ORIGINALARBEIT

Shaping-Induced Movement Therapy for lower extremity (SIMT) – a pilot study

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Abstract

Objective: Constraint-Induced Movement Therapy (CIMT) has been shown to be effective in improving use of the affected arm after stroke. Since paresis of the lower extremity after stroke also reduces the quality of life, a comparable rehabilitation therapy for that extremity is required to improve mobility and independence. The aim of this pilot study was to evaluate whether CIMT for the upper extremity might serve as a useful model for an efficacious motor therapy to improve lower extremity function.

Design: The more affected extremity was treated six hours per day for ten consecutive weekdays in 16 chronic stroke patients with the concept of CIMT, termed "Shaping-Induced Movement Therapy for lower extremity" (SIMT). Motor function was tested by self-rating assessments and newly developed motor function tests, and via established tests.

Results: Measurements of motor leg function improved in all patients and persisted for the next three months. Factors such as gender, loss of sensation, lesion side and others had no impact on functional improvement.

Conclusions: CIMT for the upper extremity can be used as a model for treatment of the lower extremity to produce a functional improvement ("proof of principle") that persists for at least the three months tested.

Key words: rehabilitation therapy, lower extremity, stroke recovery, CIMT

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Introduction

Stroke is the most common cause of chronic disability. It can affect aspects of daily life, e.g., grasp, language, walking. Lower extremity paresis after stroke reduces the quality of life since independent mobility within the community is restricted [15]. Improved walking is the most frequently stated goal of patients suffering from a stroke [10]. In the past, different types of rehabilitation and sophisticated interventions have been developed to improve lower extremity function in stroke patients, e.g., treadmill training with partial body weight support ([7, 8] for review see [6, 14]), a lower extremity robot termed Lokomat [9], electromechanical gait trainer plus physiotherapy [16], combined peripheral nerve and brain stimulation ([30], for review see also [12]). Treadmill training with partial body weight support has also been used with patients with spinal cord injury [3, 4].

In recent years, several studies have shown the efficacy of Constraint-Induced Movement Therapy for the upper extremity (CIMT). CIMT improves hand function deficits and enhances return of use of the more affected hand in patients with chronic stroke [5, 13, 17, 21, 23, 26, 34]. The concept upon which this therapy is based, the "learned nonuse" theory, is that nonuse of the more affected hand is in part a learning phenomenon, involving a behaviorally reinforced suppression of movement [19, 24]. CIMT consists of several major com-

ponents: intensive motor training of the more-affected upper extremity many hours a day for ten consecutive weekdays, the use of "shaping", individual therapy and restriction of the less-affected hand. Taub and colleagues described the use of CIMT for the upper extremity (UE) as a model for the treatment of lower extremity deficit (LE/ CIMT) after stroke [22], spinal cord injury [25], spinal cord injury and fractured hip [26]. The aim of this study was to determine whether the UE/CIMT model could be transferred to treatment of the LE (LE/CIMT) in chronic stroke patients. Stroke patients underwent individual motor training of the more affected lower extremity making use of shaping six hours daily for ten consecutive weekdays. For safety reasons restriction of the less-affected leg was not carried out. Therefore, we named this therapy "Shaping-Induced Movement Therapy for lower extremity" (SIMT) rather than CIMT for the lower extremity. It was anticipated that the CIMT model would be effective for treatment of the lower extremity. We focused on chronic stroke patients with no further motor improvement in the preceding three months and could therefore be considered to have reached a plateau in their motor recovery. This would make spontaneous improvement unlikely as an explanation for whatever improvement occurred during and after therapy. We also investigated whether gender, loss of sensation, side of brain lesion, initial motor score, interval since stroke, amount of previous rehabilitation and age influenced outcome of SIMT.

Methods

Patients

Thirty-two ambulatory patients were screened. Patients were recruited by advertising in newspapers in the context of general information about stroke therapy, by contacting local doctors, and by talking at local stroke clubs. Interested patients contact our laboratory via telephone or email. Sixteen patients (eight males; mean age: 60.8 years; range: 46-71 years) fulfilled inclusion criteria of the study. All patients were right-handed. Patients' characteristics are shown in Table 1.

Inclusion criteria consisted of: ability to walk at least a few steps alone or with help of an assistive device or one person, ability to stand for at least two minutes alone, onset of first ever stroke more than one year before starting SIMT. Exclusion criteria were: cognitive impairments or aphasia that could compromise comprehension or rapid response to test instructions, attention deficit, visual neglect, serious uncontrolled medical problems and motor improvement in the three months prior to starting SIMT. All patients had received extensive physical therapy, both in the acute and post-acute phase (see table 1). This study was approved by the local ethics committee in accordance with the Declaration of the World Medical Association. All included subjects gave a written consent.

Tests

Patients were tested (for test details see below) at least three months prior to the study (screening time, "screen"). At this time subjects underwent a physical examination to determine their eligibility for the experiment. If subjects met the inclusion criteria, they received an explanation of project procedures and signed informed consent. Further examinations were performed immediately before starting SIMT ("pre"), after SIMT ("post") and three months after SIMT ("follow-up"). We used a shorter follow-up testing (after three months) instead of usually six months follow-up investigation, because we were unaware of the duration of a longlasting therapy effect.

Tests were compared between screen and pre-SIMT to exclude patients who had spontaneous motor improvement (patients with test improvement more than 1% would be excluded).

The following tests were used: Similar to CIMT protocols for the upper extremity in which the Motor Activity Log, a structured interview, is used to determine the Amount of Use and Quality of Movement of the affected arm as rated by the patient [14], an equivalent selfassessment test has been used in this study for the lower extremities (LE/MAL). This test contains two scales: a functional ability scale (LE/MAL-FA) and a scale for "gait confidence and safety" (LE/MAL-CS). The questionnaire contains 14 items of daily activities (indoor walking; out-

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Zusammenfassung

Constraint-Induced Movement Therapy (CIMT) ist eine Therapiemethode zur Funktionsverbesserung der paretischen Hand/Arm nach einem Schlaganfall. Es beinhaltet nicht nur ein intensives Training, sondern es berücksichtigt u. a. auch die »Shaping-Technik«, supportives Feedback und Nachsorge. In diesem Gesamtkonzept ist CIMT langanhaltend effektiv, insbesondere in der Umsetzung des Erlernten im häuslichen Umfeld.

Das Ziel dieser Pilot-Studie war es zu prüfen, ob das Konzept von CIMT auf das Bein übertragbar ist.

Sechs Stunden täglich in zwei aufeinanderfolgenden Wochen wurde nach dem CIMT-Konzept das paretische Bein vorwiegend bei chronischen Schlaganfallpatienten trainiert. Im Gegensatz zum CIMT-Konzept mit der Immobilisation der weniger betroffenen Hand wurde das weniger betroffene Bein nicht immobilisiert, sodass der Terminus »Shaping-Induced Movement Therapy« (SIMT) verwendet wird. Neue Tests wurden entsprechend CIMT entwickelt. Somit wurden sowohl objektivierbare Qualitätsmerkmale und Zeiteinheiten als Messinstrumente genutzt als auch subjektive Selbsteinschätzungsskalen in der Ausübung von Aktivitäten des täglichen Lebens.

SIMT zeigt eine deutliche Funktionsverbesserung in allen Tests mit einem langanhaltenden Effekt drei Monate nach Beendigung von SIMT. Faktoren wie Geschlecht, Dauer von Schlaganfallereignis bis Beginn von SIMT, Seite der Läsion und andere Variablen zeigten keinen Einfluss auf die Effektivität von SIMT.

SIMT zeigt eindrücklich die Effektivität der intensivierten Behandlung zusammen mit den wichtigen Grundprinzipien wie Shaping-Technik, supportives Feedback und Nachsorge. Insbesondere muss berücksichtigt werden, dass Patienten durch die regelmäßige wöchentliche Physio- und Ergotherapie eine Konsolidierung ihrer Funktionsverbesserung nach dem akuten Ereignis aufwiesen, und erst mit der intensivierten Pulstherapie von SIMT eine weitere Verbesserung ihrer Funktionsdefizite zeigen konnten. Dies muss vor allem von den Leistungsträgern berücksichtigt werden.

Schlüsselwörter: Schlaganfall, Rehabilitation, Beinparese, Shaping Technik, CIMT

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door walking; up- and downstairs; go over objects; turn around from standing position; stand up from a chair; stand up from a toilette; lie down and stand up; to sit in and to come out from a bathtub; get from and into a car; open a door and go through the door; personal hygiene in standing position; remove something from a closet at shoulder level; pick up something from the ground from standing position). Patients were requested to rate their functional ability and their feeling of confidence and safety during performance of each of these activities from o (no ability to perform an activity or no feeling of confidence and safety, respectively) to 10 (normal ability to perform an activity or normal feeling of confidence and safety, respectively).

A 15-item test was developed based on the Wolf Motor Function Test, which is used in CIMT for the upper extremity [21, 33], the "Motor Function Test". The measures were functional ability (LE/MFT-FA) as rated

Patient	Age / Gender	Type / lesion side	Chronicity (years)	therapy (hours / week)
1	64/M	ischemic/L	7	2.25
2	71/M	ischemic/L	6	1.5
3	63/F	ischemic/R	7	1.5
4	58/M	ischemic/R	4.5	5.0
5	46/M	ischemic/R	4	1.5
6	59/F	hemorrhagic/L	7	1.5
7	54/M	ischemic/R	2.5	1.5
8	57/F	ischemic/L	4.5	1.5
9	71/M	ischemic/L	5	1.0
10	49/F	ischemic/R	18	0*
11	55/F	haemorrhagic/R	7	1.5
12	68/M	ischemic/R	2	1.5
13	48/F	haemorrhagic/L	1.5	1.5
14	66/F	ischemic/L	4	1.5
15	67/M	ischemic/R	3	2.0
16	64/F	ischemic/L	10	3.0

Table 1: Patients' characteristics are shown in this table. Patients' age (mean age was 60.8 years) and gender (eight females, "F" for female and "M" for male). Eight patients had leftsided lesions (ischemic or haemorrhagic; "L" for left and "R" for right). All patients' lesions involved only the middle cerebral artery. Stroke had occurred at least 1.5 years prior to this study in all subjects (mean: 5.8 years, range: 1.5 – 18 years). Amount of physical therapy in hours per week six months after onset of stroke (*Patient 10 received six months after stroke three hours physical therapy per week for ten years. Thereafter no further therapy was approved).

> by a blinded therapist from videotape and mean time (sec) required to perform individual tasks as measured with a stop-watch (LE/MFT-PT). The therapist was blinded as to pre- or post-treatment status of the patient and was not involved in the therapy. Before starting rating the therapist was instructed by a videotape of two patients who were not included into the final analysis. The test items included: stand up from a chair; walk and 360° pivot on the more and less affected leg; abduction of the affected and less affected leg from standing; pick up an object from the ground; lift affected and less affected leg onto a stair with and without two or four kg weights; walk over four shoeboxes positioned one after another with a gap; when walking turn around when the affected and less affected leg is fixed; up- and downstairs of ten stairs; when walking once look to the right side over the right shoulder and then to the left over the left shoulder and keep walking. To make sure that all patients have the same condition during tests, all test parameters (e.g. stairs, lifted object, abduction length) were standardized.

> The Rivermead Motor Assessment (RMA) and Three Minute Walk-Test (3Min Walk Test) were also employed. A subscale of RMA contains ten items (roll to affected and unaffected side from lying position; half-bridging; sitting to standing without using arms; from half-cook lying position lift affected leg over side of bed and return; from standing position step unaffected leg on and off block; from standing tap ground lightly five times with

unaffected foot; from lying position when the leg is flexed dorsal flexion of the affected ankle; from lying dorsal flexion of the affected ankle when leg is extended; flexion of the affected knee from standing), which patients were requested to perform three times. The best performance was scored either o (task cannot be performed) or 1 (task is completed successfully). For the 3 Min Walk Test, the measure was the distance (in meter) covered within three minutes without help.

Training

The aim of training was to modify the patient's use of the more affected lower extremity so that it was more nearly normal. Treatment was focused on daily activities (e.g. picking up an object from the ground, walking outside, ascending and descending stairs, weight-bearing exercises, sit to stand). Patients received intensive daily motor activities training by shaping [20] for at least six hours a day. About 20 tasks were chosen for use with each patient, the choice depending on the deficits of the patient and their expressed preferences concerning goals to be achieved. Approximately seven of these tasks were performed each day, usually in sets of 10. Shaping involved feedback on progress in performance after each repetition, emphasizing positive reinforcement for small improvement in performance. Complexity of the task was gradually increased as warranted by improved performance in previous trials. The speed at which performance requirements were changed depended on rate of improvement of a patient. Therapists took great care to avoid negative comments and not to increase task complexity too fast. Two physiotherapists and one neurologist were involved in deciding when task difficulty should be increased.

Statistical analysis

Statistical analysis was performed using SPSS (version 16.0). Since a normal distribution of patients could not be assumed, only non-parametric tests were used. In order to test clinical efficacy we compared LE/MAL-FA, LE/MAL-CS, LE/MFT-FA, LE/MFT-PT, RMA and 3 Min Walk Test using the nonparametric Wilcoxon test at different time points (screen vs. pre; pre vs. post; pre vs. follow-up and post vs. follow-up). Threshold was set at p < 0.008 to correct for multiple comparisons. The Mann-Whitney U-test was used to determine the influence of categorical factors; the Spearman test was used for the correlation with individual factors. Level of significance was set at p < 0.05. "Effect sizes" were measured by using the Cohen's d' statistic (small d' = 0.14, medium d' = 0.36, large d' = 0.57; [2, 24]).

Results

None of the patients improved during the three months before starting SIMT (screen vs. pre).

Effect of SIMT (see Table 2)

LE/Motor activity log functional ability (LE/MAL-FA) and gait confidence and safety (LE/MAL-CS) were significantly higher after SIMT (LE/MAL-FA pre vs. post p<0.001; LE/MAL-CS pre vs. post p<0.001). High scores of self-assessment after SIMT persisted three months after therapy (follow-up) (LE/MAL-FA pre vs. follow-up p<0.002; LE/MAL-CS pre vs. follow-up post p<0.001). The difference between post vs. follow-up was not significant.

LE/Motor Function Test: functional ability (LE/MFT-FA) and mean number of seconds needed for item performance, LE/MFT-PT) improved significantly (LE/MFT-FA pre vs. post p<0.001; LE/MFT-PT pre vs. post p<0.001). This functional improvement persisted without decrement for the three months after SIMT; comparison between post vs. follow-up was not significant for either measure.



Figure 1: Mean test scores after (post) SIMT and at three months follow-up (follow-up) are presented as percent change to before (pre). Motor activity log functional ability = LE/MAL-FA. Gait confidence and safety = LE/MAL-CS. Motor Function Test functional ability = LE/MFT-FA and performance time = LE/MFT-PT in sec. Rivermead Motor Assessment = RMA. Three-Minute Walk Test = 3 Min Walk Test.

		LE/MAL-F/	LE/MAL-C	LE/MAL-CS			
	pre	post ⁺	follow-up ⁺	pre	post ⁺	follow-up ⁺	
mean	5.5	6.9	7.2	6.0	7.3	7.4	
SD	1.9	1.7	1.6	2.0	1.7	1.7	
median	5.0	6.7	7.3	5.6	7.0	7.2	
	LE/MFT-FA				LE/MFT-PT(sec)		
	pre	post ⁺	follow-up [†]	pre	post⁺	follow-up ⁺	
mean	7.4	7.9	8.0	11.4	9.3	9.1	
SD	1.1	1.1	1.1	8.7	6.4	6.1	
median	7.6	8.3	8.1	8.5	7.2	7.0	
	3	Min Walk Test		RMA			
	pre	post ⁺	follow-up [†]	pre	post⁺	follow-up ⁺	
mean	93.8	105.8	104.5	4.8	5.7	5.8	
SD	57.4	65.8	61.5	2.3	2.6	2.4	
median	88.5	111.0	108.8	4.5	5.0	6.0	

Table 2: Mean, standard deviation (SD), and median of different test scores before (pre), after (post) SIMT and at three months follow-up (follow-up). Motor activity log functional ability (LE/MAL-FA) and gait confidence and safety (LE/MAL-CS); Motor Function Test functional ability (LE/MFT-FA) and performance time (LE/MFT-PT in sec); Rivermead Motor Assessment (RMA) and Three-Minute Walk Test (3Min Walk Test) in meter. (Significance of difference from pre-treatment value: p < .005; p < .001)

Rivermead Motor Assessment (RMA): scores on this test were also significantly improved after therapy (pre vs. post p < 0.004); and were not significantly diminished three months after SIMT (post vs. follow-up < 0.004).

In the 3 Min Walk Test patients walked a significantly longer distance after SIMT (p < 0.006), and this difference was still present three months after SIMT.

The "effect sizes" were large for LE/MAL-FA (d' = 0.77) and LE/MAL-CS (d' = 0.72). The effect sizes were medium for LE/MFT-FA (d' = 0.44), LE/MFT-PT (d' = 0.30), RMA (d' = 0.39) and $_3$ Min Walk Test (d' = 0.2).

Patient characteristics

None of the individual factors tested (gender, loss of sensation, side of brain lesion, initial motor score, interval since stroke, amount of prior rehabilitation and age) were significantly correlated with the observed changes following treatment.

Discussion

The present results demonstrate that motor function of the lower extremity can be improved even years after a stroke. Furthermore, this effect persisted for at least the three months tested after the treatment and occurred despite the fact that the patients had regularly received conventional physiotherapy. Improved use of the lower extremity allows more mobility and autonomy and presumably leads to a higher quality of life. Thus, this study suggests that the CIMT model can be transferred from the upper extremity to the lower extremity (SIMT). The results are similar to those obtained in another laboratory [26].

Tests

The tests used in this study are analogous of similar tests used in CIMT for the upper extremity studies [13, 17, 21, 23]. The "Lower Extremity/Motor Activity Log" (with MAL-FA and MAL-CS scales) is a self-report instrument. It was used to investigate mobility in the real world environment. It has been suggested that results obtained from these sorts of tests should be taken with some caution [32]. However, the upper extremity version of this test has been found to have strong clinimetric properties [27, 28, 29, 31]. The reliability and validity of the lower extremity versions of these tests still need to be investigated.

The Lower Extremity/Motor Function Test (LE/MFT), Rivermead Motor Assessment (RMA) and Three-Minute Walk Test (3 Min Walk Test) are administered by physiotherapists. LE/MFT was developed as an analogue of the "Wolf Motor Function Test" used in CIMT studies [13, 21, 23, 24, 33]. The LE/MFT-FA scale involves rating by a blinded physiotherapist from videotape to exclude subjective bias. Although further investigations are required to verify the clinimetric properties of the LE/MFT, we suggest that the results obtained here are valid since our patients also improved on two other tests that are commonly used to monitor functional ability after stroke (RMA, 3Min Walk Test).

An alternative or an additional rehabilitation therapy

It should be noted that this pilot study did not have a control group and the results were not compared to another active lower extremity treatment. Therefore superiority over other, more traditional therapies cannot be said to have been demonstrated. It has been shown that 30 minutes of daily lower extremity training over 20 weeks improves walking ability and walking speed, when started within 14 days after stroke onset [11]. Thirty minutes of training three times a week for four weeks is also effective when begun six months after stroke onset [1]. Further, intense conventional therapy is effective in combination with an electromechanical gait trainer [16]. However, all patients in the present study received conventional physiotherapy of one to three hours weekly (except patient 10) prior to the study; they all had reached a plateau in their motor recovery and showed no improvement in the last three months before starting SIMT. The number of hours of prior conventional lower extremity therapy did not influence the amount of functional improvement. It is not surprising that intensified therapy hours improve chronic functional deficit. But another important component which has been used in SIMT is the shaping technique. It involves frequent feedback about improvements in quality of movement, selecting tasks that are tailored to patients' motor deficits, task modelling and systematically increasing the difficulty level of tasks (see [23]). For the hand function, it has been shown that with the use of shaping, a significantly greater functional improvement occurs than with a conventional therapy with the same training duration [18]. This suggests that training duration is not the only important factor for improving functional ability. Shaping also plays a key role in SIMT in producing a superior treatment outcome when compared to other lower extremity therapies [18]. This circumstance is also supposed by a post hoc analysis when amount of conventional therapy time after SIMT was related to three months tests. In this correlation analysis we did not find any influence of lower extremity physiotherapy after SIMT on three months outcome. However, for a conclusive demonstration of the effectiveness of SIMT, it must be compared experimentally to other alternative therapies administered for the same amount of time.

Individual Characteristics

While overcoming "learned non-use" is thought to be a mechanism underlying the effectiveness of CIMT, "learned misuse" was presumed to be the important factor responsible for an important component of paresis of the leg [26]. CIMT for the arm has not been found to be related to any of the individual characteristics studied here [13, 17, 21, 26]. The data from this experiment indicates that the same is true for deficit of the leg and learned misuse after stroke. Neither gender, loss of sensation, side of brain lesion, initial motor score, interval since stroke, amount of rehabilitation and age were found to be significantly correlated with treatment effect for SIMT.

A limiting factor in this work is that patients had not been selected randomly but had instead applied for this new therapy. Therefore we can not exclude the possibility that patients (and therapists) may have had unusually high motivation to achieve therapeutic success; this might have influenced the results. This possibility can be evaluated by a study in which patients are randomly assigned to receive either SIMT or alternative treatments.

In conclusion, this pilot study has found that SIMT is feasible ("proof of principle") and that it improves mobility in the real world environment. Moreover, the treatmentinduced improvement in lower extremity function was found to persist for at least the three months tested after treatment. This study, therefore, suggests that the therapy warrants further investigation.

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Conflict of interest

There is no conflict of interests.

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