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Effects of lower limb intensive mass practice in poststroke patients: single-subject experimental design with long-term follow-up

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Objective: To investigate the effects of two weeks of intensive mass practice with a constraint-induced movement therapy approach for the lower extremity in five chronic poststroke patients, and the persistence of effects at three and six months.
Design: A single-subject experimental design (SSED) was used with an AB design and follow-ups three and six months later.
Setting: Outpatient rehabilitation at Torsby Hospital in Sweden.
Main measures: Motor function in lower extremity, mobility, dynamic balance, weight-bearing symmetry and walking ability were measured on six occasions during two weeks (A phase), with the Fugl-Meyer assessment for lower extremity, the Timed Up and Go, the Step Test, the Timed Walking Test and the Six-Minute Walk Test. During the intervention's B phase, six measurements were performed with the same time intervals as in the A phase. There were follow-ups three and six months later.
Intervention: The intervention (B phase) consisted of bicycling, training in water, strength training, standing weight-bearing, walking up and down stairs, walking indoors and outdoors and flexibility training of the lower extremity, on all weekdays, 6 h a day for two weeks.
Results: The results showed improvements in 23/30 variables (77%), 12 of them statistically significant (52%). At follow-up, 22/23 improvements persisted. For example, three of five subjects walked significantly further after the intervention and the follow-ups showed that they still walked further than before the intervention.
Conclusion: Intensive mass practice with constraint-induced movement therapy for the lower extremity can improve motor function, mobility, dynamic balance, weight-bearing symmetry and walking ability in chronic poststroke patients. Long-term follow-up showed that the effects persisted for these five subjects.

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Introduction

Stroke is among the commonest causes of invalidity in Sweden. With increasing life expectancy and survival after earlier stroke, the prevalence is increasing.[1] The situation is similar in many western countries, and is of great importance in the community.

Constraint-induced movement therapy (CI therapy) is a fairly new approach in stroke rehabilitation. It was developed by Edward Taub and colleagues and addresses stroke rehabilitation in the chronic phase, at least 6–12 months after the event.[2–5] CI therapy targets motor recovery by limiting the use of the unaffected limb and promoting normal co-ordinated movement of the affected limb through mass practice. Treatment involves placing the unaffected upper extremity in a sling and training the affected upper extremity 6 h a day for two weeks.[2,3]

The key element in CI therapy is mass practice. Other elements include placing the unaffected arm in restraint, 'shaping' (a type of training through which a desired motor objective is approached in small steps), and focus on function rather than on underlying impairments.[2] This treatment resulted in functional return of upper limb movements. Preliminary studies have also examined CI therapy in the rehabilitation of lower extremity function. Preliminary results from Taub *et al*. show substantial but less dramatic improvements compared with the upper extremity, while Vearrier *et al*. shows that mass practice of standard physical therapy produced significant results in balance after retraining poststroke patients.[4,6]

The loss of motor function can produce a learned behaviour pattern, learned non-use, in people with hemiparesis after stroke.[7,8] CI therapy for the lower extremity seeks to overcome learned misuse since walking also requires the co-operation, even if not optimal, of the affected extremity.[4] In the present study the authors use an orthosis as a restraint, to splint the unaffected leg in such a way that the subjects were compelled to use their affected limb to overcome learned misuse.

There are few published studies of CI therapy for the lower extremity. But in one study, which included 101 patients with stroke, who underwent either intensive arm training or leg training, ADL function (Barthel Index) improved more rapidly in the leg-training group than in the arm-training group.[9] In another study, a patient with stroke in the chronic phase underwent static strength training of the lower extremity for six weeks. This resulted in improved ability to rise and walk a fairly short distance, and increased walking speed and distance in a two-minute walking test, with a persisting effect after six weeks.[10]

The purpose of the present study was to investigate the effects of two weeks of intensive mass practice with a CI therapy approach for the lower extremity in five poststroke patients, and the persistence of the effects at three-month and six-month follow-ups.

Method

Five poststroke patients participated in the present study.

A single-subject experimental design (SSED) was chosen.[11–13] The A phase represented the baseline, the test period preceding the intervention, with measurements taken on Tuesdays, Thursdays and Fridays for two weeks, a total of six measurement occasions. Under the A phase non-organized training was allowed and none of the subjects were participating in any regular training. The B phase consisted of tests at the same intervals during the intervention phase, a total of six measurement occasions. After the intervention, follow-up measurements were taken at three months and six months. Each measurement occasion took 40 min. Weight distribution was measured four times: before the intervention and directly after, three months and six months after. Trial measurements with the subject were taken 2–4 weeks before the A phase, in which all the tests were carried out to reduce the learning component. All data from the trial measurements were excluded from the study.

Subjects

The subjects were recruited from outpatient rehabilitation at Torsby Hospital, Värmland County Council, Sweden. An independent physiotherapist asked patients about possible participation. Interested patients were invited to an information session about the purpose of the study. They were also informed that they could discontinue without explanation at any time, and that this would not affect further rehabilitation at the clinic.

Inclusion criteria were (1) at least six months since stroke, (2) remaining motor impairment in the affected leg, but independent walking at least 10 m indoors with or without aids, (3) able to follow verbal and visual instructions, and (4) to score over 23/30 points in the Mini-Mental State Examination.[14]

Three women and two men participated. Sex, age, affected side, time since event, functional level before intervention and result of Mini-Mental State Examination are shown in Table 1. All the subjects had followed acute institutional rehabilitation and the subsequent outpatient rehabilitation.

Measurement instruments

The Fugl-Meyer functional diagnostic test for assessing motor function, subitems for the lower extremity, with a maximum of 34 points, was used.[15]

The Timed Up and Go was used for measuring locomotive ability.[16,17] The reported intra-rater intraclass correlation coefficient (ICC) was 0.99 and inter-rater ICC 0.99.[16]

The Step Test, with a 7-cm-high stool/box, was used for assessing dynamic balance. Reported test–retest ICCs were 0.88 for unaffected leg and 0.97 for affected leg for patients with stroke.[18]

Weight distribution was measured with the subjected standing on two scales, one leg on each. The subject could not read the weight in kilos when she or he claimed to be standing with each leg equally loaded.

Walking ability was measured over 16 m, timed over the middle 10 m, when the subject was urged to walk as fast as she or he could.[19,20] In addition, the Six-Minute Walk Test was used. Subjects walked 30 m to and fro at a convenient speed with their usual aids, and were asked to walk as far they could in 6 min.[21]

To try to exclude any Hawthorne effect[22] a control variable, the Nine-Hole Peg Test, was used for the fine motor ability of the unaffected hand, to avoid the effect of possible loss of tonus consequent upon the intervention. The best of three trials was noted.[20]

The intervention

To increase the use of the affected leg, daily training included – in varying order – cycling, pool training, functional strength training in different start position (sitting down, stand up and lay down), load exercises with weight transfer, standing, weight-bearing in different directions, stair training without use of banisters, indoor walking/outdoor walking on uneven surfaces and passive (joint) mobility training on all weekdays, 6 h a day for two weeks. Each training session lasted for an hour and the subjects were active at least 40 min of every hour. They were instructed to perform as near their maximum as they could, in each session.

To immobilize the knee of the unaffected leg, a plastic whole-leg orthosis (immo-orthosis) was used for standing and walking indoors and outdoors and for rising from sitting (Figure 1). In view of the risk of falling, subjects 1 and 3 used a hyperextension bandage with the splints turned to prevent knee flexion for outdoor walking during the first two days of the intervention.

Implementation

During the study the subjects were admitted to Torsby Hospital outpatient rehabilitation and received free travel to and from the centre. Lunch and treatment were also free of charge.

Table 1 Some characteristics of the subjects included in the study

Subject	Sex	Age (years)	Affected side (right/left)	Time since stroke event (months)	Fugl-Meyer test (points, max 34)	Mini-Mental State Examination (points, max 30)
1	Woman	46	Right	34	21	29
2	Man	58	Left	6	23	30
3	Man	71	Left	41	25	30
4	Woman	81	Right	19	30	30
5	Woman	56	Left	78	27	27

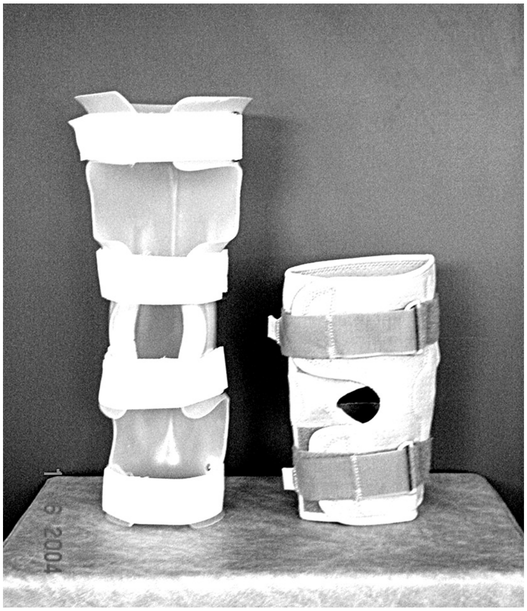

Figure 1 The immo-orthosis and hyperextension bandage used for immobilization of the unaffected leg.

The first author (IM) carried out all the measurements, at the same place and time of day, and the results were entered in separate test protocols not available on the next measurement occasion. During the intervention phase the measurements were followed directly with intensive training. IM was also responsible for the intensive training, but the physiotherapy staff assisted since the immobilization entailed increased risk of falls. Subject 1 took part in the study during May 2000, subject 2 during May 2001 and subjects 3–5 during May 2003. All patients gave their informed consent before testing and the Medical Research Ethics Committee, Örebro, Sweden approved the study.

Data analysis

Data were plotted graphically for visual assessment of changes.[12,13] For assessing any series dependence between measurement points the autocorrelation test was used, and when this was not significant two standard deviations were used as a statistical method.[11,23] Differences at the level of $P < 0.05$ were considered significant if at least two consecutive observations during the B phase were *above* the line representing the mean for baseline *plus* two standard deviations, for results with an increased number of steps, metres or points; or *below* the line representing the mean for baseline *minus* two standard deviations for results with a reduced time requirement.[13,23] If the result at three months and six months was equal to or greater than the mean value at baseline, the effect was considered persistent.

Results

Of the six measured variables per person, the subjects exhibited improvement in 23/30 (77%) of the measurements, 12 of them statistically significant (52%). The effect remained at the long-term follow-ups for 22 of the 23 positive results (Table 2).

Subjects 1, 3 and 4 demonstrated significantly increased motor function, mobility and ability to walk further in 6 min. The effect persisted at follow-ups three and six months after the completed intervention. Visual assessment of subject 5 also showed improved motor function, mobility and ability to walk further in 6 min at the three- and six-month follow-ups. While these effects were not significant, they persisted at the long-term follow-up. For subject 2 the results remained unchanged by the intervention but had worsened at long-term follow-up (Figure 2).

For locomotive ability, rise from a chair, walk and turn back, the results demonstrate significant improvement for subject 1, 3 and 4. Subject 5 also showed improved locomotive ability, but for subject 2 the result was unchanged. For all subjects except subject 2, the effect persisted at follow-ups three and six months after the completed intervention (Figure 3).

For subject 2 all results remained unchanged by the intervention (motor function, mobility, dynamic balance and walking ability). At long-term follow-up there was only an improvement for motor function, while the other results worsened (Table 2).

All the data for the fine motor ability control variable fell within the two-standard-deviations band and thus remained unchanged during the baseline, intervention and long-term follow-ups for all subjects.

Table 2 Summary of treatment effects for the different variables during the intervention

Subject	Motor function	Mobility	Dynamic balance Step Test		Walking ability	
	Fugl-Meyer test	Timed Up and Go	Unaffected leg	Affected leg	Walking 10 m	Six-Minute Walk Test
1	*	*	+	+	+	*
3 months	E	E	E	E	E	E
6 months	E	E	E	E	E	E
2	0	0	0	0	0	0
3 months	E	–	–	E	–	–
6 months	E	–	E	–	–	–
3	*	*	0	+	*	*
3 months	E	E	E	–	E	E
6 months	E	E	–	E	E	E
4	*	*	+	+	*	*
3 months	E	E	E	E	E	E
6 months	E	E	E	E	E	E
5	+	+	+	*	+	+
3 months	E	E	E	E	E	E
6 months	E	E	E	E	E	E

At the long-term follow-ups (three and six months) the result is compared with the mean value at baseline. * = statistically significant, + = positive change, 0 = unchanged, E = effect persisted at long-term follow-up, result equal to or greater than mean value at baseline (A phase), – = no persistent effect.

Measurement of weight distribution showed that, after the intervention, all subjects increased the weight they placed on the affected leg. Subjects 2, 3 and 5 had increased this distribution by the follow-up while subjects 1 and 4 maintained the weight distribution symmetry they had already achieved (Table 3).

Some subjects reported tiredness, and stiff and aching muscles, but the most common reflection was that they now could manage more daily activities independently than before.

Discussion

The intensive massed practice with a CI therapy approach gave improved motor function, mobility, dynamic balance, weight distribution and walking ability in 77% of the variables measured, of which 52% were statistically significant. This was so even though 6–78 months had passed since the occurrence of stroke. The effects persisted after three and six months.

The Step Test showed great variations in the baseline, which affected the analysis result. This test can be improved in further studies with additional measurement occasions or a longer period between each occasion, giving baseline stability.[11,13,23] A longer period between measurement occasions would also eliminate the training effect that the test situation probably involved for several subjects. The measurements took 40 min and were done three times a week, which corresponds to the recommendations for regular physical activity/training for patients with stroke.[24]

It was impossible to exclude a Hawthorne effect even though the result for fine motor ability was unchanged for all subjects. Both subjects and therapist were aware that the intervention focused on the lower limb and no improvements were expected for the upper.

It is interesting that the result variables for subject 2, which were largely unchanged between baseline and the intervention phase, had deteriorated by the time of the follow-up. This subject was just as motivated as the others, but showed

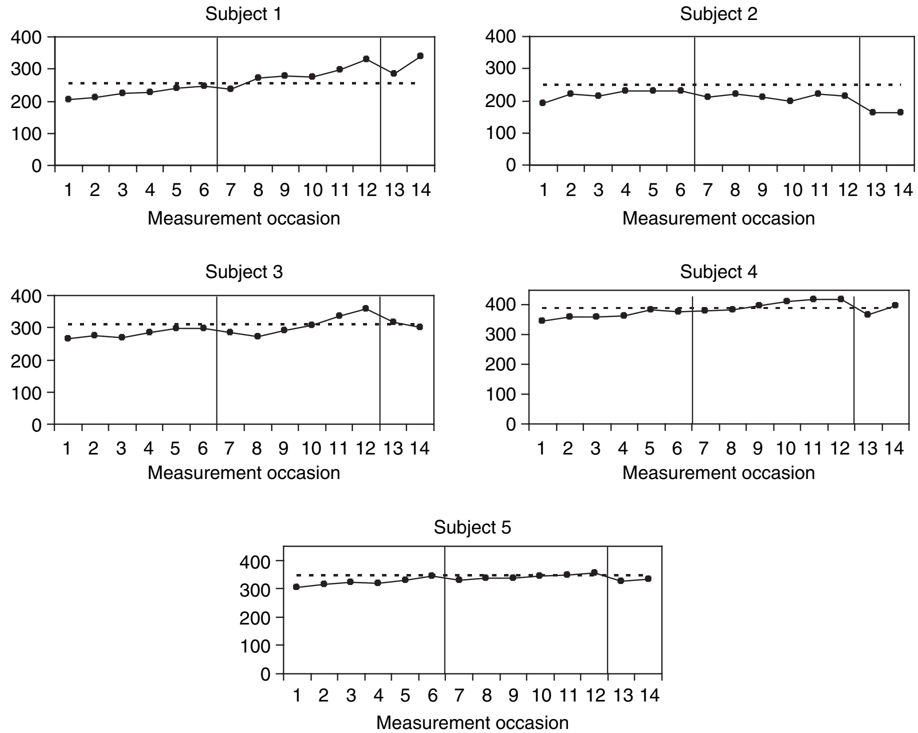

Figure 2 Walking ability, number of metres subject walked (Six-Minute Walk Test) during the A phase (measurement occasions 1–6), the intervention (measurement occasions 7–12) and the long-term follow-ups (measurement occasions 13–14) for all subjects. – – – = mean value in A phase+2 standard deviations.

impaired initiative and difficulties in implementing the newly won skills in daily life. These difficulties were not captured by the inclusion criteria, but were discovered during the intervention. Perhaps a broader assessment instrument may be used to produce better material for assessing cognitive functions, such as initiative and ability to transfer skills to daily use. There is at present no consensus concerning inclusion criteria for CI therapy for the lower extremity. Such criteria should be developed.

The weight distribution measurement carried out after six months showed that all subjects retained or increased the weight they placed on the affected leg. This gave a more even weight distribution and a hint of increased use of the affected leg after the completed intervention. A change in weight distribution by subject 2 suggests an effect of intensive massed practice even though other variables were unchanged.

A limitation of the study is that the first author carried out the treatment, data collection and analysis of the results. To have an independent colleague performing the testing would have reinforced the result of the study, but this was not practicable. A further limitation is that only one test occasion was arranged at three months and six months. It was not considered ethically defensible to have subjects travel to hospital more often than this.

Several steps were taken to improve the design of the study. The variables were defined and are reproducible. The relationships between the test situation and the treatment situation were kept constant. Measurement instruments of high test–retest reliability were used and the test procedures given were followed and implemented by one and the same tester. In addition, earlier test results were 'blind' during in the ensuing test situations. The follow-up was conducted after the

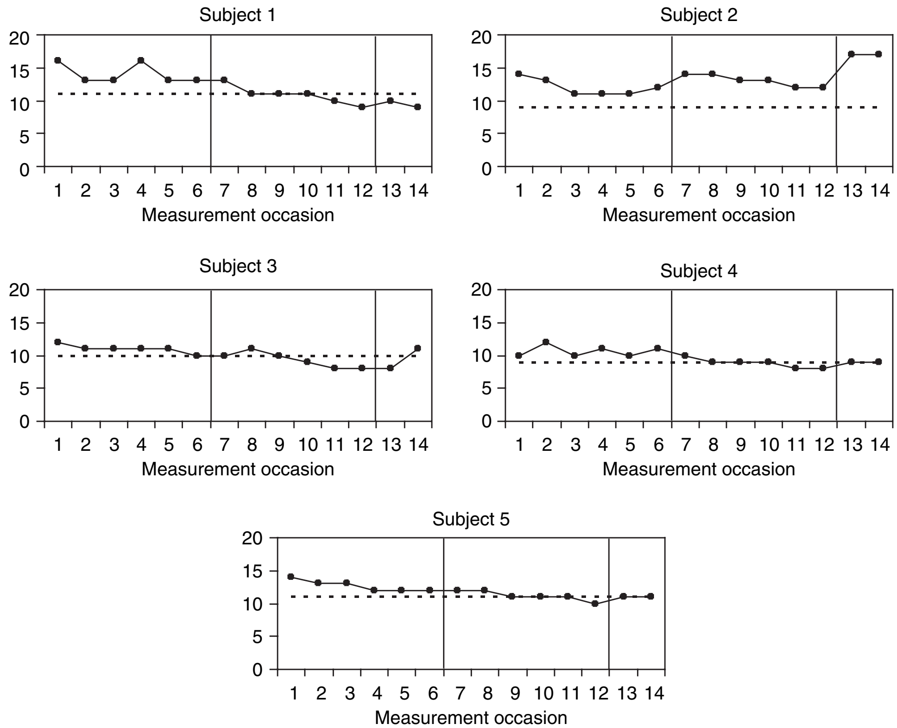

Figure 3 Locomotive ability, time subject used for Timed Up and Go Test during the A phase (measurement occasions 1–6), the intervention (measurement occasions 7–12) and the long-term follow-ups (measurement occasions 13–14) for all subjects. ------ = mean value in A phase – 2 standard deviations.

end of the intervention, and visual analysis of the results was supplemented with a statistical method. The study design was replicated with five subjects in what is termed direct replication, considered to increase the generalizability of the results.[11] In addition the subjects were well representative as to gender, time since stroke event and affected side.

Advantages of SSED are that it is practicable at small clinics, requires little in the way of costs and that it may be a first step in the evaluation of new treatment methods. A further advantage is that each patient is her or his own control, which makes it possible to study patient groups that are not homogeneous or where the use of a control group is difficult to administer.

Table 3 Weight distribution measurement for all subjects before the intervention, after the completed intervention and at the follow-ups after three and six months

Subject	Before intervention affected/unaffected (kg)	After completed intervention affected/unaffected (kg)	Three-month follow-up affected/unaffected (kg)	Six-month follow-up affected/unaffected (kg)
1	20/40	30/30	30/30	30/30
2	20/70	27/60	35/50	40/45
3	30/40	35/33	33/33	36/26
4	25/30	26/27	25/30	24/26
5	37/38	40/35	50/26	45/30

Clinical messages

- More intensive exercise therapy for the lower extremity can improve motor function, mobility and walking ability in poststroke patients.
- Long-term follow-up shows that the effects persist.
- Weight-bearing symmetry improves with immobilization of the unaffected leg.
- Even late after stroke event it is possible to get improvements.

It is hard to judge how well the results tally with earlier experience since, so far, no studies have been published on CI therapy for the lower extremity. However, one study concerning physiotherapy after stroke sought to establish what intensity gives the best effect.[25] There, a weak connection was shown between intensive physiotherapy and general improvement. In that study, intensive physiotherapy was defined as treatment for 50–120 min/day, which may be compared with the 240 min/day in this study.

The intensity of treatment for patients with stroke appears to be a decisive factor in changing function. Green *et al*.[26] in a study of 146 patients with stroke in the chronic phase, for which the treatment consisted of self-training and physiotherapy three times during 13 weeks, considered the intensity was too low, with too few treatment sessions, to achieve a persistent effect on walking speed and ADL. These studies support the use of intensive mass practice as an effective treatment alternative in stroke rehabilitation. The method is sufficiently intensive to give long-lasting results. It is relatively short, two weeks, which should be cost-effective. The method requires no special training and should therefore be easy to implement in normal work.

However, a matter that needs further elucidation is to identify the patients with stroke for whom intensive mass practice with a CI therapy approach is suitable with respect to physical function, motivation and cognitive function. More studies of CI therapy for the lower extremity should be conducted.

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Competing interests

None declared.

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