Forced use on arm function after stroke
"De lärda tvistar, och saken är ännu ej avgjord"
Ur Ars Poetica, av Horatius, född 65 f Kr
Ann Hammer

Forced use on arm function after stroke
Clinically rated and self-reported outcome and measurement during the sub-acute phase
ABSTRACT

The overall aim was to evaluate the effectiveness of forced use on arm and hand recovery after stroke by applying a restraining sling on the non-affected arm and to investigate psychometric properties of selected upper limb measures.

Papers I and II reported a randomised trial with 1- and 3-month follow-ups. Thirty patients 1 to 6 months after stroke were included and received regular training for 2 weeks of intervention. The forced-use group had in addition a restraining sling on the non-paretic arm. Outcome measures were the Fugl-Meyer Assessment, the Modified Ashworth scale, the 16-hole peg test, grip force, the Action Research Arm test, and the Motor Assessment Scale (Paper I), and the Motor Activity Log (MAL) (Paper II).

Results in Papers I and II showed no statistical difference in change between groups. Both groups improved over time.

Paper III assessed the responsiveness of the MAL and its cross-sectional and longitudinal validity. The MAL was responsive to change, with Standardised Response Means and Responsiveness Ratios larger than 1.0. Correlations between the MAL and the other measures were mostly close to 0.50.

Paper IV investigated test–retest intra-rater reliability of measuring grip force with Grippit, and assessed relationships between grip forces of both hands, and between sustained and peak grip force. The paretic hand needs to score a change of 10% or 50 N to exceed the measurement error. The mean ratio between sides was 0.66, and between sustained and peak grip force, 0.80–0.84.

In conclusion, this thesis provides preliminary evidence that forced use does not generate greater improvement on upper limb motor impairment, capacity, and performance of activity than regular rehabilitation. The findings indicate that the MAL is a responsive measure of daily hand use in patients with stroke. Correlations of construct validity indicated that daily hand use might need to be measured separately from body function and activity capacity. The coefficients calculated for repeatability and reproducibility were acceptable, and the Grippit instrument can be recommended.

Keywords: stroke, upper limb, reliability, validity, ICF, forced use, motor function, effectiveness, rehabilitation, physiotherapy, grip force
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LIST OF PUBLICATIONS

This thesis is based on the following papers, which are referred to in the text by their Roman numerals:


II. Hammer A, Lindmark B. Is forced use of the pare tic upper limb benefi- 

III. Hammer A, Lindmark B. Responsiveness and validity of the Motor Activ-
ity Log in patients during the subacute phase after stroke. Disability and Rehabilitation 2010: 1-10; online 03 Feb.


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Paper I

Paper II
Page 424, at top rows: says “..accepted 21st October 2009”. Should be “…2008”

Page 428, line 9-17. Now there is:
“………The difference in change between the groups did not at any time point reach the clinically significant difference of 0.5 score points. Nevertheless, the magnitudes of the changes tended to differ between the groups at post-intervention. Nevertheless, the magnitudes of the changes between the two pre-intervention tests was approximately 0.3 on both scales in both groups.”

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INTRODUCTION

In Sweden, 30,000 people a year are reported with stroke and the consequences are wide-ranging, not only for the affected individuals and their families, but also for the health and social care systems, costing 1 million hospital days and 12,000 to 14,000 million Swedish crowns per year. Stroke is the most common cause of adult disability in Sweden and other Western countries.

Normally, humans have enormous freedom of movement to perform daily tasks and manipulations. Our bilateral hand function uses a large range of motion around the shoulder and elbow to allow the hand to be active in many differing positions, such as scratching one's own back, taking a glass down from a kitchen cabinet, or gently stroking a kitten. All these abilities are usually taken for granted, but may be immediately destroyed or seriously impaired by a cerebral stroke.

Patients who have suffered a stroke experience loss, uncertainty, and social isolation, as stroke represents a sudden, overwhelming, and fundamental change for the survivor. Personal control over progress, optimism, and fears of dependency, as well as markers of independence and interaction with therapists, were identified as important factors influencing recovery. Treatment goals need to be related to valued activities chosen by the patient. Upper limb recovery has been viewed as a critical but neglected issue, and patients have said that the magnitude of this loss has been poorly understood or underappreciated. 'Use of the arm in everyday tasks' was considered the single most important factor associated with upper limb recovery. Use of the paralysed hand was among the most frequent of problems self-reported by younger patients after stroke (22-64 years of age).

Effective rehabilitation strategies are of utmost concern to different parts of the health care system. Their value resides both in giving people affected by stroke the best possible opportunity for their recovery as individuals and in offering health organisations the best use of limited finances and resources.

Stroke – consequences and functional recovery

Stroke was clinically defined by the World Health Organization (WHO) as: "an acute neurologic dysfunction of vascular origin with sudden (within seconds) or at least rapid (within hours) occurrence of symptoms and signs corresponding to the involvement of focal areas in the brain". Symptoms depend largely on the

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location and size of the stroke. Prevalent symptoms of a stroke are, to varying degrees, paresis, sensory deficits, hemianopsia, aphasia, and disturbances of memory, perception, and attention.\(^{143}\) Initially, some 80% of all patients with stroke experience a hemiparesis.\(^{191}\) These impairments commonly have consequences on basic daily activities like walking and moving around; eating, drinking, and talking; and reaching, grasping, and manipulating objects, which in turn often interfere with people's participation in life and their fulfillment of family, work, and other social roles and obligations.\(^{78, 182}\)

Recovery to various degrees is common among survivors, but extremely difficult to measure, not least because how many patients are counted as recovered depends on how recovery is defined. The different measures and cut-off points selected and used in clinical studies, including trials of therapeutic interventions, make a real difference to the results.\(^{67}\) Another challenge in measuring recovery is the tremendous individual variability in rates and degrees of spontaneous recovery. Stroke is a heterogeneous disorder and recovery depends on multiple factors, including the kind of stroke; type, severity, and number of accompanying neurological deficits; lesion size and location; patient characteristics and comorbid conditions; and rehabilitation therapy, among others.\(^{82}\)

Nevertheless, several authors have reported on recovery and prognosis after stroke. For example, the clinical experience of the initial grade of paresis as the most important predictor for motor recovery has been confirmed in a review of longitudinal cohort studies.\(^{87}\) In one study, on admission, 31% of stroke patients were reported to have severe motor deficits, 12% moderately severe, 21% moderate, and 36% mild motor deficit.\(^{65}\) Further, the authors concluded that, on day 1, the initial motor score accounted for only half of the variance in motor function at 6 months, whereas the 5-day motor and sensory scores explained 74% of the variance, and the 30-day motor score explained 86% of the variance.\(^{65}\) This suggests that the earliest assessment may be unreliable and that the accuracy of prediction may rapidly increase within a few days after stroke. In a similar study, 19% were reported with very severe paresis, 14% with severe, 26% with moderate, and 41% with mild paresis on admission.\(^{101}\) The differing percentages between these two single studies arise from the use of different motor measures, different outcome variables, and different choices of whether to include people who died during follow-up time.

Reports have repeatedly shown that improvements occur mainly within the first three months after stroke onset\(^{86, 124, 156, 225}\) even though these authors also
stressed later improvement for some individuals, as well as deterioration for others. Evidence of late recovery, especially for people with moderate or severe paresis, is also available. The degree of recovery, and the time course of recovery in the upper and lower extremities are generally similar, but individual disparity is also reported.

Survival has been studied by several authors, who often find close to 20% of stroke patients die within the first month and approximately 30% die within the first year. Higher age and more severe stroke are among the most important predictors of death following stroke. This was also confirmed in a large Copenhagen cohort followed for 30 years (from 1978 to 2007), where the most important factor for long-time survival was age at time of stroke. In the age group <65 years 28% survived 15 years and 8% survived 25 years. The next most important determinants for long-time survival were the severity of stroke, functional status, and cardiovascular risk factors. For all age groups, survival was poorer in stroke patients than in controls without stroke. Long-term survival improved steadily over the 30 years, and the gain in life expectancy after a stroke was larger than that of the general population.

Age at time of first-ever stroke onset increased successively during the 30-year observation period, and the risk for stroke onset at each age has decreased over the last decade in Sweden. Nevertheless, although the risk of stroke increases with age, almost 20% are 65 years or younger at stroke onset.

There are several and important differences reported for men and women regarding stroke incidence and consequences. In Sweden in 2008, mean age at onset was 73.2 years for men and 78.3 years for women. Before onset, almost twice as many women (63.9%) than men (36.3%) lived alone, and women were more dependent in activities of daily living (ADL) than men (16.3% versus 10.4%). The proportion of women with impaired consciousness on arrival at hospital was 5% to 6% higher than in men. However, not all of these differences are explained by the women’s older age. The overall percentage of patients who were independent before onset but dependent in primary ADL at 3 months post stroke was 20.7%, and similar (<15%) in men and women younger than 75 years. In contrast, women older than 75 years were more dependent than men, even when results were adjusted for age. Other results also show that female sex is an unfavourable prognostic factor – sometimes independent of age and severity of stroke – in rehabilitation results after stroke for both functional outcomes and quality of life.
Regarding paresis of the arm and hand, immediately after stroke onset about 70% of the survivors in a large and unselected population had an upper limb paresis, and 32% had a severe paresis, which was defined as the inability to move the arm against gravity or to bend the fingertips to the palm. At 3 months, 17% had severe paralysis in the upper limb, 7% moderate, 50% mild, and 26% no detectable weakness. Recent and previous studies have shown that the functional outcome of the upper limb at 6 months is highly predictable within a critical time window of 4 weeks post stroke, both in populations selected for rehabilitation and unselected populations, regardless of measurement used. About one third of stroke patients in a rehabilitation trial regained some dexterity at 6 months (Action Research Arm Test [ARAT] ≥10 points).

Taken together, these findings stress the importance of rehabilitation efforts tailored to different groups based on gender, age, and severity of stroke. Extended and repeated training, and support over time, should be offered to younger stroke patients since they may be expected to live longer with the consequences of stroke than older patients. The focus of this thesis, however, is on the moderately impaired patients commonly engaged in a rehabilitation context.

**Theories of motor control, learning and relearning – hand and arm function**

Theories of motor control are concerned with the nature and cause of movement. Different theories of motor control stress different viewpoints regarding how the brain controls movement and posture. The reflex theory, the hierarchical theory, and the motor programming theory have each contributed to our knowledge over time, but they have also been shown to have serious limitations. Treatment approaches in physiotherapy have over time been based on current knowledge and theories. A systems theory integrates the concepts from several older theories and explains the complexities of motor control in terms of the close and dynamic collaboration between cognitive, perceptual, and sensori-motor processes. This approach may suit both theoretical and practical needs of physiotherapists, since it incorporates not only aspects of previous theories, but also biomechanical conditions, context, environmental demands, and the qualities of self-organising systems.

Motor learning is the study of acquisition or modification of movement in normal subjects. To begin with, humans are born with a child’s pre-programmed development of motor functions and activities. Later on, all healthy
people, even the old, can acquire new skills throughout their lives, like driving a car, dancing, or operating computers. An adult with a brain injury affecting motor performance, has had all the abilities of movement and activity, thus, the process of rehabilitation is a motor relearning situation, aimed at the reacquisition of optimal movement abilities. Treatment of neurological conditions is a relearning process where problem-solving and strategies are important, with task-oriented, practical training, where interaction between the individual, the task, and the environment is necessary. Motor relearning aims to transfer the relearned capabilities to daily activities, and incorporate knowledge of behavioural science.

Grip strength is one essential of many factors necessary for function and ability in the hand. Other important qualities are freedom from pain, sensory information, stability, range of motion and cosmetics. For a hand to function properly, systems of motor control must interact to make the necessary contributions. The basic components are: 1) locating a target, including eye-head-trunk coordination; 2) reaching, which is the arm unit in action towards the object including the postural support; 3) grasping and releasing; and, 4) in-hand manipulation skills. All these involve a complex interaction of musculoskeletal and neural systems that also are dependent on cognitive processes such as planning and initiating. The arm and hand function as a single unit, in numerous patterns of coordination.

Hand function is dependent on the teamwork of many muscles. Movement synergies of several muscles are combined for various skilled actions. The wrist muscles are an integrated part of hand function since they stabilise the wrist in optimal positions to keep the finger muscles at a favourable length for producing tension. Due to this, grip strength is dependent on the position of the wrist.

Hand control after stroke may be impaired in various ways other than weakness of grip, causing difficulties in the performance of tasks. The details of these variations have been analysed, showing disabilities of individual patients may differ within and between different tasks. People with stroke were observed to produce not only delayed and irregular grip force compared to controls (identified as prolonged time to grip and lift objects), but also excessive grip force prior to commencing a lift, fluctuating irregular forces, and reduced adaptation. Persons with severe dysfunction were characterized by extremely slow and disorganised sequencing of the gripping and lifting forces and difficulty maintaining a stable grip.
Several other factors of the individual patient are also important in motor rehabilitation, such as motivation, arousal or awareness, attention or perception, and memory.\textsuperscript{182} Logically, therefore, focusing resources and tailoring opportunities to the individual is a core component of successful therapy. Patient involvement, individually designed goals, and rehabilitation plans have been stressed as essential in programmes.\textsuperscript{43, 216}

**Brain plasticity and learned non-use**

That brain plasticity is an important factor in the learning, relearning, and adaptation of skills throughout life, even after injury, has been known for some years, but more specific evidence has recently emerged,\textsuperscript{192, 195, 203} entailing important implications for rehabilitation. New knowledge about neurophysiology provides a basis for therapeutic interventions to exploit and optimise patient functions and capacities.\textsuperscript{123}

Acute pathophysiologic processes during stroke result in the destruction of certain brain cells, yet other cells, partly damaged, heal within the first few weeks.\textsuperscript{143, 251} Thus, early improvements are partly due to these cells revitalizing, but may also be the result of re-localising steering functions to other cells within and between the halves of the brain.\textsuperscript{123} A capacity for plasticity and reorganisation also remains long after the stroke.\textsuperscript{120, 121, 206} Knowledge about this capacity of the brain, developed over the last 50 years,\textsuperscript{45} represents a paradigm shift with positive implications for the rehabilitation of people after stroke. Previously, the regrowth of connections after acute damage in the mature mammalian brain was viewed as impossible.\textsuperscript{45} Now, the concept of brain plasticity gives hope for improvements in rehabilitation that go beyond spontaneous healing.

Time intervals are frequently classified in stroke publications as acute, subacute, and chronic.\textsuperscript{199} Several of the constraint-induced movement therapy (CIMT) authors use these terms. Definitions of precise time frames for these phases are scarce, however, and to the knowledge of the author, there is no explicit consensus for this classification. Sullivan,\textsuperscript{201} though, did suggest that these time intervals may reflect different pathophysiologic processes and stages. She defined hyperacute as from onset up to 6 hours post stroke, acute from within the first 24 hours to approximately 7 days, sub-acute from 1 week to 3 or 4 months, and chronic any time thereafter. She proposed that the effectiveness of therapy in later stages is most likely due to use-dependent changes in neuroplasticity and not to the resolution of acute post stroke physiologic events.\textsuperscript{201} In the present
thesis, patients were between 1 and 6 months post stroke, and are therefore identified as being in the sub-acute phase of recovery.\(^{199}\)

Learned non-use was presented as a theory or explanation of a behavioural adaptation occurring when the affected arm and hand after stroke were not used despite gradually returning motor ability.\(^{144, 207}\) Extrapolating from basic experiments on monkeys, Taub\(^{208}\) reported that learned non-use develops during the initial post-lesional phase when attempts to use the affected limb are punished by negative consequences, such as falling or failing to accomplish the intended task. In response to these consequences, the human, or monkey, learns to avoid using the affected limb. The hypothesis of learned non-use in human patients after stroke was also supported by an impression among clinicians that some patients used their capacity less at home than in the training situation.\(^{7}\) The concept of restraining the unaffected limb and/or intensively training the affected limb to reverse learned non-use is connected to the possibility of brain plasticity.\(^{212}\) Learned non-use was proposed as a suppression phenomenon, and it embodies many motor learning principles.\(^{173}\) The CIMT and forced use approaches to counteract learned non-use are further described in a later section of this thesis.

Rehabilitation efforts in the acute and sub-acute stages are mostly designed to improve independence in transfers, mobility, and primary daily activities,\(^{14, 173, 251}\) and usually include training to improve balance. This approach is justified as necessary not only to reduce the high risk for falls after stroke,\(^{6, 168}\) but also to minimise the burden on caregivers after patients are discharged. In the short time available at hospital, therapists teach skills that may contribute to compensation and focus attention away from the hemiplegic arm,\(^{34, 173}\) and recovery judged on general ADL skills may in fact be independent of upper extremity function.\(^{36}\)

Functional neuroimaging and mapping of the brain with different advanced techniques have been used in research to assess the role of cortical reorganisation. Several of these imaging studies have been performed in relation to overcoming learned non-use. Among brain imaging techniques reported in this context were functional magnetic resonance imaging (fMRI),\(^{105, 180, 206}\) positron emission tomography (PET),\(^{239}\) and transcranial magnetic stimulation (TMS).\(^{120, 179}\)

**Methods of rehabilitation and physiotherapy to influence motor recovery after stroke**

Rehabilitation has been defined in a number of different ways, but it may best be described, not as a single well-defined intervention, but as a continuous, ongoing,
and dynamic process that combines a complex of different medical, physical, psychological, and social measures. Rehabilitation usually involves several professional disciplines organised in coordinated, multidisciplinary teams. "Physical therapy provides services to individuals and populations to develop, maintain and restore maximum movement and functional ability throughout the lifespan." After stroke, physiotherapists are involved in treating problems of movement that vary with each patient, but always include some degree of disordered functioning. Physiotherapists are seen as applied movement scientists, training motor control based on understanding of the kinematics and kinetics of normal movement, motor control processes, and motor learning. The intention in motor rehabilitation of improving motor function, capacity and performance of daily activities has over time been the goal in different training approaches.

The aim of motor rehabilitation after stroke is to increase function, primarily through the recovery of the affected side, complemented by compensations using the nonaffected side and other adaptations. Compensation is especially important when recovery of the affected side cannot be achieved. During both processes brain plasticity is active.

The general stroke population is very heterogeneous, making the gathering of evidence for effective rehabilitation extremely difficult. This difficulty incorporates inclusion of people with different stroke severities in the same study; or inclusion of people within different time frames after stroke onset. Outcome measures and follow-up intervals also vary widely between studies. However, evidence-based interventions are important and urgently needed, because of the high incidence and prevalence of stroke disability. Since several body systems may be affected to different degrees by a stroke, individually designed rehabilitation is always necessary. Adopting the approach of Evidence-Based Practice, clinical decision-making should combine the best of current knowledge with patient preferences and needs to provide appropriate, individualised therapeutic care. The challenge in making this level of care possible lies in producing research results, systematic evidence reports, and generalised guidelines.

A scientific basis for physiotherapy interventions is emerging with a rapid increase in publications. Several important systematic reviews have analysed motor rehabilitation interventions after stroke, and strong evidence exists that organised, specialist inpatient care, such as that provided in a stroke unit, is
associated with improved outcomes.\textsuperscript{116, 251} There is also good evidence that specialist rehabilitation teams improve outcomes during resettlement at home.\textsuperscript{116, 251} So far, however, there is scant evidence that any specific therapy is superior to another.

Physiotherapy based on different principles, with a focus on recovery of postural control and lower limb function, have been compared. Pollock et al\textsuperscript{163} reviewed conventional neurophysiologic, motor learning, and orthopaedic approaches of physiotherapy. This recently updated review (20 trials; 1,087 patients) concluded that the only significant result was found in the use of a mix of components from different approaches compared with no treatment. Other reviews also found no difference in outcome between different physiotherapy approaches.\textsuperscript{71, 137}

Intense, repetitive practice has been proposed as advantageous for people after stroke, based on learning principles within movement science.\textsuperscript{116, 182} Various training approaches that increase repetitions can be used for this purpose. An extensive systematic review of repetitive functional task practice (31 trials; 1,078 patients) was not able to synthesise a firm recommendation for upper-limb interventions.\textsuperscript{75} A summary explicitly on arm therapy (13 trials; 939 patients) concluded that more intensive exercise therapy may be beneficial, but firm evidence was not found.\textsuperscript{230} Likewise, augmented therapy (20 trials; 2,686 patients) was analysed by Kwakkel et al,\textsuperscript{111} and although a positive association was found between added therapy time and outcome on ADL, the same could not be shown for upper-extremity dexterity. Van Peppen et al\textsuperscript{234} could also summarise positive effects (151 trials) from task-oriented practice for balance, gait, and lower extremity recovery, but there was insufficient evidence for increased upper limb function, as analysed in several intervention categories. No evidence was found for applying one specific neurological treatment program or particular strengthening exercises to improve grip force. Again, study pooling posed difficulties. Exercises for the upper limb, bilateral arm training, mirror therapy, biofeedback therapy, and neuromuscular electrical stimulation all showed limited support for effectiveness.\textsuperscript{234} The only significant effect found was for CIMT.

Considering the two approaches of CIMT/forced use and bilateral movement therapy, the theories behind them appear contradictory (learned non-use versus bilateral coordination). A summary of bilateral movement training in stroke rehabilitation asserted a favourable effect on motor recovery,\textsuperscript{196} but the validity of
this conclusion seemed uncertain as the results of control groups were not included in the comparisons. A Cochrane protocol focusing on simultaneous bilateral training for improving arm function after stroke has only recently been published.50

Repetitive practice for upper extremity function is a specific challenge in people hit by a severe stroke. The innovative interventions of robot therapy and electrical stimulation (e.g. EMG-triggered), designed to enable active participation in repetitive task-oriented therapy, may practice a task such as reaching by decreasing task difficulty or augmenting movement. Two different reviews of robot-assisted therapy have come to similar conclusions. A meta-analysis by Kwakkel et al113 found no overall effect (10 trials; 218 patients), although the shoulder-elbow robotics showed a significant effect on motor function but not on function in ADL. A recent Cochrane review128 also found that robot-assisted arm training was no more effective than other training or no training on ADL, but that motor function and strength in the arm did improve (11 trials; 328 patients). Both author groups encountered difficulties with design variability among studies, making their conclusions uncertain. A systematic review164 investigated whether electro-stimulation improved movement or functional ability, concluding that there was no clear evidence of benefit of electro-stimulation on the upper extremity (24 trials; 888 patients). Thus, several recent reviews have had continued problems in proving clear-cut conclusions, especially regarding the upper limb. None of these interventions was shown to improve the use of the affected arm in everyday tasks, which unfortunately was rarely measured.

A long-running discussion in physiotherapy concerns whether spasticity or weakness is the most important problem to consider when planning training. During the 1970s and 1980s, strength measuring and training were actively rejected by orthodox physiotherapists.27 The problem of hypertonicity had a major impact on treatment principles,54 and the Bobath approach27, 182 was based on inhibiting and restricting abnormal movements, while facilitating normal movements.

Bethune’s17 summarised description of ‘the upper motor neuron syndrome’ classifies as negative symptoms all the losses (reductions in strength and coordinative capabilities) and as positive symptoms all the additional features (exaggerated movements and disinhibited reflexes). She stressed the idea of not letting the older dogmas reign, but allowing newer knowledge to influence treatment strategies. At that same time, the Carr and Shepherd approach of motor relearn-
ing in task-oriented training had evolved. A review by Guiliani was among the first to acknowledge the benefits of intense therapy and strength training in stroke patients. Later results supported the loss of strength as a primary problem after stroke and several studies showed evidence of the benefits of strength training.

Nevertheless, the positive symptoms of the upper motor neuron syndrome also have an impact on rehabilitation. The incidence of spasticity in patients after stroke was at first week, at 3 months, and at 18 months. Difficulties in quantifying and measuring hypertonicity have also long been recognized. However, the subset of patients with spasticity may have increased problems with motor and activity performance, causing pain and leading to secondary complications, and therefore they need a comprehensive rehabilitation approach that includes managing their spasticity even though evidence in this area is scarce.

These reports taken together have opened physiotherapists to viewpoints favouring more intense training approaches after stroke. However, it seems to have been more difficult to draw conclusions on effective treatments for improving upper limb function than for lower limb and ADL outcomes.

**Forced use and constraint-induced movement therapy**

The umbrella concept of CIMT has been described as comprising the three components emphasised in earlier protocols: immobilization of the non-affected hand, increased training of the affected hand and arm, and high-intensity training. Newer descriptions, however, accentuate the behavioural contract patients sign about using the affected hand in daily living, as well as the immobilization and intense training. This classic CIMT involves training 6 hours per day for 2 weeks and the use of a restraining device for 90% of waking time.

The expression ‘forced use’, describes using the restraint component only, which was the original notion introduced in 1981 and 1989 for reversing learned non-use in humans. The addition of intense training to forced use led to introduction of the expression ‘CIMT’ in 1997. When the present study of forced use was planned and started in 1998, there were very few studies on humans in the area of CIMT. Consequently, the studies and terminology known at that time influenced the approach. Since then, several other studies have evaluated the restraint component only and often named their intervention forced use. The distinction between CIMT and forced use has been
pointed out in recent summaries of CIMT. In other reports, however, a broadened definition of forced use included home practice of activities determined together with the therapist, but this definition was not applied in present study. Forced use in this thesis refers to the use of a restraint in connection with ongoing rehabilitation in the departments concerned.

Learned non-use was assumed to develop in the acute and sub-acute phases after stroke. The first studies on reversing learned non-use in humans after stroke were conducted in the chronic phase and stressed the question of whether overcoming or preventing learned non-use would be more efficient in early rehabilitation because brain plasticity was thought to be greater in that phase than in the chronic phase. The first evaluation of CIMT in the sub-acute stage after stroke was a case report. Both use and function of the affected upper limb were reported to have increased after two weeks of constraint with a mitt combined with six hours of task training on weekdays.

Although most studies were conducted on patients in the chronic phase, there are, at present, about 15 randomised controlled trials (RCTs) of different CIMT interventions reported in the sub-acute phase. Several of them originate in the EXCITE study (Extremity Constraint Induced Therapy Evaluation), which is the largest study in the CIMT field, with 222 participants. The conclusion of EXCITE was that CIMT was effective for both motor function and daily hand use. Other reports of the sub-acute phase, apart from EXCITE, are on smaller RCTs (24–47 patients), whose results vary from no difference between groups, to significant differences in favour of the CIMT group. For the smallest RCTs, however, with fewer than 15 patients, results should be deemed as inconclusive, even when reported as advantageous for CIMT. One specific modification of CIMT even excluded the constraint and used mass practice only and found results in favour of the mass practice group. Uncertain conclusions reign though, since differing intensities were compared and meta-analyses did not present results by separate time intervals after stroke.

In most studies, CIMT or forced use was administered to patients who exhibited a specified amount of active extension in their affected wrists and fingers, which was an inclusion criteria in the present study as well. But many people after stroke are not able to extend the wrist and fingers actively to the required 5° to 10° and several studies have tried CIMT or modified CIMT (mCIMT) on patients with lower motor function. Given
the different degrees of impairment after stroke, but also the resource-demanding features of CIMT, several adapted approaches have been evaluated. Terms used have included ‘modified CIMT’, ‘distributed CIMT’, ‘shorter CIMT’, and ‘shortened CIMT’, and all focus training on the upper limb, but use less intense training or restraint than classic CIMT. Interestingly, Hakkennes and Keating found the effects of CIMT and mCIMT to be highly comparable from 14 RCTs summarised in a meta-analysis, although methodological consistency across trials was weak. The question seems to remain, – What is the best practice regarding intensity of training and/or restraint?

Over the years, the CIMT approach has also been evaluated for use in the upper limb in children with hemiplegic cerebral palsy, based on similar mechanisms of learned non-use as in adults. In a recent Cochrane review, three trials with an appropriate design were available for inclusion. Given the limited evidence, the use of forced use, CIMT, and mCIMT should be considered experimental in children with hemiplegic cerebral palsy.

Apart from the use on upper limb function after stroke and in children with cerebral paresis, the approach of CIMT has also been applied in some related areas. There are a few reports of CIMT use in traumatic brain injury (upper limb), the lower extremities after stroke, spinal cord injury, and fractured hip, as well as aphasia, focal hand dystonia in musicians, and phantom limb pain.

Over the ten last years there has been intense interest in CIMT, and now in 2010 there are several recently published systematic reviews and guidelines incorporating CIMT, mCIMT, and forced use. Some of these draw a conclusion supporting the use of these approaches, but most of them propose a “careful attitude” and emphasise the limited data on efficacy or effectiveness of CIMT and the uncertainty of many of the conclusions. Considering the resource demands on patients and health care in CIMT, attention has also been called to serious concerns for its implementation in clinical routine.

There are several studies concerning CIMT, mCIMT, and forced use, but most of them, as authors have pointed out, include limited numbers of subjects. The median sample size in the recent Cochrane review was 15 patients. Even though some of the studies have shown positive results, there is still no clear-cut explanation of the effect or the importance of the different components included in CIMT. Russo was the first to review the field of the ‘forced use paradigm’ and proposed the importance of distinguishing the effects of forced use from those of added training. The present thesis, measuring the effect of only
one component of CIMT, may add clarity that will be valuable in the clinical context.

**Outcome measurements and the WHO health classification**

The different components defined in the International Classification of Functioning, Disability and Health (ICF) help to structure the assessment, planning, and evaluation of rehabilitation interventions, both clinically and in research.\(^{118, 247}\) A classification is not an assessment tool; it is a means of ordering and reporting information from a range of assessment tools in a consistent way.\(^{205}\) The ICF component of body functions and structures classifies the physiological functions of body systems. The ICF component activity refers to the execution of a task or action by an individual, whereas participation refers to involvement in a life situation. The ICF divides activities and participation into two constructs, capacity and performance. Capacity addresses the execution of a task in a standardised environment – typically measured in a test situation at the clinic. The level of performance addresses what the patient actually performs in his usual or current environment. In addition, personal and environmental factors are now included in the model of ICF.\(^{247}\) Outcome measures are encouraged on all ICF components of functioning, and typical motor variables of interest may be, for example, strength and range of motion on the level of body function, and tasks of walking and dressing oneself on the level of activity and participation.\(^{177, 205}\)

In rehabilitation after stroke, various measures may be used depending on the current focus. When the objective is to evaluate arm and hand recovery, the choice is especially challenging. A general test of ADL gives information regarding a person’s degree of functional dependence/independence or level of activity.\(^{227}\) Such tests, however, do not show how the activity is accomplished, for example whether or how the affected arm is used, which means standard ADL measures are invalid for evaluating arm recovery.\(^{224}\) Within the research area of CIMT and forced use, some measures have been developed for assessing arm use in ADL, since arm and hand recovery is the major concern of this approach.\(^{221}\) These outcome measures of daily use of the affected limb relate to the construct of performance in the ICF component of activities and participation.\(^{11, 247}\)

To assess this field of real-world outcome after stroke more specifically and objectively, a few measures have been developed that focus on the affected arm and hand use in daily activities. The first one reported was the Motor Activity Log (MAL), where patients self-rate their use of the paretic hand in daily activi-
ties in a structured interview.\textsuperscript{207} Another is the Arm Motor Ability Test,\textsuperscript{107} in which a rater scores the motor ability of the hand and arm during 13 predefined ADL tasks. The Actual Amount of Use Test\textsuperscript{134,209} was also designed to videotape patients performing a set of predefined tasks without knowing that they were in an observed test situation. Both these measures are in-laboratory set-ups, which require a studio with video and other equipment, along with extensive rating resources. Clinically, it might be more appropriate and feasible to adapt accelerometers for use in studies of arm and hand use after stroke, and there are reports of their validity and reliability.\textsuperscript{55,219,220,223} So far, the MAL has been the primary measure in research.\textsuperscript{241} Judged to be relatively robust,\textsuperscript{221} it is also the most feasible and available measure for use in a clinical setting. Lately, an approach of kinematic analysis has been used to measure quality of movement objectively in research on CIMT,\textsuperscript{122,248} which may also add important knowledge. Ease and speed in movements, which may be seen as ingredients of ICF’s body functions, are probably strongly associated with patients’ potential and actual use of the affected arm and hand.\textsuperscript{203} Apart from MAL, the ABILHAND questionnaire\textsuperscript{159} is the only other real-world outcome measure that is based on a self-rated score of performance of daily upper limb use. The items it covers, though, have been identified as more complex, bilateral tasks.\textsuperscript{11}

**Measurement properties**

In rehabilitation and physiotherapy it is important to be able to evaluate the effects of an intervention.\textsuperscript{227} Quantifying results, in both clinical and research contexts requires measuring, which, as discussed above, should address different aspects of health.\textsuperscript{247} Effect is the desired difference due to an intervention, but other kinds of variability need also to be considered before measures can be used with confidence.

The use of standardising tests is fundamental to controlling many of the possible sources of variability.\textsuperscript{100} Standardisation includes ensuring uniformity of the procedure in administering and scoring the test. This implies clearly described test materials and methods, manuals for administration, norm values, an appropriate and precise description of scoring, and information on the interpretation of test findings.\textsuperscript{100}

Apart from standardised tests, further properties of measurement must be considered when choosing which measures to use.\textsuperscript{198} The concepts of validity and
reliability are crucial to judging whether measures are trustworthy. Reliability is a prerequisite, but not a guarantee, of validity. Reliability refers to the degree of accuracy, consistency, and repeatability of the scores of an instrument. It is generally understood as the extent to which a measure is stable and produces similar results when administered repeatedly. Reliability can be defined in a variety of ways, and there are many forms of reliability, including internal consistency, alternate forms, inter-rater agreement, intra-rater agreement, and test-retest. Test-retest reliability is a way of estimating the consistency of a scale when it is administered in the same individuals on two (or more) different occasions. This method of evaluating reliability is appropriate only if the phenomenon that the scale measures is known to be stable over the time interval between assessments.

The measurement error should be a small fraction of the true range to be acceptable. True variation is the variation that actually reflects difference in the construct under study, e.g., the effect of an intervention. Random error refers to ‘noise’ in the scores due to chance factors, for example, a distraction in a patient that affects his scoring. When random error is low, reliability is high. Systematic error refers to bias that influences scores in a specific direction, for example, one physiotherapist in a group who tends to rate all patients as more disabled than do other physiotherapists. In using test-retest reliability, the investigator needs to take into account the possibility of practice effects, as well as fatigue effects, which can inflate the estimate of reliability.

Reliability is quantified in two ways, as either relative or absolute reliability. Absolute reliability examines the measurement errors, which is the variability of the scores from measurement to measurement, quantified by the standard error of the measurement. Relative reliability examines the relationship between two or more sets of repeated measures. It exists when individual measurements within a group maintain their position within the group on repeated measurement, and it is quantified by values like intraclass correlation coefficients.

Validity is the meaningfulness and utility of a measurement, the degree to which an assessment measures what it is supposed to measure. Components of validity include construct, content, and criterion-related validity. Variables such as strength, speed of walking, and range of motion are more objective and may more easily be determined as valid through criterion measures. Construct validity reflects the ability of an instrument to measure an abstract concept, or construct. For several attributes, such as health, pain, function, and feelings, no gold stan-
standard exists, and support for construct validity must be gathered through investigations of cross-sectional and longitudinal validity. Cross-sectional validity is the extent to which a measure will correlate with another measures at a single point in time, while longitudinal validity is the extent to which changes on one measure will correlate with changes on another measure. In addition, responsiveness, a test’s capacity to reflect changes, is an important aspect in rehabilitation settings where outcome over time is an essential component of validity.

An unreliable measure is also an invalid measurement, because measurements with a great deal of error have little meaning or utility. A reliable measure is valid only if, in addition to being repeatable, it provides meaningful information.

A clinically useful measure must not demonstrate ceiling or floor effects. Ceiling effect occurs when test items are not challenging enough for a group of individuals. The scale cannot detect improvement at the upper end. This becomes a measurement problem when one is trying to identify changes – the person may continue to improve, but the test does not capture that improvement. Conversely, floor effect occurs when data cannot take on a value lower than a particular number. Even if function or behaviour worsens, there are no items or scaling within the test to measure decline below its lowest possible score. Another implication of floor effect is that a person may improve from a very low level, but still not reach the lowest possible score on the test, so the improvement would not be seen in the measure. Ceiling and floor effects were considered present if more than 15% of respondents achieved the highest or lowest possible score. Other specific proportions proposed were: excellent (no ceiling or floor effect) = no respondents at highest or lowest score; adequate (acceptable level of ceiling or floor effect) = <20% of patients at highest or lowest, and poor, >20%. 

**The rationale for this thesis**

The research background for this thesis arises from the emergent theory of learned non-use, supported by the first reports of human studies showing reversal of learned non-use through restraint of the unaffected arm. The clinical empiricism of the large numbers of stroke patients in clinical contexts worldwide, especially sub-acute patients in rehabilitation units, combined with the author’s own experience and interest in stroke rehabilitation, all contributed to the initiation and conduct of the studies reported here.

Uncertainty prevails as to the effects of different components of CIMT. The classic CIMT is resource demanding, and several modi-
A relevant question was whether restraining the non-affected hand would be enough to achieve a better result in arm recovery. Previous reports in this research field were all on patients in the chronic phase, and results, though promising, were inconclusive. Knowledge about facilitating conventional rehabilitation in the sub-acute phase using only a restraint on the non-affected upper limb is lacking.

Numerous tests and measures concerning stroke, covering different constructs and important areas, are available. Still, there remains a need to scrutinize the absolute reliability of the Grippit instrument for measuring grip force, and validity reports on the measure Motor Activity Log are remarkably sparse.

This thesis addresses the connected needs of evaluating whether or not adding forced use improves outcomes for upper limb recovery, investigating error in measurement of grip force, and evaluating the validity of a measurement of daily hand use after stroke. Characteristics of measures and effects were organised along the ICF classification to relate to a well-established framework.

**AIMS**

The overall aim of this thesis was to elucidate some aspects of upper limb function in the sub-acute phase after stroke in a clinical setting. This included evaluating the effectiveness of forced use on arm and hand recovery, and investigating psychometric properties of selected upper limb measures. The specific aims were:

**Paper I**
To evaluate the effectiveness of two weeks of forced use on arm function up to 3 months post-intervention. The focus was on motor impairment and capacity in an experimental group of stroke patients wearing a restraining sling in addition to receiving rehabilitation training compared to a conventional group of patients receiving rehabilitation training only.

**Paper II**
To evaluate the effectiveness of two weeks of forced use on arm function up to 3-months post-intervention. The focus was on use of the paretic hand in daily activities in an experimental group compared to a conventional group.

**Paper III**
To investigate the Motor Activity Log (MAL) for responsiveness and for cross-sectional and longitudinal validity related to measures of motor function and capacity in the sub-acute phase after stroke.

**Paper IV**
To investigate test-retest intra-rater reliability of measuring grip force with Grippit in stroke patients, to assess the relationships between grip forces of both hands and between sustained and peak grip forces.
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METHODS

Design
The designs of the four papers in this thesis are summarised below in Table 1.

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Abbreviation: ANOVA, analysis of variance.

Effectiveness of forced use (Papers I, II)
A randomised, non-blinded, clinical pilot trial was conducted to compare standard rehabilitation only and standard rehabilitation combined with use of a restraining sling (forced use). Assessments were made before and after intervention and at 1- and 3-month follow-ups. Outcomes were focused on physical motor functions (I) and on daily use of the hand and arm (II).

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Responsiveness and construct validity (Paper III)

Data collected at pre-intervention, post-intervention, and 3-month follow-up were used to investigate the MAL for responsiveness and for cross-sectional and
longitudinal validity relating to the conventional measures of physical motor functions.

**Test-retest intra-rater reliability (Paper IV)**
Consistency of grip strength measurements after stroke was assessed in a test-retest design with patients suitable for grip strength recordings. Estimates of absolute reliability were chosen to present the size of the measurement error.

**Participants and recruitment**
In all, 47 patients after stroke participated in the present studies. The diagnosis was verified through medical records. One (1) person participated in all four studies.

**Papers I–III**
The inclusion criteria were:
- 1–6 months post stroke onset
- Daily training 5 days per week at the hospital (ongoing or possible to arrange)
- Independent in transfers between chair, bed, and toilet
- Deficit of arm use, but also the ability to move the shoulder and elbow voluntarily, and to extend 20° in the wrist and 10° in the fingers of the paretic arm and hand
- Score 2 or lower on the Ashworth scale (0–5) for muscle spasticity
- Sensory function in the affected arm or hand preserved to some extent
- Absence of severe perceptual impairments, such as neglect, judged by drawing a clock and a human figure
- Score of ≥20 of 30 on the Mini Mental State Examination (MMSE)
- Ability to understand and follow instructions.

Patients were recruited by convenience sampling in both inpatient and outpatient (day-care) services. To find study patients, information rallies were conducted with rehabilitation staff in the Departments of Rehabilitation Medicine, Geriatrics, and Neurology at Örebro University Hospital. Both oral presentations and a letter of invitation were used and information was given both at study start and repeatedly thereafter. Staff members suggested participants to the researcher,
who assessed their achievement of inclusion criteria and conducted the consent procedure. From 77 patients considered, 43 were physically assessed and 30 were found eligible according to both inclusion criteria and their own consent.

The sample size of 30 patients was determined in 1998 to be suitable and large enough for a randomised trial compared to previous research on forced use and CIMT. At the time of planning this study, these previous studies had all been conducted in patients in the chronic phase of stroke.

Complementary descriptive data on participants were obtained from the Swedish Stroke Register (Riks-Stroke).

**Paper IV**

Eighteen patients diagnosed with a recent stroke were included while participating in outpatient or inpatient services at the Department of Rehabilitation Medicine at Örebro University Hospital. To be included, patients had to have motor impairment from the stroke but still be able to score a Grippit test result of more than 0 newtons. Convenience sampling was used where patients observed to perform a finger flexion were asked to participate in the study.

**Measures**

**Measures used for inclusion screening only (Papers I–III)**

To qualify to forced use intervention, specific inclusion criteria were required as listed above. Sensory, perceptual, and cognitive functions were assessed as follows:

**Sensory function** was determined as normal, impaired, or absent through touch and questioning. “Do you feel that touch?” accompanied a light touch on the paretic hand and was answered Yes/No. “How does that feel compared to the other hand?” was asked while the non-paretic hand was touched, first by itself and then bilaterally. If sensory function of light touch was very impaired, the proprioception of the paretic hand was also tested.

**The perceptual function** was tested by two pencil and pen tests, drawing a human figure and drawing a clock. The patients were first asked to draw a human figure on an empty sheet of paper. They were then asked to draw a clock, beginning with a circle, then putting all the numbers on the clock, and then drawing the two hands at a time of their choice. The researcher gave no feedback until the patient was done and had put the pen down on the table. No time limit was used. The drawings were classified as 'pass' or 'fail'. Pass was defined as
‘all parts of the figure in the right place and the same level of detail on the left and the right sides’. No attention was paid to the ‘artistic’ quality of the drawings; several patients had severe difficulties drawing with their non-dominant hand. The clock-drawing test is a reliable and valid, yet simple, measure of constructional ability and is useful for making brief judgements of cognitive impairments in patients with stroke.2, 200

**Mini Mental State Examination** (MMSE) was used as a screening tool for cognitive disturbances. The test briefly covers the areas of memory, thinking, attention, reasoning, orientation, and communication difficulties.24, 74 The test consists of 11 simple questions or tasks, and the total score is 30 points. The MMSE was developed for the detection of dementia, but its use has become more widespread,176 including patients after stroke.3, 145, 200 The requirement of 20 points or more for inclusion was similar to criteria in a previous study of forced use.107

**The ability to understand and follow instructions** was assessed during the motor and cognitive inclusion tests, where patients followed several instructions, as well as while explaining and discussing the study idea and study features with the patient. The intention was to avoid including patients showing apparent problems, such as apraxia. Additionally, it was very important that patients understand the intention of the study and the procedures to be followed, to be able to provide legitimate informed consent for participation.

**Outcome measures at the ICF level of body function**
For assessing outcome on the ICF level of body function and activity capacity (Papers I and III) six measures were chosen, which are described below. These measures are related to different categories in the ICF taxonomy (Table 2).247 All the categories of these measures have been included in the Comprehensive ICF Core Set for Stroke.78
Table 2. The outcome measures related to the International Classification of Functioning, Disability and Health

<table>
<thead>
<tr>
<th>Measure</th>
<th>ICF level</th>
<th>Activities and Participation</th>
<th>Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Body functions</td>
<td>Capacity and Performance</td>
<td>Paper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chapter 7 Neuromusculoskeletal and movement-related functions</td>
<td>Chapter 1, 3, 4, 5, 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chapter 4 Mobility</td>
<td>For details, see Table 3</td>
</tr>
<tr>
<td>Fugl-Meyer Assessment</td>
<td>-Muscle functions</td>
<td></td>
<td>I, III</td>
</tr>
<tr>
<td></td>
<td>--Muscle power functions b730 (grip, arm and wrist positions/movements)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Movement functions:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>--motor reflex functions b750 (reflex items)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>--control of voluntary movement functions b760 (arm and hand movements, timed finger-nose)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified Ashworth scale</td>
<td>-Muscle functions</td>
<td></td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>--Muscle tone functions b735 (spasticity)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-hole peg test</td>
<td>-Movement functions:</td>
<td></td>
<td>I, III</td>
</tr>
<tr>
<td></td>
<td>--control of voluntary movement functions b760 (dexterity)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grip force</td>
<td>-Muscle functions</td>
<td></td>
<td>I, III,</td>
</tr>
<tr>
<td></td>
<td>--Muscle power functions b730</td>
<td></td>
<td>IV</td>
</tr>
<tr>
<td>Action Research Arm test</td>
<td>-Movement functions:</td>
<td>-Carrying, moving and handling objects</td>
<td>I, III</td>
</tr>
<tr>
<td></td>
<td>--control of voluntary movement functions b760 (gross movement)</td>
<td>--Lifting and carrying objects d430</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>--Fine hand use d440</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>--Hand and arm use d445</td>
<td></td>
</tr>
<tr>
<td>Motor Assessment Scale</td>
<td>-Muscle functions</td>
<td>-Carrying, moving and handling objects</td>
<td>I, III</td>
</tr>
<tr>
<td></td>
<td>--Muscle power functions b730 (upper arm positions/movements)</td>
<td>--Fine hand use d440</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>--Hand and arm use d445</td>
<td></td>
</tr>
<tr>
<td>Motor Activity Log</td>
<td></td>
<td>For details, see Table 3</td>
<td>II, III</td>
</tr>
</tbody>
</table>
These tests were considered necessary and relevant to embrace different aspects of upper limb function. Furthermore, they are frequently used in research and clinically, and have been reported valid and reliable after stroke.

**The Fugl-Meyer Assessment**, upper extremity section (FMA-UE), grades motor impairments (ICF muscle and movement functions) of the arm and hand after stroke in terms of reflex activity, synergetic patterns of movement, ability to perform isolated movements, wrist and grip functions, and coordination and speed. Ratings are made on a 3-point ordinal scale (0 = cannot perform, 1 = performs partially, 2 = performs fully) for 33 items for a maximum score of 66 points. The FMA is a disease-specific impairment index designed also to assess lower extremity motor function, balance, sensory function, joint range of motion, and pain, but these items were not used in this study. Good reliability and validity have been shown in several studies and the FMA has been reported to be the most frequently used measure in upper limb stroke rehabilitation research.

**The Modified Ashworth Scale** grades spasticity (ICF muscle tone function) in a resting position through a manual, rapid, passive extension of the muscle where resistance to this extension of the muscle is evaluated. In the present study, the elbow flexors and extensors and the wrist and finger flexors were evaluated while patients were in the sitting position. The 6-point ordinal scale was used, ranging from 0 (no increase in muscle tone) to 5 (affected parts rigid in flexion or extension). The sum score of the 3 muscle scores was used for analysis (totals = 0–15). Good reliability has been shown for elbow flexors and face validity has been reported. Intra-rater agreement after stroke has also been supported.

**The 16-hole peg test** (16HPT) was used to measure dexterity (ICF movement functions). Patients were asked to place 16 pegs (2.1 x 5.9 cm) in a peg-board with 16 holes, and their time was recorded using a stopwatch. The test was performed three times with each hand on each test occasion and the best value of the paretic hand was used for analysis. When time exceeded 2 minutes, patients were allowed to stop with just one trial due to their assumed exhaustion. A normative threshold value has been reported to be 0.5 pegs/second for healthy people. Based on this, ≤32 seconds was the limit set for normative value. Reliability and validity have been supported for peg tests in stroke patients.

**The Grippit instrument** (AB Detektor, Göteborg, Sweden) was used to measure isometric grip strength in newtons (N) (ICF muscle power functions). This electronic instrument consists of a handle with 12.5 cm circumference
and a forearm trough that are board-mounted, together with an electronic unit and the electric connection. Three 10-second attempts were performed with each hand on each test occasion. Strength values are collected in the electronic unit every half-second and the specific peak, average, and final grip strengths of the 10-second trial are displayed. These values were registered in the study protocol. The procedure of measuring grip strength was standardised for the patients’ sitting position and for instructions and feedback from the researcher.98

In Papers I and III, participants began testing with the right hand. The best peak values were used to calculate a ratio of the strength of the paretic hand to that of the non-paretic hand; this ratio has been reported reliable.16 This ratio was chosen for the effect analysis because the grip strength of the non-paretic hand varied widely within the sample.

In Paper IV, the Grippit measurement procedure was also performed according to the description above, but patients started with the non-paretic hand. Definitions of grip force followed Nordenskiöld & Grimby,142 where maximal voluntary contraction (MVC) is the peak grip force of the 10 s contraction and sustained grip force is the mean value of the 10 s contraction.

Outcome measures of capacity at the ICF level of activities and participation

The Action Research Arm Test (ARAT)125 was used to grade arm and hand function on a more activity-based level (ICF mobility: carrying, moving and handling objects). All 19 items are combined movements, where 16 require handling an object. Ratings are made on a 4-point ordinal scale (0 = can perform no part of the test, 1 = performs test partially, 2 = completes test but takes abnormally long time or has great difficulty, 3 = performs test normally). A maximum of 57 points is summed from the subscales of grasping, gripping, pinching, and gross movement. Since the original test description125 lacks a definition of the number of attempts allowed, a limit of 5 attempts per item was decided. Good reliability and validity have been shown in several studies.56, 93-95, 106, 115, 125, 161, 166, 229, 231

The Motor Assessment Scale (MAS)42 was developed specifically for rating motor function after stroke. The MAS is based on a task-oriented approach to evaluation, which assesses performance of functional tasks rather than isolated patterns of movement.43 The three upper extremity items, upper-arm function, hand movements, and advanced hand activities, were used in this study. Ratings
were made on a 7-point ordinal scale (0–6). The criteria for each grade on the scale correspond to a description of the activity to be performed. The total score (0–18) of the upper extremity items (MAS-UE; ICF mobility: carrying, moving and handling objects) was used for analysis. Good reliability and validity have been shown in several studies.

Outcome measures of performance at the ICF level of activities and participation

The Motor Activity Log (MAL) was used to register the use of the paretic hand in daily activities (Papers II and III). The MAL is a semi-structured interview, during which respondents rate how much (amount of use scale [AOU]) and how well (quality of movement scale [QOM]) they use their impaired arm for accomplishing 30 predefined upper-extremity activities of daily living. Activities include opening a refrigerator, using a fork or spoon for eating, using a TV remote control unit, and brushing one’s teeth. Scores range from 0 (never used) to 5 (same as pre-stroke) and patients may select half scores. The summary score is the mean of the item scores. Reliability and validity has been supported. A clinically important change has been proposed to be 10% of the range of the scale (i.e. 0.5).

The 30 MAL items were linked to chapters and categories within the ICF framework to make an overview of the functional areas covered by the measure (Table 3). All categories in MAL except d 560 Drinking were included in the Comprehensive ICF Core Set for Stroke. The assessment of outcome on the ICF level of activity performance is related to the other categories in the ICF taxonomy (Table 2).

For all the described outcome measures, high scores represent better function, except on the Modified Ashworth scale and the 16HPT where low values indicate better function.
were made on a 7-point ordinal scale (0–6). The criteria for each grade on the scale correspond to a description of the activity to be performed. The total score (0–18) of the upper extremity items (MAS-UE; ICF mobility: carrying, moving and handling objects) was used for analysis. Good reliability and validity have been shown in several studies.

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The 30 MAL items were linked to chapters and categories within the ICF framework to make an overview of the functional areas covered by the measure (Table 3).

For all the described outcome measures, high scores represent better function, except on the Modified Ashworth scale and the 16HPT where low values indicate better function.

### Table 3. Items of the Motor Activity Log (MAL), as a measure of the construct of performance, categorised within the chapters of activities and participation in the International Classification of Functioning, Disability and Health (Paper II-III)

<table>
<thead>
<tr>
<th>Chapter 1. Learning and applying knowledge</th>
<th>ICF categories</th>
<th>MAL item no</th>
<th>MAL item description</th>
</tr>
</thead>
<tbody>
<tr>
<td>d 170. Writing</td>
<td></td>
<td>23</td>
<td>Write on paper</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 3. Communication</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>d 360. Using communication devices and techniques</td>
<td>4</td>
<td>Pick up a phone</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 4. Mobility</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>d 410. Changing basic body positions</td>
<td>16</td>
<td>Get up from a chair with armrests</td>
<td></td>
</tr>
<tr>
<td>d 415. Maintaining a body position</td>
<td>24</td>
<td>Steady yourself while standing</td>
<td></td>
</tr>
<tr>
<td>d 420. Transferring oneself</td>
<td>6</td>
<td>Get in/out of a car</td>
<td></td>
</tr>
<tr>
<td>d 430. Lifting and carrying objects</td>
<td>3</td>
<td>Remove an item of clothing from a drawer</td>
<td></td>
</tr>
<tr>
<td>d 440. Fine hand use</td>
<td>9</td>
<td>Use a TV remote control unit</td>
<td></td>
</tr>
<tr>
<td>d 445. Hand and arm use</td>
<td>1</td>
<td>Turn on a light with a light switch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Open a drawer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Open a door by turning a door knob</td>
<td></td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>Pull chair away from a table before sitting down</td>
<td></td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>Use a key to open a door</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 5. Self-care</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>d 510. Washing oneself</td>
<td>10</td>
<td>Wash your hands</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>Dry your hands</td>
<td></td>
</tr>
<tr>
<td>d 520. Caring for body parts</td>
<td>20</td>
<td>Brush your teeth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>Put on makeup/shave</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>Comb your hair</td>
<td></td>
</tr>
<tr>
<td>d 540. Dressing</td>
<td>12</td>
<td>Put on your socks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>Take off your socks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>Put on your shoes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>Take off your shoes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>Button a shirt</td>
<td></td>
</tr>
<tr>
<td>d 550. Eating</td>
<td>26</td>
<td>Use a fork or spoon for eating</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>Eat half of a sandwich or finger foods</td>
<td></td>
</tr>
<tr>
<td>d 560. Drinking</td>
<td>19</td>
<td>Pick up a glass</td>
<td></td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>Pick up a cup by a handle</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 6. Domestic life</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>d 630. Preparing meals</td>
<td>7</td>
<td>Open a refrigerator</td>
<td></td>
</tr>
<tr>
<td>d 640. Doing housework</td>
<td>5</td>
<td>Wipe off a kitchen counter or other surface</td>
<td></td>
</tr>
</tbody>
</table>
**Data collection**

**Papers I–III**
The outcome measures were collected on five occasions: (1) one week before the intervention (pre-intervention 1), (2) immediately prior to the intervention (pre-intervention 2), (3) immediately post-intervention, (4) at a 1-month follow-up, and (5) at a 3-month follow-up. The tests were performed according to the test manuals and in a set order: FMA-UE, modified Ashworth, ARAT, MAS, 16HPT, Grippit, and MAL. The test procedure took about 1.5 hours on each occasion and was usually performed in a separate room at the physiotherapy department, although three follow-up occasions took place in people’s homes. The risk for information bias was minimised by the use of separate score sheets on each measurement occasion. The researcher conducted all tests.

**Paper IV**
Patients were tested on two occasions one hour apart. On each occasion patients performed three trials with each hand. The short interval between test occasions was to ensure that the phenomenon measured was stable over the interval between assessments.

**Procedure (Papers I and II)**
Randomisation was performed after inclusion using restricted blocks of 10 (5+5). Allocation to the forced use regimen or the standard training regimen was made with marked ballots folded twice. At drawing a ballot, the mark was not visible. After randomisation, the pre-intervention test occasions were performed as soon as was convenient. After the intervention weeks, participants returned to their ordinary schedule according to their rehabilitation plan. This often included continued training, but it was less intense, and participants were asked about it at follow-ups.

The therapy staff kept a study log for every study patient during the intervention. The amount of therapy scheduled was recorded. Time spent wearing the sling and activities requiring its removal were recorded for the forced use group.

**Intervention (Papers I and II)**
All participants received their standard rehabilitation programme, but with training 5 days per week for the 2 intervention weeks. The forced-use group also wore a restraining sling (CAMP Scandinavia AB, Helsingborg, Sweden) on the non-
paretic arm for a targeted 6 hours per weekday. The difference for study between the groups was the wearing of the restraint or not (Figure 1).

*Figure 1. The restraining sling used in the forced use trial (paper I and II).*

Physical and occupational therapists in the participating departments were in charge of patient training and clinical documentation. The researcher was not involved in treating the study participants. Both physical and occupational therapists have a 3-year university education and are certified by the National Board of Health and Welfare. Therapy staff was extensively experienced in rehabilitation. Even assistant therapy staff had 7 to 30 years of experience in rehabilitation training. There were several therapists involved over the years, and a few were therapists for patients in both groups.

Each patient received individual, goal-related training in the ongoing clinical management. In the clinical context used, it was considered impossible to designate a standard treatment for all patients, but recommendations were made to continue with basic motor exercises along with task-oriented activities. Thus, exercises were planned individually depending on each patient’s resources, problems, and goals. The team set the overall rehabilitation goals independent of the study. All therapists were given a general description of expectations of training during study intervention, which declared that the ‘patient should train what he needs to train’.

**Statistical analyses**

Descriptive statistics were used to present summary of data. Data were mainly registered in Statistica 5.0 and analysed with SPSS 14.0 and 15.0.
Effectiveness of forced use (Papers I, II)
Between-group comparisons were made to examine whether the groups were different in some aspect despite randomisation. Tests used were the Fisher exact test (sex, paretic side, and department), the *t*-test for independent groups, and the Mann-Whitney *U* test (age, months post stroke, MMSE, pre-intervention upper limb scores, and amount of therapy during intervention).

Analyses of effects were performed using two approaches; from data collected, and by an intention-to-treat (ITT) analysis, where the last available value in drop-outs was carried forward to represent the missing test occasion. Both parametric and non-parametric methods were used for each of the seven measures. First, the change scores from pre-intervention 2 to post-intervention, 1-month follow-up, and 3-month follow-up were calculated. Then, these change scores were compared between groups non-parametrically with the Mann-Whitney *U* test and parametrically with t-test for independent groups. Subsequently, the change scores were analysed parametrically with a repeated-measures 2-way analysis of variance (ANOVA); within factor–time, between factor–group. The significance level was set at *p*<0.05, but, to reduce the chance of type I errors from multiple comparisons, a Bonferroni correction was applied in cases of significance.

Effect sizes according to Cohen’s *d* were calculated to judge the magnitude of the differences in treatment effect, in spite of sample size. The formula used was: mean result for experimental group minus mean result for conventional group divided by SD of the conventional group. An effect size of 0.2–0.5 is considered small, 0.5–0.8 is considered medium, and above 0.8 is considered large. A positive *d* indicates larger improvement for the experimental group than for the conventional group, and a negative *d* indicates the opposite.

Responsiveness and construct validity (Paper III)
Analyses were made with all data available from the RCT (Papers I and II) drawn from 30 participants at pre-intervention 2, 28 at post-intervention, and 26 at the 3-month follow-up. Since the two groups did not differ significantly, data from both groups were pooled in this study.

Responsiveness of the MAL was computed according to three different methods over two time intervals: from pre-intervention 2 to post-intervention, and from pre-intervention 2 to the 3-month follow-up.

- Effect size (ES): the mean change in the group divided by the SD of the baseline score in the same group
• Standardised response mean (SRM): the mean change in the group divided by the SD of the change score in the same group
• Responsiveness ratio (RR): mean change in the group divided by the SD of the change score in a stable group. The SD values used for a stable group were 0.39 for actual amount of use and 0.33 for quality of movement, which was based on an earlier report of people with chronic hemiparesis over a 2-week baseline period.

Construct validity of the MAL was examined through cross-sectional and longitudinal validity; both were determined with Spearman rank correlation coefficients. Cross-sectional validity determines the relationship between the MAL scores and the conventional measures of physical function, and longitudinal validity determines the relationship between the change scores of the MAL and the change scores of the physical function measures. The same test occasions and time intervals were used as in the responsiveness calculations.

The importance of these indices were interpreted as follows: For responsiveness, values of 0.20 or under are low, around 0.50 are moderate, and 0.80 or above are high. For the Spearman correlation coefficients, the author took into account the strength of the coefficient, where values of 0 to 0.25 indicate little or no relationship, 0.26 to 0.50 a fair relationship, 0.51 to 0.75 a moderate to good relationship, and above 0.75, a very good to excellent relationship; the coefficient of determination $r^2$; and the statistical significance of the Spearman correlation coefficient (p-value $\leq 0.05$).

**Test-retest intra-rater reliability (Paper IV)**

The size of absolute reliability was chosen to present an interpretable value of the measurement error given in the same unit as measured, N. The within-session variation was evaluated with the coefficient of repeatability ($C_{R\text{-within}}$) referring to short-term time-dependent variation. To assess the test-retest reliability, which is the between-session variation, the coefficient of reproducibility between occasions ($C_{R\text{-between}}$) was calculated. The $C_{R\text{-between}}$ was calculated for two values: the highest value and the mean of three trials. Calculations for both these coefficients use the formula $C_R = \sqrt{2} \times 1.96 \times S_w = 2.77 \times S_w$. One-factor ANOVA for repeated measures was used to determine the $S_w$ (the within-subject standard deviation). Systematic errors in differences of means were tested. Differences were considered significant if the p-value was <0.05. Since some positive skew-
ness was present, the \( CV_{\text{within}} \) (= within subject coefficient of variation [\%]) was also calculated for within-session variability and test-retest reliability\(^{21}\) using the formula \( S_w/\text{mean} \times 100 \).

The ratios between the paretic and the non-paretic hands were calculated using the highest peak value, as were the ratios between sustained grip force and peak grip force, also using the highest values in each hand at both occasions.

**Ethical considerations**

Patients were given verbal and written information about the study and their written consent was obtained prior to inclusion (Papers I–III). All participants (Paper IV) provided voluntary, informed consent before inclusion. The ethical committee at the study site approved the study protocol (Örebro County Council approval 500:16, 844/98).
RESULTS

Effectiveness of forced use (Papers I, II)

Of 77 patients identified and considered for participation, after initial discussion with the physical or occupational therapist, 43 patients were recognized as potential participants for the study. Of those 43, 13 were not included (6 declined to participate and 7 did not meet the selection criteria), thus 30 patients were included and randomised. Pre-stroke, all participants had been independently mobile indoors and outdoors as well as independent in managing dressing and toilet visits. All but 2 lived independently at home, and 10 participants had no cohabitant. On arrival at hospital, all were fully conscious; 21 presented with ischemic stroke and 9 with hemorrhagic.

The groups did not significantly differ in any of the baseline characteristics of age, sex, paretic side, MMSE, months post stroke, and department (Table 4). The pre-intervention upper limb scores were also comparable between groups.

Table 4. Baseline characteristics of the participants in the forced use trial

<table>
<thead>
<tr>
<th>Variable</th>
<th>Forced use group (n=15)</th>
<th>Standard training group (n=15)</th>
<th>Total sample (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (y)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>66.3 (10.3)</td>
<td>60.4 (11.1)</td>
<td>63.3 (10.9)</td>
</tr>
<tr>
<td>Range</td>
<td>51-83</td>
<td>31-80</td>
<td>31-83</td>
</tr>
<tr>
<td><strong>Sex: Men/Women (n)</strong></td>
<td>14/1</td>
<td>9/6</td>
<td>23/7</td>
</tr>
<tr>
<td><strong>Paretic side (n)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Right/left</td>
<td>11/4</td>
<td>8/7</td>
<td>19/11</td>
</tr>
<tr>
<td>-Dominant/non-dominant side</td>
<td>12/3</td>
<td>7/8</td>
<td>19/11</td>
</tr>
<tr>
<td><strong>Mini-Mental State Examination (score)</strong></td>
<td>28.6 (1.3)</td>
<td>27.7 (2.5)</td>
<td>28.2 (2.0)</td>
</tr>
<tr>
<td>mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time post-stroke – at pre-intervention test (months)</strong></td>
<td>2.6 (1.5)</td>
<td>2.3 (1.2)</td>
<td>2.5 (1.4)</td>
</tr>
<tr>
<td>mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Department (n)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>7/8</td>
<td>11/4</td>
<td>18/12</td>
</tr>
<tr>
<td>Medicine/ Geriatric</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: y, years. SD, standard deviation. n, number.
A total of 4 drop-outs occurred, 2 from the forced use group during intervention, and 1 from each group before follow-up. The total therapy time was similar in the groups, 3 hours per day in the forced use group and 2.7 hours per day in the standard training group. The mean value for total time using the sling was 37.4 hours.

In summary, the changes in the forced use group did not differ from the changes in the standard training group for any of the outcome measures. The only tendency for the forced use group to achieve larger improvements was immediately post-intervention on the MAL-QOM. Graphs of mean results per group are presented in Figure 2 and 3 as an overview. Below, the results are presented on each outcome measure, according to the ICF levels.

**Results at the ICF level of body function**

The FMA-UE had mean scores of 51.7 (forced use group) and 52.0 (control group) out of a maximum of 66 at pre-intervention, and both groups had improved by approximately 5 points at the 3-month follow-up (Table 5). The change scores calculated showed a medium effect size of 0.68 between-groups at post-intervention, but with the ITT analysis the value decreased to 0.50 (Table 6). At follow-ups, the effect sizes were small.

The Modified Ashworth Scale sum score for estimating spasticity was low and steady throughout the study; mean scores were close to 1 out of the maximum 15. The low baseline value was likely due to the inclusion criteria, but the lack of increase in spasticity is also a desired result, since increased hypertonicity would have been an adverse event.

Time on the 16HPT for dexterity improved in both groups (Table 5). At post-intervention, this measure showed an effect size of 0.72 between-groups, which was considered medium, and 0.57 with ITT (Table 6). Nevertheless, the variability within-groups was considerable and no significant differences were achieved between-groups.
A total of 4 drop-outs occurred, 2 from the forced use group during intervention, and 1 from each group before follow-up. The total therapy time was similar in the groups, 3 hours per day in the forced use group and 2.7 hours per day in the standard training group. The mean value for total time using the sling was 37.4 hours.

In summary, the changes in the forced use group did not differ from the changes in the standard training group for any of the outcome measures. The only tendency for the forced use group to achieve larger improvements was immediately post-intervention on the MAL-QOM. Graphs of mean results per group are presented in Figure 2 and 3 as an overview. Below, the results are presented on each outcome measure, according to the ICF levels.

**Results at the ICF level of body function**

The FMA-UE had mean scores of 51.7 (forced use group) and 52.0 (control group) out of a maximum of 66 at pre-intervention 2, and both groups had improved by approximately 5 points at the 3-month follow-up (Table 5). The change scores calculated showed a medium effect size of 0.68 between-groups at post-intervention, but with the ITT analysis the value decreased to 0.50 (Table 6). At follow-ups, the effect sizes were small.

The Modified Ashworth Scale sum score for estimating spasticity was low and steady throughout the study; mean scores were close to 1 out of the maximum 15. The low baseline value was likely due to the inclusion criteria, but the lack of increase in spasticity is also a desired result, since increased hypertonicity would have been an adverse event.

Time on the 16HPT for dexterity improved in both groups (Table 5). At post-intervention, this measure showed an effect size of 0.72 between-groups, which was considered medium, and 0.57 with ITT (Table 6). Nevertheless, the variability within-groups was considerable and no significant differences were achieved between-groups.

The grip strength analysed by Grippit ratios between hands was observed to increase in both groups up to the 3-month follow-up (Table 5). Mean values improved from 0.44 to 0.61 in the forced use group and from 0.36 to 0.50 in the conventional group, from immediately prior to intervention to the 3-month follow-up. This indicated that grip strength of the paretic hand was still substantially impaired, with half of the patients remaining at a strength ratio of \(0.50\). Only 3 participants achieved a ratio exceeding 0.9, which is a level often reported as a maximum difference between hands in healthy people. An effect size of 0.80 at the 1-month follow-up, although lowering to 0.69 with the ITT analyses, both considered medium, was the highest effect size of all measures at that time (Table 6).

Results of capacity at the ICF level of activities and participation

The ARAT mean values improved from 43.7 to 51.0 points of the maximum in the forced use group and from 47.3 to 51.6 in the conventional group, from immediately prior to intervention to the 3-month follow-up (Table 5). Effect sizes were both small and negative at post-intervention and 1-month follow-up, but medium at the 3-month follow-up, achieving the largest effect size of any measure on that occasion (Table 6).

The MAS-UE improved from 10.1 in both groups to 12.5 and 12.3 of the maximum, respectively (Table 5). Effect sizes were mostly small, and also negative at two of the occasions (Table 6).

Figure 2. Continued

Figure 3. Outcome on the Motor Activity Log, amount of use scale and quality of movement scale. Symbols: Forced use group (-----), Standard training group (----- ----).
The grip strength analysed by Grippit ratios between hands was observed to increase in both groups up to the 3-month follow-up (Table 5). Mean values improved from 0.44 to 0.61 in the forced use group and from 0.36 to 0.50 in the conventional group, from immediately prior to intervention to the 3-month follow-up. This indicated that grip strength of the paretic hand was still substantially impaired, with half of the patients remaining at a strength ratio of ≤0.50. Only 3 participants achieved a ratio exceeding 0.9, which is a level often reported as a maximum difference between hands in healthy people. An effect size of 0.80 at the 1-month follow-up, although lowering to 0.69 with the ITT analyses, both considered medium, was the highest effect size of all measures at that time (Table 6).

Results of capacity at the ICF level of activities and participation
The ARAT mean values improved from 43.7 to 51.0 points of the maximum 57 in the forced use group and from 47.3 to 51.6 in the conventional group, from immediately prior to intervention to the 3-month follow-up (Table 5). Effect sizes were both small and negative at post-intervention and 1-month follow-up, but medium at the 3-month follow-up, achieving the largest effect size of any measure on that occasion (Table 6).

The MAS-UE improved from 10.1 in both groups to 12.5 and 12.3 of the maximum 18, respectively (Table 5). Effect sizes were mostly small, and also negative at two of the occasions (Table 6).
Table 5. Change scores during the forced use trial presented as the mean changes within groups (mean and SD) and the mean differences in changes between groups (mean and 95% CI) over 2 time intervals; during intervention, and from pre-intervention to the 3-month follow-up.

<table>
<thead>
<tr>
<th>Measure (range)</th>
<th>Forced use group</th>
<th>Standard training group</th>
<th>Difference in change between groups (mean (95% CI))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change during intervention (n=13)</td>
<td>Change from pre-intervention to 3-month follow-up (n=15)</td>
<td>Change from pre-intervention to 3-month follow-up (n=14)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fugl-Meyer Assessment (0-66)</td>
<td>3.8 (3.0)</td>
<td>5.2 (4.1)</td>
<td>1.8 (2.9)</td>
</tr>
<tr>
<td>16-hole peg test, paretic hand</td>
<td>-42.0 (52.8)</td>
<td>-38.1 (48.6)</td>
<td>-15.6 (36.4)</td>
</tr>
<tr>
<td>Grippit ratio, paretic/non-paretic hand</td>
<td>0.06 (0.10)</td>
<td>0.19 (0.12)</td>
<td>0.03 (0.07)</td>
</tr>
<tr>
<td>Action Research Arm test (0-57)</td>
<td>5.0 (8.0)</td>
<td>8.2 (9.2)</td>
<td>5.3 (7.0)</td>
</tr>
<tr>
<td>Motor Assessment Scale, sum score upper limb (0-18)</td>
<td>1.6 (3.0)</td>
<td>2.2 (2.4)</td>
<td>1.8 (1.8)</td>
</tr>
<tr>
<td>Motor Activity Log, amount of use score</td>
<td>0.60 (0.41)</td>
<td>1.03 (0.78)</td>
<td>0.37 (0.31)</td>
</tr>
<tr>
<td>Motor Activity Log, quality of movement score</td>
<td>0.62 (0.37)</td>
<td>0.92 (0.74)</td>
<td>0.23 (0.32)</td>
</tr>
</tbody>
</table>

*The variable change was analysed both with the t-test for independent groups and with ANOVA. The p-value presented here is for ANOVA. Abbreviations: SD, standard deviation. n, number. CI, confidence interval. ANOVA, analysis of variance.
Results of performance at the ICF level of activities and participation

The MAL-AOU improved for the forced use group by 0.6 points during intervention and by 1.0 point from pre-intervention 2 to the 3-month follow-up. The conventional group improved by 0.4 and 0.9, respectively (Table 5). The effect size of MAL-AOU was at its largest at post-intervention at 0.74, 0.48 with ITT, considered medium and small respectively (Table 6). The clinically important change level of 0.5 points on MAL was not reached between-groups at any time.

The MAL-QOM improved similarly, with the forced use group gaining 0.6 points during intervention and 0.9 from pre-intervention 2 to 3 months. The conventional group improved 0.2 and 0.9, respectively (Table 5). The effect sizes were large to small, but largest at post-intervention at 1.19, 0.94 with ITT (Table 6). This effect size was the largest among all measures, irrespective of time. This tendency for larger improvement at post-intervention in the forced use group compared to the conventional group was reflected in a statistically significant difference in change with t-test analysis (p=0.02 with Bonferroni correction), but this significance was eliminated in ITT and ANOVA analyses.

Table 6. Effect sizes between-groups in the forced use trial (paper I and II)

<table>
<thead>
<tr>
<th>Measure</th>
<th>At post-intervention</th>
<th>At 1-month follow-up</th>
<th>At 3-month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=28 ITT</td>
<td>n=26 ITT</td>
<td>n=26 ITT</td>
</tr>
<tr>
<td>Fugl-Meyer Assessment</td>
<td>0.68 0.50</td>
<td>0.21 0.21</td>
<td>0.12 0.11</td>
</tr>
<tr>
<td>Modified Ashworth Scale, sum score upper limb</td>
<td>0.20 0.13</td>
<td>0.49 0.44</td>
<td>0.01 0.00</td>
</tr>
<tr>
<td>16-hole peg test, paretic hand</td>
<td>0.72 0.57</td>
<td>0.48 0.42</td>
<td>0.32 0.28</td>
</tr>
<tr>
<td>Grippit ratio, paretic/non-paretic hand</td>
<td>0.57 0.31</td>
<td>0.80 0.69</td>
<td>0.44 0.23</td>
</tr>
<tr>
<td>Action Research Arm test</td>
<td>-0.04 -0.13</td>
<td>0.12 0.25</td>
<td>0.50 0.56</td>
</tr>
<tr>
<td>Motor Assessment Scale, sum score upper limb</td>
<td>-0.10 -0.22</td>
<td>-0.54 -0.46</td>
<td>0.13 0.00</td>
</tr>
<tr>
<td>Motor Activity Log, Amount of Use score</td>
<td>0.74 0.48</td>
<td>0.37 0.26</td>
<td>0.15 0.06</td>
</tr>
<tr>
<td>Motor Activity Log, Quality of Movement score</td>
<td>1.19 0.94</td>
<td>0.36 0.20</td>
<td>0.07 0.06</td>
</tr>
</tbody>
</table>

Abbreviations: ITT, Intention-to-treat analysis.
Responsiveness and construct validity (Paper III)

Responsiveness
During the 2 weeks of intervention, the index of ES (Table 7) was moderate (0.51 and 0.54), but from pre-intervention to the 3-month follow-up it was high (1.02 and 1.17), while the index of SRM was high (1.03 to 1.28) during both time intervals. Nonetheless, the RR was high, especially for the follow-up interval (2.44 and 2.68), where it also exceeded the threshold of 1.96.215

Table 7. Responsiveness of the Motor Activity Log over 2 time intervals; during the 2 weeks of intervention and from pre-intervention to 3-month follow-up

<table>
<thead>
<tr>
<th>Measure</th>
<th>Time interval</th>
<th>Effect size</th>
<th>Standardized response mean</th>
<th>Responsiveness ratio</th>
<th>Effect size</th>
<th>Standardized response mean</th>
<th>Responsiveness ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAL-AOU</td>
<td>During intervention</td>
<td>0.51</td>
<td>1.28</td>
<td>1.22</td>
<td>1.02</td>
<td>1.14</td>
<td>2.44</td>
</tr>
<tr>
<td>MAL-QOM</td>
<td>From pre-intervention to the 3-month follow-up</td>
<td>0.54</td>
<td>1.03</td>
<td>1.23</td>
<td>1.17</td>
<td>1.19</td>
<td>2.69</td>
</tr>
</tbody>
</table>

Abbreviations: MAL, Motor Activity Log. AOU, amount of use scale. QOM, quality of movement scale.

Construct validity
Cross-sectional validity was determined by the relationship between the MAL (AOU and QOM respectively) and the measures of motor function (Table 8). At pre-intervention all correlations were significant and fair to moderate (−0.41 to −0.44 for the 16HPT, and 0.45 to 0.53 for the other measures), but $r^2$ was from 17% to 29%. At post-intervention correlations were fair (below 0.50) and mostly lower than at pre-intervention. Six of the ten correlations were significant, and $r^2$ was 5% to 23%. At the 3-month follow-up correlations were fair to moderate (−0.64 to −0.67 for the 16HPT and 0.32 to 0.54 for the other measures) and mostly significant again. The MAL relationships (both AOU and QOM) with 16HPT at the 3-month follow-up were the highest correlations among all meas-
Responsiveness and construct validity (Paper III)

During the 2 weeks of intervention, the index of ES (Table 7) was moderate (0.51 and 0.54), but from pre-intervention to the 3-month follow-up it was high (1.02 and 1.17), while the index of SRM was high (1.03 to 1.28) during both time intervals. Nonetheless, the RR was high, especially for the follow-up interval (2.44 and 2.68), where it also exceeded the threshold of 1.96.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Time interval</th>
<th>Effect size</th>
<th>Standardized response mean</th>
<th>Responsiveness ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAL-AOU</td>
<td>During intervention</td>
<td>0.51</td>
<td>1.28</td>
<td>1.22</td>
</tr>
<tr>
<td>MAL-QOM</td>
<td>From pre-intervention to the 3-month follow-up</td>
<td>0.54</td>
<td>1.03</td>
<td>1.23</td>
</tr>
</tbody>
</table>

Table 7. Responsiveness of the Motor Activity Log over 2 time intervals; during the 2 weeks of intervention and from pre-intervention to 3-month follow-up

Abbreviations: MAL, Motor Activity Log. AOU, amount of use scale. QOM, quality of movement scale.

Construct validity

Cross-sectional validity was determined by the relationship between the MAL (AOU and QOM respectively) and the measures of motor function (Table 8). At pre-intervention all correlations were significant and fair to moderate (−0.41 to −0.44 for the 16HPT, and 0.45 to 0.53 for the other measures), but \( r^2 \) was from 17% to 29%. At post-intervention correlations were fair (below 0.50) and mostly lower than at pre-intervention. Six of the ten correlations were significant, and \( r^2 \) was 5% to 23%. At the 3-month follow-up correlations were fair to moderate (−0.64 to −0.67 for the 16HPT and 0.32 to 0.54 for the other measures) and mostly significant again. The MAL relationships (both AOU and QOM) with 16HPT at the 3-month follow-up were the highest correlations among all measures (−0.64 and −0.67), with \( r^2 \) reaching 44%, compared with the other measures of \( r^2 \) ranging from 10% to 29%.

Longitudinal validity was determined by the relationship between the change scores of the MAL and the change scores of the measures of motor function (Table 9). During the 2 weeks of intervention, the correlation of change on MAL with change on FMA-UE was moderate to good (0.44 and 0.67) and significant, with \( r^2 \) for AOU at 19% and QOM at 45%. The other correlations, though, were weak to fair (0.05 to 0.34) and not significant. During the longer time interval, from pre-intervention to the 3-month follow-up, the change correlations with FMA-UE and MAS-UE were fair to moderate (0.39 to 0.53) and significant, and \( r^2 \) was 28% for MAS-UE to MAL-AOU. On the other hand, the change correlations with ARAT, 16HPT, and Grippit ratio were weak (−0.07 to 0.26) and not significant. Overall, change correlations were weaker than the correlations at the separate test occasions, except for FMA-UE.
Table 8. Cross-sectional Spearman correlations between the scores of the Motor Activity Log AOU and QOM and the scores of the motor function measures

<table>
<thead>
<tr>
<th>Function Measures</th>
<th>Motor Activity Log AOU</th>
<th>Motor Activity Log QOM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Correlation coefficient.</td>
<td>p-value</td>
</tr>
<tr>
<td>(a) At pre-intervention (n=30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA-UE</td>
<td>0.52</td>
<td>0.003†</td>
</tr>
<tr>
<td>ARAT</td>
<td>0.50</td>
<td>0.005†</td>
</tr>
<tr>
<td>MAS-UE</td>
<td>0.53</td>
<td>0.002†</td>
</tr>
<tr>
<td>16-hole peg test, paretic hand</td>
<td>-0.44</td>
<td>0.014*</td>
</tr>
<tr>
<td>Grippit ratio</td>
<td>0.53</td>
<td>0.002†</td>
</tr>
<tr>
<td>(b) At post-intervention (n=28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA-UE</td>
<td>0.43</td>
<td>0.022*</td>
</tr>
<tr>
<td>ARAT</td>
<td>0.23</td>
<td>0.237</td>
</tr>
<tr>
<td>MAS-UE</td>
<td>0.41</td>
<td>0.031*</td>
</tr>
<tr>
<td>16-hole peg test, paretic hand</td>
<td>-0.30</td>
<td>0.119</td>
</tr>
<tr>
<td>Grippit ratio</td>
<td>0.45</td>
<td>0.016*</td>
</tr>
<tr>
<td>(c) At the 3-month follow-up (n=26)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA-UE</td>
<td>0.43</td>
<td>0.030*</td>
</tr>
<tr>
<td>ARAT</td>
<td>0.51</td>
<td>0.007†</td>
</tr>
<tr>
<td>MAS-UE</td>
<td>0.52</td>
<td>0.007†</td>
</tr>
<tr>
<td>16-hole peg test, paretic hand</td>
<td>-0.64</td>
<td>0.000‡</td>
</tr>
<tr>
<td>Grippit ratio</td>
<td>0.41</td>
<td>0.038*</td>
</tr>
</tbody>
</table>

* = p < 0.05.
† = p < 0.01.
‡ = p < 0.001.

Abbreviations: AOU, amount of use scale. QOM, quality of movement scale. FMA-UE, Fugl-Meyer Assessment, upper extremity. ARAT, Action Research Arm Test. MAS-UE, Motor Assessment Scale, upper extremity.
Table 9. Longitudinal Spearman correlations between the change scores of the Motor Activity Log AOU and QOM, and the change scores of the motor function measures

<table>
<thead>
<tr>
<th>Function Measures</th>
<th>Motor Activity Log AOU</th>
<th>Motor Activity Log QOM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Correlation coefficient</td>
<td>p-value</td>
</tr>
<tr>
<td>(a) During 2 weeks of intervention (=28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA-UE</td>
<td>0.44</td>
<td>0.020*</td>
</tr>
<tr>
<td>ARAT</td>
<td>0.34</td>
<td>0.072</td>
</tr>
<tr>
<td>MAS-UE</td>
<td>0.12</td>
<td>0.535</td>
</tr>
<tr>
<td>16-hole peg test, paretic hand</td>
<td>-0.23</td>
<td>0.231</td>
</tr>
<tr>
<td>Grippit ratio</td>
<td>0.18</td>
<td>0.363</td>
</tr>
<tr>
<td>(b) From pre-intervention to 3-month follow-up (n=26) (≈28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA-UE</td>
<td>0.39</td>
<td>0.048*</td>
</tr>
<tr>
<td>ARAT</td>
<td>0.22</td>
<td>0.279</td>
</tr>
<tr>
<td>MAS-UE</td>
<td>0.53</td>
<td>0.006†</td>
</tr>
<tr>
<td>16-hole peg test, paretic hand</td>
<td>-0.20</td>
<td>0.332</td>
</tr>
<tr>
<td>Grippit ratio</td>
<td>0.26</td>
<td>0.197</td>
</tr>
</tbody>
</table>

* = p < 0.05  
† = p < 0.01  
‡ = p < 0.001

Abbreviations: AOU, amount of use scale. QOM, quality of movement scale. FMA-UE, Fugl-Meyer Assessment, upper extremity. ARAT, Action Research Arm Test. MAS-UE, Motor Assessment Scale, upper extremity.
Test-retest intra-rater reliability (Paper IV)
The 18 participants recruited (14 men and 4 women) had sustained a stroke 2 to 25 weeks earlier (median 9.5). The mean age was 54.9 years (SD±5.7; range 38–63). Hemiparesis was right-sided in 13 patients and left-sided in 5. All but 3 had pre-morbid right hand dominance, according to self-report, and 12 had their paresis in the dominant hand.

The results of test occasion 1 for the 18 patients are presented in Figure 4 to give a visual impression of the variability, which was clearly much wider between subjects than within subjects, in both hands. Regarding systematic errors, calculations showed no learning or fatigue effect during measurement, although MVC tended to be lower on the second occasion in both sides at all three trials (Table 10). These differences, however, were non-significant (p>0.05). There were no significant differences between the means of the three trials (p>0.05), although

Figure 4. Results of test occasion 1 in the test-retest study of grip force (paper IV). Individual line plots of peak values at the three trials, n = 18, paretic and non-paretic side respectively.
the means tended to decrease successively in the paretic hand. The difference between sides was approximately 100 N (p≤0.001).

Table 10. Grip force at each of three trials, recorded on two occasions with an interval of one hour (n = 18); peak values (N = newton)

<table>
<thead>
<tr>
<th>Occ</th>
<th>Hand</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>P</td>
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<td>100-504</td>
<td>274</td>
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Abbreviations: Occ, occasion. P, paretic side. NP, non-paretic side. SD, standard deviation.

Within-session reliability of MVC, repeatability
The coefficient of repeatability (C_{R-within}) was around 55 N in the paretic hand and 43 N in the non-paretic hand. Corresponding values of CV_{within} (the within subject coefficient of variation) were 11% and 5%, respectively. Values were similar on both occasions independent of the hand. This implies that for the paretic hand a difference in the same session needs to be more than 55 N to exceed the measurement error and to be called a true difference in 95% of the observations. Expressed by CV_{within} the measurement error was 11%.

Test-retest reliability, reproducibility
For the paretic side, C_{R-between} was 48 N when calculated with the mean of the three values and 55 N when calculated with the highest values. C_{R-between} for the non-paretic side was 45 N and 48 N, respectively. The coefficients of variation (CV_{within}) were similar with either method: for the paretic side 9.8 and 10.4%, and for the non-paretic side 5.9 and 6.0%. This implies that for the paretic hand a change from one occasion to another needs to be more than 48 N to detect a genuine change in grip force in 95% of the observations. Expressed by CV_{within} the measurement error was 10% in the paretic hand and 6% in the non-paretic.
Ratios between hands and forces
The mean ratio between the paretic and the non-paretic hand was 0.67 (SD±0.37) at occasion 1, and 0.66 (SD±0.35) at occasion 2. Ratios ranged from 0.07 to 1.29 with a total of 5 ratios exceeding 1.0, representing the paretic side as stronger than the non-paretic.

The mean ratios between sustained grip force and peak grip force were bilaterally similar. In the paretic side, this mean ratio was 0.80 (SD±0.08) at both occasions and ranged 0.66–0.90. In the non-paretic side, it was 0.82 at occasion 1, and 0.84 at occasion 2 (SD±0.06 and 0.09, respectively), ranging 0.59–0.93.
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**DISCUSSION**

**Discussion of results**

**Effectiveness of forced use (Papers I, II)**

The rationale for these investigations was to transfer the idea of restraining the unaffected arm after stroke into a clinical environment in order to evaluate whether this model could be favourable for patients without costing extra therapy-staff time. Could we better facilitate motor recovery for sub-acute patients during hospital rehabilitation? Treatment effectiveness was determined in two separate domains: optimal motor ability, as evoked on request in clinical motor tests, and actual spontaneous use of the more affected upper limb in a real world setting. Both the forced-use group and the conventional group demonstrated improvements in both domains, but no between-group differences could be detected.

Generally, there have been many promising results for CIMT, along with much, diverse scientific literature reporting on CIMT issues. A zero result, however, has been reported from other authors for all of the acute, sub-acute, and chronic phases.

Comparison with results of other research reports is difficult since several design differences occur. One issue is the recovery phase after stroke (acute, sub-acute, or chronic), with some studies including a mixture of patients in sub-acute and chronic phases. Time since onset of stroke has been reported as important to any intervention study. Another issue is the intervention approaches compared, each research group make their own set up. In addition, measurements, follow-up times, and selection of moderately or severely motor-impaired patients included differ from study to study.

The participants (Paper I, II) had compromised but residual ability in the affected arm and well-preserved cognition. Results from other studies performed with similar patients in sub-acute stage may appropriately be compared with ours. Present results support those of Brogardh et al, where the experimental group wore a restraining mitt on the non-affected hand 90% of their waking hours, but patients in both groups showed similar improvements following arm and hand training 3 hours per weekday. The largest study, EXCITE, compared classic CIMT in an experimental group to a control group receiving no or much less intervention, and reported significant improvements in the CIMT group. Myint et al reported on mCIMT with patients exclusively in sub-acute phase and found it superior to equivalent doses of conventional therapy on MAL and motor...
studies, no clear-cut heterogeneity of evidence has been presented. Despite several intervention for participants with varying chronicity, but the control group improved up to 6 months and the group difference disappeared. Despite several studies, no clear-cut heterogeneity of evidence has been presented.

Several reasons may explain why the present study did not achieve larger improvements in the forced-use group than in the conventional group. First, the contrast of interventions between the groups may not have been large enough. The mean restraining time was only 37.4 of targeted 60 hours (~ 62%), and the total amount of training time was similar in both groups. This may have been too little to produce a significant difference. Training content cannot be compared, and the design did not claim only upper limb training, so training was probably divided between lower limb-, balance-, and upper limb-training. Compared with the beneficial study results of Page et al, where less intense training and restraint were used for 10 weeks, the present duration of a lower intensity may have been too short.

Second, the small sample size could have shadowed a significant result (type II error). This possibility is, however, improbable given that effect sizes from ITT analyses were generally small and the magnitude of between-groups differences was not clinically important.

Third, if a behaviour contract had been used, as is included in recent definitions of forced use, a more pronounced effect might have been seen. This component is however a component of the classic CIMT approach, and it has only recently received more emphasis.

Despite these possible explanations to the ‘zero result’, the size of score improvement, 1.0 on MAL over study time, is actually similar to studies from different recovery stages, both sub-acute and chronic. Similar improvement in both study groups (Paper I, II) may imply that standard rehabilitation was adequately designed to help people after stroke improve substantially. Notably though, as per common practice, therapists in the present study encouraged all patients to be active and to use their affected side as much as possible. Additionally, the theory of learned non-use and the approach of CIMT is now well known by therapists. Even some patients knew about the approach of CIMT because it has been publicly exposed in daily papers and television.
Even though the critical elements of CIMT have been inconclusively investigated, the really new component of the concept was, and is, the restraint. The protocol for classic CIMT\textsuperscript{135} points out the importance of a physical restraint as a reminder to limit the use of the unaffected limb. A sling or a mitt is an obviously more substantial marker than no physical restraint for the facilitation and encouragement of arm exercise and use,\textsuperscript{242} probably having an influence not only on the patients, but also on therapists and others encountering the marked ‘forced’ patient.

The issue of labelling an intervention performed is somewhat challenging. When the present study was initiated, CIMT was presented only in the classic version,\textsuperscript{207} as opposed to the earlier descriptions of forced use.\textsuperscript{144, 240} The intent of this thesis was to add the restrictive sling to ongoing rehabilitation, and the author did not think this would qualify her to use the term ‘CIMT’ because the intervention was neither intensified nor focused exclusively on the upper limb. Therefore, ‘forced use’ was felt as a more appropriate label for the present intervention.

**Responsiveness and construct validity (Paper III)**

Responsiveness and construct validity of MAL was investigated for patients in the sub-acute phase after stroke. As expected, MAL showed moderate to high responsiveness over time intervals of active rehabilitation in a sample of participants qualifying for a forced use trial. The MAL is intended to assess daily activities in this selected and motivated population of patients after stroke, those who are also able to perceive and self-rate their variable daily hand use. In other populations, the MAL might not be an appropriate measure. The present results support the use of MAL as a responsive measure in the sub-acute phase. To the knowledge of the author, such support for MAL has not previously been reported, even though the measure has been used in most trials in the sub-acute phase.\textsuperscript{12, 37, 53, 139, 149, 241, 243, 248}

More unexpectedly, the MAL had fairly weak correlations with the traditional tests of arm and hand function. Most cross-sectional correlations were close to 0.50, and only 16HPT reached correlations of −0.64 and −0.67 at the 3-month follow-up. Of the measures used, 16HPT may place the most demands upon coordination, dexterity, and endurance.\textsuperscript{227} A properly functioning and useful hand require precision, as Sunderland and Tuke proposed,\textsuperscript{203} spontaneous use may be determined by the relative ease of moving the limb. Even fewer of the longitudi-
The measurement errors of Grippit defined in this thesis were identified as acceptable and similar for both hands as well as within and between sessions. A clinician could use these coefficients of repeatability and reproducibility to be confident of whether or not a true change has occurred in a stroke patient’s grip strength. The Grippit instrument can be recommended for stroke patients in a rehabilitation setting even though the size of the measurement error requires rather large changes to register. The error seemed quite high in both arms, but it was similar to error in healthy persons. 114 Similar indices of absolute reliability have been reported in other studies of stroke patients measured with other grip strength devices. 30, 46

The choice of a randomised design was appropriate since it was anticipated that effectiveness of forced use (Papers I, II) would not be influenced by recovery after stroke, such as functional status, sex, age, side of stroke, and other potential factors which may influence recovery after stroke, such as functional status, sex, age, side of stroke, and other potential factors which may influence recovery after stroke. The ratio of grip strength between hands in a stroke sample obviously depends on the severity of the stroke, albeit the most impaired cannot produce any grip strength at all, so in those cases such a ratio cannot be calculated. In the present study these ratios were wide-ranging within the sample (mean 0.66 SD±0.35), mirroring the heterogeneity of patients’ grip force. Participants in the RCT in this
thesis (Paper I) had a more affected and less heterogeneous grip strength at pre-intervention (mean 0.40 SD±0.26) than did the people in the reliability study (Paper IV).

The ratios between peak force and sustained force suggest that stroke weakness affects both equally, since both hands had similar ratios and these ratios were close to those of healthy people.¹⁴²

**Methodological issues of the studies performed**

**Effectiveness of forced use (Papers I, II)**

The choice of a randomised design was appropriate since it was anticipated that all patients in a sub-acute setting would make significant functional improvement as a result of interdisciplinary rehabilitation services, spontaneous recovery, and participation in a study explicitly studying arm motor improvement. Since selection bias is prevented by randomisation,⁵, ²¹ requirements for reporting RCTs have been developed and defined by the CONSORT document (Consolidated standards of reporting trials).¹³³ One merit of randomisation is the assignment of subjects to different conditions, thereby allotting different known and unknown prognostic variables randomly between groups of patients. Factors that may influence recovery after stroke, such as functional status, sex, age, side of stroke, time since stroke onset, were comparable between the present study groups. The randomisation was performed after the decision to include a patient. A limitation of present randomisation, since the block random procedure was not varied by block size, was that the researcher who recruited patients was the same person who retained the list of allocations, so by end of a block it would have been possible to predict group assignment. If the study was redone, the allocation to groups should be concealed and performed using a computer randomisation programme. Next to a randomised design, a blinded assessor is regarded as the gold standard in outcome trials to prevent assessment bias,⁵, ²¹, ¹³³ but resources did not allow blinding in this study. A non-blinded assessor collected data; however, this did not seem to have favoured the forced use group. Neither patients nor therapists could have been blinded, and this is a reality in most physiotherapy trials.¹⁸, ⁶⁰

Participants were recruited 1 to 6 months post stroke. This target group was chosen not only because it had not been investigated in earlier studies of CIMT or forced use, but also because these patients are often still involved in rehabilitation and may therefore be more available. Convenience sampling as opposed to consecutive sampling was used in present studies. Consecutive sampling is con-
considered a more appropriate method to detect all eligible patients, and to produce a sample as representative as possible of the intended population.\textsuperscript{21, 60} However, the resources needed to screen every stroke patient, even at one single hospital, were not available. Screening takes considerable resources and a low recruitment rate may be the result of strict inclusion criteria involved in CIMT trials. For instance, the EXCITE study screened 3.626 patients, of whom only 222 were randomised, a 6.1\% ‘enrolment ratio’ from 247 facilities at 7 sites over 24 months,\textsuperscript{23} and the VECTORS study screened 1.853 patients and found 52 to randomise; a 2.8\% ‘enrolment ratio’.\textsuperscript{63}

Which stroke patients would be appropriate for CIMT, mCIMT, or forced use has been discussed.\textsuperscript{33, 210} Various measures of motor function have been used to decide upon inclusion,\textsuperscript{185} but arm and hand motor function are not the only deciding factors in eligibility to CIMT approaches. There are several other functions to consider, such as balance, language, and cognitive deficits. The patients in this thesis could be labelled as higher functioning according to the motor inclusion criteria.\textsuperscript{134, 207, 208, 240} However, the results on the 16HPT, Grippit ratio, and MAL certainly represented substantial deficits of motor function, justifying additional interventions, e.g., forced use or CIMT approaches.

Notably, women in the present sample were fewer than anticipated, at only 23\%. Among those considered for participation but not included, 38\% were women. The total number of Swedish registrations of stroke onset is almost equal between sexes,\textsuperscript{170} but the incidence is highly related to age, and men have their stroke ~ 5 years earlier than women.\textsuperscript{10, 170} Consequently, the low rate of women may be explained by the mean age of 63 in present sample. Nevertheless, the EXCITE study recruited 36\% women,\textsuperscript{241} and the VECTORS study 60\%,\textsuperscript{63} both with patients similar in age to those in present study. The 19 trials of CIMT and forced use recently summarised had enrolled 37\% women.\textsuperscript{185} Questions we need to consider are: Do we tend to offer demanding approaches, like CIMT or forced use, more often to men? Is discharge from rehabilitation units more hurried in women? And if so, is this due to staff decisions or due to social preferences from the women themselves? Additionally, the women included in present study tended to be unevenly distributed between groups. In any case, the small study sample made it impossible to compare outcomes between men and women, which would otherwise have been interesting.

Since the actual aim was to evaluate forced use in the standard clinical environment, a pragmatic perspective was taken and the training was not controlled.
The time recorded for training was similar between groups, but content in training was not measured for similarity between groups, which may have introduced systematic bias between groups. But as Morris et al.\textsuperscript{135} pointed out, many facets of motor interventions make recording of training very challenging: the chosen activity or task, the progression of levels of difficulty, duration and intensity, feedback methods, movements emphasised, and interactions between the therapist and the patient, such as coaching, encouragement, and modelling. Also, the study was designed to be performable in the actual clinical environment at the site. Since the participants had several needs in rehabilitation training, and resources were limited, the classic CIMT regime with 6 hours per day of individual training directed at the affected arm could not be applied. In addition, when comparing the total amount of training time between the departments involved, a statistically significant difference was found between 32.2 vs. 22.5 hours (t-test p = 0.003), which reflects the implications that differences in resources and organization have on intense rehabilitation interventions.

Several reasons may explain why the targeted constraint time was not achieved; the mean sling use was ~ 62% of the targeted 6 hours per day. The most important factor, however, was that all but one of the patients in the forced use group who completed the intervention were outpatients. The only participant fulfilling the sling intervention as an inpatient achieved the highest value for sling use, 58 hours in 10 days. Patients were to wear the restraint only during hospital time, not at home. A day at one of the outpatient units was seldom as long as 6 hours, and the clinical resources could not be extended to 6 hours per day for most study participants. Resources were, however, extended for several participants due to the study, with postponed discharge, increased intensity, or both during the 2 intervention weeks (extension from 2–3 to 5 days per week). Another less important explanation for the shorter constraint time was the interruption of sling use during two-handed activities. Consideration while planning the study was also given to the strain patients may experience from long-time restrictions in this sub-acute phase, as was later reported.\textsuperscript{22, 148, 162} Larger demands on participants may have reduced recruitment as well as increased the risk for drop-outs.

Outcomes were examined with several measures in terms of three levels of motor function (impairment, activity/capacity, and activity/performance) as per the ICF.\textsuperscript{247} Patient burden may not have allowed more measures, but other areas of interest were not investigated. First, the state of pain was not specifically fol-
lowed in present thesis. Supporting clinical experience, pain is reported as a frequent problem in the more general stroke population, which has deep long-term impact on patients’ lives. A subset of patients participating in the EXCITE study had relatively low pain, and pain did not increase during the 2 weeks of CIMT; similar findings were reported by Ploughman and Corbett.

Another very interesting area of study would be patient experiences of forced use. Considering the many CIMT publications, reports on this issue are stunningly scarce. One description of patients’ own experience of training with lower-limb CIMT has recently become available, with informants reporting the training as tough, but also absolutely necessary for achieving functional gains. It gave them knowledge of their bodies, and their functional improvements gave them hope for further progress, which increased their independence and self-esteem. Boylstein et al made in-depth ethnographic field observations in a context of CIMT sessions, and interviewed therapists and participants with an emphasis on their interactions. The patterns of social interaction found were: 1) coaching (teaching proper technique), 2) ‘cheer-leading’ (offering praise and encouragement), 3) reminding (e.g., of the mitt use according to the behavioural contract), 4) changing (modifying a task) and, 5) contemplating (assessing and communicating progress). The findings indicate that regardless of how controlled the therapy environment is during an experimental protocol, human interaction between therapists and participants is a major component of CIMT and, of course, people are different. The authors concluded that people who participated in CIMT routinely balance any improvement against the cost of using an affected limb that is still not fully functional. Gillot et al explored the perceptions and described the experiences of two participants in CIMT home programs. Both participants believed that formal rehabilitation had ended before many achievable functional gains had been accomplished. Divergence of pre-CIMT expectations was reported. One respondent expected “remarkable results”, but was disappointed to some degree when resulting improvements were slow, effortful, and incomplete; the other respondent “decided to participate to see whether improvements could still occur” and his motivation to carry out CIMT appeared to increase as he made functional gains, but he also had a decrease in satisfaction with his performance, reflecting his increased expectations of his own functional ability. These qualitative findings represent important aspects, not identified in results of formal outcome studies, that may greatly influence the ongoing process of rehabilitation and recovery.
Outcome measures

Several measures of motor function representing different constructs in the ICF were used.\textsuperscript{118, 247} Therefore, it is highly unlikely that an effect would have been missed. However, there were certain problems connected with the measures used, and two of the measures were more thoroughly investigated than the others.

Five measures with ordinal rating scales were used. Several measures are designed to produce sum scores from different items, or from sub-sums of groups of items. The total score is interpreted in relation to the maximum score of the trait measured. Methodological concerns and apparent advantages of sum scores have been presented.\textsuperscript{132} Timed scores have been presented as objective, straightforward, and more sensitive to change over time than ordinal measures.\textsuperscript{177, 227}

**FMA-UE** was early reported to reflect changes in people after stroke with severe, moderate, or mild deficits.\textsuperscript{56} The participants in this thesis were all well in the upper half of the score range at pre-intervention, so there was a chance of ceiling effects, even though no one achieved the maximum score of 66. Improvements were steady and occurred continuously with very few declines in score. The FMA-UE was definitely an accurate measure, but due to the risk of ceiling effect more sensitive measures should be used to complement it.

**The Modified Ashworth Scale** has frequently been criticised and its validity and value are widely questioned, but it is nevertheless used in several studies.\textsuperscript{153, 227} The inclusion criteria required a low level of spasticity, and if the scores had increased throughout intervention, they could have been viewed as an index of an adverse event – increased spasticity. In that sense, the Modified Ashworth Scale was not an outcome measure able to show improvement from the forced use intervention.

**The 16HPT** left room for improvement in all participants’ scores and was therefore a sensitive and valuable measure. But if patients had been slightly more impaired, it would have been impossible for them to perform the test, indicating a floor effect. The 16HPT scores showed heterogeneity within the groups, making group differences difficult to discover, and there is to the knowledge of the author no suggestion in the literature for minimal clinically important differences (MCID) in peg tests.

**The Grippit** instrument was analysed by the ratio of strength of the paretic to the non-paretic hand. The Grippit ratio improved for most participants, but results show that few affected hands become as strong as the non-affected hands.
Grippit could detect low grip strength scores, which could not be detected by the Jamar instrument. 127 This would make the Grippit instrument suitable for measuring the various grip strengths in patients after stroke. Grip strength has been reported to be sensitive and to have no ceiling effect. 36, 202, 227 The scores of present participants supported these findings, showing room for improvement in all participants, which shows it to be a valuable measure.

Questions have been raised, especially in regard to peg tests and grip strength measures, about whether to perform one or more trials, and whether to use the mean or the best of several trials in an analysis. 114 People with neurological deficits may not be able to optimize their performance in dexterity or strength tests at the first trial due to impaired sensory and motor function. This possible fluctuation in ability makes it relevant to use more than one trial and to use the maximum value for comparison. 204

The ARAT showed ceiling effects with 6 participants scoring the maximum of 57 at both pre-intervention tests. At the 3-month follow-up 7 additional participants achieved the maximum score. The ARAT scores showed somewhat more dramatic score changes than the FMA-UE. The larger gains over study time reached 10 to 32 points, but large decreases of 7 to 25 points from one occasion to the other were also seen. The ARAT was not appropriate for effect detection in the present study.

The MAS-UE did not seem sufficiently sensitive due to different ceiling effects. The maximum item score of 6 points was achieved by 6 and 7 participants respectively on the items ‘upper extremity function’ and ‘hand movements’ at pre-intervention 2. This represented ≥20% of the sample, which demonstrates a ceiling effect. 11, 176 The third item, ‘advanced hand activities’, proved difficult for participants to achieve more than a score of 2 on. Inconsistencies in the scoring hierarchy for these items have been reported. 58, 165, 174

Data for the validity and reliability of the MAL were limited at study start. However, it was the best available measure and some reports on measurement properties later became available. 222, 224, 233 The MAL is discussed at length in the other sections, but further aspects of the measure warrant mentioning here. No floor or ceiling effects were present for MAL in the sample, where only 3 of 30 participants had a pre-intervention score >2.5. This measure definitely reflects other and more difficulties than FMA-UE and ARAT, whose scores were gathered in the upper third of the scale ranges. There is the challenge of subjectivity with MAL, as with all self-report measures, and patients need to be able to per-
ceive and self-rate their daily hand use. Patients’ answers may be influenced by experiencer bias, or by difficulties in interpreting the true meaning of the score or item description, or by inaccurate recall. Several comments made by patients in the present study pointed out these areas. Moreover, some patients in both groups noted that the measure per se helped them to get ideas about tasks for the affected hand, which could also have prompted the use of that hand.

**Responsiveness and construct validity (Paper III)**

Between-session changes are the context for outcome measurements. Responsiveness is thus essential for instruments designed to measure change over time. Unfortunately, there is no complete agreement on the most appropriate method for quantifying responsiveness. Therefore, three different aspects were reported in this study. The magnitudes of the different indexes are interpreted in the same way, which has been pointed out as problematic. The three indexes are all independent of sample size, which strengthens present results since a moderate sample size was used. As the methods used were distribution-based, the clinical importance of the changes is not defined. The MAL is probably limited to use in similar circumstances for a population with moderate motor problems and preserved cognitive abilities. A stable group for calculation of the RR was not easy to find in the literature, since several measurement values are reported within intervention studies. Thus, the control group may be stable only in untreated chronic patients. Regarding the sub-acute phase after stroke, MAL has shown a slight increase of scores during a 2-week control period and such scores are not proper to include in an RR analysis.

The relation between the MAL and the measures of motor function were of interest. A repeatedly reported pattern of moderate to low correlations between them is surprising, but rather convincing. These results, as well as the present, suggest that the underlying constructs of daily hand use and the conventional measures of motor function are somewhat different, even though reports of strong correlation in the chronic phase after stroke are available. Moreover, reports of relationship between self-reported and objective measures of arm use show conflicting results, so there is yet no definite picture of these relations. An accompanying and larger problem with MAL is the scarce reporting regarding content validity, which analyses whether the items in the scale comprehensively represent the concept, and consider the severity of disease. Issues of item generation and item selection, in particular, are absent in reports
on MAL. Items in a scale must reflect areas that are important to the target population that is being studied, and comprise representative samples of the concept of concern, e.g. ‘daily hand use’. At comparison, the items covered by ABILHAND have been identified as more complex, bilateral tasks, than those covered by MAL. There is a continued need to investigate psychometric properties of measures evaluating upper limb function after stroke, especially measures focusing on daily hand use.

**Test-retest intra-rater reliability (Paper IV)**
The reliability of a measurement is influenced by many factors, including the sources of variability studied, the subjects selected, and the range of scores exhibited by the sample. Reliability of an instrument should be determined using the individuals on whom the instrument will be used in practice.

Improvement of functions over time was expected in a sub-acute rehabilitation setting. The one-hour interval between testing was established to minimize the effect of a possible spontaneous recovery, a confounding variable that could affect the result of reliability. In order to reflect clinical practices where testing occurs within therapy sessions, testing took place during an actively scheduled day at the unit.

The choice for evaluating reliability of grip strength was more than threefold. First, the Grippit instrument had long been used in clinical duty at the rehabilitation departments in the present hospital, and it had also been included for evaluation of effect in the randomised trial (Paper I). For these reasons, it was important to scrutinize the instrument. Second, training and measuring strength in general have long been controversial issues in stroke rehabilitation. Views have gradually changed, and measurement and training of strength are now regarded as clinically relevant. Last, the choice was also supported by methodological considerations, including the level of data produced from the instrument, i.e. numerical data, making it appropriate for parametric analysis using ANOVAs to calculate the coefficients. The patient burden was also judged as acceptable for a short test that could be repeated three times at each of two occasions just one hour apart. Moreover, the Grippit instrument is probably suitable for testing stroke patients since the test position is fixed.
**General discussion**

**Effects and measures – interdependence**

Using different measures and different cut-off points will affect the interpretation of study outcomes. Measurement is an integral part of both research and clinical documentation. Effect and measurement are each other’s prerequisites. Sufficient study validity depends on accurate measurement procedures to make valid comparisons of results among studies. Differences in administration may affect treatment outcomes. For instance, concerns have been raised regarding the variability of scoring in the ARAT, in particular the difficulty of differentiating both the scores 1 and 2 and the scores 2 and 3. In the present study, the use of one single assessor and standardised measurement procedures and equipment was arranged to minimize threats to internal validity. The EXCITE trial evaluated the procedures of testing and training in the trial extensively, including scoring each of the study personnel. This immense quality assurance effort used a 90% adherence criterion and a feedback and correction procedure, which supported the validity of the conclusions of that multi-site project.

Information from one single measure was believed to be too limited, so seven different measures were chosen: FMA-UE, Modified Ashworth Scale, 16HPT, Grippit ratio, ARAT, MAS-UE, and MAL. One reason to use several measures is that no measure is considered the ‘gold standard’ in the field of upper limb function after stroke. To cover different dimensions of arm and hand function in one or a few ‘ideal’ measures is also difficult. Functional, patient-related outcomes on the ICF levels of body function, activity, and participation should be the primary choice when generating evidence for rehabilitation interventions. A comprehensive description of arm and hand function was needed to be able to capture the presumed improvements while minimizing the risks of floor and ceiling effects of the various measures.

**Recruitment problems, sample size, and other obstacles conducting a controlled trial in a clinical setting**

The recruitment rate in this single-centre study was slow for several reasons. Many patients fell below or exceeded the inclusion criteria, which included not being discharged from rehabilitation. Some patients did not wish to participate (because of the daily intensity or reluctance to use the sling), which was respected. Practical issues, including nursing vacancies on the stroke ward, staff vacations, staff changes, and the competing duties of the researcher, had a part in
slowing recruitment, as did obstacles in the health care organization, which prevented prolonged stay or participant referrals from other hospitals.

An important issue contributing to the slow recruitment rate was the requirement of daily training, but this was a necessary and crucial issue throughout this clinical study. Among the 34 patients “not eligible after initial discussion with therapists”, the problem of arranging training 5 days per week was common. Many patients also are discharged from inpatient care within the first month after stroke, and there is a pressure for shortening lengths of stay, limiting those patients available for recruitment. As discussed above, the clinical set-up in outpatient day care units rarely offers daily training. Had the criteria of daily training not been settled before inclusion, more patients would likely have dropped out.

Sensory function was required for inclusion, but several participants had more or less impaired sensory function. Generally, sensory feedback is seen as critical to movement control, and patients with sensory deficits have greater difficulties in achieving motor function recovery than patients with preserved sensory function. Interestingly though, patients with sensory disorders in another study of forced use therapy achieved larger clinically relevant improvements than the ones in regular therapy. Conversely, however, a retrospective analysis of the EXCITE data found that patients with impaired proprioception had only 20% of the probability of success of those with intact proprioception. The present sample was too small to make such subgroup analysis, and the problem of reliably assessing sensory function would make such analysis difficult.

Domholdt says sample sizes in clinical studies of about 30 participants per group enable valid generalizations to be applied to the larger population and meet assumptions for particular statistical tests. Larger samples may also be more representative of their parent population. Power analyses were performed retrospectively using pre-intervention values from the own sample (Paper I, II) and published estimates of clinically important differences. The ARAT had been reported with 5.7 points and the MAL with 0.5 points for MCID. To have a power of 80% for finding these MCIDs between the study groups, inclusion of 58 and 64 people in each group, for ARAT and MAL respectively, would have been necessary. The participants were sub-acute and moderately impaired, and SDs from the literature might be based on other cohorts/samples. Despite the several inclusion criteria restricting the recruitment basis, the present sample was nevertheless, to some extent heterogeneous, which was seen in the wide confidence intervals, standard deviations, and inter-quartile ranges in some measures. This variability
may have contributed to the difficulties in proving a benefit for the most appropriate patients. Moreover, there is still the general problem of finding ‘clinically relevant changes’ in the literature for different measures, and such values are necessary to inform a power analysis. Well over ten years ago, MCIDs were even more unavailable, and the issue of sample size calculations was not focused in rehabilitation and physical therapy literature to the extent it is now.

**Learned non-use?**

"He can but does he?" was the title of a critical investigation published 30 years ago, when patients were found not to perform on the same activity level at home as at the day care hospital. This was in line with the theory on learned non-use introduced somewhat later. The learned non-use theory presumes that patients have a capability that is not used because of a learnt behaviour with non-use of the paretic hand. A continued problem is the inability to assess objectively the presence or severity of learned non-use. The real world is much more complex than the environment at the training centre, and real life activity cannot be measured with a ‘laboratory motor test’. This may explain why the patient cannot make use in everyday life of his paretic hand, which may still be weak, poorly coordinated, lacking speed, and unreliable. The patient may use his function optimally, but the theory of learned non-use suggests that he does not. There is no validated method to diagnose learned non-use in humans. All the same, the aim of improving arm function and daily use of the hand after stroke is important enough that the theories should not prevent efforts to bring about recovery. Because spontaneous use of the affected limb may rely on the relative ease of its movement, improving impaired motor control and transferring trained capability to the daily environment are challenges that deserve much careful attention. Such a process would therefore be one of reinforcement of learned use rather than an extinction of learned non-use.

But the larger questions remain: When, for whom, with how much intensity, duration, and repetitions, and with what type of training or restraint or combination of the two will improvements in body function, capacity, and daily use of the upper limb be best accomplished post stroke? The answers will emerge through several studies, since one study can hardly examine all of the interconnected facets. The present thesis is believed to contribute to the knowledge base concerning forced use in the CIMT concept.
The present results did not support the hypothesis that forced use therapy is superior to equal doses of conventional therapy in a sub-acute setting. No significant differences were found between the groups on the seven outcome measures covering physical motor functions and daily hand use. The study participants were moderately impaired and results may be generalisable only to people with similar levels of cognitive and motor function after stroke. Based on the present findings, it would not be appropriate to perform a larger similar study. This preliminary evidence does not support adding forced use of the paretic arm to a clinical routine, since application of a restraining sling on the non-paretic arm did not promote better recovery in the context of ongoing conventional rehabilitation at reasonable intensity.

One major finding was that the conventional measures of impairment and disability did not tell us much about the real world outcome, which was self-rated by patients with the MAL, a specific measure of daily use of the paretic hand. The MAL seemed to be a responsive measure of daily hand use in patients participating in active rehabilitation in a sub-acute setting. Moderate correlations of the MAL with the other measures indicate that daily hand use may need to be measured separately from physical motor function tests, which is in accordance with the ICF classification that suggests measurement on all levels of functioning.

The Grippit instrument can be recommended for measuring grip force in appropriate patients in the sub-acute phase after stroke. Although the measurement error of 10% or 50 N was considerable, this level of error was similar to results in healthy people.

The present findings support the clinical use of the MAL and the Grippit instrument, and suggest the use of different measures for physical motor functions and daily hand use.

The participants in these studies formed a small but representative sample of patients who have recently sustained a stroke, have moderately impaired arm function, and participate in active rehabilitation. To strengthen the findings of the present thesis, studies of the MAL and Grippit should be repeated in larger samples of similar patients.
CONCLUSIONS AND CLINICAL IMPLICATIONS

The present results did not support the hypothesis that forced use therapy is superior to equal doses of conventional therapy in a sub-acute setting. No significant differences were found between the groups on the seven outcome measures covering physical motor functions and daily hand use. The study participants were moderately impaired and results may be generalisable only to people with similar levels of cognitive and motor function after stroke. Based on the present findings, it would not be appropriate to perform a larger similar study. This preliminary evidence does not support adding forced use of the paretic arm to a clinical routine, since application of a restraining sling on the non-paretic arm did not promote better recovery in the context of ongoing conventional rehabilitation at reasonable intensity.

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Future research
There is a need to further examine the importance of different aspects of intensity, both in training and in restraint in upper limb rehabilitation after stroke. It is still difficult to draw a definite conclusion as to whether restraint improves use of the paretic hand, given that the patient groups compared performed fairly extensive and active training of similar durations, amounts, and content. Improved design details, such as the randomisation to groups being concealed through a computerised procedure and the use of a blinded assessor, are among many other considerations that should be taken into account when planning and performing a sound clinical trial of rehabilitation and physiotherapy interventions.

As CIMT approaches are frequently studied for outcomes, patient experiences of the performance of, and the perceived impact from, these interventions need to be investigated.

Clinically relevant changes for different measures of upper limb function after stroke are very important and urgently need to be defined, both for research and clinical purposes. Judging the effects of interventions, consuming research as a clinician, and informing power calculations while planning studies, are some areas of interest.

While there are plentiful reports on the measurement properties of FMA, MAS, and ARAT, there is a lack of specific reports on the responsiveness and usefulness of measures of grip force and dexterity after stroke.

The MAL warrants further investigation regarding its content validity, including clarifications of the construct ‘daily hand use’ and of the correspondence of items selected in the measure to environmental demands in normal daily activities. A measure needs to be a complete, but also an accurate, representation of the construct of concern.

Collaboration between researchers in different, but closely related, upper limb areas would probably be beneficial. Patients after stroke, with a unilaterally impaired hand and arm, have problems using that hand. Children with hemiparetic cerebral paresis have a similar situation of impaired hand use, and a clinically rated measure with a focus on the affected hand use has been developed.70,91 Also, for people with an upper-limb reduction deficiency, or amputation, the application of a myoelectric prosthetic hand has focused on the ability and use of that hand. Measures for that intervention have recently been developed.88 All these interventions are intended to make people as two-handed as possible. The use of
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SVENSK SAMMANFATTNING (Swedish summary)

"Forced use" för armfunktion efter stroke. Kliniskt bedömda och självrapporterade resultat samt mätmetoder i subakut fas.

Bakgrund


Teorin om learned non-use, dvs inlärd ickeanvändning, har inom strokerehabilitering använts som grund för träningsmetoden Constraint-induced movement therapy (på svenska kallat CI-terapi). Teorin antar att patienter tillägnar sig en inlärd överkompensation genom att använda sin "starka" hand till vardagsuppgifter trots att motorisk funktion med tiden delvis återkommer i den drabbade armen. CI-terapi förhindrar den "starka" armen att vara aktiv samtidigt som intensiv träning utförs med den drabbade armen. Träningsmetoden har fått mycket uppmärksamhet inom sjukgymnastik och rehabilitering runt om i världen, men diskussion pågår emellertid om metodens effektivitet och vad som är den verkliga komponenten. Tidigare resultat har ofta varit positiva men ändå inte enstaka.

Forced use innebär att förhindra den "starka" armens funktion, t ex med en slynga, som enda förändring av standardterapin. Detta fanns inte tidigare utvärderat i studier med randomiserad design, och inte heller i subakut skede efter stroke.

För att utvärdera behandlingsinsatser som syftar till att optimera förmågan att använda den drabbade handen efter stroke krävs det specifika test, och dessa ska vara giltiga och pålitliga (reliabla och valida). Vid litteraturgenomgång identifierades vita luckor kring olika instrument. Motor Activity Log (MAL) är ett nyutvecklat instrument som syftar till att utvärdera hur patienter efter stroke använder sin påverkade hand i dagliga aktiviteter och detta instrument behövde ytterligare...

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terligare valideras. Måttelet vid greppkraftmätning efter stroke behövde undersökas för att underlätta tolkning vid användning i klinik och forskning.

**Det övergripande syftet** med denna avhandling var att hos patienter i subakut skede efter stroke utvärdera effekterna av forced use på motorisk funktion samt förmåga i arm och hand, och på användningen i vardagsaktiviteter. Syftet var också att undersöka vissa psykometriska egenskaper hos några av mätmetoderna inom detta område.

**Metod**


*Delarbete III:* Data från delarbete I och II användes för att beräkna mätegenskaper hos Motor Activity Log. Detta innefattade att undersöka känsligheten för förändring (responsiveness), samt begreppsvärdet, vilket dels innebar att beräkna sambandet för Motor Activity Log med testen för motorisk funktion och förmåga vid respektive mät tillfälle men också longitudinellt.


Studierna är genomförda vid Universitetssjukhuset Örebro.
Resultat

Delarbete I: Motorisk funktion och förmåga hade förbättrats i arm och hand både direkt efter behandlingsperioden och vid 3-månadersuppföljningen jämfört med före behandlingen, men inte mer av forced use än av traditionell träning. Medelvärdet förbättrades statistiskt signifikant i båda grupperna från strax före interventionen till 3-månadersuppföljningen enligt följande: Fugl-Meyer test från 52 till 57 poäng av maximala 66; Motor Assessment Scale från 10.1 till 12.4 poäng av maximala 18; pinnprovet från >92 sekunder till 60 sekunder; och handstyrketestet från 0.40 till 0.55 (kvoten mellan den drabbade och ”starka” handen). Spasticitet enligt Modified Ashworth scale var oförändrat låg under studietiden.

Delarbete II: Båda behandlingsgrupperna ökade sin självskattade förmåga att använda den hemiplegiska handen i vardagliga aktiviteter över tid med cirka 1 poäng på Motor Activity Log, men inga säkerställda skillnader mellan gruppernas utveckling fanns. En tendens kunde ses att forced use-gruppen erhöll större förbättring under behandlingsperioden, men detta kunde inte säkerställas helt, och den lilla skillnaden hade jämnats ut till 3-månadersuppföljningen.

Delarbete III: Motor Activity Log visades vara känsligt för förändring. Index för responsiveness (känslighet för förändring) var med olika beräkningssätt mellan 0.51 och 2.69. Sambanden mellan Motor Activity Log och testen för motorisk funktion och förmåga var starkare vid respektive mätfällen än longitudinellt. Vid respektive mätfällen var sambanden måttliga, ofta cirka 0.50 eller något lägre, och det högsta sambandet fanns vid 3-månadersuppföljningen mellan Motor Activity Log och pinnprovet ($r_s = -0.64$ och $-0.67$). Det longitudinella sambandet var svagare, ofta med $r_s$-värden 0.30 eller lägre. Tydligast var sambandet med Fugl-Meyer sensomotoriska test ($r_s = 0.39-0.67$).

Delarbete IV: Mätning av greppkraft med Grippit tycktes vara ett tillförlitligt och reproducierbart mätinstrument i subakut skede efter stroke även om patienternas prestationer var något mer variabel i den paretiska handen än i den ”starka”. Det krävdes en ändring med 10 % eller 50 newton av greppkraften i den paretiska handen för att överskrida mätfelet inom och mellan respektive mätfällen. Kvoten mellan den drabbade och ”starka” armen var 0.66 och kvoten mellan uthållighet och maximal kraft var 0.80-0.84.

Sammanfattningsvis visar de randomiserade behandlingsstudierna i denna avhandling att ett speciellt behandlingstillägg med forced use inte gav större effekt än traditionell behandling på arm-handfunktion hos personer i subakut skede efter stroke. Detta mättes upp till 3 månader efter behandlingen. Därtill visades
att Motor Activity Log mäter ett fenomen som tycks något skilt från de traditionella testen av motorisk funktion och förmåga, och att instrumentet var känsligt för förändring. Därutöver visades att koefficienterna för upprepbarhet och reproducerbarhet med Grippit var acceptabla. Detta underlättar för kliniker och forskare som ska mäta handfunktion då det ger en vägledning för differentiering mellan faktiska förändringar och mätfelet. Slutsatserna får dras med viss försiktighet då de studerade patientgrupperna var måttligt stora.

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This study was carried out in the Departments of Rehabilitation Medicine, Geriatrics, and Neurology at the Örebro University Hospital, Sweden, and at the School of Health and Medical Sciences, Örebro University, Sweden.

I could not have completed this thesis on my own. I wish to express my warmest gratitude to all those who have helped and supported me throughout this work. I sincerely appreciate all of you who have stood beside me through the years, who contributed to this work, encouraged me to continue with the project, and supported me in so many different ways. My special gratitude goes to:

All the participants in the studies for giving so much of your time and effort;

All the physical therapists and other staff members from the departments involved, for their assistance with recruiting participants and implementing the studies, as well as for their supportive interest, cooperation, and assistance throughout the study;

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