ORIGINAL REPORT

SHORTENED CONSTRAINT-INDUCED MOVEMENT THERAPY IN SUBACUTE STROKE – NO EFFECT OF USING A RESTRAINT: A RANDOMIZED CONTROLLED STUDY WITH INDEPENDENT OBSERVERS

Christina Brogårdh, PT, PhD1,2, Monika Vestling, OT, MSc2 and Bengt H. Sjölund, MD, DMSc1,3,4

From the 1Rehabilitation Medicine, Department of Community Medicine and Rehabilitation, Umeå University, Umeå, 2Department of Rehabilitation, Lund University Hospital, Lund, Sweden and 3Rehabilitation and Research Centre for Torture Victims, Copenhagen and 4University of Southern Denmark, Odense, Denmark

Objective: To examine the effect of using a mitt during shortened constraint-induced movement therapy for patients in the subacute phase after stroke.

Subjects: Twenty-four patients with stroke (mean age 57.6 (standard deviation 8.5) years; average 7 weeks post-stroke) with mild to moderate impaired hand function.

Methods: The patients were randomized to mitt use or no mitt use on the less affected hand for 90% of waking hours for 12 days. All patients received 3 h of arm and hand training per day for 2 weeks. Assessments were made by blinded observers using the modified Motor Assessment Scale, the Sollerman hand function test, the 2-Point Discrimination test and Motor Activity Log test.

Results: Patients in both groups showed significant improvements in arm and hand motor performance and on self-reported motor ability after 2 weeks of therapy and at 3 months follow-up. However, no statistically significant differences between the groups were found in any measures at any point in time.

Conclusion: In this study, no effect of using a restraint in patients with subacute stroke was found. Thus, this component in the constraint-induced therapy concept seems to be of minor importance for the outcome.

Key words: constraint-induced therapy, rehabilitation, restraint, stroke.

J Rehabil Med 2009; 41: 231–236

Correspondence address: Christina Brogårdh, Department of Rehabilitation, Lund University Hospital SE-221 85 Lund, Sweden. E-mail: christina.brogardh@skane.se

Submitted December 20, 2007; accepted October 1, 2008

INTRODUCTION

Constraint-induced movement therapy (CIT) is a family of treatment techniques that aims to increase the use of the more affected hand in daily activities and to improve motor function following a central nervous system lesion. The therapy is based on primate research in which somatic sensation was surgically abolished by dorsal rhizotomy of a single forelimb. Deprived of sensory feedback, the monkeys did not use the forelimb unless they were forced to do so, and consequently it has been assumed that they developed a learned non-use phenomenon (1–3). The mechanism of learned non-use is thought to apply also to humans who suffer from hemiparesis after stroke.

In traditional CIT, the patients perform exercises for 6 h per day and simultaneously wear a mitt on the less affected arm for 90% of waking hours during 2 weeks to overcome the learned non-use phenomenon (4–7). There is concern about the resource issues necessary to carry out CIT according to the original model of Taub (8). Therefore, to make the CIT clinically adaptable, various modifications of the original concept have been attempted; for example, shortened CIT (sCIT) (9), forced use therapy (FUT) (10, 11), modified CIT (12), automated delivery of CIT (13), distributed CIT (14) and group CIT (15).

Few studies concerning CIT have been published for stroke patients in the subacute phase (usually defined as 0.5–3 months post-stroke (6)). Promising trends in improved function have been reported both after traditional CIT (7, 16) and after modified CIT (17–19) (consisting of 3 h of training per week for 10 weeks with the intact arm in restraint for 5 days/week during 5 h/day) in the subacute phase after stroke.

It is, however, not clear which aspects of the CIT treatment regime – the amount and mode of training per day or the restraint – are necessary for a beneficial effect. Only a few researchers have investigated the effect of wearing a mitt. Promising results have been reported after FUT in patients with chronic stroke and traumatic brain injury (TBI) (20) and after mitt use in patients 1–12 months post-stroke (21), but there were no control groups in these 2 studies. In another randomized study (10) only small improvements in hand function were found in favour of the FUT group (being restrained) compared with the control group. In our previous study (15) no additional effect on arm and hand function was seen after extended mitt use.

To gain a better understanding of which component in the CIT concept is important for the outcome, the aim of this study was to determine whether wearing a mitt enhances a possible improvement in arm- and hand-function in patients with subacute stroke. In this early phase after stroke onset we used a 3-h training protocol for 2 weeks, corresponding to sCIT (9). The patients were randomized to mitt use or no mitt use and were assessed by blinded observers.
PATIENTS AND METHODS

Patients

Patients were recruited consecutively between September 2001 and November 2005 to the Department of Rehabilitation at Lund University Hospital, Sweden, where the stroke rehabilitation team works mainly with patients below retirement age. After providing informed consent, the patients were offered participation in the study as soon as they met the following criteria: (i) a history of a single stroke onset; (ii) between 1 and 3 months post-stroke; (iii) ability to dorsiflex (extend) the wrist on the more affected hand at least 10° and to extend 2 fingers at least 10° and to abduct the thumb at least 10° (i.e. had mild to moderate impairments of hand function); (iv) had a grasping score ≥65/80 points on the Sollerman Hand Function Test (22, 23); (v) only minimal balance problems, i.e. were able to walk 20 m within 40 sec; (vi) no gross language deficits (≥4 out of 6 parts on the Token test) (24); (vii) no severe cognitive impairments (Mini-Mental State Examination > 24/30 (25)). The exclusion criteria were: deformity of the more affected arm due to previous injury, drug abuse, epilepsy, mental disorder (ICD-10), and botulinum toxin injections for spasticity treatment.

Patients included

Twenty-four patients agreed to participate in the study (18 men and 6 women; mean age 57.6 (standard deviation (SD)) 8.5 years; mean time post-stroke 7.0 (SD) 2.7 weeks). Sixteen patients had right-sided hemiparesis and the dominant hand was affected in 14 patients. The patients’ characteristics for the mitt group and the non-mitt group can be seen in Table I. No differences in assessment measures were seen between the groups at study entry.

Protocol

At study entry the patients were randomized to sCIT either with (mitt group) or without a mitt (non-mitt group). Randomization was performed from a computer-generated list of consecutive random numbers. All patients received approximately 3 h of training per weekday of the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks. Those randomized to the mitt group were requested and encouraged to wear a mitt on the more affected arm and hand for 2 weeks.

Intervention

The arm and hand exercises consisted of:

- task practice, such as moving objects from one shelf to another, pouring water into mugs from a jar, putting objects through a slot, typing;
- fine motor practice, such as fastening nuts on bolts, putting pegs in a board, buttoning and unbuttoning, writing;
- general activity training, such as laying the table, cleaning a window, making coffee or lunch, washing the dishes, office work, handicrafts, playing games and indoor sports.

The patients performed the exercises supervised by staff (physiotherapists, occupational therapists and staff nurses) during most of the daily 3-hour training periods. There was no turn-over of staff during the study period and the trainers had many years of experience of stroke rehabilitation. The training programme was individualized for each patient in accordance to the patient’s sensorimotor capacity and goals. The tasks were approached in steps of progressively increasing difficulty and included verbal feedback on the quality of the movements, similar to the “shaping” described by Taub et al. (26). The patients in both groups were encouraged to use the more affected hand as much as possible in different activities. The patients in the mitt group used log books to document the time of use of the restraint during the 2 weeks. The mitts were taken away at discharge.

Outcome measures

All patients were assessed by independent and blinded assessors (licensed occupational therapist and physiotherapist) before and after 2 weeks of therapy as well as after 3 months. The instruments used for assessment were: (i) the modified Motor Assessment Scale (MAS) (27–29), tested for validity and reliability (28, 29) (items used for upper extremity only; both arms were tested) consisting of 15 tasks from gross arm to fine finger movements in a 0–5 point scale; (ii) the Sollerman Hand Function Test (22), tested for validity (22) and found to be reliable for patients with stroke (23), consisting of 20 sub-tests reflecting daily hand activities (type of grasp, quality of movement and speed of performance assessed in a 0–4 point scale); (iii) the 2-Point Discrimination Test (2-PD) (30) that measures the tactile somatosensation in a 0–10 point scale with 2 mm interval between the points (if the patient could not estimate the 10 mm distance between the points of the affected fingers, the total score was set to 50); and (iv) the Motor Activity Log (MAL), tested for validity and reliability (31–33), a 30-item questionnaire adapted version by Taub et al. (34), which asks the subject how often (amount of use (AOU)) and how well (quality of movement (QOM)) the affected hand is used for the daily activities in a 0–5 point scale.

Statistical analyses

All data were tested for normality using the Graph Pad Instat® program. The data for the MAS test was found to be skewed at the 3 months follow-up. To detect significant mean differences within groups pre- and post-treatment and at 3 months follow-up repeated measures
analysis with analysis of variance (ANOVA) and Tukey’s post-hoc test was used for the 2-PD test (parametric data), whereas the Friedman test with Dunn’s post-hoc test was used for the Sollerman hand function test as well as for the MAS and the MAL tests, respectively (non-parametric data). In clinical practice as well as in research the total sum scores of the Sollerman hand function test and the MAS test are often used. They represent a clinically relevant overall measure of hand and arm function, albeit non-linear, and were analysed here with non-parametric tests. For one patient in the mitt group, data was missing at the 3-month follow-up (due to a new stroke onset), and the post-treatment assessment values were used in the ANOVA analysis at 3-month follow-up (according to the “last value carried forward” principle (35)).

To detect significant mean differences between groups (mitt/non-mitt) pre- and post-treatment as well as post-treatment and the 3 months follow-up, independent sample t-test was used for the 2-PD test, whereas the Mann-Whitney U-test was used for the Sollerman hand function test and for MAS and MAL, respectively. The data were analysed using the Graph Pad Instat® program and the Statistical Package for the Social Sciences (SPSS) version 12.0 Software for Windows (SPSS, Chicago, IL, USA). A p-value < 0.05 was considered significant.

The research protocol was approved by the medical ethics committee of Lund University.

RESULTS

Effects of training

Large improvements in arm and hand function were found in both the mitt group and the non-mitt group on the Sollerman hand function test (p < 0.0001)/(p < 0.001; Friedman), on the MAS test (p < 0.0003)/(p < 0.004; Friedman) and on the MAL test (p < 0.0002)/(p < 0.001; Friedman), respectively.

The median score difference for the mitt group (n = 12) on the Sollerman hand function test (Fig. 2A) was 16.5 points (p < 0.05) pre-to post-treatment, 5.0 points (p < 0.05) post-treatment to 3 months follow-up and 21.5 points (p < 0.001) pre-treatment to the 3 months follow-up (Dunn’s post-hoc test). The median score difference on the MAS test (Fig. 2B) was 2.0 points (p < 0.05) pre-to post-treatment, 2.0 points (p < 0.05) post-treatment to the 3 months follow-up and 4.0 points (p < 0.01) pre-treatment to the 3 months follow-up. The median score difference on the MAL test (Fig. 3A) was 0.5 points/(p < 0.05) pre-treatment to the 3 months follow-up and 0.7 points (p < 0.01) pre-treatment to 3 months follow-up. The median score difference on the MAL test AOU/QOM (Fig. 3A and B) was 0.5 points/0.7 points (p > 0.05) pre-treatment to post-treatment, 1.0 points (p > 0.05) post-treatment to the 3 months follow-up and 6.0 points (p < 0.01) pre-treatment to 3 months follow-up. The median score difference on the MLA test AOU/QOM (Fig. 3A and B) was 0.5 points/0.7 points (p > 0.05) pre-treatment to post-treatment, 0.65 points/0.4 points (p < 0.05) post-treatment to the 3 months follow-up and 1.15 points/1.1 points (p < 0.01) pre-treatment to the 3 months follow-up. No significant changes in sensory discrimination (2-PD test; Fig. 4) were found (p = 0.7) within the non-mitt use group.

Thus, both groups improved their arm and hand motor performance significantly, but no differences (p > 0.05) were found between the groups in any measures at any point in time.

Mitt compliance

According to the logs, 10/12 patients reported successful accomplishment in using restraints for approximately 90% of waking hours. The remaining 2 patients had some difficulties in compliance and used the mitt for approximately 80% of waking hours.

DISCUSSION

The present results indicate that scIT for 2 weeks in a selected group of patients after subacute stroke with a moderately impaired hand function is beneficial, but wearing a mitt on
the less affected hand does not seem to add further value to improve upper extremity function.

The mitt did not enhance improvements in arm function after 2 weeks of training in this study, despite satisfactory mitt compliance in the mitt group. This result disagrees with other published studies that have evaluated the effect of forced use therapy (i.e. mitt use) (20, 21). Reasons for the differences in outcomes might be that the patients in our study were in the early post-stroke phase, but also that control groups in the 2 studies by Wolf et al. (20) and Burns et al. (21) were missing. In another randomized control study (10) only small gains in hand function were reported in favour of the FUT group compared with the bimanual group (without using a restraint). It may be argued that our results differ from others because no behavioural contract was administered, something other workers have tried to counter by introducing a “transfer package” (36), and that our patients did not comply with our recommendations to wear a mitt during the whole period. However, our mitt log data speak against such an explanation.

We have previously examined the effect of extended mitt use in a group of patients with chronic stroke (15). Significant improvements in arm function were observed after 2 weeks of group CIT, but no further improvements could be demonstrated after an extended mitt use for another 3 months. Taken together, these findings indicate that mitt use might be of minor importance for improving upper extremity function and may therefore question the original “learned non-use hypothesis”. In humans, but not in monkeys, there is also the possibility of a “cognitive mitt effect”, i.e. patients who have agreed to participate in CIT are often highly motivated and aware of the importance of using their more affected hand in daily activities to be able to achieve motor improvements. This awareness and determination might in fact limit the need to use a mitt on the less affected hand. Alternatively, the present group of patients with subacute stroke may not yet have developed a full “learned non-use” phenomenon and hence the effect of mitt use would be more difficult to demonstrate.

In our study, improvements in arm and hand motor function were observed in both groups after 2 weeks of sCIT. The lack of change in the 2-point discrimination test is not unexpected since it is a measure of somatosensory function rather than of motor plasticity.

Improvements in arm and hand function after intensive training (6 h/day for 2 weeks) without using restraint have been reported in patients with chronic stroke (4, 5, 37, 38). The gains after therapy were comparable to those who had been restrained with a sling and had received shaping exercises or task practice (4, 37). However, at 2 years follow-up the remaining effects were somewhat higher for the group that had been restrained (37). In a systematic review Van der Lee et al. (39) concluded that only a more intensive arm and hand exercise therapy appears to be beneficial.

The findings of motor improvements for the non-mitt group contrast with the results of other published studies concerning modified CIT (17–19) and traditional CIT (7) in the subacute phase after stroke. The training for the non-mitt group in our study was more focussed on hand training than described in the other studies mentioned above (17–19). Since it has been found previously that the main part of spontaneous recovery occurs within the first 3 months after the stroke (40), it might be argued that the improvements observed here in patients mainly below retiring age and with a mean of 7 weeks post-stroke are partly due to spontaneous recovery. However, the results from the previously quoted studies (7, 17–19) speak against such an interpretation. For ethical reasons, it is not possible to leave any patients without “treatment as usual” (i.e. a control group without training) in modern healthcare and therefore, one has to resort to therapy comparison designs.

Taub and co-workers (4, 5, 26) have emphasized the importance of shaping exercises in CIT, but the results from different studies are contradictory (11, 41). When the present study was designed, detailed information on the execution of shaping exercises was not generally available from the literature. The training given to our patients had a gradually increasing level of difficulty and feedback was mainly given concerning the quality of movements.

A limitation in our pilot study is the relatively small sample size and the lack of a pre-study power analysis. However, a post-hoc power analysis utilizing the standard deviations observed, indicate that for within-group comparisons, based on 12 pairs, the sensitivity is sufficient to detect a difference of 12–13 points with 80% power. On the other hand, the between-group comparison showed minimal insignificant differences here and would take 300 patients per group to have sufficient sensitivity at 80% power to detect systematically differences at such small magnitudes. Had the differences between the mitt and the non-mitt groups been of similar magnitudes as those within groups, there would have been no difficulty in detecting them with this design.

Even so, this study is larger than most of the hitherto published studies concerning shortened CIT for patients with subacute stroke (16–19, 42). We aimed to include 30 patients in the study, but due to problems of recruiting patients (to meet the inclusion criteria) we decided to close the study after 4 years with a total of 24 patients. During these years most of the staff was the same, which optimized the standardization conditions for the training and assessment procedures. Even
though the trainers were aware of which patients wore a mitt, the present results do not indicate an expectancy effect from either the trainers or the patients, possibly other than that on the MAL. Nevertheless, the MAL has the limitations of being a self-assessment instrument.

In conclusion, 3 h of sCIT during 2 weeks in the subacute phase after stroke seems to be beneficial, but wearing a restraint does not seem to be necessary. Thus, the importance of this component in the CIT concept can be questioned. Future larger and controlled studies of specific practises vs restraint use are needed to demonstrate which component is most important for a beneficial outcome.

ACKNOWLEDGEMENTS

The authors would like to thank the patients and staff, especially Drs Bertil Tufvesson and Elisabeth Wannfors, Department of Rehabilitation, Lund University Hospital, for recruiting patients and showing interest in the study. We also thank the independent observers. The study was supported by Umeå University and by the Council for Health Research, Lund Health Care District Administration.

REFERENCES