the measurement of real-world functional outcomes, (2) the previously demonstrated success of upper extremity CIMT for chronic progressive MS,[19] and (3) the strong imposition that impaired mobility has on the quality of life in MS, we undertook a pilot trial of lower extremity CIMT for persons with chronic MS who had impaired mobility but were still capable of walking. We hypothesized that, similar to the patients with MS who had undergone experimental upper extremity CIMT, persons with relatively stable chronic MS and impaired mobility would demonstrate large treatment effects in real-world mobility and maintain their improvement long after the end of treatment. In addition, in accordance with prior studies in stroke rehabilitation, including CIMT,[15-18,29] we anticipated that changes in neurologic impairment might not parallel changes in real-world disability. We report here the immediate posttreatment results as well as follow-up results over 4 years.

List of abbreviations:

CIMT	**Constraint-Induced Movement therapy**
d'	**effect size**
EDSS	**Expanded Disability Status Scale**
FP	**functional performance**
LE-MAL	**Lower Extremity Motor Activity Log**
LE-MFT	**Lower Extremity Motor Function Test**
MS	**multiple sclerosis**
6MWT	**6-minute walk test**
T25W	**timed 25-foot walk test**
VAS	**visual analog scale**

Methods

Participants

Four ambulatory adults with chronic MS and moderately severe mobility impairments were recruited from our institution's MS clinic. Inclusion criteria included MS diagnosed according to the revised McDonald criteria,[30] no disease relapse for at least 3 months, gait impairment attributable only to MS based on the clinical impression of a specialty MS neurologist (K.B.), no more than mild pain in the lower extremities, absence of medical conditions that would preclude intensive lower extremity training (eg, foot ulcers, advanced arthritis), ability to walk at least 16m 5 times a day with or without an assistive device but without the aid of another person, score $\geq$24 on the Mini-Mental State Examination, and score $\leq$6.5/10 on the functional performance (FP) subscale of the Lower Extremity Motor Activity Log (LE-MAL, see the Outcomes section). The clinical and demographic features of the participants are provided in table 1. Progressive forms of MS (either primary progressive or secondary progressive disease) had been diagnosed in 3 of the patients. These patients had Expanded Disability Status Scale (EDSS)[31] scores of 6.5 to 7.0 (maximum possible, 10.0), indicating the need for constant bilateral assistance from devices to walk short distances without resting. Although the fourth patient had received a diagnosis of relapsing-remitting disease, she could not recall having had any disease relapses. She had a milder EDSS score of 4.0, indicating that she could walk without assistance at least 500m, but nonetheless required an ankle-foot orthosis for right lower extremity stabilization because of mild hemiparesis.

Intervention

Regardless of the specific adaptations used, the core features of CIMT are (1) massed practice with the impaired part of the body on functionally relevant tasks, (2) discouragement of compensatory activities, (3) shaping of behavior on training tasks to progressively improve performance in small steps, and (4) a set of procedures to transfer gains from the clinic to the real world.[32,33] The latter set of procedures, collectively termed the "transfer package," includes a behavioral contract to carry out agreed-on activities signed by the patient, therapist, and a witness, daily reporting by the patient of the extent of real-world use of the impaired function, problem solving to help overcome perceived barriers to improved performance, daily home practice exercises, and a home practice diary. In so doing, the transfer package is