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Faculteit Geneeskunde en Levenswetenschappen

master in de revalidatiewetenschappen en de kinesitherapie

Masterthesis

The effectiveness of a modified constraint induced movement therapy program in patients with acute or subacute stroke: a real-life study

Lore Petré
Bram Poelmans

Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie, afstudeerrichting revalidatiewetenschappen en kinesitherapie bij kinderen

PROMOTOR :
dr. Ilse LAMERS

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Prof. dr. Peter FEYS

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Thesis title: The effectiveness of a modified constraint induced movement therapy program in patients with acute or subacute stroke: a real-life study.

Research question: “Does a two-week Modified CIMT-program provided in a clinical setting, improve the upper limb capacity in acute and subacute stroke patients.”

Findings:

- There was a significant increase in the upper limb section of the Brunnstrom Fugl-Meyer (UL-BFM)) and Action Research Arm Test (ARAT) between the pre- and post-measurements ($p < 0.0001$) for the total group (n= 43)
- There was a significant increase in the UL-BFM and ARAT over time ($p < 0.0001$) in both the mild and the moderate-severe group
- For both the UL-BFM and the ARAT, the MCID value was exceeded by 15 patients after the mCIMT program. Of these 15 patients, there were 10 patients who exceeded the MCID value for the ARAT as well as for the UL-BFM.
- The moderate-severe group improved significantly on the UL-BFM ($p < 0.0001$), in comparison with the mild group.

Petré Lore
Poelmans Bram
Promotor: dr. Ilse Lamers
Co-promotor: Prof. dr. Feys Peter
External co-promotor: Mr. Michielsen

Acknowledgement

To end our 'Master in rehabilitation sciences and physiotherapy' at the University of Hasselt, we would like to present our master thesis. This master thesis consists of contains research within the neurologic rehabilitation, which fits in both our specializations 'Master in Neurological rehabilitation' and 'Master in Paediatric rehabilitation'.

In order to make this possible, we received help from a number of people, which we are very grateful for. Furthermore, we would like to thank our promotor, dr. I. Lamers and co-promotor, Prof dr. P. Feys, for the opportunity to participate in this research. To continue, a thank to our promoter, dr I. Lamers and Dra. J. Raats, who assisted us in the elaboration of our master thesis. In conclusion, we would like to thank Mr. M. Michielsen, head of paramedical services of the Jessa Ziekenhuis Revalidatiecentrum St. Ursula (Herk-de-Stad), for the cooperation, guidance, and entrusting us with all their data we needed in our research.

Sint-Truiden, Gorsemweg 242, June 2, 2018 L.P.

Hasselt, Lentestraat 28, June 2, 2018 B.P.

Context of the Master Thesis

This master thesis is situated in a neurorehabilitation context. More specifically, it focuses on patients who have had a stroke. Stroke is the second most common cause of death worldwide. The incidence of stroke has increased in the last few years. Heuschmann et al. (2009) estimated that the stroke incidence in Europe ranges between 94.6 per 100,000 women and 141.3 per 100,000 males (Heuschmann et al., 2009).
The impairments after stroke consist out of a broad range of symptoms like swallowing disorders, fatigue, neglect, motor and/or sensory deficits in the upper or lower limbs, etc.
Upper limb problems are one of the problems which have a large impact on patients' everyday life (eating, dressing, showering, housekeeping, etc.) and the patient 's quality of life (J. H. Morris, van Wijck, Joice, & Donaghy, 2013); Cramer et al., 1997). The paretic arm, from patients post stroke, shows a reduction of use during activities of daily living (ADL) like eating, dressing, showering, housekeeping, etc. (Koninklijk Nederlands Genootschap voor Fysiotherapie, 2014).
Because of the large impact of upper limb impairments after stroke this master thesis will focus on the rehabilitation of the upper limb.

Different rehabilitation strategies are used in clinical practice to improve the quality of life and increase the capacity of the upper limb. Constraint induced movement therapy (CIMT) is a therapy form, which consists of immobilisation of the non-paretic arm, combined with task-specific training of the paretic arm with a large amount of repetitions (KNGF, 2014). The task-oriented practice of the affected arm can take up to six hours a day for a minimum of two consecutive weeks (D. M. Morris, Taub, & Mark, 2006). The non-paretic arm of the patient is also constrained for 90% of the waking hours, so the patient is forced to use the affected arm during the day.
In recent literature, more articles are describing a modified constraint induced movement therapy program (mCIMT). This form of therapy has the same content as CIMT, but the intensity and therapy time are lower than the traditional form (KNGF, 2014). Earlier RCT studies on a mCIMT program shown promising results. In their results they found significant increase on ICF function, activity and participation level (Corbetta, Sirtori, Castellini, Moja, & Gatti, 2015; Sirtori, Corbetta, Moja, & Gatti, 2009; Veerbeek et al., 2014).
The study described in this master thesis was performed in JESSA rehabilitation centre St. Ursula Herk-de-Stad under supervision of Mr. Marc Michielsen, head of paramedical services.

An application was made for a retrospective study at both the ethical committee of the University of Hasselt as the medical ethics committee of Jessa Hospital.

The mCIMT programs as described in this master thesis are used for several years in this rehabilitation centre. The therapists collected pre- and post-data and performed the mCIMT. The Researchers of this master thesis (L.P. and B.P.) collected all the data of the mCIMT program in Herk-de-Stad, analysed it and looked for significant changes. Unfortunately, they were unable to follow a mCIMT group at the start of therapy, due to changes in the strategy to treat upper limb with these patients.
The writing of the data-extraction, results, and discussion was divided between the two independent students. The master thesis was written in accordance with the central format.

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1. Abstract

Background: Research on CIMT has been conducted in a research setting but not in a vivo research setting. The standardized, artificial manner, is not always possible to achieve in a rehabilitation context. Due to these differences, it is possible that the results of mCIMT program are different in a research versus a clinical setting.

Objectives: The aim of this study was to investigate whether a two-week Modified CIMT-program provided in a clinical setting, improves the upper limb capacity in stroke patients.

Participants: The patients were selected in the rehabilitation centre of Sint-Ursula, Herk-de-Stad. Inclusion criteria were (1) at least one month post stroke, (2) > age of 18 years, (3) the patient should meet the Taub criteria which means they should be able to: actively extend the wrist on the affected side for a minimum of 10 degrees, actively extend two digits on the affected side for a minimum of 10 degrees, and actively abduct the thumb on the affected side for a minimum of 10 degrees , (4) being able to walk independently or with a walking aid , (7) understanding simple motor commands.

Measurements: To measure the upper limb capacity, the Action Research Arm Test (ARAT) and the upper limb section of the Brunnstrom Fugl-Meyer (UL-BFM) were used.

Results: In total, 43 patients were analysed. There was a significant increase in the UL-BFM and ARAT over time ($p < 0.0001$). The mean difference for the ARAT and UL-BFM was 9.07 (SD = 9.36) and 6.42 (SD = 7.43), respectively. The mean results for the ARAT and UL-BFM were below the minimal clinical important difference (ARAT = 12 and UL-BFM = 9.5). However 15 patients had an improvement which was above the MCID of the ARAT and the UL-BFM.

Conclusion: These findings suggest that a mCIMT program in a clinical setting can lead to significant improvements of the upper limb capacity in acute and subacute stroke patients.

2. Introduction

Stroke is a common disorder that affects a large number of people in the world. Current data indicate that worldwide, 16.9 million people get a stroke each year, which represents a global incidence of 258 strokes out of 100.000 people each year (Bejot, Bailly, Durier, & Giroud, 2016). Stroke leads to death in 20% of the patients within the first three months (Bejot et al., 2007). Of those who survive circa 40% to 80% suffer from hemiparesis and upper limb disabilities six months after stroke, which has a large impact on the performance of their daily activities (Cramer et al., 1997). The severity of these upper limb disabilities is largely determined by the presence or absence of spasticity, muscle weakness, and loss of sensation (Raghavan, 2015).

Persons after stroke (un)consciously use their affected arm less, despite the capacities of the arm. A possible explanation is the loss of reliable sensory input, or the impairment to execute a well-coordinated movement during task performance, as mentioned earlier. These limitations lead to more effort to execute a task in comparison with their unaffected arm. This phenomenon is called *Learned non-use*, which can be defined as: “Not using the deafferented limb, even though they possess sufficient motor innervation to do so.” (Taub, 2006, p. 241) To overcome this compensatory strategy, a series of behavioural strategies were employed (Fritz, Butts, & Wolf, 2012). One of these behavioural strategies is constraint induced movement therapy (CIMT) (Kwakkel, Veerbeek, van Wegen, & Wolf, 2015).

The main characteristic of CIMT is the forced use of the affected arm for several hours during the day. The three different types of CIMT are: the traditional CIMT, forced use therapy, and Modified CIMT (mCIMT). The first type is the traditional CIMT which consists of three important items. Firstly, it contains task-oriented practice of the affected arm up to six hours each day for a minimum of two consecutive weeks. Secondly, the unaffected arm of the patient is constrained for 90% of the waking hours, so the person is forced to use the affected arm during the day (Morris, Taub, & Mark, 2006). Thirdly, activities are not only trained in a rehabilitation context but is also made as a transfer to the ADL of the patient. The second type of CIMT is forced used therapy. The patient’s unaffected arm is immobilized by a sling or resting splint for at least 90% of the waking hours. The difference with traditional CIMT is that no additional task-specific therapy is given by the therapist (Corbetta, Sirtori, Castellini, Moja, & Gatti, 2015).

The third type is the modified CIMT, which has the same three principles as the traditional CIMT but at a lower dose. It consists less hours of therapy and constrainment [RJ1] of the affected arm (Morris et al., 2006; Page, Levine, Leonard, Szaflarski, & Kissela, 2008; Veerbeek et al., 2014). mCIMT can range from 30 min up to 6 hours of task-oriented training of the affected arm for 3-5 times a week. The constrainment of the unaffected arm ranges from 2 up to 6 hours of therapy spread over 2-10 weeks (Peurala et al., 2012; Veerbeek et al., 2014).

mCIMT seems as good as or even better than traditional rehabilitation therapy in terms of outcome measures. On top of that, mCIMT is less time consuming than the traditional CIMT. Shi et al. (2011) found more significant improvements for the Brunnstrom Fugl-Meyer Assessment and Action Research Arm Test scores in favor of the group which received mCIMT, compared with the traditional rehabilitation group (Shi, Tian, Yang, & Zhao, 2011). Peurala et al. (2011) found that 2-6 hours of mCIMT practices, spread over 2 weeks, increased the hand mobility compared with a non-specified control treatment. Even mCIMT for 30 minutes up to one hour, three times a week for 10 weeks, increased the hand mobility compared with no treatment or control treatment. mCIMT can thus improve hand mobility, the use of the affected hand in daily activities and self-care of the patient.

Already a lot of research has been done on this topic but most of the researches were conducted in a research setting and not in clinical practice (e.g. real rehabilitation setting). In a research setting, the therapist treats patients in a very standardized, artificial manner, which is not always possible in a rehabilitation context. There are also strict inclusion and exclusion criteria, which are less extensive in a rehabilitation context. Due to these differences, it is possible that the results of a task-specific mCIMT program are different in a research setting versus a clinical setting. Therefore, the aim of this study is to investigate whether a two-week Modified CIMT-program provided in a clinical setting improves the upper limb capacity.

3. Methods

3.1. Study design and procedure

The study was a retrospective case series study conducted between January 2009 and November 2016. Stroke patients who had a moderate to mild arm-hand function were assessed in the rehabilitation centre of Herk-de-Stad in Belgium. The baseline measurements were taken at the start of the 2 weeks mCIMT intervention.

The study was approved by the Medical Ethic Committee of Hasselt University and the local Ethical Committee of JESSA on the 20th of September 2017 (SME2017/757).

3.2. Participants

Participants consists out of a broad range of acute and sub-acute stroke patients with a mild to severe upper limb impairment. The selection criteria were made by a physiotherapist in the rehabilitation centre of Herk-de-Stad, based on previous CIMT rehabilitation programs.

Participants were selected using the following inclusion criteria: (1) Patients had to be at least one month post stroke, (2) Patients had the minimum age of 18 years, (3) Patient met the Taub criteria, which means patients had to be able to actively extend the wrist on the affected side for a minimum of 10 degrees, actively extend two digits on the affected side for a minimum of 10 degrees and actively abduct the thumb on the affected side for a minimum of 10 degrees (Taub, Uswatte, & Pidikiti, 1999) , (4) The patient had to be able to walk independently or with a walking aid (cane, walker) (5) provided written informed consent, (6) patients had to understand simple motor commands.

Participants were excluded if they (1) could not tolerate Modified Constraint induced movement therapy (mCIMT), this was when patients and/or therapist found the protocol was physical or mentally too stressful for the patient, (2) had a pathology like peripheral neurologic disorder, rheumatoid arthritis, fractures of the upper limb, osteo-arthrosis, etc., which could cause upper limb impairment, (3) were medical unstable, (4) could not understand Dutch verbal instructions or (5) experienced a new stroke during the intervention period.

3.3. Outcome measures

3.3.1. Descriptive measures

The patients' descriptive measures that were used in the study are age, gender, stroke type, side of lesion, lesion site, time post stroke and recurrence of stroke. These measures were collected at the beginning of the study.

3.3.2. Experimental measures

The primary outcome measures used in the study were the Action Research Arm test (ARAT) and the Upper limb section of the Brunnstrom Fugl-meyer Assessment (BFM).

The ARAT consists 19 items evaluating the grasp, grip and pinch function of the hand, and gross movements of the whole upper limb. Every item receives an ordinal score, ranging from 0 to 3 (0 = not able to perform the task, 1 = able to partially perform the task, 2 = able to perform the task with effort, 3 = able to perform the task in time), with a maximal total score of 57. The ARAT is suitable to detect changes over time (Lin et al., 2009) and is a reliable and valid test for acute stroke patients (Hsieh et al., 2009; Nordin, Alt Murphy, & Danielsson, 2014).
In this study, the researchers only used the total score of the ARAT. The Minimal clinical important difference regarding the ARAT for acute-subacute patients is 12 for the affected arm (Lang, Edwards, Birkenmeier, & Dromerick, 2008).

The Brunnstrom Fugl-Meyer assessment (BFM) consists 55 items. Every item receives an ordinal score, ranging from 0 to 2 (0= no activity/performance, 1= partial performance, and 2= full performance). The total score is 114 points. The researchers only used a part of the test, which evaluated upper limb activity and function. That part of the UL-BFM consists out of 32 items with a total score of 66. The UL-BFM is a reliable and valid test for stroke patients (Sanford, Moreland, Swanson, Stratford, & Gowland, 1993).
The Minimal clinical important difference for the UL-BFM for acute-subacute patients is 9 (Arya, Verma, & Garg, 2011).

3.4. Intervention

3.4.1. Study procedure

During the period of January 2009 and November 2016 several mCIMT programs were performed. The intervention group received 5 hours of mCIMT therapy each day, five days a week for two weeks. The five hours of therapy were divided in five different blocks of one hour of therapy with at least 30 minutes of rest between the therapy blocks in the morning and the afternoon. The order of the second, fourth and fifth block were randomized and varied in different treatment days. In all the blocks, the principles of motor learning were used. Therapists also divided functional exercises in different parts, which is called 'part practise' (Motor Control, Translating Research into Clinical Practice, 4th ed. Philadelphia: Lippincott Williams & Wilkins).
The therapy in all the blocks focused on a correct posture and movement of the affected arm of the patients. The patients were encouraged to use the affected arm between the therapeutic sessions as much as possible. The staff in the rehabilitation centre was informed to stimulate the patients to use the affected arm during the day.

3.4.2. Content of therapy

The first block

In the first block of therapy, patients practiced different tasks they normally attend during breakfast. The therapy started with a correct posture of the patient in a chair in front of the table. Patients learned how to use cutlery correctly with their affected arm, to set the table and to clean it up afterwards while maintaining a correct posture. These therapy sessions were guided by an occupational therapist.

The second block

The second block consisted out of specific arm-hand rehabilitation given by a physiotherapist. Individual goals (chosen through an agreement between patient and therapist) such as how to take money out of their wallets or how to fill a cup with water... were practiced during this hour of therapy.

The Third block

In the third block of therapy patients practiced different tasks they normally attend during dinner. The therapy started with a correct posture of the patient in a chair in front of the table. Patients

learned how to use cutlery correctly with the affected side, to set the table and to clean it up afterwards while maintaining a correct posture. These therapy sessions were guided by an occupational therapist.

The fourth block

The fourth block consisted out of ADL sport exercises. The patients participated together in different sports to train the upper limb such as basketball, badminton, etc. Two occupational therapists guided the sessions. The size of the group varied between six and eight participants. Patients had to use their affected arm as much as possible. First the exercises consisted of simple movements like throwing a ball or learn how to hold a racket correctly.
When the patients learned the basics of the sport, more forms of competitions were done.

The fifth block

The last block consisted of tranquil exercises. These exercises were chosen by the patients. These various exercises ranged from playing a card game or board game with the affected arm to games on the Nintendo WII®.

	Intervention	**Time**
Block 1	ADL: having breakfast - Correct sitting posture - Using cutlery with the affected hand - Setting up and cleaning up the table	60 minutes
	Rest	*30 minutes*
Block 2	Specific arm-hand rehabilitation - Individual and specific goal-oriented training	60 minutes
	Rest	*30 minutes*
Block 3	ADL: having dinner - Correct sitting posture - Using cutlery with the affected hand - Setting up and cleaning up the table	60 minutes
	Rest	*30 minutes*
Block 4	ADL sport exercises - First, they start with simple sport specific exercises and movements - Second, they practice a sport and play competition	60 minutes
	Rest	*30 minutes*
Block 5	Tranquil arm-hand exercises	60 minutes

3.5. Data-analysis

Statistical analyses were performed with the statistical software JMP®. For all tests that were conducted, Alpha was set at 0.05.

Means (Ms) and standard deviations (SD) were calculated for the demographic data.

The distribution of the ARAT and UL-BFM was checked using a multiple Shapiro-Wilk test. The O'Brien, Brown-Forsythe, Levene, and Bartlett tests were used to check the homoscedasticity. There was a significant difference in variance if one of these tests had a p-value less than 0.05.

The effect of a mCIMT program on the UL-BFM and ARAT was checked with a non-parametric test, more specifically a Wilcoxon Signed Rank Test was used. These analyses were performed in the total group and in 2 subgroups based on the baseline results of the UL-BFM. Patients with a baseline measurement of the UL-BFM ≤ 19 were classified in the severe group, a UL-BFM score between 19 and 47 were classified in the moderate group, and a UL-BFM score >47 were classified in the mild group (Woodbury et al., 2013). For data representation: boxplots and tables were used.

To investigate if the factor 'severity of the upper limb impairment' had an influence on the measurement results, a non-parametric One-Way Analysis of Variance was performed. This possible influencing factor was checked for the ARAT as well as for the UL-BFM. Hereby the delta value of the ARAT and UL-BFM between the mild and moderate-severe group was checked.

The minimal clinical important difference (MCID) threshold values of the UL-BFM and ARAT were used to see if the results after the mCIMT-program were clinically relevant. The number of patients who exceeded the MCID values were collected. Thereby, also the mean differences of the subgroups for the ARAT and UL-BFM were collected, to see if they exceeded the MCID values.

4. Results

Participants

In total 82 patients followed the mCIMT program between January 2009 and November 2016. Due to a system update, data of 12 patients got lost, whereby data were recovered from 66 patients. Due to missing complete pre- and post-data, only the data of 43 patients were analysed (Figure 2). Of the 43 patients, following data were missing: age of 14 patients, gender of two patients, time post stroke of 14 patients, stroke type of 20 patients and lesion site of 26 patients. The patient characteristics of the included patients are shown in table 1.

Effect of mCIMT in the total group

There was a significant increase in the UL-BFM and ARAT scores after the intervention ($p < 0.0001$) for the total group (n= 43) (Table 2).

On the average the total group improved for 9.1 (± SD 9.4) points on the ARAT and for 6.4 (± SD 7.4) on the UL-BFM, which is below the minimal clinical important difference (ARAT = 12 and BFM = 9.5).

Effect of mCIMT in different upper limb disability subgroups

Based on the baseline measurements of the BFM, one patient was classified into the severe group, 16 patients were classified into the moderate group, and 26 patients into the mild group. Because only one patient was classified in the severe group, he or she was added to the moderate group. This patient had a baseline UL-BFM-score of 13. In total 17 patients were classified into the moderate to severe group and 26 patients into the mild group.

The data of the UL-BFM were normally distributed in both the mild ($p = 0.1566$) and moderate-severe group ($p = 0.1900$). For the ARAT there was no normal distribution of the data for the mild ($p = 0.0127$) nor for the moderate-severe group ($p = 0.0246$).

After checking the normal distribution, the homoscedasticity was checked. For both the ARAT and the UL-BFM, the O'Brien test and Bartlett test had a p-value less than 0.05, from which we can conclude that there is no equality of variances for both tests.

There was a significant increase in the UL-BFM and ARAT scores after intervention ($p < 0.0001$) for both the mild ($p < 0.0001$) and the moderate-severe group ($p < 0.0001$) (Table 2). In Figure 3 and figure 4 the boxplots of the ARAT and UL-BFM difference scores (post – pre) are presented.

The average improvement over time on the ARAT and UL-BFM for each subgroup are shown in table 3, which shows that the moderate group had a mean difference of the UL-BFM which was above the MCID.
Nevertheless, 15 patients had an improvement that was above the MCID for the ARAT and 15 patients for the UL-BFM, whereby 10 patients had an improvement above the MCID for the ARAT as well as for the UL-BFM (Table 4).
Of the 15 patients with an improvement above the MCID for the ARAT, seven patients had a moderate to severe upper limb disability level and eight patients had a mild upper limb disability level. Of the 15 patients with an improvement above the MCID for the UL-BFM, three patients had a mild upper limb disability level and 12 patients had a moderate to severe upper limb disability level. From the 10 patients with an improvement above the MCID for the ARAT as well as for the UL-BFM, three patients had a mild upper limb disability level and seven patients had a moderate to severe upper limb disability level.

To check if the factor 'severity of the upper limb impairment' had an influence on the measurement results, a non-parametric One-Way Analysis of Variance was performed. For the delta value of the ARAT, no significant difference was found between the mild group and the moderate-severe group ($p = 0.3010$). This means that the factor 'severity of the upper limb impairment' had no influence on the measurement results of the ARAT. For the delta value of the UL-BFM, the moderate-severe group made a significant greater progress than the mild group ($p < 0.0001$). This means that the factor severity of the upper limb impairment had an influence on the measurement results of the UL-BFM.

5. Discussion

The aim of this present study was to investigate the effect of a mCIMT program provide in a rehabilitation setting in acute-subacute stroke patients. In the total group (n=43) a significant increase in the UL-BFM and ARAT ($p < 0.0001$) were found after intervention. 15 patients had an improvement which was above the MCID for the ARAT and 15 patients for the UL-BFM, whereby 10 patients had an improvement above the MCID for the ARAT as well as for the UL-BFM. This means that the treatment can have clinical important difference for patients in ADL.

The significant results found in the total group of this study showed similarities with the literature. Wu et al. (2007) also found significant effects of mCIMT for the UL-BFM in moderate impaired subacute and chronic stroke patients. However, the mean age of the intervention group was 20 years older than the mean age of the participants in this thesis. As seen in previous research, age can have an important influence on the results (Lang, Lohse, & Birkenmeier, 2015).

Other studies like Dromerick et al. (2000), Page et al. (2007) and Kwakkel et al. (2016) found significant improvements in ARAT and UL-BFM in moderate to severe impaired acute stroke patients (Dromerick, Edwards, & Hahn, 2000; Kwakkel, Veerbeek, van Wegen, & Wolf, 2015; Page, Levine, Leonard, Szaflarski, & Kissela, 2008). However, they only included acute stroke patients (time post stroke <14 days). This master thesis also included subacute stroke patients. Not only age is an important factor in rehabilitation, also time post stroke can have an important influence on the recovery of the patient (Lang et al., 2015).

Some studies found significant improvements in favour of the mCIMT group on ADL performance measured by the Functional Independence Measure (FIM), Supportive Intensity Scale (SIS) and the Motor Activity Log (MAL) (Dromerick et al., 2000; Wu, Chen, Tsai, Lin, & Chou, 2007). In this master thesis no ADL or quality of life scales were used, therefore no conclusions can be made on the impact of a mCIMT program on the patient's everyday life.

Patients were divided in a mild and a moderate-severe subgroup to look if severity of the upper limb impairment had any effect on the primary outcome measurements.

There was a significant increase in the UL-BFM and ARAT outcome measures over time ($p < 0.0001$) for both the mild ($p < 0.0001$) and the moderate-severe group ($p < 0.0001$)

For the UL-BFM, the moderate-severe group made a significant greater improvement than the mild group. Recent literature indicated that rehabilitation has a different influence on the neurological reorganization between moderate and severe impaired patients in acute stroke

patients (Rehme, Fink, von Cramon, & Grefkes, 2011).In less impaired patients more activation is seen in brain regions which are typical involved in upper limb movements in healthy subjects (ipsilesional primaire motor cortex (M1) and contralesional cerebellum). In severe patients, there is also an initial increase in ipsilesional M1, but there is also more activation in contralesional brain areas (primary motor and premotor cortex). It is possible that different motor outcomes after rehabilitation are due to the difference in neurological reorganization between moderate and severe impaired patients (Rehme et al., 2011).

A possible explanation of the between-group significant difference in favour of the moderate-severe group, in the UL-BFM score and not the ARAT score, could be that the first part of the UL-BFM tests the ICF function level and the ARAT tests the ICF activity level. A lot of the items of the UL-BFM are necessary to complete parts of the ARAT (functional reach and grasps tasks). For example, a patient with mild impairment of the upper limb (who has a full range of motion of the shoulder and the elbow, but has a weak paresis of the distal parts (hand, fingers)) can have a moderate to high score on the UL-BFM assessment (the first part of the UL-BFM consists of selective movement), while the patient may not be able to execute the functional reach and grasp task of the ARAT (because the distal parts of the upper limb are necessary to complete the reach and grasps tasks). Mild impaired patients with distal paresis will therefore have a higher baseline score on the UL-BFM than the ARAT.

Patients with moderate-severe upper limb impairment on the other hand (who have more impairment in the proximal and the distal parts of the upper limb) will have a lower baseline UL-BFM and ARAT score in comparison with the mild subgroup. Therefore moderate-severe impaired patients with a low baseline score can increase by a larger amount on the UL-BFM in comparison with the mild group who already have a higher UL-BFM score. The mild and the moderate-severe subgroup will on the other hand not have a large difference in improvement of the ARAT, because the difference in the ARAT score is lower between the mild and the moderate-severe impaired group.

It is difficult to compare the results of our thesis with the results found in different mCIMT studies due to the different doses that were used. The studies of Page et al. (2008), Kwakkel et al. (2015), Wu et al. (2007) and Dromerick et al. (2000) used a therapy session of 1-3 hours for 3-5 times a

week for 2-10 consecutive weeks (Dromerick et al., 2000; Kwakkel et al., 2015; Page et al., 2008; Wu et al., 2007).

Our thesis consisted of 50 hours of therapy given over two weeks. The systematic review of Peurala et al. (2012) compared different doses of mCIMT therapy. The largest dose consisted ~~out~~ of 60-72 hours of therapy and the smallest consisted of 15-30 hours of therapy spread over two weeks (Peurala et al., 2012). The systematic review found most improvement in the intervention group with the largest rehabilitation dose on motor mobility. However the study was unable to determine the optimal level of constraint-induced movement therapy and to elucidate concurrent therapy protocols because of different demographic characteristics of the intervention group between studies. It is unknown if the improvement came due to the larger amount of therapy or due to different demographics characterises of the intervention groups.

Some experimental studies even combine mCIMT with forced use therapy. After intensive therapy sessions, the patients non-affected arm remains restrained. Studies like Page et al. (2008) and Dromerick et al. (2000), restrained the non-affected arm by a padded mitten for five till six hours per day (Dromerick et al., 2000; Page et al., 2008). This different rehabilitation approaches, demographic characteristics and therapy time makes it difficult to compare different mCIMT studies with each other and our master thesis.

The patients for the mCIMT program were chosen based on the experience of a physical therapist in the rehabilitation centre of Herk-de-Stad. When the therapist thought the patient was able to perform the mCIMT program, he/she was included even if he didn't meet all inclusion criteria. This is the reason why two chronic patients participated in the mCIMT program. Because data from only two chronic patients were included, their influence on the results will be rather small.

5.1. Limitations

There were some limitations in this experimental study. First of all, there was no control group, which makes it impossible to make a conclusion if a mCIMT program is better than a traditional physical therapy program or a traditional CIMT program.

Secondly the number of patients with detailed demographic information in this study was relatively small. 48% (n =39) of the initial number of included patients (n= 82) in the study could not be analysed because of missing pre and/or post measurements. Only from 27 included patients the time post stroke was available. This makes it difficult to make any statements about

the influence of the time post stroke in the rehabilitation. The reason of the missing data was that the medical file of the rehabilitation centre in Herk-de-Stad got a new update and a lot of data of the mCIMT study got lost.

Thirdly, 12 patients reached the maximum score of the ARAT (57) and seven patients reached the maximum score of the UL-BFM (66) after two weeks of therapy. Seven patients had a maximum score for both ARAT and UL-BFM. It is possible that some patients made even more progress, but the tests were unable to measure it.

In this master thesis no conclusion could be made about the long-term effect of a 14 days mCIMT program, because there were only one month follow up data from seven patients.

5.2. Recommendations for future studies

At this moment, there is some evidence that a modified CIMT program leads to the same or even higher improvements than a traditional CIMT therapy program. However, future studies need to compare different forms of mCIMT to examine which dose leads to the best results. It is possible that the same improvements in the upper limb can be obtained by even less than five or four hours of therapy given in a mCIMT program. This could mean that therapists can rehabilitate more patients in lesser time.

In the future researchers also have to use ADL measurement to investigate the impact of a mCIMT program on the ADL and the patient's quality of life.

The researchers recommend for future research to divide the patients according to their time post stroke, whereby therapists can examine at what time post stroke patients benefit the most from an intensive mCIMT program. Not only the time post stroke but also the severity of the impairment can play an important role in the rehabilitation. Future studies have to divide patients in subgroup to investigate which patients benefit most from a mCIMT program.

6. Conclusion

The present study examined the effect of a mCIMT program on the upper limb capacity in a clinical setting instead of an experimental setting. The findings suggest that a mCIMT program is feasible and well tolerated by acute-subacute stroke patients. The mCIMT program leads to significant improvements in the upper limb capacity measured by the ARAT and the UL-BFM. In addition, an influence of the severity of the upper limb impairment was found, whereby patients with moderate upper limb impairments at the baseline measurements, have greater improvements after the mCIMT-program.

Future research should compare different doses of mCIMT and use outcome measurements that investigate the impact of a mCIMT program on the ADL of the patients.

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8. Appendices

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List of abbreviations

ADL	Activities of daily life
ARAT	Action Research Arm Test
BFM	Brunnstrom Fugl-Meyer
CIMT	Constraint Induced Movement Therapy
FIM	Functional Independence Measure
MAL	Motor Activity Log
MCID	Minimal Clinical Important Difference
mCIMT	Modified Constraint Induced Movement Therapy
M1	Primary motor cortex
SD	Standard deviation
SIS	Supportive Intensity Scale
UL-BFM	Upper limb section of the Brunnstrom Fugl-Meyer

Table 1. Baseline characteristics of the included patients

Characteristics	Whole group	Subgroups	
		Moderate - Severe	Mild
Total number (n)	43	17	26
Age (y), mean (SD)	63.8 ± 13.3	62.8 ± 13.9	64.4 ± 13.3
Gender (n,%)			
Female	14 (32.6%)	4 (23.5%)	10 (38.5%)
Male	27 (62.8%)	12 (70.6%)	15 (57.7%)
Unknown	2 (4.6%)	1 (5.9%)	1 (3.8%)
Side of lesion (n,%)			
Left	14 (32.5%)	5 (29.4%)	9 (34.6%)
Right	11 (25.6%)	4 (23.5%)	7 (26.9%)
Unknown	18 (41.9%)	8 (47.1%)	10 (38.5%)
Stroke type (n,%)			
Haemorrhagic	7 (16.3%)	4 (23.5%)	3 (7.7%)
Ischemic	16	5 (29.4%)	11 (42.3%)
Others	1 (2.3%)	1 (5.9%)	
Unknown	20	7 (41.2%)	13 (50%)
Lesion site as diagnosed			
Cerebri media	5 (11.6%)	1 (5.9%)	4 (15.6%)
Pontine	2 (4.7%)		2 (7.7%)
Frontal area	3 (7%)	2 (11.8%)	1 (3.8%)
Frontoparietal area	2 (4.7%)	2 (11.8%)	
Basal ganglia	1 (2.3%)	1 (5.9%)	
Frontotemporal area	1 (2.3%)		1 (3.8%)
Ventricular area	1 (2.3%)		1 (3.8%)
Thalamus	1 (2.3%)		1 (3.8%)
Parieto-occipital area	1 (2.3%)		1 (3.8%)
Unknown	26 (60.5%)	11 (64.6%)	15 (57.7%)
Time post stroke (days),	102 ± 84	90.9 ± 58.9	104.6 ± 96.2

SD= standard deviation

Table 2. Rate of improvement over time of patients regarding ARAT and UL-BFM

			Pre	Post	P-value
Mild (n = 26)	**ARAT**	Mean ± SD	43.7 ± 11.6	51.0 ± 8.0	< 0.0001*
		Median	43.5	53	
	UL-BFM	Mean ± SD	58.2 ± 5.8	62.0 ± 4.3	< 0.0001*
		Median	59.5	64	
Moderate – severe (n = 17)	**ARAT**	Mean ± SD	23.9 ± 15.8	35.7 ± 17.6	< 0.0001*
		Median	20	34	
	UL-BFM	Mean ± SD	36.8 ± 10.1	49.7 ± 11.2	< 0.0001*
		Median	40	54	
Total (n = 43)	**ARAT**	Mean ± SD	35.9 ± 16.5	44.9 ± 14.6	< 0.0001*
		Median	40	52	
	UL-BFM	Mean ± SD	50.0 ± 12.6	56.4 ± 10.4	< 0.0001*
		Median	52	58	

ARAT= action research arm test; UL-BFM= Brunnstorm Fugl-Meyer test; pre= at baseline; post=14 days later.
* significant difference (p-value <0.05)
Data-analysis: Wilcoxon Signed Rank Test

Table 3. Mean and standard deviations of the difference scores (post – pre) per subgroup per test

	Mild	Moderate - Severe
ARAT (Mean ± SD)	7.3 ± 6.7	11.8 ± 12.1
UL-BFM (Mean ± SD)	3.8 ± 3.5	12.9 ± 5.8

SD = standard deviation, ARAT= Action research Arm test, BFM = Brunnstrom Fugl-Meyer

Table 4. Number of patients whose outcome scores exceeded the MCID thresholds within a subgroup for ARAT and UL-BFM.

	Total (n)	Mild (n,%)	Moderate – severe (n,%)
ARAT	15	8 (53%)	7 (47%)
UL-BFM	15	3 (20%)	12 (80%)
ARAT + UL-BFM	10	3 (30%)	7 (70%)

ARAT= Action research Arm test, BFM = Brunnstrom Fugl-Meyer

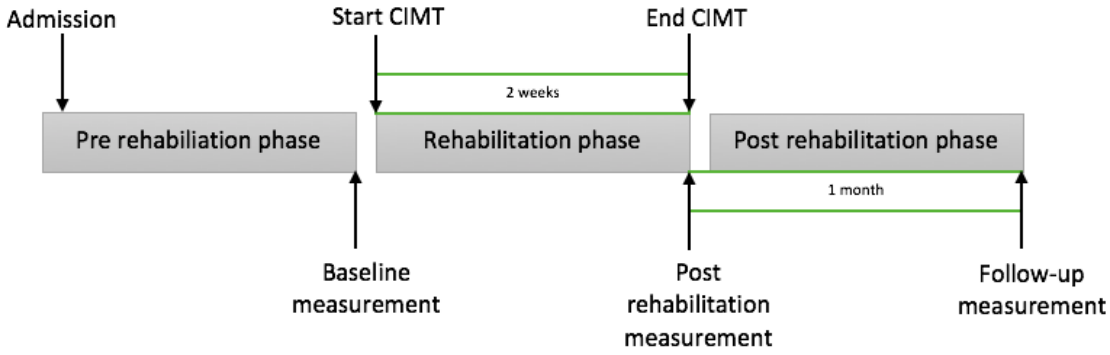

Figure 1. Overview of the intervention and measurement timing

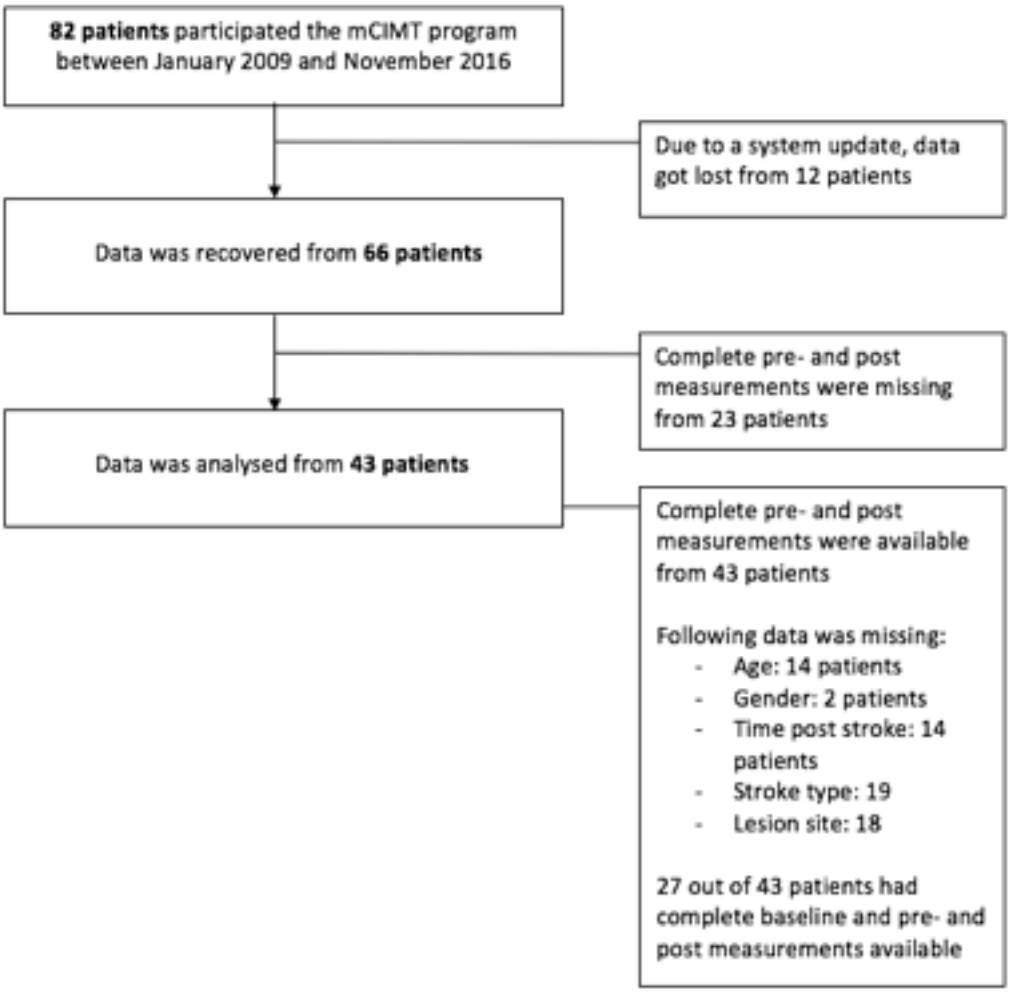

Figure 2. Flowchart of the selected data

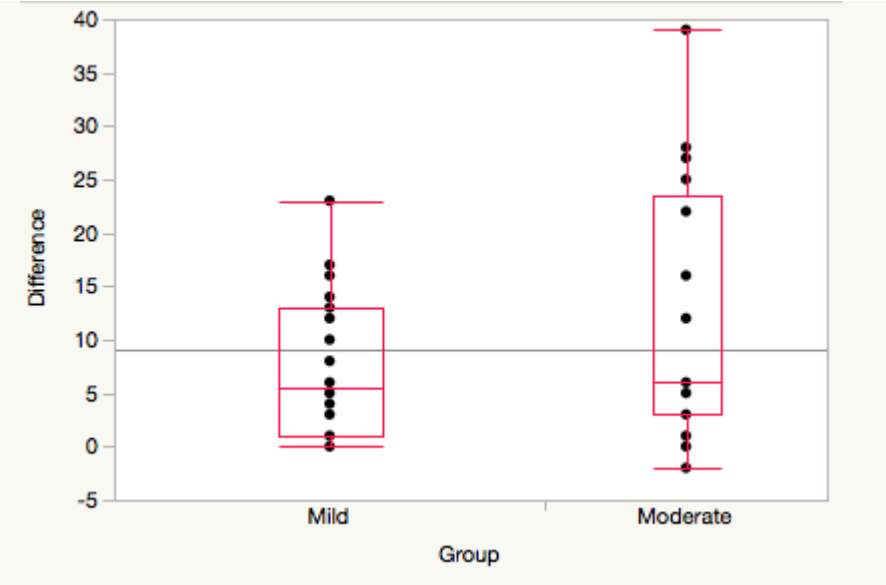

Figure 3. Boxplot of the ARAT difference scores (post – pre) for both groups

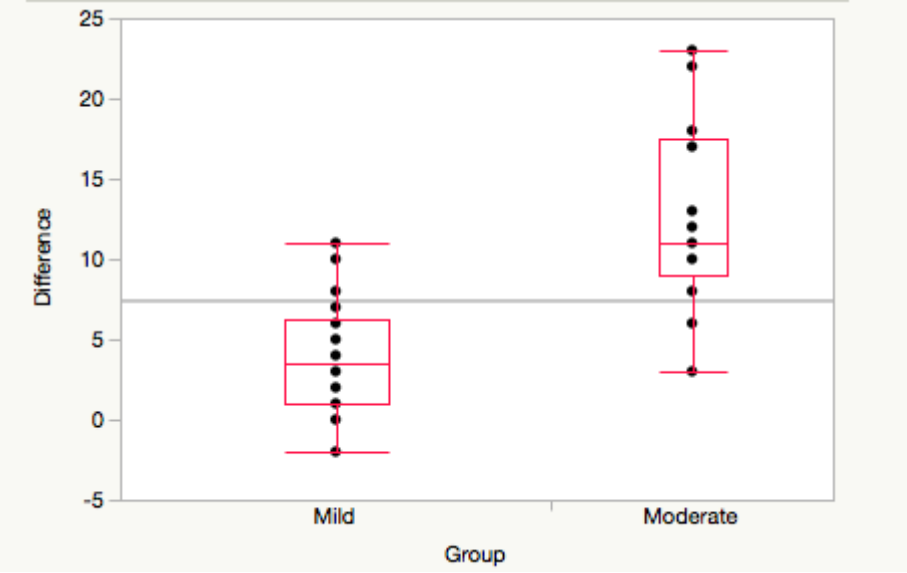

Figure 4. Boxplot of the UL-BFM difference scores (post – pre) for both groups.

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VOORTGANGSFORMULIER WETENSCHAPPELIJKE STAGE DEEL 2

DATUM	INHOUD OVERLEG	HANDTEKENINGEN
11/10 2017	Bespreking inhoud masterproef deel 2 + onderzoek	Promotor: Copromotor: Student(e): Student(e):
01/02 2018	Overleg stand van zaken + vastleggen deadlines	Promotor: Copromotor: Student(e): Student(e):
06/04 2018	Skype gesprek ; data-analyse, participanten	Promotor: Copromotor: Student(e): Student(e):
23/04 2018	Overleg masterproef ; statistiek, resultaten en discussie	Promotor: Copromotor: Student(e): Student(e):
18/05 2018	Bespreking feedback masterproef deel 2	Promotor: Copromotor: Student(e): Student(e):
22/11 2017	Informerend gesprek m.b.t. data verzamelen. Mvr. Marc Michielsen St. Ursula Herk-de-Stad	Promotor: Copromotor: Student(e): Student(e):
21/12 2017	Data verzamelen St. Ursula Herk-De-Stad	Promotor: Copromotor: Student(e): Student(e):
22/12 2017	Data verzamelen St Ursula Herk-de-Stad	Promotor: Copromotor: Student(e): Student(e):
14/02 2018	Data verzamelen St. Ursula Herk-de-Stad	Promotor: Copromotor: Student(e): Student(e):
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Definitief Gunstig advies

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ons kenmerk	uw kenmerk	Diepenbeek
CME2017/757		25/09/2017

Titel protocol	**Dossieranalyse bij personen die een specifieke arm/hand revalidatie, modified constraint induced movement therapy (mCIMT) kregen**
Nummer protocol	
Opdrachtgever	Universiteit Hasselt
Eudractnummer	nvt
Belgisch nummer	
Onderzoeker	*Prof. dr. Peter Feys, Joke Raats*

Geachte collega,

Het hierboven vermeld dossier werd, met bijzondere aandacht voor de punten 4°, 6°, 7° van paragraaf 4 van artikel 11 van de wet van 7 mei 2004, besproken en goedgekeurd. Deze retrospectieve studie valt niet onder deze wet.

Het comité bevestigt dat de onderzoeker en zijn medewerkers voldoende bekwaamheid bezitten om deze studie uit te voeren.

Het instituut beschikt over voldoende faciliteiten om deel te nemen aan deze studie.

Na inzage van de informatie en documenten met betrekking tot dit dossier is het Comité van oordeel dat deze studie, zoals beschreven in het protocol, wetenschappelijk relevant en ethisch verantwoord is. Het comité verwacht dat de privacy te allen tijde wordt verzekerd.

Er dient eveneens een toelating te worden gevraagd aan de Ethische Toetsingscommissie van het Jessa Ziekenhuis.

Het gunstig advies betreft:
- Brief 20/09/2017

Het Comité voor Medische Ethiek van UHasselt handelt volgens de geldende richtlijnen van de 'International Conference of Harmonization (ICH) Good Clinical Practice (GCP)' en volgens alle geldende en van toepassing zijnde wetten en reglementen.

Met oprechte hoogachting,

Prof. dr. Ivo Lambrichts
Voorzitter Comité voor Medische Ethiek

Auteursrechtelijke overeenkomst

Ik/wij verlenen het wereldwijde auteursrecht voor de ingediende eindverhandeling:
The effectiveness of a modified constraint induced movement therapy program in patients with acute or subacute stroke: a real-life study

Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij kinderen**
Jaar: **2018**

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Petré, Lore **Poelmans, Bram**

Datum: **5/06/2018**