A one-year follow-up after shortened Constraint Induced Movement Therapy with and without mitt after stroke

by

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Running title: The long-term effect of sCIMT after stroke.

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Objective: To explore the long term benefits of shortened Constraint Induced Movement Therapy (sCIMT) in the subacute phase after stroke.

Design: A one year follow-up after sCIMT (3 hours of training/day for 2 weeks) where the participants had been randomized to a mitt group or a non-mitt group.

Setting: A university hospital rehabilitation department.

Participants: Twenty post-stroke patients (15 men and 5 women; mean age 58.8 years; on average 14.8 months post stroke) with mild to moderate impairments of hand function.

Outcome measures: The Sollerman hand function test, the modified Motor Assessment Scale and the Motor Activity Log test. Assessments were made by blinded observers.

Results: One year after sCIMT, participants within both the mitt group and the non-mitt group showed statistically significant improvements in arm and hand motor performance and on self-reported motor ability compared to before and after treatment. No significant differences between the groups were found in any measure at any time.

Conclusion: sCIMT seems to be beneficial up to one year after training, but the restraint may not enhance upper motor function. To determine which components of CIMT are most effective, larger randomized controlled studies are needed.

Key words: Follow-Up Study, Restraint, Rehabilitation, Stroke, Upper Extremity

Abbreviations:

CIMT= Constraint Induced Movement Therapy

MAL= Motor Activity Log

MAL AOU= Motor Activity Log – Amount of Use

MAL QOM= Motor Activity Log – Quality of Movements

MAS= Motor Assessment Scale

sCIMT= shortened Constraint Induced Movement Therapy

INTRODUCTION

Constraint Induced Movement Therapy (CIMT) is a promising rehabilitation intervention after stroke to improve upper extremity function and self-reported use of the more affected hand in daily activities.[1, 2] The traditional therapy consists of repetitive, task oriented training of the more affected hand, including shaping exercises where movements are approached in steps of progressively increasing difficulties, six to seven hours per day during two weeks. Simultaneously, the less affected hand is restrained with a sling or a mitt 90% of waking hours.[1] Most studies of CIMT have been performed in chronic stroke patients [1-13] but in recent years also in the subacute [12, 14-18] and the acute phase after stroke.[19-22] In the early post-stroke phase, modified forms of CIMT [15-17, 19, 20], with shorter daily therapy but sometimes for several weeks, have been used most frequently.

Improvements in arm and hand function have been found, both after traditional CIMT and modified forms of CIMT. There is, however, uncertainty how the training should be administered and which component in the concept – the restraint, the mode or the intensity of hand training – is most important. In some studies [3, 20, 23], the restraint has been described to be a useful and important component to improve upper extremity function, whereas others [11, 17, 18, 24] have found the restraint to be of minor importance for the outcome.

The short-term benefit of mitt use after shortened Constraint Induced Movement Therapy (sCIMT, i.e., 3 hours of training per day during two weeks) in the subacute phase after stroke was evaluated by Brogårdh et al.[17] Large improvements in arm and hand function were found, both in the mitt group and the non-mitt group after treatment, as well as after three months, but no significant differences between the groups were observed. Thus, the restraint did not seem to enhance improvements in arm and hand function in the short-term perspective.

Since there is a need to explore the long-term benefits of CIMT and the importance of the different components of the therapy, the aim of this study was to investigate the arm and hand function and self-reported use of the more affected hand one year after participation in the sCIMT programme with and without using a mitt.

METHODS

This was a one year follow-up study of a single blind randomized controlled trial evaluating the effectiveness of mitt use during sCIMT in patients with sub-acute stroke (1-3 months post-stroke). The study was carried out at the Department of Rehabilitation Medicine, Lund University Hospital, Sweden. Detailed information about the trial, sCIMT intervention and the mitt use has been reported previously.[17]

Participants

All individuals that had participated in the randomized controlled trial were invited for a 12 month follow-up. Of the 24 possible participants, four dropped-out (one in the mitt group and three in the non-mitt group) since three had had a re-stroke and one declined to participate. The remaining 20 individuals (15 men and 5 women; mean age 58.8 years; on average 14.8 months post stroke) gave their informed consent to participate. In Table 1 the characteristics of the participants in the mitt group (n=11) and the non-mitt group (n=9) at the 12 month follow-up are presented. The research protocol was approved by the Medical Ethics Committee of Lund University Sweden, Dnr LU 386-00.

Description of the shortened Constraint Induced Movement Therapy (sCIMT)

In summary, all participants were 1-3 months post stroke and had mild to moderate impairments of hand function (i.e. had ability to extend the wrist of the more affected hand at

least 10 º, to extend two fingers at least 10 º and to abduct the thumb at least 10 º), had only minimal balance problems, (i.e. were able to walk 20 m within 40 secs), and had no gross language deficits, severe cognitive impairments or neglect. Exclusion criteria for participating were: deformity of the more affected arm due to previous injury, epilepsy and botulinum toxin injections for spasticity. The participants were consecutively randomized to a mitt group or a non-mitt group (control group). They received approximately three hours of focused hand training per day of the more affected arm for two weeks. Those randomized to the mitt group wore a mitt on the less affected hand 80-90% of waking hours during the two weeks, which was registered in a log book. The exercises consisted of task practice, fine motor training, muscle strength training, muscle stretching, swimming-pool training and general activity training. Tasks were approached in small steps of progressively increasing difficulty including verbal feed-back (i.e., similar to shaping-exercises). [17] The exercises in the sCIMT program were similar to the traditional CIMT program but the amount of training was reduced to 3 hours per day instead of 6 hours per day. Shorter daily constrained-induced movement therapy with 3 hours of training per day during two weeks has been described earlier by Sterr et al. [6]

Assessments and outcome measures

The 12 month follow-up was undertaken at the Department of Rehabilitation Medicine, Lund University Hospital. All participants were assessed by independent and blinded assessors (licensed occupational therapist and physiotherapist). The assessments lasted about two and a half hours for each participant. The Sollerman hand function test [25] and the modified Motor Assessment Scale (MAS) [26-28] were used to examine the arm and hand function. The Motor Activity Log (MAL) [29, 30] was used to reflect self-reported daily hand use (amount of use;

AOU) and quality of movement (QOM). These measures were used previously to evaluate the short-term benefit of sCIMT.[17]

The Sollerman hand function test [25] consists of 20 subtests reflecting daily hand activities; the type of grasp, quality of movement and speed of performance is assessed on a 0-4 point scale. The instrument has been shown to be reliable after stroke.[31] The modified MAS, tested for validity and reliability [26-28], consists of 15 tasks from gross arm to fine finger movements on a 0-5 point scale; only the items for upper extremity were used and both arms were tested. The MAL is a 30-item questionnaire, tested for validity and reliability, [29, 30, 32] and scores how often (AOU) and how well (QOM) the more affected hand is used for 30 daily activities on a 0-5 point scale.

Statistical Analyses

All data were tested for normality using the Graph Pad Instat^{R} program (Instat guide to choosing and interpreting statistical tests. GraphPad Software Inc, 1998, San Diego, CA, USA). To detect significant differences within the two groups, the Wilcoxon Signed Rank Test was used for the Sollerman hand function test and the MAS and MAL tests, respectively. In clinical practise as well as in research the total sum scores of the Sollerman hand function test and the MAS test are often used. This represents a clinically relevant overall measure of arm and hand function, albeit non-linear, and was therefore analysed with a non-parametric test.

To detect significant differences between the two groups (mitt vs. non-mitt), the Mann Whitney U- test was used for the Sollerman hand function test and for the MAS and the MAL, respectively. The data were analysed using the Statistical Package for the Social Sciences (SPSS) version 16.0 Software for Windows (SPSS, Chicago, IL, USA). Differences

between distributions (rejection of the null hypothesis) were considered significant when $p < .05$.

RESULTS

Changes in arm and hand function and self-reported daily hand use

In Table 2, data for the Sollerman hand function test, the modified MAS and the MAL tests on all test occasions are presented for the mitt group and the non-mitt group, respectively. In Table 3, the results of the statistical analyses are presented. Twelve months after sCIMT the participants in the mitt group had improved their arm and hand function and self-reported daily hand use and quality of movement significantly in comparison with before and after treatment. In comparison with three months follow-up further statistically significant improvements were found only in the hand function score, as measured by the Sollerman hand function test and self-reported quality of movement score, as measured by the MAL QOM test. The participants in the non-mitt group also showed statistically significant improvements in arm and hand function scores and on self-reported daily hand use and quality of movement 12 months after treatment in comparison with before. In comparison with after treatment further statistically significant improvements were found only in the hand function score, as measured by the Sollerman hand function test, and on self-reported quality of movement, as measured by the MAL QOM test. In comparison with the three months follow-up the participants in the non-mitt group had maintained and slightly improved their hand function and self reported daily hand use, but the differences were not statistically significant.

Even if the improvements in arm and hand function at the 12 month follow-up were in favour of the mitt use group no statistically significant differences between the groups in any measures at any point in time were found (Table 3).

DISCUSSION

One year after sCIMT the participants in both the mitt group and the non-mitt group had improved their hand function significantly as compared to before and after treatment. In comparison with the three months follow-up, statistically significant changes in hand function and quality of movements was found only in the mitt use group. Since no statistically significant differences between the groups were found at any time, there was no apparent positive mitt use effect in the short-term or long-term.

At the 12 month follow-up the participants in both groups had high median scores on all outcome measures. The recovery was, however, highest during the first three months. One year after sCIMT the participants had maintained and even slightly improved in hand function as measured by the Sollerman hand function test. The median score in the non-mitt group increased by 13 points between the three month and the 12 month follow-up, but the difference was not significant. The reason might be the small sample size (n=9) and large inter-quartile range. On the MAS test no change in median differences was seen between the three and the 12 month follow-up in any of the groups. The median scores were already high (29 out of 30 points) at the three month follow-up in both groups. Even if the test has been shown to be valid and reliable [27, 28], there was an obvious ceiling effect and small changes in arm and hand function could therefore not be detected. The self-report use (AOU) and quality of movements (QOM), as measured by the MAL, was slightly increased over time in both groups. The MAL scores in our population (n=20) were in accordance with, and even higher, than the MAL data in the EXCITE study [12] where the participants were included for CIMT between 3-9 months post stroke. The MAL has been showed to be valid and reliable for 28 out of 30 items.[30]

Few studies with control groups have investigated the effect of using a restraint in a short-term [17, 18, 20] and long-term perspective.[1, 24] Ploughman et al.[20] (n=23) found 20%

more recovery in the more affected arm in the Forced Use Therapy (FUT) group (being restrained) than in the control group post treatment. In contrast, Hammer et al.[18] (n= 26) could not clearly demonstrate any additional effect in daily hand use in the forced use group as compared to the conventional group. Van der Lee et al.[24] reported a small but lasting effect on dexterity in the forced use group as compared to the bimanual group one year after training (n= 58). Taub et al.[1] reported gains up to two years after using a restraint (n=4), as compared to the control group (n=5) but the sample size was very small. In the present study, and in our previous study evaluating the short-term benefit of sCIMT [17], no statistically significant differences in arm and hand function were found between the mitt group and the non-mitt group. Thus, our results are in agreement with the findings of Hammer et al.[18]

In another study, Brogårdh et al. evaluated the effect of extended mitt use in a group of patients with chronic stroke.[11] Significant improvements in arm function were observed after two weeks of group CIMT, but no further improvements could be demonstrated after extended mitt use for another three months. Taken together, these findings indicate that the mitt use might be of minor importance to improve upper extremity function.

Since the effect of wearing a restraint seems to be unclear, one could speculate if the intensity and mode of training are more important for the outcome than the mitt use itself. In a systematic review, van der Lee et al.[33] reported that more intensive arm and hand exercise therapy appears to be beneficial. This is in accordance with our study. The participants in our non-mitt group also improved in arm and hand function after two weeks of intensive training.[17] A possible explanation might be that all participants were highly motivated and were aware of using their more affected arm in daily activities to achieve motor improvements. This awareness might have limited the need to use a mitt on the less affected hand. Twelve months after sCIMT the arm and hand function in the non-mitt group was maintained and had even slightly improved, even if statistically non-significant.

Improvements in arm and hand function after intensive training without using a restraint have been reported earlier, especially in patients with chronic stroke.[2, 34-36] The results in this study are in agreement with those findings.

A limitation of the present study was the relatively small sample size and the lack of a pre-study power analysis. However, a post-hoc power analysis was performed. At the 12 month follow-up the standard deviation of the Sollerman hand function test was 10 points within both the mitt group and the non-mitt group. To detect a 9 point difference at 80% power, 20 patients in each group would have been needed.

As described earlier, traditional CIMT [12], group CIMT [13] and forced use therapy [24] with 6 hours of training per day for two weeks may have a positive long-term effect on upper extremity function and daily hand use in patients with stroke. However, it is still unclear whether a restraint is necessary in the CIMT concept to improve upper extremity motor function. A shortened programme of CIMT with only 3 hours of training per day for two weeks, performed in the subacute phase after stroke, might be a more clinically attractive and beneficial alternative to traditional CIMT.

CONCLUSION

Shortened Constraint Induced Movement Therapy during two weeks in the subacute phase after stroke seems to be beneficial up to 12 months after training. The restraint does not seem to enhance upper extremity function in a short-term or long-term perspective. To determine parameters for training and to elucidate which components of CIMT are most effective, larger randomized controlled studies are needed.

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Table 1: Participant characteristics at the one year follow-up in the mitt group and the non-mitt group.

	Mitt group (n=11)	**Non-mitt group (n=9)**
Age (years; mean (SD))	59.2 (6.4)	58.2 (11.9)
Months post stroke; mean (SD)	14.7 (0.6)	15.0 (0.6)
Sex (men/women; n)	9/2	6/3
Dominant hand affected (n)	7	6

SD = standard deviation

Table 2. Data for all outcome measures on all test occasions in the mitt group (n=11) and the non-mitt group (n=9), respectively.

	Mitt group (n=11)	**Non-mitt group (n= 9)**
	Median (interquartile range)	Median (interquartile range)
Sollerman score		
Before sCIMT	40.0 (30-59)	52.0 (39-54)
After sCIMT	60.0 (44-72)	62.0 (55-69)
After 3 months	67.0 (52-73)	64.0 (61-75)
After 12 months	71.0 (62-78)	77.0 (69-78)
MAS score		
Before sCIMT	24.0 (22-26)	23.0 (21-24)
After sCIMT	26.0 (24-29)	28.0 (24-29)
After 3 months	29.0 (26-29)	29.0 (25-29)
After 12 months	29.0 (27-29)	29.0 (27-30)
MAL AOU score		
Before sCIMT	2.3 (1.8-2.6)	3.0 (2.2-3.3)
After sCIMT	3.0 (2.6-3.7)	3.0 (2.6-3.6)
After 3 months	3.5 (3.0-4.3)	3.4 (2.9-4.0)
After 12 months	3.8 (3.3–4.3)	3.8 (3.1-4.6)
MAL QOM score		
Before sCIMT	2.0 (1.6-2.5)	2.6 (2.0-3.0)
After sCIMT	2.7 (2.6-3.5)	3.0 (2.7-3.5)
After 3 months	3.1 (2.7-3.9)	3.4 (3.1-3.6)
After 12 months	3.6 (3.2-4.1)	3.8 (2.9-4.1)

Sollerman= Sollerman handfunction test; MAS= Motor Assessment Scale; MAL= Motor Activity Log (AOU=Amount of Use, QOM=Quality of Movement)

Table 3. Within and between group differences for the mitt group and the non-mitt group on the Sollerman hand function test, the Motor Assessment Scale (MAS) and the Motor Activity Log (MAL) test on amount of use scale (AOU) and quality of movement scale (QOM).

	Within-group differences between different observation times			Between-group differences
	12 months vs before sCIMT	12 months vs after sCIMT	12 months vs after 3 months	
Sollerman score				
Mitt group	+ 31.0†	+ 11.0†	+ 4.0*	NS
Non-mitt group	+ 25.0†	+ 15.0*	+ 13.0	
MAS score				
Mitt group	+ 5.0†	+ 3.0*	0	NS
Non-mitt group	+ 6.0 *	+ 1.0	0	
MAL AOU score				
Mitt group	+ 1.5†	+ 0.8*	+ 0.3	NS
Non-mitt group	+ 0.8*	+ 0.8	+ 0.4	
MAL QOM score				
Mitt group	+ 1.6†	+ 0.9†	+ 0.5*	NS
Non-mitt group	+ 1.2*	+ 0.8*	+ 0.4	

Median differences (points), * = $p < .05$, † = $p < .01$, NS = No significant differences between the groups at any time