Getting up when falling down

Reducing fall risk factors after stroke through an exercise program

Eva Holmgren
"If I have the belief that I can do it, I shall surely acquire the capacity to do it even if I may not have it at the beginning."

Mahatma Gandhi
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ABSTRACT

Falls can lead to serious consequences that can affect everyday life. While the risk of falling is larger for older people than for the general population, older people with stroke have a doubled risk of falling compared to a matching age population without stroke. Injuries and fractures can result from a fall, but with or without these possible consequences, the fall can in itself lead to fear of falling and thereby result in restriction/avoidance of activities. It is therefore of great importance to identify the potential faller before the fall occurs.

The purpose of this thesis was to identify fall risk stroke victims (over 55 years of age) by validating a fall risk index, and to evaluate the impact of an intervention program on fall risk factors in post-stroke individuals with high risk of falls.

A previously developed fall risk index was validated, modified, and re-validated, resulting in a sensitivity of 97% and a specificity of 26%. However, this outcome was not considered sufficiently accurate; the score was significantly associated with fall risk, but the suggested labeling of individuals as low-, intermediate-, and high-risk groups could not be confirmed. Therefore, a modified index was created in the Validation sample and re-validated with the Model fit sample. This modified index was reduced to three (from the original seven) items and included postural stability, visuospatial hemi-inattention, and male sex. This modified fall risk index displayed better accuracy in both the Validation and Model fit samples.

The intervention program contained High-Intensity Functional Exercises (HIFE) as well as implementation of these exercises in real life situations and group discussions on fall security. The participants were enrolled and randomized three to six months after their stroke. The time point permitted the first spontaneous recovery to occur, allowed the participants to have enough time to experience their own everyday situations at home, and provided time to reflect on the everyday situation and its possible problems. Individuals with stroke diagnoses were pre-screened for participation during their inpatient rehabilitation time. The assessments at 3-6 months after stroke onset (at the time of study inclusion) were performed at the Clinical Research Center at Norrlands University Hospital. The assessments prior to study inclusion included measures relevant to the various fall risk factors previously identified.

The measurements in this intervention included; balance, activities of daily life (ADL), falls–efficacy, lifestyle activities, health-related quality of life (HRQoL), presence of depressive symptoms, functional lower-limb strength, and gait. Medical history and other relevant background data were obtained from medical records and from the participants directly. This study was a single blinded, randomized controlled trial (www.clinicaltrials.gov NCT00377689). The Intervention Group (IG) received a program of 30 exercise sessions and five theoretical group
discussions and the Control Group (CG) received a total of five theoretical group discussions. The CG’s discussions differed from the IG’s discussions, in that they were more focused on addressing various hidden dysfunctions that often occur after a stroke and how to master the situation.

Twenty-six falls were documented during the follow-up after the intervention, but there were no significant differences in fall frequency between the IG and CG.

The intervention program demonstrated an improvement in the IG in ADL at the six month follow-up (p<0.05 by generalized estimating equations with repeated measure statistics). Falls-efficacy also improved in the IG compared to the CG at the three month follow-up (p<0.05) and also at the six-month follow-up (p<0.03). The intervention program did not generate a statistically significant impact on Balance or Lifestyle activities.

Statistically significant (p<0.05) improvements were observed in the IG vs. the CG post intervention compared with baseline in double support time for the non-paretic leg (DSTnp), variability (measured as coefficient of variation, COV) in step time for the paretic leg (STCOVp) and the non-paretic leg (STCVnp), and in variability in cycle time for the paretic (CTCOVp) and non-paretic leg (CTCOVnp); at 3-months follow-up compared with baseline improvements were observed in DSTnp, STCOVp, CTCOVp and CTCOVnp, and DSTCOVp compared to baseline. At 3-months follow-up, the decrease in the STCOVnp and the variability in step length of the non-paretic leg (SLCOVnp) were more pronounced in the CG than in the IG.

For HRQoL, the SF-36 mental component scale (SF-36 MCS) and the SF-36 subscale of mental health (MH) at the 3 month follow-up registered an improvement in the CG compared with the IG (p<0.02). There were no significant differences between the two groups regarding the presence of depressive symptoms.

In conclusion, the intervention program was related to improvement in ADL at 6 months, falls-efficacy at 3-6 months follow-up, and reduced variability in gait at post-intervention and 3-months follow-up. However, the intervention program did not affect balance and lifestyle activities. Based on the findings of HRQoL aspects, we suggest that the intervention programs’ theoretical discussion in the future also contain the dysfunction topics discussed in the control group, in order to positively impact the psychological segment of the rehabilitation process. By reducing fall risk factors, the fall risk for some stroke victims could potentially be decreased, and thereby stimulating a more independent and active lifestyle.
SVENSK SAMMANFATTNING

Ett fall kan leda till allvarliga konsekvenser som kan påverka vår vardag. För äldre personer är risken att falla större än för övriga i befolkningen. För en äldre population är risken för att råka ut för ett fall dubbelt så stor efter stroke, jämfört med personer i samma ålder som inte haft stroke. Konsekvenser efter ett fall kan vara skador som blåmärken, skrapsår etc. eller mer allvarliga i form av t.ex. traumatiska hjärnskador eller frakturer. En annan konsekvens kan vara att fallet för med sig en rädsla för att falla igen. Denna rädsla kan ofta leda till att man begränsar och undviker aktiviteter.

Det är viktigt att kunna känna igen de som är i riskzonen för att falla innan själva fallet inträffar. Syftet med den här avhandlingen var att identifiera individer med en fallrisk efter stroke genom att validera ett fallriskindex och att hos dessa individer med risk för att falla, över 55 år, även utvärdera effekterna av ett träningssprogram.

Ett index för att lätta på att identifera fallare har tidigare utvecklats. Detta har i denna avhandling testats, modifierats och återtestats. Det modifierade indexet minskade till tre (från de ursprungliga sju) variabler och dessa var: postural stabilitet + halvsidigt synfältsbortfall + manligt kön. Det modifierade indexet visade sig vara mer precis i både den nya gruppen av individer samt i ursprungsgruppen.

Funktionella övningar utförda i hög intensitet samt överföring av dessa övningar till vardagliga rörelser och aktiviteter. Detta, tillsammans med gruppdiskussioner om fall och säkerhet utgjorde interventionsprogrammet som har utvärderats i den här avhandlingen. I den här studien (www.clinicaltrials.gov, NCT00377689) rekryterades deltagarna tre till sex månader efter sin stroke. Den här tidpunkten valdes för att tillåta den första spontana återhämtningen att ske och för att deltagarna skulle ha haft tillräckligt med tid för att uppleva sin egen vardags situation i hemmet samt att reflektera över eventuella problem som de upplever i vardagen. Samtliga rekryterade personer testades första gången 3-6 månader efter sitt insjuknande i stroke på Kliniskt Forsknings Centrum vid Norrlands Universitetssjukhus. De bedömningar som gjordes i denna studie var för; balans, aktiviteter i dagliga livet (ADL), förtroende till egen förmåga att inte falla, livsstilsaktiviteter, hälsorelaterad livskvalitet, förekomst av depressiva symptom, samt gångförmåga. Olika gångvariabler mättes med hjälp av en elektronisk gångmatta. Genomfört variabler som mättes var; hastighet, antal steg/minut, stegtid, gångcykeltid, tid för samtidigt stöd av båda benen, steglängd samt stegbredd. Sjukdomshistoria samt annan nödvändig information hämtades från medicinska journaler och från deltagarna själva.

Träningsgruppen (IG) deltog i ett program som innehöll 30 träningstillfällen samt 5 teoretiska gruppdiskussioner, sammanlagt 35 träffar. Kontrollgruppen (KG) deltog i sammanlagt 5 teoretiska gruppdiskussioner. KG:s diskussioner skilde sig från IG:s diskussioner då
KG's diskussioner var mer inriktade på att bemöta olika dolda funktionshinder som ofta uppstår efter stroke och hur man kan hantera dessa på ett bra vis.

Interventionsprogrammet visade på en förbättring för IG i ADL vid sex månaders uppföljning efter träningprogrammet. Förutom till sin egen förmåga att inte falla visade också en förbättring för IG jämfört med KG vid tre månaders uppföljning efter träningprogrammet och även vid sexmånadersuppföljningen. Interventionsprogrammet hade inte en tillräckligt hög godkänd effekt på balans eller på i vilken utsträckning deltagarna deltog i olika aktiviteter.

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**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADL</td>
<td>Activities of Daily Living</td>
</tr>
<tr>
<td>BBS</td>
<td>Berg Balance Scale</td>
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<td>BI</td>
<td>Barthel Index</td>
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<td>BP</td>
<td>Bodily Pain</td>
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<td>DI</td>
<td>Downton Index</td>
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<td>FAI</td>
<td>Frenchay Activities Index</td>
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<tr>
<td>FES-I</td>
<td>Falls Efficacy Scale International</td>
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<tr>
<td>FIM</td>
<td>Functional Independence Measure</td>
</tr>
<tr>
<td>GDS-15</td>
<td>Geriatric Depression Scale</td>
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<tr>
<td>GH</td>
<td>General Health</td>
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<tr>
<td>ICF</td>
<td>International Classification of Functioning, disability and health</td>
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<tr>
<td>MH</td>
<td>Mental Health</td>
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<tr>
<td>MMSE</td>
<td>Mini-Mental State Examination</td>
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<tr>
<td>OCSP</td>
<td>Oxfordshire Community Stroke Project classification</td>
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<tr>
<td>PF</td>
<td>Physical Function</td>
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<tr>
<td>RE</td>
<td>Role Emotional</td>
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<tr>
<td>RP</td>
<td>Role Physical</td>
</tr>
<tr>
<td>SF</td>
<td>Social Functioning</td>
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<tr>
<td>SF-36</td>
<td>Short Form Health Survey 36 questions</td>
</tr>
<tr>
<td>TOAST</td>
<td>Trial of Org 10172 in Acute Stroke Treatment classification system</td>
</tr>
<tr>
<td>VT</td>
<td>Vitality</td>
</tr>
<tr>
<td>SL</td>
<td>Step Length</td>
</tr>
<tr>
<td>SW</td>
<td>Step Width</td>
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<td>ST</td>
<td>Step Time</td>
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<tr>
<td>CT</td>
<td>Cycle Time</td>
</tr>
<tr>
<td>DST</td>
<td>Double Support Time</td>
</tr>
<tr>
<td>COV</td>
<td>Co-efficient Of Variation</td>
</tr>
<tr>
<td>p</td>
<td>paretic side</td>
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<tr>
<td>np</td>
<td>non-paretic side</td>
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### DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Activity</td>
<td>The execution of a task or an action by an individual [1]</td>
</tr>
<tr>
<td>Falls</td>
<td>Incidents in which the individual, due to unexpected loss of balance, came to rest on the floor or an object below knee level [2]</td>
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<tr>
<td>Function</td>
<td>Attributed to the body's ability to perform a movement</td>
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<tr>
<td>Functional activity</td>
<td>Fundamental task-oriented activities used in daily life</td>
</tr>
<tr>
<td>Gait</td>
<td>The pattern of movement of the limbs during locomotion</td>
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<tr>
<td>High Intensive</td>
<td>To do something at the limit of one's own ability</td>
</tr>
<tr>
<td>Older people</td>
<td>Age ≥60 years</td>
</tr>
</tbody>
</table>
ORIGINAL PAPERS

I  "Validation of a fall risk index in stroke rehabilitation"  (Olsson E, Löfgren B, Gustafson Y, Nyberg L. J Stroke Cerebrovasc Dis. 2005 Jan-Feb;14(1):23-8)


III  "What is the benefit of a High Intensive Exercise Program after stroke on Gait? - A Randomized Controlled Trial" (Holmgren E, Nordin E, Lindström B, Wester P. Manuscript)

INTRODUCTION

Falls are a common problem in the general population of older people and in the stroke population in particular. A fall can have different effects, ranging from just a small bruise to a hip fracture to a traumatic brain injury, or in the worst case, death. Investigations into the identification of risk factors for falls and fall risk indexes have been created and evaluated [3-13], but further action is required to prevent the expansion of this problem.

The focus of the present thesis is to describe the various impacts of a high intensive exercise program on fall risk factors in older people following stroke.

According to The Swedish Civil Contingencies Agency, every year at least 1400 deaths are attributable to accidental falls, and more than 70 000 individuals are treated in hospital each year. Nearly three times as many deaths result from accidental falls as from traffic accidents. Nine out of ten people who die from accidental falls are 65 years of age or older, as are nearly two-thirds of those treated in hospital after falling accidents [14]. An upward trend in these numbers, primarily for women, seems to be taking place. Additionally, an unknown number of deaths, perhaps a few thousand every year, may be due to the fact that many older people develop serious sequelae after a fall, as a result of traumatic brain injury, fractures, or other injuries. For example, if a lung embolism led to death more than a month after the accident, the fall is not registered as a cause of death [14].

The yearly direct costs to society of older peoples' accidental falls is estimated to amount to more than 4.7 billion SKR, equally divided between the county councils and municipalities [15]. The direct costs for counties and municipalities are predicted to increase from 4.7 to 7.9 billion SKR in the year 2035, this increase is due to a projected increase of 27% in number of people 65 years of age and older [15]. Indeed, a third of the world’s population in the developed countries will over 60 years of age by 2050, versus 19% in 2000 [16]. Ultimately, the number of people in Sweden over 65 who require care due to an accidental fall will increase from 42 000 to almost 70 000 per year over the next 30 years [14]. These figures illustrate the scale, and urgency, of this rapidly growing problem.
Falls as a consequence of a stroke
The risk of falling after a stroke is high compared to a non-stroke population [7, 8, 17, 18] and some studies have reported that the risk is twice as high [7]. A systematic review of complications after stroke shows that the incidence of falls varies between 2% - 25% in the acute to sub-acute stage [19]. Stroke contributes to the risk of fractures after a fall, increasing the risk up to 2-4 high among long-term stroke survivors [20].

Fall frequency in stroke rehabilitation has not been widely studied, but two studies have reported 580 falls per 100 person-years [21] and 650 falls per 100 person-years [12]. Estimates that 14% [18, 22] and 39% [21, 23] of people with stroke have had one or more falls during their hospital stay exist. Six months after discharge from hospital approximately three-fourths of stroke patients have fallen [17].

Stroke, a well known world-wide disease, is a generic term for infarction in the brain (about 85%), intracerebral hemorrhage (10%) and subarachnoid hemorrhage (~ 5%) [24]. It is the second largest cause of death around the world, in middle income countries it is the leading cause of death [25]. The number of stroke events in Europe are expected to increase from 1.1 million per year in 2000 to more than 1.5 million per year in 2025 solely due to demographic changes [26].

According to the Swedish National Register of Stroke, Riks-Stroke, 24,459 strokes (TIA excluded) were registered in their database in 2008 and 73% of these are first time ever stroke [24]. Riks-Stroke has a known ratio of registering 83% of all strokes that occurs [24]. When including strokes that have been missed, either because the patient may not have noticed them or they have not been recorded in RIKS-Stroke the estimated figure would end up at approximately 30,000. The corresponding figures from the Swedish National Board of Health and Welfare is 30,570 stroke events [27]. The risk of a stroke increases with age, approximately 80% of those affected are over 65 years of age [24]. Given the expected increase in population for this particular demographic group, the proportion of people with stroke will also increase.

With a stroke come several complications. Some complications occur directly, and some take time to identify. A 2008 study indicated that the most common complications in the acute stage were pain (23.9%), followed by temperature greater than or equal to 38 °C (23.7%), progressing stroke (18.4%), and urinary tract infection (16.0%). Non-serious falls accounted for 7.4% of reported complications, and deep venous thrombosis and serious falls were each present in at most 2.5% of patients. After three months, 82.4% of patients had experienced at least one complication, the most common of which were pain (53.3%), urinary tract infection (27.9%), and non-serious falls (25.0%) [28].

Fall risk factors after a stroke
In order to take pre-emptive action against stroke-induced falls, it is important to identify the potential fallers before the fall occurs. Several
Introduction

Fall risk instruments of varying quality are available but there is no golden standard in stroke rehabilitation since different situations require different instruments. Every individual must be analyzed individually according to his/her individual risk factors [29]. Widely used fall risk instruments are the Downton fall risk instrument [30] and the STRATIFY fall risk instrument [31]. Some studies have indicated that an experienced clinical judgment is as good as, or better, than an instrument [32, 33]. Fall risk factors must be addressed in order to improve mobility and to reduce fall frequency.

Known factors associated with increased risk of falls after stroke include:

- reduced mobility and poorer balance among fallers and recurrent fallers [6, 8, 12]
- gait deficits [34, 35]
- postural sway [11]
- unstable (near-falls) in hospital with poor upper limb function (unable to save themselves) [3]
- lower functional independence [12]
- lower arm, foot and leg motor scores [6, 12]
- the rate of rise in force in sit-to-stand movement [4, 5]
- increased motor response time to visual stimuli [9]
- rightward-orienting bias among right hemisphere stroke patients [13]
- attention deficits [34, 36]
- cognitive deficits [12]
- depressive symptomatology [6, 7, 13]
- falls related self-efficacy [37]

The interactions between risk factors, falls, and consequences of falls are many and they are summarized in Figure 1.
Rehabilitation

The World Health Organization defines rehabilitation as follows: “Rehabilitation of people with disabilities is a process aimed at enabling them to reach and maintain their optimal physical, sensory, intellectual, psychological and social functional levels. Rehabilitation provides disabled people with the tools they need to attain independence and self-determination [38].” Physical activity is associated with a decreased risk of morbidity and all-cause mortality; inactivity is a major risk factor. Three principles have been identified to achieve an effective rehabilitation after stroke: functional approach targeted at specific activities (walking, activities of daily living), frequent and intense practice, and rehabilitation commencement in the first days or weeks after stroke [39]. Community rehabilitation therapy delivered within one year of hospital discharge has been shown to prevent functional deterioration and at least maintain ADL [40]. However, the optimal setting for community rehabilitation has yet to be explored [40]. Medically stable patients with mild or moderate impairment can complete initial rehabilitation in their

Figure 1. Interactions between fall risk factors, falls and consequences of falls.
home environment if a multidisciplinary team with stroke expertise is employed [40]. This conclusion is also supported by the Swedish National Board of Health and Welfare (2009), which states that medically stable patients with mild to moderate impairment may benefit from home-based rehabilitation delivered by a multi-disciplinary rehabilitation team. The team should include physiotherapists and occupational therapists with access to doctors, nurses, speech therapists, and counselors who are specially trained in stroke, and are in close contact with the stroke unit that meets regularly to discuss the patients [41].

Physical therapy
Physical therapy is an important part of rehabilitation after stroke. The Physical Therapists’ (PT) strategies are designed to retrain motor control in order to regain functional movement. The strategies can include changing a movement, increasing the capacity to move, or both [42]. In physical therapy, the critical task is to identify both normal and abnormal movement patterns. With this knowledge it is possible to create a program of specific tasks designed to achieve better motor control and functional movement. However, a movement emerges from the interaction between the individual, the task, and the environment in which the task is being carried out. Thus, the result of the movement is due to a three-way relationship among perception, cognition, and action systems [42]. Physical activity, particularly exercise, is a way to achieve better motor control and functional movement.

Exercise in older people
Regardless of whether a decline in functional capacity results from a normal aging process or from a disease, it is logically followed by frailty and dependence. Physical activity is one intervention that may reduce the number of years of dependent living [43]. There is little support that general leisure activities reduce the odds of dependent living for older adults [43], but routine exercise that improves cardio-respiratory fitness, including walking, does reduce the risk of becoming dependent in later life [44]. Progressive resistance training (PRT) results in improvements in muscle strength in older individuals [45]. Physical activity, particularly strength training [46], has been found to be effective in reducing the incidence of falls in older people [46, 47]. The American College of Sports and Medicine (2009) states that the effect of exercise on physical performance is poorly understood and does not seem to be linear [48]. Resistance training has been shown to favorably impact walking, chair standing, and balance, but more information is needed to understand the precise nature of the relationship between exercise and functional performance [48].

The American College of Sports Medicine (2009) recommends resistance exercise for older adults at a frequency of at least 2 days per week and an intensity of moderate- (5–6) to vigorous- (7–8) intensity on a scale of 0 to 10. This strategy involves 8–10 exercises of 8–12 repetitions each involving the major muscle groups, including stair climbing and other
strengthening activities [48]. A 2007 review recommended moderately vigorous cardio-respiratory activities (brisk walking), strength and (or) power training for maintenance of muscle mass and specific muscle-group performance, "balance-mobility practice," and flexibility (stretching) exercise for older adults to regain and maintain functional capacity and independence [44].

Exercise in older people with stroke
The effects of exercise on death, dependence, and disability after stroke are unclear [49]. There is adequate evidence to support the incorporation of cardio-respiratory training, involving walking, within post-stroke rehabilitation in order to improve speed, tolerance, and independence during walking [49]. High-intensity PRT can improve muscle strength and muscle endurance after stroke [50].

Task-specific repetitive exercises have a central role in rehabilitation for motor impairments, leading to improvements in transfer ability and balance [51]. There has been some debate whether increased strength also results in improved activity; some strengthening studies may show a carry-over effect on activity [52]. It is recommended that strength training, preferably with functional tasks and intensive training, should be part of every stroke rehabilitation program [51-53].

The time aspect
What is the optimal timing of rehabilitation after stroke? Is early or late training after stroke superior? There is no consensus on what “early” means in terms of hours/days. The European Stroke Organization reports studies that define “early” as therapy that begins within 30 days [54] and 20 days [55] of stroke onset [40]. The AVERT study (A Very Early Rehabilitation Trial, 2008) began therapy within 24 hours of ictus [56]. The results are not conclusive, but they tend to recommend early onset of rehabilitation as superior to later training [57]. Experiments in mice also tend to show a beneficial effect of early training after stroke [58]. Physical therapy is often administered soon after stroke. The Swedish National Guidelines for Stroke Rehabilitation conclude that early mobilization of stroke patients is not dangerous, and that comprehensive stroke unit care experiences support of early mobilization, activation, and training [41].

Most motor recovery occurs within the first three months, plateauing at six months, with more cognitive than physical improvement after three months [59]. Positive effects on activity through increasing strength have been demonstrated, accompanying recommendations that strengthening exercises be incorporated in rehabilitation during the first six months [52]. Functional activity was found to be greater for those who received training in the acute phase (less than six months) following stroke. However, improvements were observed even after the first six post-stroke months, but not to the same extent. While these results have been
supported by numerous studies [53], it has not been possible to support the impact of strength exercises on increased activity.

**International Classification of Functioning, disability and Health, ICF**

In this thesis, the International Classification of Functioning, disability and Health (ICF) has been used to classify the various outcome measures [1]. The ICF consists of two parts, functioning and disability. Functioning is a concept that includes all body functions, activities and participation. Disability encompasses impairments, activity limitations and participations restrictions. Functioning summarizes non-problematic, neutral aspects of health while disability summarizes problems such as; impairment, activity limitations or participations restriction. Both components contain information about bodily functions and structures, as well as environmental and personal factors.

**Where is the gap?**

The American College of Sports Medicine and the American Heart Association Guidelines (2007) currently recommend balance exercise for individuals who are frequent fallers or for individuals with mobility problems. However these associations admit the lack of adequate research evidence to describe specific frequency, intensity, or type of balance exercises for older adults at risk of falls [60].

While it is generally agreed that identifying risk factors in order to prevent post-stroke falls is critical, very few studies have addressed the mechanism by which falls in stroke patients may be prevented. More intervention studies are needed to reach a consensus regarding the ideal fall risk preventive intervention. The results from studies in progress, together with existing knowledge and this thesis, will hopefully shed light on this globally growing dilemma.

The main outcome of most previous studies has been the fall risk factors, not the actual prevalence of falls. One study attempted to describe the motivation behind movement rehabilitation: task-specific training has the potential to drive brain reorganization toward more optimal functional performance. The author emphasized the importance of incorporating the validated training methods most likely to positively impact this process [61].

An intensive physical therapy (task-oriented) delivered to stroke patients in a massed-practice paradigm focused on functional mobility, such as ambulation and various upright static and dynamic balance tasks, but also addressed underlying impairments including limitations in strength and range of motion. Positive improvements were observed in laboratory measures of reactive balance control as well as clinical measures of anticipatory and steady state postural control [62].

A randomized controlled trial where participants were allocated to either an agility exercise group or stretching/weight-shifting exercise group,
demonstrated greater improvement in step reaction time and paretic rectus femoris postural reflex onset latency for the agility group. In addition, members of this group also experienced fewer induced falls on the platform [63]. Both groups improved postural reflexes, functional balance, and mobility, possibly leading to a reduction of falls in older stroke patients [63].

Regarding balance, individually prescribed exercise programs that included muscle strengthening and balance retraining were most beneficial for increasing balance and mobility [46]. Symmetrical body-weight distribution training may improve sit-to-stand performance and, consequently, decrease the number of falls by stroke patients [5]. Finally, the latest Cochrane review (2009) on physical fitness for patients with stroke emphasizes the need for more strength training trials, with non-exercise attention controls, long-term training, and follow-up [49].
RATIONALE AND AIMS

Accidental falls are a problem for the individual and for society, as has been elucidated by numerous studies. An accidental fall often leads to injury and/or fracture(s), and society incurs the cost for inpatient and outpatient care, home care due to the loss of independence for the individual, rehabilitation costs, etc. Individual cost may occur in the form of loss of income, reduced quality of life, and pain and suffering, also known as human value loss.

Accidental falls may have various underlying causes from different diseases. Individuals with stroke, as a group, have a doubled risk of falls compared with age-matched populations. There is not only one reason for an accidental fall, a fall after stroke is multifaceted with many known risk factors [3-9, 11-13, 34, 35, 37]. It is critical to find ways to prevent these accidental falls.

It is interesting to evaluate whether a training program specifically targeted to strengthen a variety of areas of functioning that can be affected after a stroke can have effects on previously identified risk factors. We wished to evaluate whether a training program specifically targeted to strengthen a variety of stroke-affected functional areas can impact previously identified risk factors. Therefore, we created an exercise-based intervention program that also contained fall information and education and included safety aspects. The idea was to strengthen functions such as strength, balance, and endurance, while giving individuals the opportunity to practice difficult but meaningful activities.

It was important to evaluate the training in more than just the physical and activity dimensions, such as balance and ADL. To be able to design future effective exercise programs that address as many risk factors as possible, the relationship between exercise type and functional effect must be determined. This training program was designed specifically for physical outcome measurements, but we also explored the effects such a program would generate in terms of level and presence of falls-efficacy, depression, and health-related quality of life (HRQoL). This knowledge may take us further in the development of training programs, in order to achieve the best possible outcome for stroke patients in preventing accidental falls.
Aims of the thesis

- To validate the predictive accuracy of a previously developed index (Paper I)
- To evaluate the impact of a high intensive exercise program on balance, ADL, lifestyle activities and falls-efficacy after stroke (Paper II)
- To evaluate the impact of a high intensive exercise program on gait after stroke (Paper III)
- To evaluate the impact of a high intensive exercise program on HRQoL and depression after stroke (Paper IV)
Methods

This thesis is based on two studies that have thus far resulted in one published article [64] and two accepted articles [65, 66] and one manuscript in progress. The first study (Paper I) was a validation of a previously developed fall risk index [64]. The second study was an Intervention study in Umeå, during 2005-2007 (Paper II-IV) [66]. (Table 1)

Study design
The study designs presented in this thesis are a cross-validation (paper I) and a randomized controlled trial (paper II-IV). The cross-validation study consisted of two samples, 158 participants from 1991/1992 (sample A) and 135 participants from 1997/1998 (sample B). The randomized controlled trial consisted of 34 participants (sample C) from 2005-2007 (Table 1 & 2).

<table>
<thead>
<tr>
<th>Paper</th>
<th>I</th>
<th>II, III, IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Cross-validation study</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Data collection</td>
<td>Assessments during first week of rehabilitation. Data collected from patients, their relatives, medical records and CT scans</td>
<td>Assessments and self-reported measures pre-intervention, post-intervention, three months and six months after intervention.</td>
</tr>
<tr>
<td>Setting</td>
<td>Geriatric rehabilitation ward</td>
<td>Out-patient center</td>
</tr>
<tr>
<td>Participants</td>
<td>158 and 135</td>
<td>34</td>
</tr>
<tr>
<td>Analysis</td>
<td>Descriptive statistics, Cox regression, Kaplan-Meier analysis and survival analysis</td>
<td>Descriptive statistics and repeated measures analysis</td>
</tr>
</tbody>
</table>

Ethical approval
In paper I all participants or their proxies signed an informed consent form during inpatient rehabilitation at the Geriatric Clinic, Norrlands University Hospital. Ethical approval was given by the Research Ethical Committee of the Medical Faculty of Umeå University (see 84/97, dnr 97-70). In paper II-IV, all participants signed an informed consent for study participation at the time of baseline and study inclusion. Ethical approval was given by the local Ethics Committee for Human Research at Umeå University (dnr 04-022).
Participants

The sample from which the original Fall Risk Index was constructed (sample A) included 135 individuals from 1991 to 1992. The sample used to validate the original Fall Risk Index (sample B) included 158 individuals from 1997 to 1998. Both samples consisted of patients consecutively admitted to a specialized geriatric stroke rehabilitation ward at Norrlands University Hospital during one year. The mean age in sample A was 76.4 ± 8.6 years, and in sample B it was 74.8 ± 8.9 years. Women represented 54% of sample A members, and 49% of sample B members (Table 2).

The sample in the Intervention study (sample C) included individuals consecutively admitted to the Umeå Stroke Unit at Norrlands University Hospital during the years 2005-2007. The mean age in sample C was 77.7 ± 7.6 years for the IG and 79.2 ±7.5 years for the CG. Women were nearly evenly distributed between the IG (40%) and CG (37%) groups (Table 2).

Procedure

Paper I: the Validation study

Participants in this study were included during their stay at a geriatric rehabilitation ward at Norrlands University Hospital from 1997 to 1998. All participants were assessed during their first week of stay at the geriatric rehabilitation unit. Medical histories and previous falls were registered from medical records, from the patients themselves, or from a family member/caregiver.

The inclusion criteria for this study were: cerebrovascular accidents or clinically similar conditions, and a requirement of further rehabilitation after the acute phase at the stroke unit. All patients who met the inclusion criteria were included after informed consent had been obtained either from the patients themselves or, for a few individuals, from their relatives. Patient characteristics are summarized in Table 2.

Exclusion criteria were: completely immobile and bedridden throughout their entire stay, with no locomotion efforts and no sign of rehabilitation potential. To match the original study, patients were studied for 8 weeks (56 days), from their admission to the geriatric rehabilitation unit up to their discharge or death. The patients were studied for a median period of 34.5 days (range 3 to 56 days).
Falls were defined as incidents when the subject, due to an unexpected loss of balance, came to rest on the floor or an object below knee height [2]. All falls that came to the study personnel’s attention during the study period were recorded on special fall-report forms. The fall risk index was then scored for each subject. All participating staff at the ward were blinded to the study protocol scores.

<table>
<thead>
<tr>
<th>Table 2. Study sample characteristics at inclusion in study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample I</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Sex (M/F)</td>
</tr>
<tr>
<td>Stroke classification</td>
</tr>
<tr>
<td>TOAST</td>
</tr>
<tr>
<td>- large artery thrombosis</td>
</tr>
<tr>
<td>- cardioembolic stroke</td>
</tr>
<tr>
<td>- lacunar infarct</td>
</tr>
<tr>
<td>- other specified stroke</td>
</tr>
<tr>
<td>- unknown stroke</td>
</tr>
<tr>
<td>- n/a</td>
</tr>
<tr>
<td>OCSP</td>
</tr>
<tr>
<td>- total anterior cerebral syndrome</td>
</tr>
<tr>
<td>- partial anterior cerebral syndrome</td>
</tr>
<tr>
<td>- lacunar cerebral syndrome</td>
</tr>
<tr>
<td>- posterior cerebral syndrome</td>
</tr>
<tr>
<td>mRS</td>
</tr>
<tr>
<td>Inpatient rehabilitation days</td>
</tr>
<tr>
<td>Previous stroke</td>
</tr>
<tr>
<td>Home help service</td>
</tr>
<tr>
<td>MMSE</td>
</tr>
<tr>
<td>Postural instability %</td>
</tr>
</tbody>
</table>

Results are presented as proportion or mean ± SD.

TOAST = Trial of Org 10172 in Acute Stroke Treatment classification, n/a = TOAST not applicable due to intracerebral hemorrhage. OCSP = Oxfordshire Classification of Stroke, mRS = modified Rankin Scale, MMSE = Mini Mental State Examination. *figures represent mean (first and third quartiles).

**Paper II-IV: the Intervention study**

In the Intervention study, all individuals hospitalized with a stroke diagnosis were screened for participation during their stay at the Stroke Unit of Norrlands University Hospital. Study inclusion occurred three to six months after stroke onset. During the stay at the Stroke Unit, a wider set of inclusion criteria were used to screen for potential participation later on. Basic characteristics of included individuals are summarized in Tables 2 and 3.
Methods

Table 3. Participant living situations, paper II-IV.

<table>
<thead>
<tr>
<th>Living situation</th>
<th>Intervention Group (n=15)</th>
<th>Control Group (n=19)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>own house</td>
<td>5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>own apartment</td>
<td>8</td>
<td>11</td>
<td>.694</td>
</tr>
<tr>
<td>senior housing</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>other</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>married/cohabitant</td>
<td>9</td>
<td>8</td>
<td>.492</td>
</tr>
<tr>
<td>widow/widower/single</td>
<td>6</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Home help service</td>
<td>5</td>
<td>9</td>
<td>.495</td>
</tr>
<tr>
<td>Home care rehabilitation</td>
<td>9</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Day care rehabilitation</td>
<td>1</td>
<td>5</td>
<td>.196</td>
</tr>
</tbody>
</table>

Groups were compared using the Chi-squared (Pearson’s or if applicable Fisher’s exact test) or independent samples t-test for the baseline assessments.

The inclusion criteria were: acute stroke three to six month prior to inclusion, age of 55 years or greater, capable of walking 10m indoors with or without a walking device or support of another person, and the ability to understand and comply with instructions in Swedish. The individuals should also have a risk of fall according to subjective clinical observations. The exclusion criteria were the ability to walk outdoors independently (without personal assistance or walking device), severe aphasia or severe vision or hearing impairment. For the entire screening and inclusion process see Figure 2.

Two weeks before the baseline assessments, a telephone call was made to those individuals previously highlighted as potential study participants, in order to estimate changed function and capacity since inpatient rehabilitation. Of the previously screened individuals, a few had deteriorated to the extent that they were no longer suitable for participation. The majority of the individuals had improved from being at fall risk to not being at fall risk three to six months after inpatient rehabilitation. Those who still met the inclusion criteria were brought to an assessment evaluation at the Clinical Research Centre at Norrlands University Hospital, where they underwent medical assessments by the doctor and nurse assigned to the Intervention study, as well as physiological and psychological assessments by a PT. If the individuals met the inclusion criteria after these assessments, and accepted participation in the study, they were included. This assessment was considered their baseline assessment.
Methods

Figure 2. CONSORT flowchart of the screening process of Intervention study, from stroke onset to final inclusion in the study and all follow-ups. CONSORT= Consolidated Standards of Reporting Trials.

To be able to reach the estimated number of participants needed to achieve power for the Berg balance scale (see statistical analysis section), screening, assessments, and randomization took place on three different occasions between 2005 and 2007. Randomization into either IG or CG occurred directly after the baseline assessment. A minimization program was used to avoid imbalances between the relatively small groups. The minimization program, MiniM [67], was programmed to take into account two different variables. These variables were cognition, using the Mini Mental State Examination, MMSE (≤ 24/ ≥ 25) [68], and fall risk, using the Fall Risk Index validated in the first paper (value ≤ 1/ ≥ 2) [64]. This Fall Risk Index takes into account postural stability (<10/14), signs of visuospatial hemi-inattention, and male sex [64].
Methods

Two investigators were responsible for the randomization of individuals into the two groups (EH and PW). The thesis author (EH) was responsible for screening all individuals at the Stroke Unit and making the follow-up phone calls. All individuals received a code number in order to ensure blind randomization. This code number was then re-coded three times to receive a final code number not recognizable to EH. PW had no knowledge of the individual’s code number at any time.

At the assessments, the participating nurse and PTs did not have any knowledge of the group allocation of the individuals. They were instructed to fill out an incidence report if they had any suspicion of the group allocation. This happened once, and the suspicion was false. The PT and Occupational Therapist (OT) responsible for carrying out the programs for the intervention and control groups reviewed the participants’ baseline assessments before the study began, in order to be well-prepared for the actual intervention and to have a prepared rehabilitation program for the individuals. The staff in the intervention did not take part in any of the assessments. They had no insight in the follow-up test records.

The assessments and the randomization took place the week before study start. The individuals were contacted by telephone and were informed about the randomization results by EH. All logistics around the intervention were handled by EH, including travels by taxi, follow-up assessment, etc. The study was registered before study start at www.clinicaltrials.gov as NCT00377689.

Assessments

The participants in the Validation study were assessed once, during the first week of stay at the Geriatric ward. The participants in the Intervention study were assessed four different times. The baseline assessments were first, then a follow-up assessment directly after the intervention, and a three-month post-intervention follow-up. The six-month follow-up was conducted by telephone by RB, the research nurse at the Umeå Stroke Unit who participated in all assessments in the Intervention study. Naturally, only outcome measures possible to conduct over the telephone were included in the six-month follow-up. Outcome measures in the different papers (Table 4) were assessed using the following instruments:
For diagnostic and medical outcomes:
In the Validation study, the medical diagnose was based on clinical examination and computed tomographic (CT) scans. The National Institutes of Health Stroke Scale (NIHSS) is a method used to estimate the severity of a stroke; the NIHSS was used in the Intervention study. Two stroke classification systems were used in the Intervention study to shed light on the stroke localization, the Trial of Org 10172 in Acute Stroke Treatment (TOAST) [69] and the Oxfordshire Community Stroke Project (OCSP) [70].
The modified Rankin Scale (mRS) is a commonly used scale for measuring the degree of disability or dependence in the daily activities of stroke patients, and it has become the most widely used clinical outcome measure for stroke clinical trials [71]. This instrument was used in the Intervention study.
The line bisection test was used for determining the presence of visuospatial hemi-inattention [72]. The score range from 0 to 9 with ≤7 indicating impairment. The presence of perceptual impairment was also estimated in a multidisciplinary team consensus (paper I) following comprehensive clinical assessment, including observation during activities. Visuospatial hemiinattention was defined as a positive finding in either of these two ways in the validation study. In the Intervention study only the line bisection test was used.
For physical outcome measures:

To assess upper and lower limb motor function in the Validation study the Motricity Index (MI) was used [73]. The maximum score for each body side is 100 (no impairment). The mean scores for both body sides were recorded. In the original Fall Risk Index, it was noted whether or not bilateral motor impairment was observed.

Balance was assessed using the postural stability sub-score of the Brunnström–Fugl–Meyer Scale [74] (paper I) and the Berg Balance Scale (BBS) (paper I+II) [75]. The postural stability sub-score of the Brunnström–Fugl–Meyer Scale ranges from 0 to 14, with higher scores indicating less impairment. The BBS scores balance of 14 items, with a 5-point (0–4) scale per item. Scores from 0 to 20 indicate a wheelchair user, 21–24 indicate a subject who walks with assistance, and 41–56 indicates independence. Both scales were used in both studies.

Two instruments were used to assess Activities in Daily Life (ADL). In the Validation study, the Katz ADL index was used [76], including six items: bathing, dressing, toileting, transfer, continence, and feeding. The score ranges from A to G, with A indicating independence in all 6 activities and G indicating total dependence (0 denotes unclassifiable cases).

In the Intervention study, the Barthel Index (BI) was used to assess ADL [77]. The Index measures the degree of independence in three categories of ADL, self-care, bowel and bladder continence, and mobility. The Barthel Index uses a 2–4 points grading level per item, with the maximum score of 20 points indicating total independence in personal ADL.

To estimate the level of lifestyle activities, the Frenchay Activities Index (FAI) was used in the Intervention study [78]. The FAI comprises 15 items each scored 0–3 points (0 = never to 3 = most frequent) and divided into three domains: domestic, outdoor and leisure/work activities with a maximum score of 45 points. FAI measures certain performed activities in the last three months and the last six months. In this study it means that the six-month interval, for some individuals, included the period before the stroke. This issue has been handled by analyzing the three-month section separately and analyzing the entire instrument afterward to look for differences. In paper III the three month section is called FAI-3.

A fall calendar documented the number of falls during the Intervention study and was used throughout the six-month follow-up. Falls were defined as incidents in which the individual, due to unexpected loss of balance, came to rest on the floor or an object below knee level [79].

In the Intervention study, gait parameters were collected through an electronic walkway mat, the GAITRite ® Walkway System (www.gaitrite.com) (Figure 3). The walkway was 10 meters long, with a registration centre of 6.1 meters. The walkway system registered the time and placement of every footstep and provided temporal and spatial gait parameters.
Methods

The Borg Rating of Perceived Exertion (RPE) Scale [80, 81] was used in the Intervention study to estimate the general level of intensity (in this study, perceived exertion) of the HIFE and to regulate the level of exercises. This scale is an ordinal scale with values from 6 to 20 where 6 represents no exertion at all and 20 represents maximal exertion. If the participants rated their perceived exertion lower than 15 the exercises were made progressively more difficult/strenuous.

Perceived exertion of the lower limb muscles (strength and balance exercises) was measured on a separate scale (1 = high, 2 = medium, and 3 = low exertion). The individuals rated their perceived exertion according to the Borg RPE Scale and the perceived exertion for the lower limb muscles at each training session.

For psychological outcome measures:
The participants cognitive state was assessed with the Mini Mental State Examination (MMSE) in both studies [82]. The score ranges from 0 to 30, with <23 points indicating significant cognitive impairment.

In the Intervention study, Falls Efficacy Scale – International (FES-I) was used to assess the participants’ beliefs in their own ability to perform an activity without falling [83]. This instrument measures the level of concern about falling when performing any of 16 activities on a 4-point Likert scale (1 = not at all concerned to 4 = very concerned).

The Intervention study also included the Short Form-36 Health Survey (SF-36) to assess Health-Related Quality of Life (HRQoL) [84-86]. It is a generic instrument measuring self-reported physical and psychological aspects of health. SF-36 includes eight subscales: physical functioning, role functioning physical, bodily pain, general health, vitality, social functioning, role functioning emotional, and mental health. The total score in each sub-scale is 100, with higher numbers indicating a higher degree of perceived health. In addition to the eight different scales, which are considered to be universal and to represent basal human function and well-being [87], there are two dimensions, a physical dimension (PCS) and a mental dimension (MCS). The dimensions are calculated by weighing the different load of the eight scales into these dimensions.

The Geriatric Depression Scale-15 (GDS-15) was used to assess symptoms of depression in the Intervention study [88]. The GDS-15 is a basic screening measure for symptoms of depression in older adults, using 15 questions with a Yes/No answer alternative. Depending on age, education, and complaints, the scores from 0 to 4 indicate normal (no depression), 5 to 8 mild depression, 9 to 11 moderate depression, and 12 to 15 severe depression.

The estimated level of the participants’ motivation was graded by a scale from 1-5 as follows: 1=very positive, 2=positive, 3=neither positive nor negative, 4=has to be convinced to participate, 5=present but not participating.

All instruments used for the assessments (except the lower leg exertion score and the motivation assessment) have been tested for validity and reliability in populations similar to the populations in these studies [68, 71-74, 76, 89-102]. The assessments were always carried out in the same
environment, using the same equipment and the same procedure. All outcome measures have been chosen and classified according to the ICF (Table 5).

<table>
<thead>
<tr>
<th>Body structure (impairments)</th>
<th>Activities (limitations to activity – disability)</th>
<th>Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Motricity Index</td>
<td>1. Katz ADL</td>
<td>1. Short Form - 36</td>
</tr>
<tr>
<td>2. Postural Stability Sub-Score</td>
<td>2. Barthel Index</td>
<td>2. Geriatric Depression Scale - 15</td>
</tr>
<tr>
<td>4. Line Bisection test</td>
<td>4. Frenchay Activities Index</td>
<td>4. Level of motivation</td>
</tr>
<tr>
<td></td>
<td>5. Fall Efficacy-Scale-I</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. GAITRite</td>
<td></td>
</tr>
</tbody>
</table>

ICF = International Classification of Functioning and disabilities, ADL = Activities of Daily Living.

**Intervention program**

All participants regardless of group allocation participated in a five-week structured intervention program. The IG program consisted of seven sessions per week for five weeks each week contained three days of sessions and each exercise session lasted approximately 45 minutes. Each week contained a one hour educational group discussion session led by a PT and an OT. This schedule resulted in a total of 30 exercise sessions and 5 educational group discussions.

The focus of the exercise was on physical activity and functional performance. The intervention was based on HIFE program, with the goal of improving the individuals’ lower-limb strength, balance, and gait ability. The HIFE Program is based on exercising in functional weight-bearing positions (figure 4.) The program includes lower-limb strength (e.g. chair stand) and balance exercises (weight shifting outside support surface), in standing (knee bend) and walking (obstacle crossing course) [103, 104].
The HIFE Program contains instructions on how to choose the level of exercises based on each participant’s capacity [104]. For more examples of exercises, see Figure 4.

All exercises were performed at high intensity, if possible, by the individuals [103-105]. “High intensity” was defined as: 1) strength exercises comprising at least 2 sets of exercises with 8-12 repetitions (maximum); 2) the balance exercises close to the individuals’ balance maximum, and 3) the subject did not rest more than necessary [104]. The maximum was determined by the participants experienced exertion in performing the exercise for the first times. In addition to the regulation described in the HIFE program the exercise intensity was regulated with the help of the Borg RPE scale.

Every day the first session of the Intervention Program was performed according to the HIFE-Program. The second session consisted of 45 minutes of implementing the previously performed exercises in an environment closely related to the participants own home environment.
The exercises performed at this session were transferred to match activities in real life situations. All participants were required to describe their experienced and perceived problems at study start and these problems were included in the rehabilitation plan. A home visit was conducted by a PT and an OT at the start of the Intervention Program to determine each subject’s ability to perform ADL and lifestyle activities and to experience the subject’s daily difficulties in their own environment. All HIFE exercises and implementation activities were individualized based on this home visit, tailor made for each participant before the first day of study.

During the last week of Intervention, an individualized home-based exercise program was designed by the PT for each subject in the IG. This home exercise program was part of the Intervention program and consisted of a maximum of three different exercises similar to the exercises performed during the five-week intervention. The intensities of all exercises were adjusted, so they could be modified as the subject progressed. The instructions were to perform this home-based exercise program three times a week at least until the three-month follow-up.

The CG met once a week for a one-hour educational session during the five-week period, which was led by an OT. The group discussions were about communication difficulties, fatigue, depressive symptoms, mood swings, personality changes, and dysphagia (all more or less hidden dysfunctions after stroke), and how to cope with these difficulties. There was no special focus on the risks of falling in these discussions. For a full description of the IG and CG programs, see Appendices 1 and 2.
Methods

Category A. Static and dynamic balance exercises in combination with lower limb strength exercises.

Category B. Dynamic balance exercises in walking.

Category C. Static and dynamic balance exercises in standing position.

Illustrations from the HIFE Program [104], reprinted with permission of the publisher.
Category D. Lower limb strength exercises with continuous balance support.

Category E. Walking exercises with continuous balance support.

Figure 4. Examples of exercises from the different categories in the HIFE-program. Illustrations from the HIFE Program [104], reprinted with permission of the publisher.
Methods

Statistical analyses

Paper I

Falls and injuries are described as numbers, percentages, or incidence rates with 95% confidence intervals (CI). The incidence rate of falls is presented as number of falls per 100 patient years.

Survival analyses were used to describe the fall risk as a function of time. The association between index score and the time to first fall was analyzed by a Cox regression. Time to first fall was compared between individuals belonging to low-, intermediate-, and high-risk groups by Kaplan–Meier analysis with a log-rank test for statistical significance [106]. Each Fall Risk Index item was associated with the time to first fall using Cox regression.

Based on the findings from the foregoing analyses, a remodeling of the index was performed. Principal components analysis (varimax rotation, eigenvalue ≥1) was used to identify index items closely related to each other. In cases where two or more index items strongly loaded on the same factor (factor loading ≥0.6), the item that exhibited the strongest bivariate association with the risk of fall was chosen for further remodeling. Factors with P values ≥0.15 in bivariate analyses were excluded at this step from further analyses.

Stepwise multifactorial Cox regression modeling was used to identify the combination of index items showing the best association with falling in the validation sample (sample C). The remodeled index was then tested backwards in the model fit sample (1991-1992) using Cox regression and Kaplan–Meier analyses with the log-rank test. A P value ≤0.05 was taken to indicate statistical significance.

Paper II-IV

All descriptive statistics are presented in frequency tables as means with 95% CI. All assessments were tested for normal distribution. Groups were compared using the Chi-squared (Pearson’s or if applicable Fisher’s exact test) or independent samples t-test (Table 6) for the baseline assessments.

General linear model with repeated measure statistics were used to analyze the follow-up data in paper II-IV (Table 6). This analysis considers the fact that each individual had multiple assessments and that the assessments were over a period of time.

A Poisson regression was performed using the number of falls as the dependent variable to estimate the correlation of the outcome variables (in paper II) to falls after the intervention. The mean values presented in paper II-IV are the actual means of the two groups rather than the estimated means that the statistic estimation model used in the repeated measure analysis. This was to give the clinician/reader a clearer picture of the participants’ real level on each outcome measure.

Confidence intervals presented in paper II-IV represent separate values in the IG and CG at baseline and at the respective follow-ups while such estimates are not possible to retrieve directly in the repeated measure analysis.
Methods

Power
Power estimation was not conducted for the Validation study. The study group was chosen to match the original study sample from 91/92. Power was calculated to determine the sample size needed in the Intervention study (papers II-IV) for the Berg Balance Scale [91]. A clinically significant difference of ≥ 5 points in the BBS (p <0.05, two-tailed test) was the basis for this calculation. The calculation estimated the number of individuals needed as 34, 17 in the IG and 17 in the CG.
To have a substantial marginal for potential losses (for example dropouts), we set a goal of 50 participants, twenty-five in each group. We included participants during three different intervention rounds to meet this goal; however we did not reach our goal of participants in time. In the end, 34 individuals were included.
All data analyses were performed using the SPSS software package, in paper I version +10.0 and in paper II-IV version 17.0.
RESULTS

Validation of a Fall Risk Index in Stroke Rehabilitation – Paper I

Thirty-nine (25%) patients fell at least once. The incidence rate was 349 (95% CI, 254-444) falls per 100 patient years, compared with the corresponding rate of 756 (95% CI, 616-897) in the original sample. The Fall Risk Index score was significantly associated with the time to first fall (hazard ratio: 1.22; CI: 1.03-1.44), but the specificity was low (26%). The Fall Risk Index managed to capture all those who fell, with one exception (97% sensitivity). The low specificity was due to classification by the Fall Risk Index of 30 patients that didn’t fall, as fallers.

The grouping of the individuals into no, low, medium, or high risk of falls did not show any significance. On the basis of these results, the index was modified and re-validated with the original sample (Model Fit Sample). The original Fall Risk Index consisted of seven items, while the stepwise Cox regression modeling resulted in three items (Figure 5).

Figure 5. Kaplan-Meier analysis of fall risk in individuals assigned to the low-risk (dotted line), intermediate-risk (solid line), and high-risk (fat solid line) groups. Log-rank test for validation sample, 5.19, (P =0.075).
Results

Because of these results, the index was modified, and re-validated in the original sample (model fit sample). The original Fall Risk Index consisted of seven items, the stepwise Cox regression modeling resulted in the 3 items:

1. postural stability score 10/14 (Item 1)
2. signs of visuo-spatial hemi-inattention (Item 2)
3. male sex (Item 3)

These three remaining items were grouped together to form an index following an accumulated model.

Item 1.  \[\text{Score}=1\]
Item 1 + Item 2  \[\text{Score}=2\]
Item 1 + Item 2 + Item 3  \[\text{Score}=3\]

This score was significantly associated with fall risk in both samples; the hazard ratio (95% CI) was 1.9 (1.4-2.7) in the Validation sample and 1.8 (1.4-2.4) in the Model Fit Sample (Figure 6a+6b).

Figure 6a+b. Kaplan-Meier analyses of the relation of the revised index to the fall risk among patients in the validation sample (A) and in the model fit sample (B). The dotted line indicates a score of 0; the solid line, a score of 1; the fat dotted line, a score of 2; and the fat solid line, a score of 3. Log-rank test for the validation sample, 18.2 (\(P < 0.001\)), for the model fit sample, 23.3 (\(P < 0.001\)).
The Intervention study - Paper II-IV
All but one participant completed the five-week intervention period. Three participants dropped out during follow-up due to worsening overall medical condition. The IG participants completed the home exercise program 2-3 times per week according to the self-reporting questionnaire.

What is the benefit of a High Intensive Exercise Program? – Paper II
Balance, ADL and falls
The high intensive exercise program did not result in a significant difference in balance as assessed by the Berg Balance Scale (IG vs CG). Twenty-six falls were documented by the participants in their fall calendars. Severe pain or injury was documented in five falls, but there were no differences between the two groups. Eleven participants (32%) fell during the study (five IG individuals and six CG individuals), and almost a fifth of the participants fell more than once. These figures correspond to a fall frequency of 1.35 falls/person/year. Three participants in each group (18%) fell more than once, and the most falls for any single subject was six. The Poisson regression did not reveal any significant differences in the number of falls between the IG and the CG.

Activities in daily life
Barthel’s Index showed a significant positive mean difference of 1 point for the IG (IG 18.6 ±1.1 > 19.2 ± 1.3 vs. CG 18.8 ±1.9 > 18.5 ± 2.3) compared with the CG at the six-month follow-up vs. the baseline assessment (p < 0.05, effect size 0.15).

Falls efficacy
The FES-I instrument showed an improvement for the IG, but not for the CG. The improvement were seen directly after the intervention with a mean difference of 3.1 points (IG 31.3 ± 9.6 > 26.7 ± 4.5 vs. CG 28.0 ± 10.9 > 26.5 ± 11.3, p < 0.05, effect size 0.09) and at three-months post-intervention with a mean difference of 4.2 points (IG 31.3 ± 9.6 > 27.8 ± 6.9 vs. CG 28.0 ± 10.9 > 28.7 ± 10.0) compared with the baseline assessments (p < 0.03, effect size 0.13).

Lifestyle activities
The improvements in ADL and in FES-I did not reflect any expanded social activities as measured by the Frenchay Activities Index. No significant differences were detected between the two groups in terms of lifestyle activities as assessed by the Frenchay Activities Index (FAI-3).
The impact of an high intensive exercise program on gait after stroke - Paper III

Of the 34 included individuals, 32 (IG = 14, CG = 18) were eligible for gait characteristics analysis. Two were excluded, as there was no specification of paretic/non-paretic side. A lack of intra-individual overlapping walking velocity measurements between assessments obstructed comparisons of gait characteristics at a normalized velocity for five individuals (4 IG and 1 CG). Four individuals only had data from the baseline and post-intervention follow-up. Twenty-three participants had complete sets of data (baseline/post-intervention/three month follow-up) and were analyzed in this study. However, there were no significant differences in baseline characteristics or gait parameters between those who lacked the possibilities of normalizing the gait speed and the remaining participants. Visual example of the registered walks can be seen in Figure 7.

Two variables were significantly different between the two groups at baseline, step length for the paretic leg (IG 49.7cm ±12.2 vs. CG 55.6cm ±12.0 , p=0.05) and the variability in step length for the paretic leg (IG 7.2% ±5.4 vs. CG 6.0% ±3.0, p=0.04). These differences were however faded out at the post intervention assessments. There were no other differences in the remaining baseline data or the baseline characteristics between the IG and the CG. (Table 6)

Gait variability improved after the intervention for the IG compared to the CG both at the post-intervention assessments and at the three-month follow-up assessments. The only significant difference in basic temporal parameters was the double support time for the non-paretic leg, all other improvements were in the variability of the different gait parameters.

In double support time, the IG decreased their time spent in the most stable phase of the gait cycle for the non-paretic leg after the intervention, while the CG did not change at all (IG 0.9 sec ± 1.3 › 0.4 sec ± 0.2 vs. CG 0.4 sec ± 0.2 › 0.4 sec ± 0.1, p ≤ 0.001). This change persisted even at the three-month follow-up (IG 0.9 sec ± 1.3 › 0.4 sec ± 0.1 vs. CG 0.4 sec ± 0.2 › 0.4 sec ± 0.3, p ≤ 0.001 ). For the variability in step time for the paretic (p < 0.01) and non-paretic leg (p < 0.01), the double support time for the non-paretic leg (p < 0.001), and the variability of cycle time for both the paretic and non-paretic leg (p < 0.01), the IG decreased their variability while the CG increased their variability (Table 6).
Results
Results
Results

Baseline Velocity sec=0.34 m/s

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<tr>
<th></th>
<th>Paretic</th>
<th>Non-paretic</th>
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<tr>
<td>Step Time sec</td>
<td>0.66</td>
<td>0.74</td>
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<tr>
<td>Variability in Double Support Time (%)</td>
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<td>9</td>
</tr>
<tr>
<td>Variability in Gait Cycle Time %</td>
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<td>6</td>
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<tr>
<td>Step Width mm</td>
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<td>120.6</td>
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<tr>
<td>Step Length cm</td>
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Post intervention follow-up Velocity: 0.42 m/s

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<tr>
<td>Step Time sec</td>
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<td>0.74</td>
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<tr>
<td>Variability in Double Support Time (%)</td>
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<td>6</td>
</tr>
<tr>
<td>Variability in Gait Cycle Time %</td>
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<td>106</td>
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<tr>
<td>Step Length cm</td>
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Three month follow-up Velocity=0.41 m/s

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<td>Step Time sec</td>
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<td>Variability in Double Support Time (%)</td>
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<td>10</td>
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<tr>
<td>Variability in Gait Cycle Time %</td>
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<tr>
<td>Step Width mm</td>
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<tr>
<td>Step Length cm</td>
<td>30.1</td>
<td>28.2</td>
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Figure 7. Exemplified gait characteristics by visual footsteps for one individual in the Intervention Group in self-selected normal speed at baseline, post intervention and three month post intervention follow-up.

However, two categories favored the CG: variability in step length and step time for the non-paretic leg at the three-month follow-up. Both groups decreased their variability in step time but the CG’s decrease was larger (p < 0.001). In the variability of step length for the non-paretic leg, the IG increased their variability while the CG decreased (p < 0.001).
Results

What’s the benefit of A High Intensive Exercise Program’s on Health–Related Quality of Life and Depression after stroke - Paper IV

HRQoL and depressive symptoms
A significant difference between the two groups was detected in the SF-36 MCS and MH subscale at the three-month follow-up in favor of the CG (p < 0.02). There were no differences between the IG and the CG in terms of depressive symptoms as measured by GDS-15.

SF-36
There were no differences in SF-36 PCS at baseline between the IG and the CG. At the three- and six-month follow-ups, there was partial normalization of the SF-36 PCS for the whole study group versus values at baseline (p < 0.05). However, there was no significant difference for SF-36 PCS between the IG and CG over time (Table 6). Regarding the individual components of the SF-36 PCS (physical function, role physical, bodily pain, and general health), there were no significant differences between the IG and the CG at baseline or over time post-intervention (Table 6).

A significant difference existed in the SF-36 MCS between the IG and CG at three-month follow-up in favor of the CG (p = 0.02). The MH sub-scale also showed a similar significant difference at three-month follow-up (p = 0.02). The results for the remaining individual components of the SF-36 MCS (vitality, social functioning, and role functioning-emotional) were without significant differences between IG and CG at baseline and over time after intervention (Table 6).

There were no differences in the SF-36 MCS at baseline between the IG and the CG (Table 6).

Geriatric Depression Scale-15 (GDS-15)
There was no statistically significant difference in GDS-15 between the IG and CG at baseline. There was no difference over time in the GDS-15 between the IG and CG. All levels of GDS-15 were without signs of depression. (Table 6)

General assessments the Intervention study, paper II-IV.

Motivation
Motivation was estimated in IG and CG members by the responsible PT or OT. The mean level of motivation in the IG was 1.19, compared to a level of 1.98 in the CG (Table 7).
Intensity
The level of intensity was estimated in the Intervention group for the exercise sessions by rating the perceived exertion using The Borg RPE Scale [80, 81]. The level of intensity in the exercises was also regulated by the same rating. The mean level of perceived exertion during HIFE was calculated by summing all estimation values from every session and dividing them by the number of attended sessions. The overall mean level of intensity was 16.2 (±1.4) the perceived exertion for the lower limb muscle strength exercise was 1.1 (±0.1) and for balance 1.1 (±0.2). These figures indicate that the estimated level of high intensity in the exercise sessions was reached (Table 7).

<table>
<thead>
<tr>
<th>Table 7. Level of intensity and motivation.</th>
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<tr>
<td>Intervention Group, n=15</td>
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<tr>
<td>Attendance in allocated group</td>
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<tr>
<td>Motivation</td>
</tr>
<tr>
<td>Exercise intensity, strength</td>
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<tr>
<td>Exercise intensity, balance</td>
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<tr>
<td>Exercise intensity, lower leg</td>
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Groups were compared using the Chi-squared (Pearson’s or if applicable Fisher’s exact test) or independent samples t-test for the baseline assessments. Results presented as proportion or means with Standard Deviation (SD). n/a=not applicable.
DISCUSSION

Main findings
The main result of this thesis was that the validated Fall risk index received a modification to achieve a better specificity and sensitivity. The Fall Risk Index was also shortened and thereby made easier to administer in the clinic. With the knowledge from the index validation and modification, of several fall risk factors, an intervention program was constructed with the goal of influencing these risk factors through exercise. Although the primary outcome (BBS) did not show any significant results, the Intervention study had a positive effect on ADL, falls-efficacy, and gait variability (Table 6). No significant results were seen in the intervention group for balance, lifestyle activities, signs of depression, and HRQoL. On the contrary, the Control group demonstrated a significant improvement compared to the IG in HRQoL.

Balance
Balance was the primary outcome variable in the Intervention study; the BBS was used to estimate the level of balance. The lack of a significant improvement in balance for the IG was disappointing. Reduced balance is a well-known risk factor for falls after stroke [11, 12, 107]. Probable causes of the lack of results in this intervention could be initial relatively high BBS scores and the short time of intervention. The BBS score for both groups was low at baseline, but perhaps not to the extent needed to benefit from this short-term intervention.

Cut-off BBS scores regarding the identification of fallers vary. A score of 45 has been used clinically for a long time to estimate fall risk for stroke patients [108]. A score of ≤ 49 has been proposed to be predictive of falls [109], as have scores of ≤ 46 [110] and ≤ 29 for single falls [12, 107]. However, the use of the BBS as a dichotomous scale has been discouraged in favor of a likelihood ratio for predicting multiple falls, since it preserves the risk gradient across the whole range of scores [111]. The BBS cutoff-score used in this Intervention study was ≤ 45; it was not an inclusion criterion in this study, but it was used for guidance at the Stroke Unit to classify patients as at risk or non-risk of fall. Many of the participants in this study did have a somewhat higher BBS score but were still classified as at risk for falls. The higher the score on BBS, the more improvement is probably needed to see results in the scoring. As a result of this, a lower score on BBS could also indicate a larger improvement potential.

Five weeks are a short period for an exercise program, and one cannot expect remarkable results. It was, however, interesting to evaluate this shorter intervention, since five weeks is a period easy to administer when implicating a program in clinical settings. To achieve effects on balance and other physical outcomes such as strength and balance through PRT
alone, intervention durations of eight to twelve weeks have been described [45]. However, the review by Latham did not show any evidence that PRT effected physical disability when measured activity or HRQoL outcomes [45].

Activities in daily life
The Intervention study resulted in improved activities in daily living (ADL) at the six month follow-up. The separate items in the Barthel Index were not analyzed in this study; for future comparisons and for more specific knowledge on where the improvements were most pronounced these analyses would be essential. A study of 191 older people living in residential care facilities demonstrated that the same high-intensity functional weight-bearing exercise program (performed over a period of three months) effected indoor mobility in older people dependent in ADLs according to the Barthel Index, most of whom had severe physical or cognitive impairments [112]. An increase in ADL and hence a less dependent living situation is an important result. An effect on activity appears when training physical components, with a focus on task-specific exercises but there was no significant change in the physical outcome measured by balance. Studies have evaluated ADL in similar interventions but few have succeeded; progressive resistance training has been shown to affect strength and balance but not reduced physical disability [45].

The main focus in this Intervention study on functional performance and activity, with task-specific exercises, is probably the main reason for this significant result. Task-specific exercises have been shown to be superior to other exercises in improving function after stroke [113]. Strengthening exercises, preferably with functional tasks and intense training, have a carry-over effect on activity [52]. However, more evidence of the impact on ADL and other activity measures has been called for [114]. It has been suggested that functional training, where intensity and task-specific exercise therapy are important components, may be the optimal stroke rehabilitation strategy [114].

The most desirable outcome is that the participants’ ability to perform an activity is superior to that of performing on a certain level of a functional test, such as the BBS. We argue that by improving the ability to perform ADL, the individual can achieve an increased level of physical activity just by performing the daily routines. Functional decline could be postponed by performing these activities, and therefore a remaining level of function could also be considered an improvement.

Gait
To have a “normal” gait, certain factors must be present and cooperative: the synergetic activation of muscles, and the abilities to stop and start, to alter stepping patterns, and to adapt to different settings (such as speeds and surfaces). Of the various gait outcomes measured in the Intervention study, almost only the variability measures returned significant
differences between baseline and after the intervention compared with the CG. This study demonstrated gait variability that was characteristic for individuals with stroke. The gait variability was quite large for several gait variables, such as step time, cycle time, double support time, and step length. There were no significant differences in step width in this Intervention study. Since step width is a speed-dependent variable [115], a difference might not be expected as there was no change in velocity (Table 6).

The median velocity of stroke patients in this Intervention study was comparable to healthy older people with no history of falls (1.0 m/s vs. 1.03 m/s). The range, however, was much wider in the Intervention study (0.3 – 1.5 m/s vs. 0.8 – 1.2 m/s) [116]. There were also differences in step width and step length between healthy older individuals with no history of falls and our stroke patients at baseline. The median step-width difference was 22 mm (111 mm vs. 89 mm) for the paretic leg and 24 mm (114 mm vs. 89 mm) for the non-paretic leg. The step width in the healthy controls was represented by the median step width of both left and right legs. The median difference in step length was approximately 16 cm (44.4 cm vs. 60 cm) [116]. These figures clearly reflect the variability in stroke gait, a gait that is much more asymmetric than the “normal” gait in a similar but healthy population.

The significant results for variability in this study could be clinically more important for some variables than others. The variations in step time for the paretic leg, for double support time for the non-paretic leg, and for cycle time for both paretic and non-paretic legs improved in the IG, while the CG increased their variabilities. These opposite results indicate the importance of rehabilitation for no further decline in gait after stroke. The significant decreases in step time and step length variability for the CG may be due to an outlier in the IG. To fully understand this, further analysis needs to be done. The lack of significant changes in the respective gait variables could be due to the short exercise duration; it would be easier to achieve a variability change before actual changes in the parameters are noticeable.

FES-I

Falls-efficacy improved both at the post-intervention assessments and at the three month follow-up for the IG compared to the CG. Living with fear of falling is very restrictive for a person. Fear of falling associated with activity restriction in an elderly population is an independent predictor of decline in physical function [117] and a strong association has been demonstrated between the FES-I and functional outcome four months after discharge from a geriatric setting [118].

The term self-efficacy could be explained by an individual's belief's in their own ability to perform a specific behavior in a specific situation [119]. If applying self-efficacy to a situation from a fall risk perspective, the proper term to best describe this would be Falls-efficacy. Bandura (1994) originated what could be seen as a model of factors influencing
self-efficacy [119]. He suggested that people's beliefs in their efficacy are developed by four main sources of influence.

They included:

1. mastery experiences, e.g. previous experience of having managed the specific task.
2. seeing people similar to oneself manage task demands successfully.
3. social persuasion that one has the capabilities to succeed in given activities.
4. inferences from somatic and emotional states indicative of personal strengths and vulnerabilities.

All four of these components can be applied to our intervention program. By task-specific exercises and the implementation of them in to everyday situations that the individual experienced as difficult (from a fall risk perspective), the individual had the opportunity to practice and cope with these activities during the intervention program. By performing the intervention program in a group context, the possibility of seeing the other individuals successfully perform similar exercises and tasks could stimulate to achieve higher self-efficacy. All sessions, both exercise and theoretical sessions were supervised by professionals such as physical therapists and occupational therapists. The ability to perform exercises and activities under their supervision and encouraging feedback could be referred to the influence of social persuasion. The individuals' somatic and emotional experience of performing the exercises and activities could enhance self-efficacy. However, this is a two-way relationship; a negative experience could as well influence a decreased self-efficacy.

A decreased score (indicating improvement) on the FES-I should in turn lead to an increase in physical function, which is supported by our results. The FES-I results are in concordance with the performance of daily life activities results and the results of reduced variability in gait in our intervention program. If the fear of falling is diminished or reduced, then a higher level of performing activities would be predicted. When performing more activities, the experience of completing the activity strengthens the individual’s efficacy and also provides an unconscious exercise effect.

The gait improvements are strengthened clinically by results from the FES-I, in which IG members more positively estimated their ability to carry out various activities without fear of falling than CG members. A previous study showed that fear of falling influenced spatial and temporal gait parameter changes in older people more than the ageing process itself [120]. With a more secure gait the individuals own feeling of increased security would tend to reflect on the falls-efficacy.
Discussion

Falls
During the validation of the Fall Risk Index, a modification of the previously developed index was performed. In this modified Fall Risk Index, the third and last item became male sex, a finding that seems contrary to previous investigations regarding individuals who fall; however, the existing evidence is inconclusive. Our observation, supported by a previous study [121], could be due to the fact that gender itself is not the key issue. Risky behavior by the men may be the risk factor, not the actual sex. How to measure this? The critical feature of this behavior may be difficulty in self-assessment of restriction in ability. This hypothesis is an interesting speculation on the nature of falls, and is appropriate for further research.

HRQoL and Depression
HRQoL after stroke is an important element that requires further examination in stroke rehabilitation studies. Depression is known to have a negative effect on rehabilitation in general [122, 123]. Several studies have evaluated function and activity outcomes in terms of balance, strength, ADL, etc. Indeed, post-stroke quality of life did not improve in the Canadian population between 1996 and 2005 [124], even though medical management has improved and there are no signs that Canada’s outcome should be different from other western countries.

One method for improving our knowledge of HRQoL is to evaluate the various exercise rehabilitation approaches present today for their effect on HRQoL. Our goal was to evaluate a high-intensity exercise program for several areas of interest for the rehabilitation process. The program was primarily designed for physical outcomes, but we intended to evaluate other areas as well.

Disability and post-stroke depression are consistent determinants of HRQoL [125]. The lack of significant HRQoL changes in the IG could be due to the fact that the participants in this study did not exhibit signs of depression. Perhaps the degree of disability was too high in our study population, even though they were at risk for fall. There were no significant differences in depression between the two groups, but the CG tended to have a slightly higher score (more negative) on the GDS-15 at all assessments. Depression has a more substantial effect on HRQoL than functional disabilities [126], which may explain the significant SF-36 results in favor of the CG. Group discussions may also have been critical; the CG did not discuss falls and safety arrangement, instead focusing on managing hidden post-stroke dysfunctions. Perhaps this content fits the HRQoL outcome better. Separate analysis of the discussion sessions may lead to an elucidation of this relationship.

When evaluating the significant results from the Intervention study, it is obvious that a connection exists between the outcome measures. A positive cycle seems to have been established, given the improvement after intervention in ADL, gait, and the FES-I. When the individual experiences a higher capacity in gait and a more secure gait, the falls-
efficacy increases. With the increase in falls-efficacy, ADL becomes more feasible, and the individual's ADL increase. This activity renders an exercise effect that hopefully generates a continuum of achieved levels of function and activity.

Methodological considerations

The Intervention study was planned with the previously identified fall risk factors and modified fall risk index in mind. When we planned for the Intervention trial, we took into account the latest published evidence on exercise and duration, as well as the recommendations from the American College of Sports and Medicine and the American Heart Association. The underlying motivation for this Intervention study was that by making the training as task-specific as possible through use of everyday activities, we would bring about a training situation in which individuals remained at their entrenched level of function and activity. The possibility of a carry-over effect from the PT training sessions to the everyday life at home, and compliance with the home-based exercises, would increase.

We chose the five-week duration, instead of a longer period of time (8-12 weeks), because a five-week program should be easy to incorporate in most clinical settings. We reached a longer period of cohesive training by adding a home-based exercise program to the original high-intensity exercise program. Home-based rehabilitation for stroke patients has proven to be effective, and has been incorporated in the Swedish national stroke care guidelines for medically stable patients with mild to moderate impairments [41]. The compliance to our home-based exercises also supports the feasibility of this rehabilitation approach.

Although the inclusion criteria was >55 years of age, the mean age in the Intervention study was almost 80 years. This is a very representative mean age for persons with stroke since most of those who suffer from stroke are in this age bracket. However, with our inclusion criteria one could perhaps have suspected a somewhat lower mean age in this study. The youngest person included in the Intervention study was 60 years of age.

When the lack of an effect on balance was discovered, as measured with the BBS, we realized we needed to reflect on whether the BBS was a sound instrument to use in this setting. The BBS is an often-used instrument in stroke rehabilitation, and it has been used in many previous intervention studies. However, the BBS exhibits some ceiling effects, leading us to suspect that a different instrument may have provided different results [127]. Other possible instruments included the postural stability sub-scale of the Fugl-Meyer test [74] and the Postural Assessment Scale for Stroke Patients (PASS) [128]. The postural stability sub-scale was used in the Fall Risk Index and thus was also present in this study. However, the BBS evaluates balance in
normal ADL such as chair stands and transfers, and therefore is considered to be superior for this study. The BBS is also a widely used instrument among Swedish PTs, particularly in stroke and geriatric settings. The PASS is the most recent instrument of the three mentioned, developed by Benaim et al in 2002 [128]. They adapted items from the Fugl-Meyer test and developed a new scale for measuring balance function in stroke patients. In an analysis and comparison of the psychometric properties of these three balance measures, all provided acceptable levels of reliability, validity, and responsiveness. However, the PASS instrument demonstrated slightly better psychometric characteristics than the other two measures [129].

Other outcome measures of HRQoL, such as the Stroke Impact Scale (SIS) [130] or the Health-related Quality of Life In Stroke Patients (HRQoLISP) [131], could have been used in this study. We choose SF-36 because our study population had a mean age of 79 years and a co-morbidity of other illnesses. It would therefore have been difficult to ensure the origin of the symptoms. The SIS and the HRQoLISP are disease-specific instruments compared to the SF-36, a generic instrument for the evaluation of general health and HRQoL. The SF-36 is also a widely used instrument in research, and could therefore be used for comparing our results with several other HRQoL studies.

Power calculations revealed that 34 study participants would be necessary for significant detection of a five-point improvement on the BBS. Our intention was to include at least 25 individuals in each group to preserve power even if drop-outs and missing values occurred during the follow-ups and assessments. This goal was not achieved, since almost half of those eligible for inclusion in the study declined to participate. A power calculation should have been made for the secondary and tertiary outcome measures, which would have provided estimates of how many individuals were necessary to achieve a reasonable power for all outcome measures. However, with the present inclusion criteria, it would have been difficult to identify additional potential participants during this short inclusion time (three separate three-month periods).

The power calculation was made for the BBS effect; the lack of an effect on balance may reflect insufficient targeting of the intervention to an at-risk group. Wider inclusion criteria may have solved this problem. The reason for not including independently ambulatory participants (able to walk outside independent of walking devices or assistance from another person) was that we did not consider them to be at the same fall risk as the presently included individuals. A larger impression may have been made by including individuals with a more limited ability to walk. We set the limit of the ability to walk at 10 m with or without a walking device. Perhaps we could have added “or with the assistance of another person” or maybe include individuals bound to a wheelchair to that criterion to include more individuals. To find individuals with a walking capacity but still in a wheelchair would have been harder to identify but not impossible.
Unfortunately, the repeated measure statistics only calculated complete datasets, and thus the participants with data from two assessments were not included in the final analysis. If the statistical analysis included the data from these participants for as long as they participated in the study, the possibility of an intention-to-treat approach could have been evaluated. An alternative approach would have been to analyze the data with another statistical approach, such as ANOVA.

The blinding of the assessment staff to group allocation was successful. Baseline measurements were taken before the randomization took place, and therefore there was no risk of revealing the group allocations. At the post-intervention follow-up, the three-month follow-up, and the six-month follow-up, the participants were instructed repeatedly not to reveal anything that could render a suspicion on group allocation to the assessment staff. The staff was instructed to fill out an incidence report if they believed they had revealed the participants’ group allocation. One incidence report was filed, and the suspicion was false.

The participants were enrolled and randomized three to six months after their stroke. Most spontaneous recovery occurs within the first six months [132]. This time point was chosen to allow the first spontaneous recovery to occur, for the participants to have enough time to experience their own everyday situations at home, and to permit reflection on the everyday situation with its possible problems [132].

Limitations

The Intervention study was very small (34 participants), even though we attempted to include individuals during three different enrollment periods. This situation resulted in loss of power very soon after the intervention started, due to dropouts. Twenty-seven of the eligible individuals declined participation, and the main reason given was a feeling of fatigue. Another limitation in the study was that one repetition maximum [133] was not estimated and tested. This calculation would have made the exercise level descriptions more clear, and would have made possible the evaluation of the size of potential strength increase.

Fatigue is not present as an outcome in this Intervention study. Stroke patients are known to experience fatigue, and the main reason given for non-participation in this study was the occurrence of fatigue. If fatigue had been incorporated as an outcome measure, it would have been possible to describe the study population in relation to the stroke population in general regarding fatigue. While we currently believe that our study group was overall composed of more alert individuals, this might not be the true reality.

There are limitations with the registration of gait variables on the electronic walkway. We instructed our participants to walk in two different self-selected speeds, normal and maximal. However, this strategy was not sufficient to achieve overlapping speeds among the three assessments (baseline/post-intervention follow-up/3-month follow-up). Five individuals (15%) were thereby excluded from the gait analysis. A
total of nine individuals (28%) were excluded when adding the individuals that did not complete the follow-up.

**Strengths**

This study was a single-center, single-blinded, randomized, controlled trial. The study protocol and all the outcomes measured in this study were pre-specified and registered in advance at http://www.clinicaltrial.gov/ (NCT00377689). We planned the study using the current best evidence on rehabilitation techniques, and incorporated them to the best of our abilities in a setting that should be easy to transfer to a clinical rehabilitation setting.

EH was responsible for most of the planning, logistics, and analyses in the Intervention study, enhancing the study reliability.

When evaluating all the significant results from the Intervention study it is obvious that a connection can be noticed between these outcome measures. With an improvement after intervention within ADL, gait and the FES-I it could be described as a positive cycle. When the individual experiences a higher capacity in gait, a more secure gait, the falls-efficacy increases. With the increase in falls-efficacy, the activities in daily living becomes more feasible and the individual’s activity in ADL increases. This activity renders an exercise effect which hopefully generates a continuum of the achieved level of function/activity.
Clinical implications

A high intensive exercise program after stroke is feasible for individuals aged ≥ 55 years three to six months after stroke onset.

Important fall risk factors can be impacted even with a duration of only five weeks, which should be easy to incorporate in a clinical setting. Adding the home-based rehabilitation exercises after the intervention program is an option to extend the intervention.

ADL, gait, and FES-I are responsive to change after a high-intensity exercise program.

To achieve changes in HRQoL measures, the discussion sessions should include hidden post-stroke dysfunctions along with the physical themes such as fall risk and safety arrangements.
CONCLUSION

The high intensive exercise program positively affects several previously identified fall risk factors,

- improving activities of daily living,
- diminishing variability in gait, and
- improving falls-efficacy.

These results are achieved by requiring task-specific exercises, implementing the exercises in real life situations for five weeks, and adding a home-based exercise program.

The results from the present papers contribute to the quest for the most effective fall risk-preventive intervention.
Appendix I

Intervention program
Individuals in each group participated in a five-week structured program with assessments at baseline, post-intervention, three-month follow-up and six-month follow-up.

Intervention Group Program
The Intervention Group (IG) received seven sessions per week for five weeks, divided over three days (Monday/Wednesday/Friday). A total of 30 exercise sessions and five educational sessions were attended over these five weeks, adding up to a total of 35 sessions. The exercise sessions were six per week, two each day, for approximately 45 minutes. A one-hour educational discussion session occurred one day each week. The overall focus of the discussions was physical activity and functional performance. The intervention exercises at the first daily session were based on the High-Intensity Functional Exercise (HIFE) Program [103, 105, 134], in order to improve the individuals’ lower-limb strength, balance, and gait. The HIFE Program is based on exercising in functional weight-bearing positions. The program includes lower-limb strength (chair stand) and balance exercises (weight shifting outside support surface), in standing (knee bend) and walking (obstacle crossing course) [103]. By “high intensity,” the program states that the strength exercises comprised at least two sets of exercises with 8-12 repetitions (maximum), the balance exercises were close to the participants’ balance maximum, and the participant did not rest more than necessary [104]. The maximum was determined by the participants’ experienced exertion in performing the exercise for the first time. When the individuals increased their lower limb strength and/or balance, the exercises were made progressively more intense by increasing the load of resistance training, using a weight belt with more weights or increasing the range of motion (in knee bends, single leg squats, or step-ups).

In the Intervention program, all participants were required to describe their experienced and perceived problems at study start, and these comments were included in the rehabilitation plan. A home visit was conducted by a physiotherapist (PT) and an occupational therapist (OT) at the start of the program. This visit was to determine each subject’s ability (or inability) to perform activities of daily living (ADL) and lifestyle activities, and to experience the subject’s daily difficulties in the pertinent environment. All HIFE and implementation activities were individualized, based on the home visit, and tailor-made for each participant before the first day of the study. The HIFE Program contains instructions on how to choose the level of exercises from each participant’s capacity [103, 105].

Each day, the sessions began with a training session of individualized HIFE for strength and balance [103, 105, 134]. All exercises were
performed in weight-bearing positions. The HIFE session was followed by a 30-minute break with refreshments. The second daily session contained one hour of translation of the previously performed weight-bearing exercises into real-life situations, such as transfers, walking on stairs, walking outdoors, vacuuming, and shoveling snow.

If possible, all exercises were performed at a high intensity by each subject. To estimate the general level of intensity (in this program, perceived exertion) of the HIFE, the participants rated their perceived exertion according to the Borg RPE Scale at each training session [80, 81]. This scale ranges from 6 to 20 points, where 6 points represent no exertion at all and 20 points represent maximal exertion. The intensity level of the exercises was also monitored throughout the five-week intervention program by the RPE. In addition to the instructions of the HIFE Program, the intensity level of the exercises was regulated and made progressively more difficult/strenuous if the participants rated their perceived exertion lower than 15. To be able to rate the local exertion of the lower limb muscles, the perceived exertions of lower limb muscles (strength and balance exercises) were measured on a separate scale (1 = high, 2 = medium, and 3 = low exertion). The perceived exertion was rated at each exercise session, in combination with performing the exercises.

In addition, one day each week there was a one-hour educational discussion session. This discussion was focused on the increased risks of falls as a complication after stroke. Two PTs led the IG’s training sessions, and the educational sessions were led by one PT and one OT. The following topics were covered in the educational discussions:

1. Stroke and fall risk, factors affecting;
2. Aids at home / housing adjustment / adaption;
3. Fear of falling in connection with activities;
4. Strategies for transfers / activities;
5. Summary of topics 1-4.

During the last week of intervention, an individualized home exercise program was designed by the PT for each subject in the IG. This program consisted of a maximum of three different exercises that were based on the individual’s difficulties in performing different activities. The exercise intensities should be easy to adjust so that they could be modified as the subject progressed. The instructions were to perform this home exercise program three times a week at least until the three-month follow-up.

A journal for each IG and CG member was filled out by the care providers in each group. The IG contained information about all the chosen exercises, number of exercises, level of exercises, and the participants’ feeling of exertion during the different exercises.

Control Group Program
The Control Group (CG) program consisted of group discussion about non-obvious post-stroke dysfunctions and how to manage these difficulties. An educational discussion group together with an OT met once a week for one hour during the five weeks. A new subject was addressed each week. The OT led each discussion and held a short introduction to each subject. The discussion then took place among the participants, who related their own experiences on the subject. They exchanged experiences and tips on how you can overcome any problems or obstacles related to the stroke and the subject of the day. The following subjects were covered:

1. What happens to the body after a stroke?
2. Living with difficulties in perceiving one's body;
3. Depression, mood swings, and personality changes;
4. Difficulty in eating and drinking;
5. Summary of 1-4.

There was no special focus on the risk of falling in the CG discussion.
Appendix II

Example of home based rehabilitation program

1. **Exercise 1**: Nordic walking.
   Walk outdoors at a fast pace.
   Expand the number of walks per week when you feel able to do more.

2. **Exercise 2**: Split squat step.
   Change the forward leg every two steps. Take a big step forward with one leg, bend at the knee, then return to the starting position. Repeat with the other leg, take a big step forward and bend at the knee. Repeat 20 times. To make the exercise more demanding, wear a weighted backpack or increase the number of repetitions/leg.

3. **Exercise 3**: Stand-ups in walking position.
   Rise from a chair with one foot a bit ahead of the other. Repeat 12 times and then change the front foot. Repeat each side 12 times. To make the exercise more demanding, wear a weighted backpack or increase the number of repetitions/leg.
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