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Gait following Hip Fracture

Identification of key characteristics of gait and interventions to maximise gait recovery

Thesis for the degree of Philosophiae Doctor

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NORSK SAMMENDRAG:

Gangfunksjon etter hoftebrudd

Identifisering av gangkarakteristika og intervensjoner for å optimalisere gangfunksjon

I Norge er det vel 9000 hoftebrudd hvert år. Årlige kostnader er 4.5 milliard og det vil være en stor samfunnsøkonomisk gevinst knyttet til bedring av behandlings- og rehabiliteringstilbudet for denne gruppen. Hoftebrudd rammer i all hovedsak eldre. Et hoftebrudd representerer ofte en dramatisk endring i livssituasjon, tap av selvstendighet i daglige funksjoner og økt hjelpebehov. Få gjenvinner samme gangfunksjon som før bruddet, flertallet blir avhengig av ganghjelpemidler og risikoen for nye fall er betydelig. Tapet av funksjon er ofte større enn hva skaden alene skulle tilsi, og dette forklares gjerne med at eldre med hoftebrudd representerer en særlig sårbar gruppe pasienter. I dag er det begrenset kunnskap om hvilke type behandling og rehabilitering som kan bidra til å redusere funksjonstapet og optimalisere gangfunksjon hos denne sårbare pasientgruppen.

Avhandlingen er basert på gangdata fra totalt 620 hoftebrudds pasienter, inkludert i to ulike klinisk randomiserte studier, en med fokus på sykehusbehandling og en med fokus på fysioterapi i kommunal regi. Fire ulike gangkarakteristika: dobbel standfase, gangratio, variabilitet og asymmetri ble identifisert ved hjelp av faktoranalyse, og blir foreslått som gode indikatorer på gangkvalitet etter et hoftebrudd. Resultatene viste at pasienter som hadde fått behandling på en geriatrisk sengepost i forbindelse med hoftebruddet hadde bedre gangkvalitet et år etter bruddet, rapporterte bedre mobilitet og det var flere som fremdeles var i stand til å gå et år etter, sammenlignet med pasienter som hadde fått standard behandling på en ortopedisk sengepost. Treningsstudien viste at en stor andel av eldre som har hatt hoftebrudd er i stand til å gjennomføre et relativt intensivt treningsprogram når det foregår i hjemmet under veileding av fysioterapeut. Det ser imidlertid ut som kognitiv svikt kan være en barriere for deltagelse, noe som indikerer at dette er en gruppe som krever ekstra oppmerksomhet.

Disse funnene indikerer at mange eldre med hoftebrudd i dag ikke får et optimalt tilbud med tanke på å gjenvinne gangfunksjon, og at det er et potensiale for å bedre behandlings og rehabiliteringstilbudet ved å innføre modeller basert på geriatrisk utredning og behandling.

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Abstract

Hip fractures are associated with severe decline in gait function and can represent a dramatic change in life situation for older people. At present, knowledge is scarce on type, timing and organisation of interventions to maximise gait recovery after hip fractures, and few intervention studies have included measures of gait characteristics beyond gait speed. The overall aim of this thesis is to identify and describe relevant gait characteristics in older community-dwelling people who have sustained a hip fracture, and to provide a better base of knowledge for the development of more targeted interventions to maximise gait recovery after hip fracture.

This thesis is based on four papers, the first two with a methodological approach and the last two with a clinical approach. Paper I aims to examine to which extent spatial and temporal gait characteristics are comparable when analysed with different software-products, while paper two aims to identify the most relevant gait characteristics to describe gait recovery following hip fracture. Paper III is an evaluation of the long term effect of early multidisciplinary and multicomponent hospital intervention on gait, while paper IV is a protocol paper describing the rationale for a municipality based exercise trial targeting gait control, including also data on inclusion and attrition rate.

Data were collected through two randomised controlled clinical trials including a total of 620 community-dwelling older adults with hip fracture: i) The Trondheim Hip fracture Trial comparing comprehensive geriatric care with conventional orthopaedic care, and ii) the EvaHip trial, aiming to evaluate the added effect of a home based exercise programme delivered four months following the fracture, compared with routine practice in the municipality. Data on spatial and temporal gait characteristics were collected using an instrumented walkway (GAITRite®) four and 12 months following the fracture.

Results showed high level of agreement for gait variables between software-products. Four gait domains; Pace/rhythm, postural control, variability and asymmetry, and four corresponding key gait variables; double support time, walk ratio, step velocity variability and single support asymmetry were identified using a factor analysis approach. Gait characteristics following hip fracture demonstrated reduced gait control, increased fall risk and high energy costs of walking.

Significant group differences in favour of participants who had received comprehensive geriatric care in the early preoperative and postoperative stages were found for double support, walk ratio and asymmetry. Inclusion and attrition rate reported in the protocol paper indicated that a relatively high proportion of community-dwelling older adults were able to participate in an exercise programmes when performed in a home setting, but that participants who refused to participate had lower pre-fracture cognitive function compared to those who were randomised.

Results from the hospital study showed that a relatively short multicomponent intervention improved gait outcome as long as one year following the fracture and suggest that targeting the vulnerability of these patients in the early stage is important for long-term gait outcomes. Inclusion an attrition rate reported in the protocol article indicates that reduced cognitive function is a barrier for participation in municipality based rehabilitation programmes. Further work should aim to develop integrated care pathways covering both hospital and municipality rehabilitation and to develop better tailored and targeted interventions to maximise gait recovery.

Acknowledgement

This work has been carried out in close collaboration between the GeMS research group at NTNU, the Unit for Physiotherapy Services in the Trondheim municipality and the Orthopaedic and Geriatric Departments at St Olav University Hospital. The Liason Committee between the Central Norway regional Health Authority and NTNU funded the work.

I would like to express my gratitude to all the patients and their relatives who participated in two studies and made this work possible.

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Thanks to family, colleagues and colleagues who have become close friends of mine during this period, especially Mona, Bård, Karin and Gro.

List of Papers:

Paper I.

Egerton T, Thingstad P, Helbostad JL. Comparison of programs for determining temporal-spatial gait variables from instrumented walkway data: PKmas versus GAITRite. *BMC research notes.* 2014;7(1):542.

Paper II

Thingstad P, Egerton T, Ihlen E.F, Moe-Nilssen R, Helbostad J.L. Identification of gait domains and key gait variables following hip fracture
Manuscript: Submitted BMC geriatrics; 06.07.2015

Paper III

Thingstad P, Taraldsen K., Saltvedt I., Sletvold O.; Vereijken B.; Lamb S.E., Helbostad J.L. The long term effect of Comprehensive Geriatric Care on gait after hip fracture: The Trondheim Hip Fracture Trial - a randomized controlled trial. Submitted: Osteoporosis International; 26.6.2015

Paper IV

Thingstad P, Taraldsen K, Hagen G, Sand S, Saltvedt I, Sletvold O, Helbostad, J.L. Effectiveness of task specific gait and balance exercise 4 months after hip fracture: protocol of a randomized controlled trial - the eva-hip study. *Physiotherapy research international : the journal for researchers and clinicians in physical therapy.* Jun 2015;20(2):87-99.

Abbreviations:

CGC	Comprehensive Geriatric Care
OC	Orthopaedic Care
THT	**T**rondheim **H**ip **F**racture trial
EvaHip	**EVA**luation of rehabilitation after **Hip** fracture
CoM	Center of Mass
SD	Standard deviation
CV	Coefficient of variance
ICC	Intraclass Correlation Coefficient
MDC	Minimal Detectable Change

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Figures

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"A life breaking event"

"In sharp contrast to a clinical orthopaedic perspective, in which a hip fracture is often considered trivial and simply a routine case requiring uncomplicated treatment, from the patient's perspective a hip fracture is an intensely unpleasant and serious incident that has severe effects on their entire life"

p.807, Ziden, L. "A life breaking event" [1]

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Introduction

Hip fractures are common, and represent a severe threat to health and wellbeing at old age. Residual lifetime risk for women at 60 years of age is 44 percent.[2] Consequences are severe in terms of reduced function, loss of independence, new falls and high societal costs.[3] This decline in function is closely related to gait impairments. With recent advances in surgical techniques, more or less full recovery of gait could be expected after hip fracture. However, few of those who experience a hip fracture will ever regain pre-fracture gait function.

There are numerous studies describing the poor outcome following hip fractures and predictors for poor outcome. Far less is known about effectiveness of interventions aimed at improving gait outcome and the mechanisms underlying the observed decline in gait function. Gait speed is reported in a few clinical trials, but gait characteristics beyond speed have so far not been reported in larger trials. The knowledge is therefore sparse concerning what characterises gait in old people with hip fractures and which aspects of gait that should be targeted in interventions.

The overall aim of this work is to present a stronger fundament for improving hip fracture care and recovery of gait in this vulnerable group of older people, and to reveal relevant aspects of gait to be targeted in interventions to maximise gait recovery. Further, it aims to explore the hypothesis that gait decline could be prevented by improving pre- and post-surgery treatment, and to present the rationale for a municipality based exercise intervention targeted at maximising gait recovery.

Background

Worldwide, there are 1.6 million hip fractures each year.[3-7] The majority of hip fracture patients are old and two thirds are women. Hip fracture incidence increases exponentially with increasing age, from 7.75 per 1000 person year in the age group 70-79 years to 70.18 per 1000 person year in women aged 95 years and older.[8] Despite a tendency towards reduced incidence due to a healthier older population[9], an increasing aging population, an increasing relative proportion of the oldest old combined with an increasing incidence of hip fractures among the oldest old[10] suggest that the extent of this health burden will grow in the coming years.

Hip fracture is a general description for several different types of fractures in the proximal end of the femur, classified according to the anatomical location of the fracture. The main types are fractures of the femoral neck (intra-capsular fractures), and fractures through the muscle insertions distal to the femoral neck (extra-capsular fractures). The ratio of trochanteric versus femoral neck fractures are about 50/50, but the portion of trochanteric fractures increases by age in female patients and is associated with higher mortality, morbidity, disability and costs than femoral neck fractures.[11-13] In the western world almost all hip fractures are treated with surgery. Osteosynthesis is the main treatment for trochanteric fractures, while femoral neck fractures are treated either with arthroplasty or internal fixation. Recently it has become increasingly common to choose arthroplasty for the majority of patients with displaced femoral neck fractures.[14-17]

Falls in vigorous older people mainly occur outside the home and can be related to trips, slips and environmental hazards.[18] However, 90percent percent of hip fractures are low-energy trauma resulting from a fall from standing height or lower,[5] about 80 percent occur indoors during normal daily activities and few of these fractures can be attributed to falls caused by environmental hazards.[19, 20] Older people who have sustained a hip fracture frequently report a period of reduced community ambulation just prior to the fracture, often related to another health problem.[21] Such observations suggest that a hip fracture should not be regarded a genuine accident, but rather as an indication of reduced health and function.

Even if there is a large heterogeneity in function among older people who sustain a hip fracture, the majority of community-dwelling hip fracture patients are relatively independent in activities of daily living prior to the fracture. Seventy-seven percent have been reported to be able to walk independently and 68 percent able to care for themselves.[22] However, severe decline in gait function,[23] and independence in activities of daily living (ADL)[24-26] following the hip fracture appear to be common and long lasting.

Changes in body composition, with 3.6 percent increase in fat mass and 6 percent decrease in muscle mass, have been found to occur between 10 and 60 days following the fracture, and to remain one year later. This is much higher than the 1.7 percent increase in fat and 1 percent decrease in muscle mass observed in healthy older adults.[27, 28] Even among elderly without mobility limitations prior to the fracture, the majority become dependent in daily life tasks like outdoor walking, stair negotiation and walking short distances indoors.[25, 29-31] The risk of new falls and fall-related injuries is high. Within the first two years after the fracture, 56 percent of hip fracture patients have experienced a new fall, 28 percent recurrent falls, 30 percent an injury; 12 percent a fracture and 5 percent a new hip fracture.[32] About 20 percent of hip fracture patients become nursing home residents as a consequence of the fracture.[33] There is a 5- to 8-fold increased risk of all-cause mortality the first 3 months after hip fracture, and mortality is increased up to ten years after the fracture.[34] The permanent decline in function is larger than could be expected from the injury alone and suggests that older people who fracture their hip are particularly vulnerable. This is further supported by the high prevalence of comorbidity and complications following the fracture.[35] Almost half of the patients are anaemic already at admittance to hospital[36] and the complication rate is reported to be 12-28 percent, with pneumonia and urinary tract infections as most common.[37] About half of the hip fracture patients develop delirium during the peri-operative period[38] and the prevalence of cognitive impairment has been reported to be between 33 and 88percent.[39, 40] Prevalence of depression varies between 9 and 47percent in hip fracture patients and is much higher than in the general population.[39, 41]

Reduced health and function prior to the fracture are amongst the most frequently reported risk factors for hip fracture and poor outcome.[26, 31, 42-44] Slower recovery after hip fracture surgery has been observed in older patients,[45] in groups with low pre-fracture mobility,[46] in patients with cognitive decline[47] and in patients with a high level of inflammation markers.[48] Inflammation also seems to play a role in the pathogeneses of depression after hip fracture.[49] Dementia, cognitive decline[31, 50] and depression[51] are well known predictors for poor outcome after a hip fracture and delirium is an independent risk factor for institutionalisation and functional decline.[52, 53] The differences in recovery between subgroups of patients appear to be related to frailty status. Frailty is described as a state of vulnerability due to a cumulative age-related decline in physiological reserves.[54] Injuries like hip fractures require energy for recovery, repair and restoration of homeostatic equilibrium, and challenge the already reduced capacity and scarce energy reserves. Abnormal levels of resting metabolic rate have been found in pre-frail and frail women,[55] and higher levels of resting metabolic rate than normal in old age have been found to be related to increased mortality[56] suggesting that resting metabolic rate could be a relevant indicator of frailty.[57] Older people with frailty are at increased risk of functional decline due to reduced capacity to respond adequately when facing even minor stressors. Compared to more robust individuals, old people with frailty experience a more dramatic decline in function following a hip fracture, need longer time to recover, and the end result is often a permanent loss of function.[54, 58]

Interventions to improve gait outcomes after hip fracture

Early intervention

Frail older people sustaining a hip fracture are faced with substantial stressors, including the fall incident itself, the surgery and the strain associated with multiple examinations and the hospitalisation. Reduced capacity to respond adequately to this strain may result in homeostatic dysregulation and risk of subsequent adverse outcomes.[59] This could explain the accelerated loss of muscle mass and high rate of complications like infections and delirium It could also explain the dramatic decline in gait function and why gait recovery is slow, with so few ever regaining pre-fracture gait function.[54] Therefore, it is important to prevent complications and optimise health condition in the very early stage in order to improve homeostatic balance and thus reduce gait decline, improve gait recovery and avoid permanent gait impairments.

There is ample evidence that geriatric patients benefit from interdisciplinary and multicomponent interventions based on principles of comprehensive geriatric assessment and care.[60-63] Such models delivered during the inpatient stage for hip fracture patients have been found to reduce complications[64, 65] mortality, length of stay and nursing home admittance.[60, 63, 66, 67] A positive effect of comprehensive geriatric assessment in hip fracture patients has been found in activities of daily living, mobility and gait function up to two years following the fracture,[64, 65, 68-70], and the effect appears to be even stronger in hip fracture patients with cognitive decline.[71, 72] There are, however, few studies evaluating the effect of very early pre- and post-surgery interventions, as most in-hospital interventions include a relatively long sub-acute rehabilitation phase.[65, 69, 73]

Extended rehabilitation

Another explanation for suboptimal recovery of gait following hip fracture could be that frail old people need more time to recover compared to more robust individuals. Thus, the rehabilitation could be ended too early and at a time where frail older individuals still has a potential for further gait recovery. While basic ADL activities reach maximum recovery about four months after the fracture, gait and more complex I-ADL functions reach maximum recovery about one year after the fracture[29, 31]. Qualitative research has shown that returning to the home after rehabilitation is associated with feelings of pessimism, loss of autonomy and coping,[21] and that feelings of insecurity and restricted life remain one year following the fracture.[74] These findings point to the need for longer follow-up and a focus on critical transitions especially between institutional rehabilitation and the daily life setting.

Type of exercises and patient characteristics

Systematic reviews have concluded that the evidence is sufficient to claim that exercise and physiotherapy is beneficial for gait and mobility after hip fracture. There is, however, a lack of knowledge concerning timing and content to maximise gait recovery.[61, 75, 76] Interventions that have been evaluated include progressive high dosage strength training targeting isolated muscle groups,[77-82] functional strength exercises targeting muscle synergies in specific tasks,[82-87] and general fitness programmes including exercises for endurance, strength and flexibility without a specific focus.[88] In addition, rehabilitation programmes, including early supported discharge and training of daily tasks based on individual goals but not necessarily protocol driven exercise programmes have been subject to evaluation.[89-94]

Progressive strength training has been subject to evaluation both in very early postoperative phase[77] and as extended exercise programmes performed after the end of ordinary rehabilitation. Research shows that progressive strength training is feasible for about 20 percent of hospitalised hip fracture patients within the first few days after the operation.[78] Several reviews point to progressive strength training as a promising approach to improve outcome after hip fracture. This is mainly based on a few relatively large studies on extended exercise programmes performed in an outpatient setting.[79-82] These studies evaluate exercise programmes including 24 - 72 supervised sessions at 70-90percent of 1RM and lasting up to half a year. Patient characteristics suggest that a relatively selected group of patients with reduced physical function but with intact cognitive function have been included.[76, 79-82, 90] Some trials have evaluated home-based progressive strength training: One of these home-based trials showed effect on muscle strength, gait speed, endurance and physical performance one year following the fracture, by exercising on a portable leg press machine[95]. Decline in muscle strength and function in the control group during the follow-up period suggest that such interventions can prevent decline in muscle strength rather than improving it. Progressive strength training included as part of a multicomponent programme targeting frailty has shown relatively large beneficial effects on nursing home admittance, gait endurance and use of walking aids despite no reports of increased lower extremity strength.[90]

Another approach has been to include more functionally oriented exercises; weight bearing exercises including stepping and step-ups, based on principles of progressive strength training using for example weight wests. [83-87] Most of these trials have been performed in a home setting and have included participants with relatively intact cognitive function who were able to perform the training on their own with relatively few follow-up visits. These studies have shown positive effect on gait speed, mobility, function and balance. One study performed in an outpatient setting showed effect only in a subgroup of participants with cognitive impairment.[83]

The majority of rehabilitation interventions have been delivered during the inpatient stage, but there are also models of early supported discharge and home-based long term follow-up. These have been shown to reduce mortality, admittance to nursing home, use of assistive devices and perceived difficulties in negotiating stairs, and to increase independence in self-care and instrumental activities of daily living, falls efficacy and the ability to walk outdoors up to one year following the fracture.[89-94]

Interventions based on principles of motor control and task specific exercises have been argued to improve gait, especially in fall prone elderly people.[96, 97] So far there is sparse knowledge about the effect of such interventions following hip fracture. However, in older people with slow and variable gait, interventions targeting gait control have been found to reduce energy costs during walking and to improve confidence in walking, when compared to traditional impairment oriented training.[98]

There is limited support for fitness programmes without specific focus. A home-based programme including general exercises for endurance, flexibility and strength failed to demonstrate effect despite long and close follow-up including up to 56 visits during a twelve month period. The authors explained this by the selection of participants and suggest the participants were too healthy to benefit from the programme.[88]

To conclude, there seems to be evidence for an overall beneficial effect of exercises on gait even long after ordinary rehabilitation is ended, especially progressive strength training and functionally oriented strength training. With exception of a few trials, this evidence is restricted to participants with intact cognitive function who are able to attend an out-patient setting or to follow instructions for exercising on their own. Although reviews conclude that exercise interventions seems to be beneficial after hip fracture,[61, 75, 76] these recommendations are not necessarily applicable for the frailest individuals and those with cognitive impairment.

Gait characteristics and hip fractures

Gait speed as an indicator of health and function

Preferred gait speed is regarded a global indicator of health and function, and is recommended as a vital sign, similarly to blood pressure or body temperature, to indicate whether there is a dysregulation of vital processes.[99] Decline in preferred gait speed has been identified as a strong predictor of disability, mortality, hospitalisation, placement in long-term care and cognitive decline[99, 100 101] Preferred gait speed is regarded a robust and sensitive measure of health and function and a relevant outcome for intervention trials involving old people and has been suggested as a relevant and single indicator of frailty.[102] Walking requires coordinated function of multiple physiological subsystems, from metabolic systems including mitochondrial function and the cardio-respiratory system, to effector organs like the musculoskeletal system and information processing systems involving sensory systems and brain structures. Both changes in brain structures and muscle morphology have been associated with slowing of gait,[101, 103] but it may be the accumulation of deficits in multiple systems more than deficiency in a single systems that has the closest association to slow gait.[104]

Compensating strategies and energy costs of walking

The age-related slowing of gait has been described as a consequence of reduced energy reserves as slow walking reduces the amount of energy spent per time unit.[105] The association between slowing of movements and mortality is not unique for humans. Mobility is essential for surviving for most animals and remains relatively stable until late life, when a rapid decline is observed. This observation is consistent across species and suggests that mobility is so vital to life that energy is shifted away from mobility only when other vital processes are threatened.[106] Maximal energy expenditure, and the capacity to perform vigorous activities decline with age, starting at the age of 30 years.[107] Most daily activities involve walking. While young and healthy individuals perform most activities of daily living at a workload well below their maximum energetic capacity, even the most basic tasks could challenge energetic limits in frail older adults with energetic demands close to the upper limits of their metabolic boundaries.[108]

While slow walking reduces the energy costs per time unit, the energy costs per distance increase exponentially with reduced speed, and higher energy cost when walking at preferred self-selected speed has been found in older compared to younger adults.[109] Preferred walking speed in healthy adults corresponds to the speed that minimise energy expenditure and is around 1.3 m/sec, while both higher and slower gait increases the energy costs of walking with a J-shaped relation between energy cost of walking and speed.[110, 111] Estimates based on exercise testing and physiological research indicate that older adults with gait impairments use up to 75-87percent of their maximum capacity during usual walking, leaving only a small energy reserve for other daily tasks and activities.[112, 113] Higher energy cost during walking has been related to poorer self-reported function in elderly[113] and to fatigability,[114] and is a potential risk factor for inactivity and further functional decline.

Biomechanical factors can also explain higher energy cost of slow walking. The gait cycle can be described in terms of a pendulum analogy.[115] During the single support phase, the swing leg act as a pendulum and the stance leg as an inverted pendulum, resulting in an energy-efficient cyclic movement. Walking at slower speed alter normal pendulum actions, resulting in less use of passive stored energy and more demand on muscle activity.[116]

Gait control and dynamic balance

Another biomechanical explanation for age-related slowing of gait is that it reflects compensating strategies to increase gait stability. Walking requires fine-tuned control of the trajectory of the body's centre of mass (CoM) over a narrow and changing base of support.[117, 118] Falls resulting in hip fractures usually occur while walking indoors during seemingly non-risk daily life activities. Walking related to daily life activities is characterised by short abrupt walking bouts, including frequent shifts in direction and adjustments of velocity, and initiations and terminations of gait.[119] From a biomechanical point of view, walking as part of daily life activities could be more challenging to balance than continuous walking over longer distances. Biomechanical modelling has demonstrated that human gait comprises passive stability properties in the fore-aft direction, and is rather resistant to moderate perturbations in this direction. On the other hand, mediolateral control requires feedback and active control and rely more on sensory-perceptual and cognitive capabilities.[115, 120] Several authors have argued that an impaired ability to control CoM in the lateral direction during gait appears to be particularly relevant to the problem of falling among older people,[121-123] and inadequate control of weight shifting has also been shown to be the dominant cause of falling in frail older adults.[124, 125]

The most prominent gait characteristic associated with ageing along with reduced gait speed, shorter steps and widening of the base of support, is a change in time spent in double support phase relative to single support phase during the gait cycle.[112, 117, 126, 127] The pendulum analogy implies that active control is mainly performed during the double support phase. During the double support phase both legs contribute to the redirection of CoM, and the heel strike of the leading leg redirects the CoM velocity and initiates the next step. This suggests that weight shift and medio-lateral control during gait is mainly performed during the double support phase.[128] Increased double support time has been found to be associated with degenerative changes in brain regions related to executive functions and visuospatial orientation, important for gait control.[129]

Slow walking is inherently more unstable than walking at normal speed, and the most effective strategies to stabilise gait are shorter and faster steps along with a widening of base of support,[123, 130, 131] these changes are however associated with higher energy costs of walking.[112, 132]

Gait speed is the product of step length and step frequency. In terms of energy costs there is an optimal ratio of length and frequency at a certain gait speed, and walking with slower and longer steps or shorter and faster steps than the optimal ratio will increase energy costs.[133] In healthy subjects there seems to be a linear relationship between step length and cadence with increasing gait speed, which has led to the suggestion that this relation, the step length – cadence ratio, also called walk ratio, can express central control mechanisms and represents a way to simplify gait control. Changes in the walk ratio can therefore be interpreted as an indication of more conscious control of gait.[134]

It seems that the most commonly reported age-associated changes in gait characteristics reflect a trade-off between energy expenditure and compensating strategies to increase stability of walking. A better understanding of these mechanisms could help develop interventions that are targeted better to improve gait control. This would require exploration of gait characteristics beyond walking speed, but so far there are few reports on this, both in frail populations in general and in hip fracture patients in specific.

Variability

Gait variability is defined as fluctuations in gait characteristics from one step or stride to the next. There is an increasing body of knowledge linking reduced cognitive capacity, fall risk, impaired mobility and frailty to gait variability.[135-137] Variability is suggested as a more sensitive predictor of mobility decline than gait speed,[138] and a better predictor of fall risk and cognitive decline than gait speed.[136]

Step-width variability represents a different construct than step-length variability and variability in temporal gait characteristics.[139] This is supported by findings linking stance time variability to cortical functions and step width to sensory impairments.[140] Step-length and step-width variability have opposite association with speed, with higher step-length variability and lower step-width variability associated with lower gait speed.[141] Low variability in medio-lateral direction has been interpreted as reduced flexibility in walking and a freezing of degrees of freedom-strategy.[142] The interpretation of step-width variability is not straight forward, with both too much and too little step width variability associated with increased risk of falls.[143]

Asymmetry:

A hip fracture is a unilateral injury associated with pain[26] and changes in muscle function of the injured hip.[144] Asymmetry in weight loading and muscle strength of the lower limb persist long after the fracture has healed.[145, 146] In healthy older adults gait asymmetry have been associated with increased fall risk and low gait speed, suggesting asymmetry is related to aspects of gait control and not only muscle strength and pain.[147, 148] Gait asymmetry therefore appears to be a relevant target for interventions aimed to improve safety of walking.

Spatial and temporal gait data collected by instrumented walkways

Measurements of spatial and temporal gait characteristics by use of instrumented walkways are common in research describing gait in older people. Different methods are available, including hardware for data collection and software for extraction of variables. Different gait protocols are used, different gait variables are reported, and the way variables are calculated varies. These differences in methodological approach represent a challenge when results from different studies are to be compared. Documentation of comparability of different methods is therefore important, as it is a clear rationale and theoretical foundation for the selection of gait protocol and selection of gait variables to report.

Aims and research questions

The overall aim for this thesis was to reveal important aspects of gait in hip fracture patients and to identify important targets for intervention aimed at maximising gait recovery. The first part has a methodological approach; to examine level of agreement between different software-products for processing of data from instrumented walkways, and to identify the most relevant gait variables to report in this population. The second part has a clinical approach; evaluating the long term effect of a pre- and post-surgery multicomponent intervention on relevant gait variables, and description of a protocol for an exercise programme targeting gait control, delivered at a stage where ordinary rehabilitation is usually ended.

Paper I

Aim: To examine the level of agreement between the PKMAS software and the GAITRite® software for processing of instrumented walkway data.

Research question: What is the level of agreement between data processed by the PKMAS software and the GAITRite software?

Paper II

Aim: To reveal key gait characteristics that cover important features of gait in older people with hip fracture and explore how these characteristics are related to known predictors for poor outcome.

Research question: Can commonly reported gait variables be classified into domains represented by key gait variables and how are these key variables related to known predictors for poor outcome?

Paper III

Aim: To evaluate the long-term effect of Comprehensive Geriatric Care on key gait.

Research question: Will early pre- and post-operative geriatric care result in better gait control and gait efficiency compared to conventional orthopaedic care four months and one year after the fracture?

Paper IV
Aim: To describe the protocol for an exercise intervention targeting gait control delivered four months following the fracture, and to describe characteristics of included participants and those lost to follow-up during the trial.

Research question: Will an extended exercise programme customised to the needs of frail participants and targeting gait control, be able to reach a representative sample of hip fracture patients?

Synopsis of the papers

Paper I
The use of different methods to collect data on gait characteristics from instrumented walkways represents a challenge when comparing results from different studies, and there is need for documentation of comparability of results from studies using different methods. Paper I aimed to examine the level of agreement between a well-established software with documented reliability, GAITRite® and a newly developed software the PKMAS, claiming to be superior in processing of atypical footsteps. Absolute and relative agreement between parameters of gait calculated from exactly the same steps with both programmes indicated that for most variables data can be used interchangeable. However, different algorithms for footfall identification resulted in systematic differences in step width. The conclusion is that the PKMAS software can be used interchangeable with the GAITRite® software if systematic differences are accounted for.

Paper II
A large number of gait variables have been reported in the literature and except for gait speed, there is little consensus concerning which variables reflect important aspects of gait, and which are redundant. Paper II aimed to identify independent domains of gait and corresponding key characteristics using a factor analysis approach. Four domains; pace/rhythm, postural control, variability and asymmetry and four corresponding key characteristics; double support time, walk ratio, step velocity variability and single support asymmetry were identified. These gait characteristics were associated with known predictors for poor outcome following hip fracture and are suggested as relevant outcome measures in interventions aimed at maximising gait recovery.

Paper III

Older people are at high risk of developing permanent gait impairment and mobility limitations following a hip fracture. This gait decline may possibly be related to high prevalence of frailty. Paper IV aimed to evaluate the long term effect of comprehensive geriatric care on gait as compared to conventional orthopaedic care using a randomised controlled design. Three hundred and ninety seven participants were randomised. One year following the fracture, gait characteristics indicated better gait control and more efficient gait in participants who had received CGC in the very early pre- and post-surgery stage as compared to those who had received orthopaedic care.

Paper IV

Frail older adults would normally require more time to recover after sickness and injury than more robust individuals, suggesting that ordinary rehabilitation is ended before full potential for recovery of gait is reached. Paper IV is a protocol paper describing design and rationale for a single component exercise intervention targeting gait control delivered four months following the fracture. Two hundred and twenty three participants were included (90 percent of eligible patients) during the hospital stay and 142 randomised to either exercise or conventional follow-up in the municipality after a run-in period of four months. Inclusion and attrition rate in the study is reported in the protocol paper and indicate that a relatively large proportion of older hip fracture patients are able to attend home-based exercise programmes but that cognitive impairment could be a barrier.

Material and Methods

Setting and participants

This work is based on two randomised controlled clinical trials; The Trondheim Hip fracture (THF) trial[149-151] which has been reported in full previously, and the EvaHip trial – Evaluation of rehabilitation after hip fracture,[152] where the protocol, inclusion and data collection was completed at the time this thesis was concluded. In total 620 older participants with hip fracture were included in these two trials. In addition, a dataset with gait characteristics for a sample of 86 healthy older adults participating in an exercise study, the Generation 100 study was included in paper I. These were participants invited from a total birth cohort (1936-1942) to participate in a randomised controlled trial evaluating the effect of 5 years exercise training on mortality.[153]

Inclusion criteria and outcomes for the THF and EvaHip trials were basically the same. Target population was older community-dwelling hip fracture patients. No exclusion criteria were set for cognitive function. No medical exclusion criteria were set for the THF trial, while contraindication for exercising as evaluated by a geriatrician was an exclusion criterion for the EvaHip trial. Inclusion and exclusion criteria are presented in Table 1.

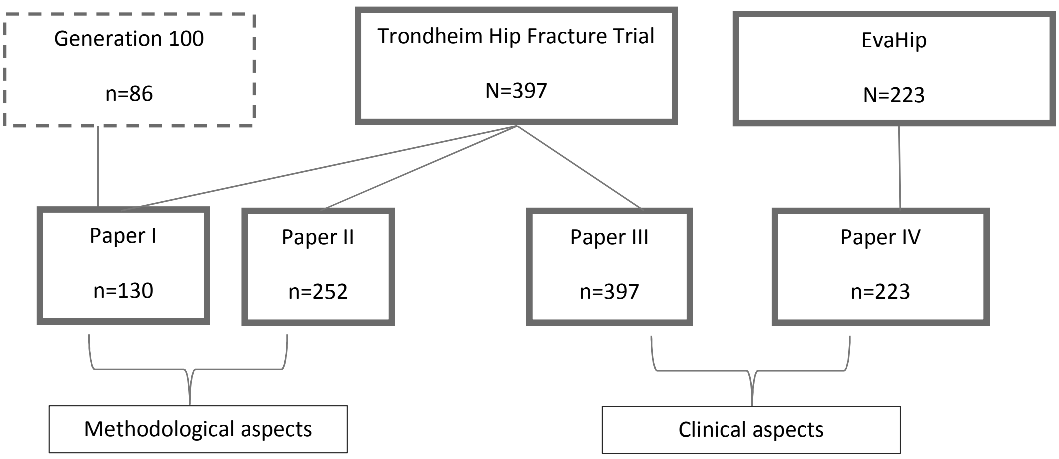


Figure 1 Overview of studies and papers included in the thesis

Table 1 Inclusion and exclusion criteria for the THF and the EvaHip trials

Inclusion criteria	Exclusion criteria
Confirmed intra or extra capsular hip fracture hip fracture (ICD-10, 72.0- 72.2)	Life expectancies shorter than 3 months
Age > 70	Pathological fracture
Community-dwelling at time of the fracture	High energy trauma
Living in the catchment area	
Able to walk 10m prior to the fracture	
EvaHip (at 4months, baseline):	
Able to stand upright and walk a few steps with support	Medical contraindications for exercising

Gait assessments were performed four and 12 months following the fracture. Participants who were unable to attend the outpatient clinic were offered a home visit. These participants performed a reduced assessment protocol which did not include gait analysis by use of the GAITRite mat. If possible a registration of gait speed using the 4m gait speed test from as part of the Short Physical performance Battery that was the primary outcome in the THF trail was performed.[154]

A subset of the first 44 patients from the THF trial were used for evaluating level of agreement in paper I, combined with a dataset of healthy older adults from the Generation 100 study (n=86). The complete dataset from the gait assessment at four months in the THF trial were used for the factor analysis in paper II, while the complete dataset from both four and 12 months gait assessments were used for the evaluation of treatment effect of CGC in the THF trial in paper III. Pre-fracture patient characteristics are presented in Table 2 for THF trial and the Eva-Hip trial separately.

Table 2 Characteristics and pre-fracture function of participants in the Trondheim Hip Fracture (THF) trial and the EvaHip trial.

	THF n=397, mean (SD)		EvaHip n=223, Mean (SD)	
Age (yrs)	83.3 (6.1)		83.4 (6.2)	
Barthel (0-20)	18.2 (2.5)		18.5 (2.1)	
Nottingham Extended I-ADL (0-66)	42.2 (17.6)		42.1 (16.7)	
Clinical Dementia Scale (0-18)	2.7 (3.9)		1.7 (3.2)	
	N and % [a)]		N and %	
Women	298/397	75%	159/223	71%
Indoor fall	275/374	74%	168/214	79%
Walk aid assistance indoor	91/382	24%	58/ 219	27%
Walk aid assistance outdoor	132/367	40%	98/215	46%
Intracapsular fracture	245/397	62%	131/223	59%
Arthroplasty [b)]	163/397	66%	114/131	87%

[a)]Number of participants with complete data varied between tests and is reported in proportion of those with complete data [b)]proportion of intracapsular fractures

Overview of design for the hip fracture trials

Design, inclusion criteria and outcome measures were essentially the same for both the THF trial and the EvaHip trial. Both trials are two-armed, longitudinal, pragmatic randomised controlled clinical trials, aimed at measuring effectiveness of interventions performed in routine clinical practice with usual care as comparator. The THF trial focused on multi-disciplinary in-hospital treatment and the EvaHip trial on physiotherapy provided in a community-based setting four months following the fracture. In the THF trial, participants were randomised at admittance to the hospital, while participants in the EvaHip trial were included during the hospital stay and randomised after a run-in period of four months. The design of the EvaHip trial was chosen to allow for registration of a complete cohort of hip fracture patients in order to give a more complete description of pre-fracture function in those lost to follow-up for the exercise intervention.

Recruitment and inclusion

Inclusion in the THF trial was performed between April 2008 and December 2010, and inclusion in the EvaHip between February 2011 and April 2013. In the THT trial, patients were included and randomised in the emergency room by the nurse in charge and transferred directly to the allocated ward. In The EvaHip trial eligible patients were identified through operation lists and the patients were approached within 4 days post-surgery by a study coordinator and invited to participate. Then, after a run-in period of four months, participants were invited for baseline testing and randomisation. Patients who at this stage did not want to attend the exercise programme were still encouraged to meet for study assessments during the follow-up period.

Randomisation

We used a web-based computerised randomisation service developed by, and administrated from the Unit of Applied Clinical Research at the Norwegian University of Science and Technology (NTNU). The computer generated sequence was prepared by the Unit of Applied Clinical Research, and was not revealed until inclusion was closed and the data analysis plan finalised. The computerised solution was administrated by nurses in the emergency room for the THF trial and by an administrative coordinator in the municipality for the EvaHip trial.

Informed consent

Patients gave written informed consent about inclusion before participation. Next-of-kin provided a preliminary consent for patients deemed not competent to give consent at inclusion. Repeated information about the trial was provided at each follow-up.

Ethical approval

Ethical approvals for the studies were granted by the Norwegian Ethical Review Board for Medical and Health Research (REK). The Trondheim Hip fracture Trial (REK4.2008.335), the EvaHip trail (REK4.2008.335) and the Generation-100 (2013/787b) respectively.

Interventions

The THF trial intervention was a relatively short hospital-based intervention delivered before and early after surgery. It included an interdisciplinary and a multicomponent approach, resulting in an individualised plan with short and long term goals for treatment and rehabilitation. The EvaHip intervention was a ten weeks home-based exercise intervention delivered four months following the fracture. It included a single component physiotherapy approach that was protocol driven and including five standardised exercises specifically targeting balance and gait control. The exercises were progressive and with described according to five levels for each exercise.

Usual care was comparator in both trials. For the THF trial, usual care meant treatment in an orthopaedic ward following national standards. For the EvaHip trial usual care could vary from no follow-up to rather extensive interdisciplinary rehabilitation.

The Trondheim hip fracture trial - Comprehensive Geriatric Care

The model of Comprehensive Geriatric Care (CGC) was originally developed for geriatric patients. It was well established and had previously been shown to be effective for geriatric patients.[155, 156] The main elements of CGC are systematic and standardised evaluation of medical, mental, physical and psychosocial functions, through a team approach, including a formal structure for the team collaboration. This approach results in individualised treatment and rehabilitation goals based on pre-fracture function, knowledge of the home environment and the medical status. In collaboration with the orthopaedic department, this model was adjusted to implement routines for orthopaedic pre- and postoperative care.[150] Five beds in the geriatric ward were reserved for older fracture patients and dedicated personnel with special competence in geriatric care were assigned. The number of staff per patient bed was higher in the geriatric ward than compared to the orthopedic ward; nurses 1.67 vs 1.48, doctors 0.13 vs 0.11, physiotherapists 0.13 vs 0.09 and occupational therapist 0.13 vs 0.0.[150]

No specific gait exercise programme was included in the intervention. The main difference compared to the orthopaedic ward was the organisation of the team and routines for mobilisation and gait training. This included individualised goals for mobilisation, as part of the care plan which also allowed for systematic and planned priorities of patients who did not progress as expected. Mobilisation, gait training and discharge planning was a shared responsibility for the team, with the physiotherapist focusing on patients who did not progress as expected. There were established routines to enhance physical activity through motivating patients to spend time in the common areas instead of the bed rooms, and to promote frequent short walks integrated into the daily routines, like walking to the dining room. Discharge planning and evaluation of the need for rehabilitation was a team responsibility.

Trondheim hip fracture trial - Usual care

Orthopaedic care was delivered within an orthopaedic trauma department, where hip fracture patients and other trauma patients were treated by the same personnel. Physiotherapists were not organised as a part of the department, but within a separate unit serving different departments. There were no regular formal collaboration between the nursing staff and the physiotherapists. Patients were routinely referred for physiotherapy, while the content and amount of physiotherapy were based on the individual physiotherapist's priorities. The physiotherapist had the main responsibility for mobilisation and gait training, while nurses were responsible for discharge planning. As part of standard care, some few patients received assessment by geriatricians on request from the orthopaedic surgeons.

Development of the The EvaHip exercise trial

The exercise intervention in the EvaHip trial was developed in close collaboration between researchers at NTNU and physiotherapists in the Municipality of Trondheim. The overall aim of this work was to develop a programme that was well founded in daily practice and could be implemented without larger adaptations if shown to be effective. A project group including physiotherapy researchers and clinical physiotherapists from the municipality collaborated in designing the exercise programme, including selection of type of exercises and descriptions of progression. Choice of exercises were partly based on exercise programmes described in earlier studies, including functionally oriented strength exercises,[79, 86, 157] but with a strong focus on elements of balance and gait control. Five exercises were selected: 1) Walking, 2) Stepping in a grid pattern 3) Stepping-up on a box, 4) Sit-to-stand, and 5) Lunges. Each exercise was described at five difficulty levels to allow for standardised registration of individualisation and progression. Criteria for selection of exercises were that they should involve control of centre of mass relative to a changing base of support during gait, include movement tasks relevant to daily life, and that exercises should be suitable for a home setting. Furthermore, exercises should allow for individual tailoring and progression and be appropriate for a heterogeneous sample. The physiotherapists who performed the intervention were selected to represent the variation in experience and background found in normal clinical practice.

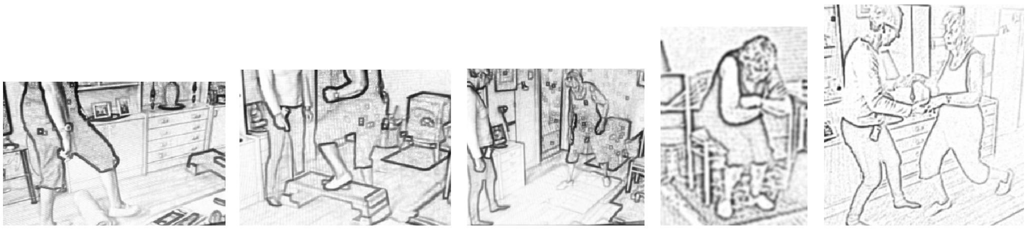


Figure 2 Illustration of the five exercises in the EvaHip trial from paper IV

Gait assessment

Data collection procedures and outcomes were the same for the THF trial and the EvaHip trial. Only gait data from the THT is presented in the papers included in the thesis. Spatial and temporal gait parameters were collected using the GAITRite mat, an instrumented walkway with pressure sensitive sensors embedded in a grid pattern 1.2 mm distance apart. The system allows for use of walking aids and no equipment needs to be attached to the participants.

Gait test protocol

Participants performed a total of eight walks at preferred, slow and fast speeds and a dual task condition at preferred speed. Only data from the preferred speed condition is used in the present work. Participants walked back and forth along an 8m walkway (4.9 m active area), starting from quiet standing. The instruction was walk at normal, comfortable speed. Walking aids were only permitted if participants were unable to walk without. Participants unable to perform all eight walks due to reduced capacity or pain performed only the preferred speed condition or only one walk in each condition. Table 3 shows number of participants in the THF trial who performed a reduced protocol, who used walking aids during the test, who normally used walking aids indoors, and the number of participants who performed each test condition.

Table 3 Overview of number of participants in THF trial who performed different test conditions

	Reduced protocol (4m gait speed test)	Walk aid indoor	Walk aid during test	Preferred	Slow	Fast	Dual
4 months	48	154/254	68/254	254	241	242	237
12 months	34	104/228	57/228	228	222	222	212

Data processing

In paper I, data from the GAITRite mat were processed using both the GAITRite and the PKMAS software-products. The PKMAS software was used for processing of data for paper II and III. The same person did all the processing for paper II and III, while two persons processed the data in paper I.

Differences between PKMAS and GAITRite algorithms

PKMAS is newly developed software for processing instrumented walkway data. According to the manufacturer, some of the solutions allow for more accurate processing of difficult gait patterns including incomplete, asymmetric and overlapping steps, compared to the GAITRite software. (http://www.protokinetics.com)

The PKMAS gait algorithms differs from the GAITRite in two important ways: In GAITRite, the direction of progression equals the total length of the mat. In PKMAS, the direction of progression is calculated according to each stride as the vector from the heel of one foot to the consecutive heel of the same foot (the projection angle of the stride), as illustrated in Figure 3. While the GAITRite uses the footfall trapezoid to calculate the heel-centre and toe-centre, PKMAS uses the minimum volume-bounding ellipse as illustrated in Figure 4. PKMAS computes the ellipse with the smallest area that wholly encloses all sensors of a footfall and consider the shape of the entire footfall. The ellipse's major axis is used to determine foot placement angle.

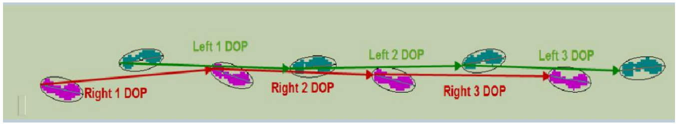


Figure 3 PKMAS line of progression

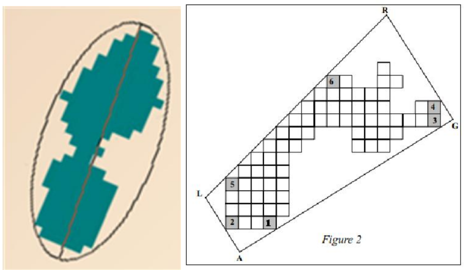


Figure 4 The minimum bounding ellipse (PKMAS) to the left and the footfall trapezoid (GAITRite) to the right

Mean spatial and temporal gait characteristic

Gait is a repetitive and cyclic movement. Each cycle starts with a heel strike and ends by subsequent heel strike of the same foot. The gait cycle can be described in terms of a loading phase (the stance phase) and an unloading phase (the swing phase). The loading phase consists of a single support phase where only one foot is loaded and a double support phase where both feet are loaded. The single support phase is equivalent to the swing phase on the opposite foot. The double support phase can be reported as total double support or separated into an initial and a final double support phase as illustrated in Figure 5.

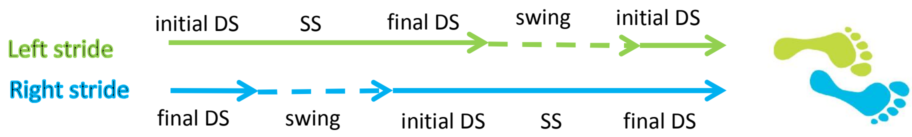


Figure 5 Temporal Gait Characteristics

Commonly reported temporal gait variables are combinations of single and double support phases including double support time, step time (initial double support + single support), stance time (step time + final double support) and stride time (stance time + swing time). Spatial characteristics include step or stride length and step width, as illustrated in Figure 6. These gait characteristics can be reported either in absolute time or space or as a relative measure, in percentage of the gait cycle. Gait parameters are typically calculated as mean over several steps or as the standard deviation (SD) or coefficient of variance (CV) to express variability. From the mean values various variables can be derived including temporal and spatial left/right asymmetry measures and walk ratio (step length/cadence).

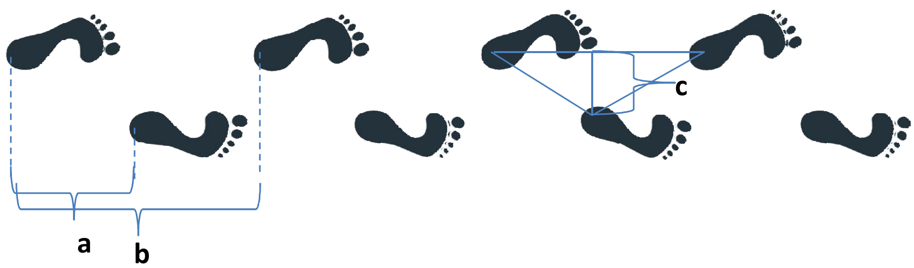


Figure 6 Spatial Gait Characteristics: a) Step length and b) Stride length, c) Step width

Selection of gait parameters

The PKMAS software provides values for single footsteps as well as mean, SD and CV for left and right steps separately or combined for each walk within the following categories: 1) toe/heel location, 2)foot length/width/area, 3)Step/stride time, length, and width, 4)Stance-, swing- and gait cycle, 5)Stance, swing and single/double support in percent, 6)Velocity and cadence, 7) foot angle and direction of progression, 8) left to right ratios. Except for 1, 2 and 7, all categories were included in this work. 1 was regarded less relevant for description of gait in this population. Foot angle and line of progression were not included because these parameters are less commonly reported and the interpretation less well understood, and the intra subject variability high.[158]

For this work, steps were selected above strides. Steps allow for calculations of left/right gait asymmetry. When number of steps are limited, steps will give more reliable results than strides.[142] High ICC values have been reported for velocity, cadence, step length and step-, stance time (0.81-0.95) and swing time (0.70-0.82), while moderate ICC values have been reported for step width in older people (0.49-0.75). [158-161]

Variability parameters

Gait variability is defined as fluctuations in gait characteristics from one step or stride to the next. CV is the most frequently reported parameter used to describe gait variability.[162] CV has the advantage that it is dimensionless and allows for comparison across studies and parameters. However, SD is the preferred parameter when mean and SD are unrelated. If CV is used under such circumstances, the CV value would be proportional to the mean value and spuriously indicate higher variability in individuals with high mean values.[142] More inconsistent findings and lower ICCs have been reported for variability parameters when compared to mean gait parameters. In a structured review by Lord et al, based on studies including community dwelling older adults[162], it was found that reliability estimates for variability varied (0.11-0.88), but were mostly fair to moderate. Responsiveness was reported in three studies and found to be poor for stride time and -length CV in older hospital-admitted adults[164] and moderate for stance time and swing time SD in community-dwelling older adults.[163] Concurrent validity between gait variability and six health outcomes was assessed in one study, where stance time was found to correlate with all health outcomes, while step length and width were associated with selected outcomes.[164]

Asymmetry parameters

Different calculations have been used for expression of left/right asymmetry in gait, but so far, there are no clear recommendations about which formula to use.[165] The formula presented by

Plotnik et. al (GA= abs(ln(left/right)) x 100) was used in this work.[148, 166] Using this formula perfect symmetry is expressed as zero and higher values would mean increased asymmetry. GA values ≤ 20 are approximately equal to the percentile difference between left and right leg, and were therefore assigned percentile units.[167] Asymmetry data are skewed by nature and applying the natural logarithm reduces the skewedness of data which is one of the advantages of using this formula.

Frailty indicators

Frailty indicators are not reported in any of the papers, but included in the results of the thesis to elaborate on the discussion. The proportion of participants in the THF trial that were defined as frail according to the Fried markers of physical frailty are presented with reference to four of the five markers: Slowness, weakness, lack of energy and reduced activity.[168] Slowness was defined as gait speed below 0.8 m/sec,[102] weakness as grip strength below 20 kg for women and 30 kg for men[169] or inability/more than 16.7 sec to complete 5x sit-to-stand.[170] Lack of energy was defined according to a single yes/no item from the Geriatric Depression Scale, "do you feel full of energy?"[171] Cut-off values for activity measured as time spent in upright position were based on a study reporting activity levels in healthy community-dwelling older adults, defined as the lowest quintile.[172] Indicators of cognitive frailty were defined as Mini Mental State Examination score (MMSE) (0-30) < 27 points or Clinical Dementia Rating Scale (CDR) (0-18) > 1 point.

Predictors for key gait characteristics

Some of the most commonly reported predictors for poor functional outcome after hip fractures are high age, male gender, cognitive decline[58] and extra-capsular fractures.[12, 13] High levels of pain have been reported long after the fracture [26] and frailty and sarcopenia has been suggested important causes for poor outcome following hip fracture.[58] To validate the gait characteristics, the association between these known predictors for poor outcome and the identified gait characteristics were explored. Pain level in the hip while walking was registered using an 11-point numeric rating scale. Global cognitive function was assessed by using The Mini Mental Status Examination.[173] Grip strength was measured with a JAMAR® handheld dynamometer, using the highest value of two attempts performed by the strongest hand. Grip strength is regarded a marker of frailty and sarcopenia.[169]

Statistical procedures

Paper I: Inter programme agreement

To describe levels of agreement in paper I, systematic and random differences, the mean absolute percentage difference, absolute agreement (ICC 2.1) (Two way random single measures) and consistency (ICC 3.1) (Two way mixed single measure) were calculated. Bland Altman plots were used to visualise mean difference, systematic differences and outliers.[174] High ICC levels suggest that the two programmes can be used interchangeably, while a difference between systems in absolute agreement and consistency (relative agreement, regardless of systematic errors) indicate systematic differences. Systematic differences can be accounted for, and indicate that reliability and validity for the two systems are the same. In this study, where the exact same footfalls where compared, ICC values close to 1.0 would be expected in order to claim that the two programmes could be used interchangeably.

Paper II: Explorative Factor analysis

Explorative factor analysis of the four months follow-up data was used to identify gait domains and key gait characteristics. Factor analysis is a technique for identifying clusters of variables and thereby reduce a large dataset to a more manageable size while retaining as much of the original information as possible.[175]

Factor analysis requires variables to be correlated, but multicollinarity could be a problem if the correlation among variables is extremely high. Gait variables derived from the same steps are expected to be highly correlated, thus an initial procedure to eliminate redundant variables from the thirty-one variables initially considered was performed. This selection procedure was based on the following guidelines:[175] The correlation matrix determinant should not be approaching zero (>0.00001). Measures of sampling adequacy, the Kaiser-Meyer-Olkin statistics (KMO) should be above 0.5 for individual variables and above 0.7 for the overall KMO, and Bartlett's test for sphericity should be significant (p<.0001). The correlation matrix was inspected to identify variables with very high correlation (>.9). For correlations above this level, only one variable was kept. A model including variables that provided both an acceptable correlation matrix determinant and KMO statics was selected for the factor analysis. Principal component analysis was used for extraction of factors, and oblique rotation was used as factors were assumed to be correlated. For each domain, one key characteristic with a combination of high factor loading and low cross loading was selected. Additional analysis was performed to i) see whether excluding participants using walking aids during the assessment changed the results, ii) if the same factor solution emerged when repeating the analysis based on the twelve months data and iii) when using a replication of the analysis performed by Lord and colleagues[176] where slightly different variables were included.

Five multivariate linear regression analysis models using an enter method were run to validate the key characteristics. In these analysis only participants with complete data for all variables, 242 at four months and 215 at twelve months, were included.

Data were checked for normal distribution by inspection of Q-Q plots. Positively skewed data were log transformed both for the factor analysis and for the multivariate regression models.

Paper III Modified intention to treat analysis

Intention to treat analysis is the recommended way of analysing data in randomised controlled trials. This requires a complete data set or that missing data are handled in a sound manner to avoid biased results. Thus the first step in analysis of the gait data from the THF trial was to investigate patterns of missing data, including extent and reason for missing data, and differences in pre-fracture function both according to reason for lost to follow up and to treatment arm.[177]

Based on this first step, a decision was made to perform a primary analysis where data were transformed into a five level ordinal scale based on quartiles within the control group, and with participants who had lost their ability to walk as a fifth category. A sensitivity analysis, where participants who had deceased were included in same category as those who had lost ability to walk was conducted to see how this affected the results. In addition, a complete case analysis was performed including only participants with a full gait protocol.

Non-parametric statistics were used for testing of group differences, as gait variables were not normally distributed. Mann-Whitney U-test was used for continuous data and Chi-square statistics for categorical data.

Additional analysis

Relative and absolute reliability for the four key gait characteristics derived from the factor analysis and included in the prediction model were calculated based on the back/forth walk at preferred speed for ICC (model 1.1 and 1.2) and minimal detectable change (MDC = SEM x 1.96 x $\sqrt{2}$ =SEM x 2.77). Mean difference and 95 percent limits of agreement are presented using Bland Altman plots.

Results:

Paper I and II: Methodological aspects

Paper I: Inter program agreement

Consistency between the PKMAS and The GAITRite softwares was perfect (ICC=1.0) for all mean-variables except step width (ICC=0.97) and foot angle (ICC=0.98). Absolute agreement for step width was lower (ICC=0.86) than consistency (ICC=0.97), suggesting a systematic difference between the software-products for this parameter. Mean and absolute percentage differences were negligible (< 2 percent) for all mean-gait variables, except for step width (21 percent) and foot angle (66 percent).

Consistency and absolute agreement were between 0.95 and 1.0 for all variability parameters except for step length SD (ICC= 0.84). Percentage difference in variability (SD) varied between 7 percent for stride duration SD and 32 percent for step length SD.

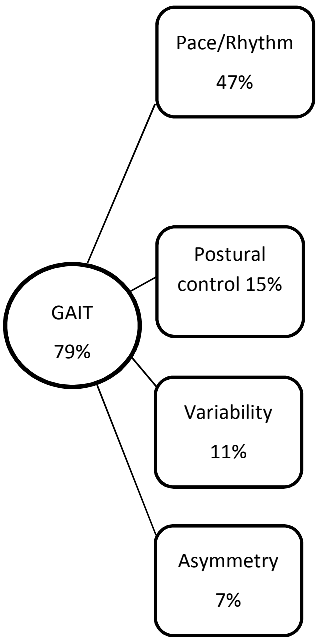
Paper II Gait domains and key characteristics

A four domain model of gait after hip fracture

The factor analysis was based on GAITRite data from 249 participants undergoing the four months assessment. Thirty-one variables were initially considered for the factor analysis. After the initial variable selection procedure, sixteen gait variables were retained for the factor analysis. The factor analysis revealed four gait domains explaining 79 percent of the variance: 1) Pace/Rhythm (47 percent), 2) Postural control (15 percent), 3) Variability (11 percent) and 4) Asymmetry (7 percent). Table 4 shows the pattern matrix of the oblimin-rotated solution with factor loadings and proportion of variance explained for each domain.

A similar factor solution was found using the twelve months data and when performing a sensitivity analysis excluding participants using walking aids during the assessment. A replication including the same variables used by other authors with healthy older adults provided a similar four domain factor solution, thus strengthening the validity of our results.

Table 4. A four domain model of gait after hip fracture. The pattern matrix of the oblimin rotated solution showing factor loadings and proportion of variance explained by each domain. Factor loadings above 0.3 are in bold.



	Pace/Rhythm	Postural control	Variability	Asymmetry
Step velocity	**-.721**	**-.353**	.218	-.110
Step time	**.978**	**-.394**	-.224	-.052
Single support %	**-.495**	**-.473**	.161	-.224
Double support time	**.857**	.108	-.194	.100
SD step time	**.888**	.057	.162	.066
SD single support time	**.847**	.031	.168	.028
SD double support time	**.855**	.108	.129	.048
Walk Ratio	-.135	**-.900**	.019	-.177
Step length	**-.436**	**-.653**	.155	-.148
Step width	.051	**.635**	.122	-.078
SD step velocity	.036	.237	**.820**	.095
SD step length	**.508**	.149	**.660**	.028
SD step width	-.159	-.163	**.666**	-.013
Step length asymmetry	-.062	.215	-.070	**.725**
Step time asymmetry	.028	-.121	.089	**.935**
Single support time asymmetry	.024	-.109	.016	**.953**

SD =Standard Deviation

Key characteristics

One key gait variable, defined as a variable with high factor loading combined with low cross loadings was identified for each of the four domains; double support time, step velocity variability, walk ratio and single support asymmetry. High loadings and low cross loading were found for both double support time and SD of step time, SD single support and SD double support for the pace/rhythm domain. Double support time was selected above temporal variability based on literature reporting lower reliability for variability than mean values.[162]

Predictors for the key characteristics

Results for the five multiple linear regression models are presented in Table 5. Together these six predictors explained up to 18 percent of the variance in each of the key characteristics. Age was not a significant predictor for either speed or the four gait characteristics. Being male was associated with lower speed, longer double support and higher asymmetry. Extra-capsular fractures were associated with increased asymmetry and longer double support, while pain did not explain variability in either of the gait characteristics. Reduced global cognitive function was associated with lower speed and increased double support at four months, and also with lower walk ratio at twelve months. Grip strength was associated with lower gait speed, increased double support and reduced walk ratio. Neither of the clinical features were significant predictors for variability, but global cognitive function had a p-value of .067.

Unpublished results

Table 5 Multiple linear regression analyses with the key variables and speed as dependent variable

4 months	**Double Support**		**Walk Ratio**		**SD step velocity**		**SS Asymmetry**		**Speed**	
Adjusted R^2	0.150		0.182		.008		.074		.240	
	B	p	B	p	B	p	B	p	B	p
age	,087	,186	-,113	,080	,114	,107	,048	,481	.113	.070
gender	-,227	**,007**	-,087	,288	,031	,735	-,200	**,022**	,201	**,011**
fracture	,160	**,008**	,008	,892	-,063	,330	,199	**,002**	-,190	**,001**
pain	,026	,672	-,076	,199	-,024	,718	,115	,070	-.060	.296
MMSE	-,208	**,001**	,100	,104	-,125	,067	,014	,827	,205	**,001**
grip strength	-,267	**,003**	,296	**,001**	,100	,309	-,094	,320	,374	**,000**

MMSE mini mental state examination, SS=single support

Gait speed (Figure 7) and each of the four key gait variables (Figure 8) are presented as boxplots with interquartile range, maximum, minimum, median and mean in order to describe the distribution of each of the variables. Intra session reliability and minimal detectable change (based on walking back and forth at preferred speed) are presented in Table 6. Bland-Altman plots showing the mean difference and 95 percent limits of agreement between the back and forth walk at preferred speed are presented for the four months data for each key variables (Figure 9). These are data not reported in the papers.

Gait speed

The boxplots show the distribution of data on gait speed at four (n=254) and 12 months (n=228) and Bland-Altman plots the mean difference and 95percent limits of agreement for the back fort walk at four months. Data were normally distributed. ICC was 0.96 (four months) and 0.95 (12 months), MDC 11.0 cm/sec (four months) and 13.0 cm/sec (12 months).

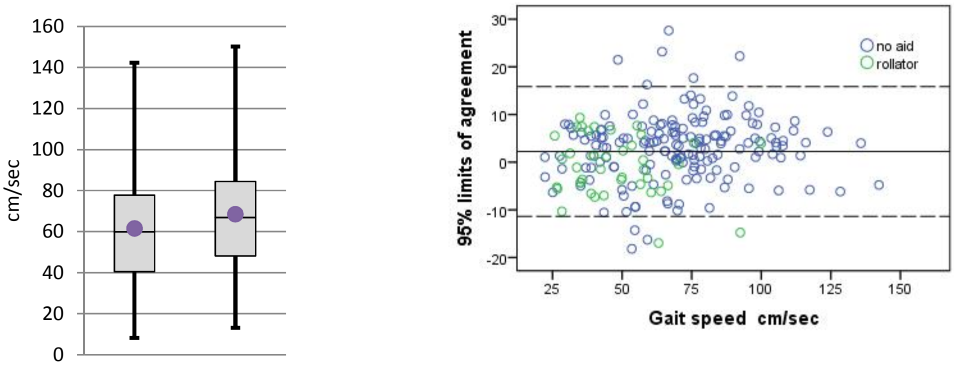


Figure 7 Box plot (interquartile range, median and mean, maximum and minimum values) and Bland- Altman plot (mean difference and 95 percent limits of agreement) for gait speed.

Key variables

Walk ratio was the only variable that was normally distributed. ICC was 0.87(four months) and 0.93 (12 months) for double support, 0.94 (four and 12) for walk ratio, 0.35 (four) and 0.34 (12 months) for step velocity variability, and 0.85 (four) and 0.72 (12) for single support asymmetry. Minimal detectable change for double support time was 0.10 and 0.13 sec, 0.06 steps/cadence for walk ratio, 2.6 and 3.1 cm/sec for step velocity variability and 11.0 percent and 10.1 percent for single support asymmetry.

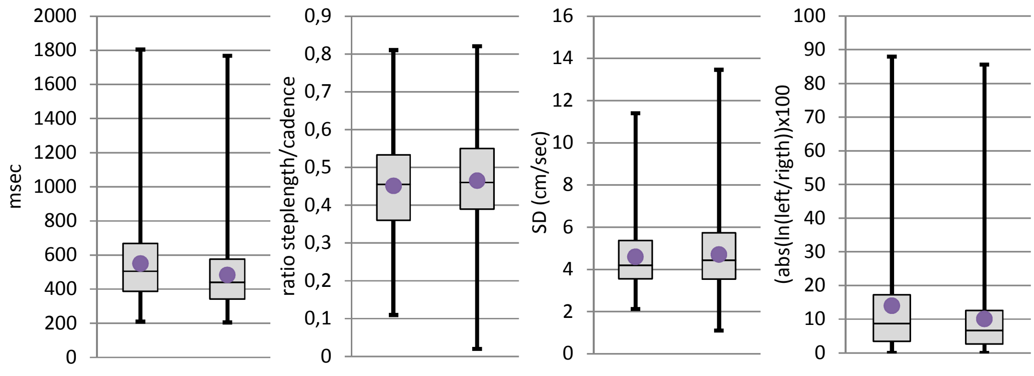


Figure 8 Box plots with interquartile range, median, mean and minimum and maximum for the four months and the 12 months data

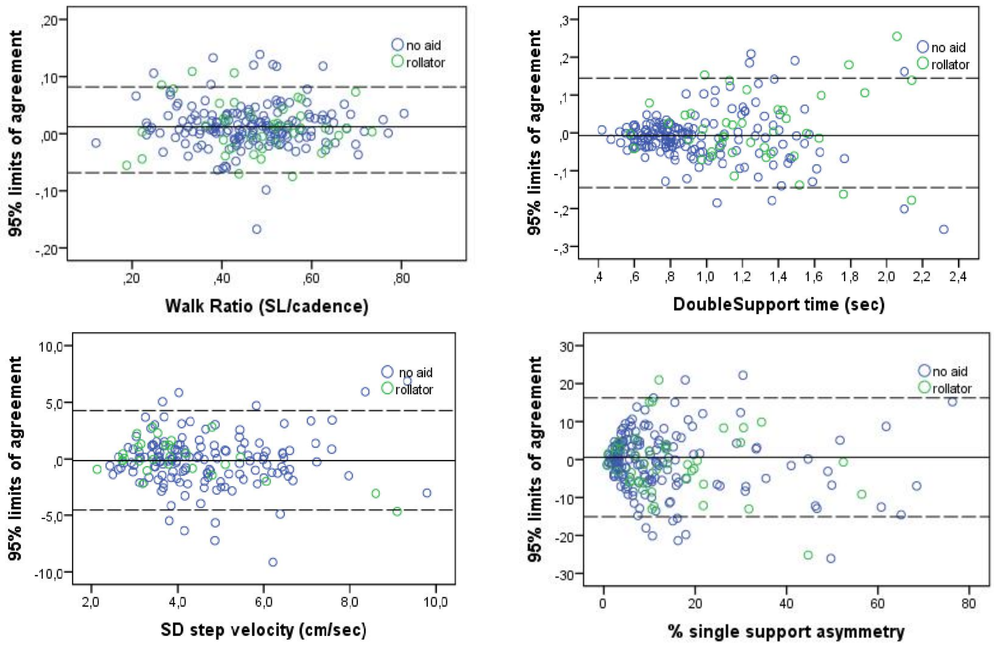


Figure 9. Bland-Altman plots showing mean difference and limits of agreement for the back forth walk for each of the key variables

Table 6. ICC and minimal detectable change (MDC) four and 12 months for gait speed and the four key gait variables

Gait variable	4 months					
	Mean(SD)	ICC(1.1)		ICC(1.2)		MDC
Speed (m/sec)	0.61(0.26)	.96	.94-.97	.98	.97-.98	0.13
Double support(sec)	0.56(0.28)	.93	.91-.95	.96	.95-.97	0.10
Walk Ratio	0.45(0.13)	.94	.92-.96	.97	.96-.98	0.06
SD step velocity (m/sec)	0.05(0.02)	.34	.22-.49	.51	.36-.63	0.03
Asymmetry Single Support%	14.6(15.7)	.85	.81-.87	.92	.90-.94	11.0
	12 months					
	Mean(SD)	ICC(1.1)		ICC(1.2)		MCD
Speed (m/sec)	0.67(027)	.95	.94-.96	.98	.97-.98	0.11
Double support(sec)	0.48(0.12)	.87	.83-.90	.93	.91-.95	0.13
Walk Ratio(length/cadence)	0.47(0.12)	.94	.92-.96	.97	96-.98	0.06
SD step velocity (m/sec)	0.05(0.02)	.34	.21-.46	.51	.35-.63	0.03
Asymmetry Single Support %	10.7(15.5)	.72	.65-.78	.84	.79-.88	10.1

Paper III and IV: Clinical aspects

Paper III: Long term effects of Comprehensive Geriatric Care on gait

In Figure 10, gait status at four and 12 months are presented for the CGC-group and the CGC-group separately. In addition, the number of participants who were unable to walk unsupported during the GAITRite assessment is marked in the figure.

A higher proportion of participants who had received CGC were able to perform either the GAITRite or the 4m gait speed test at both four months (p= .049) and 12 months (p= .005). Four months following the fracture, a higher proportion of participants in the OC-group were unable to walk (p=.006) or were unable to walk unsupported (p=.006). At 12 months these numbers were not significantly different between groups, but the proportion of participants who performed the GAITRite assessments were higher in the group who had received CGC (p= .037).

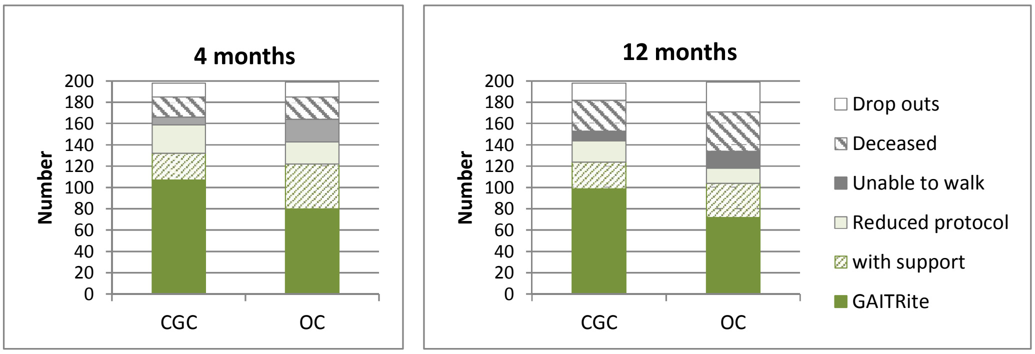


Figure 10 Proportion of participants within categories according to walking capability at four and 12 months

Description of patterns of missing data revealed significant lower prefracture Nottingham E-ADL score among those who performed a reduced protocol (p=.001), were unable to walk (p= .001) or died (p> .001) as compared to those who performed the GAITRite assessment at 12 months. Significant lower CDR score was found among those who performed a reduced protocol (p= .036) or died (p< .001) as compared to participants who performed the GAITRite assessment at 12 months. A higher proportion of participants in the OC group were unable to walk 12 months following the fracture, and pre-fracture cognitive function was lower in these participants than in the CGC group (p=.001). Pre-fracture cognitive function was also lower among participants in the OC group who were lost to follow-up during the trial (p= .017).

Differences between the CGC and the OC-group in gait speed and for the four key gait characteristics at four and 12 months are reported in Table 7. Results from the primary analysis including participants unable to walk and the complete case analysis are presented. In the primary analysis, beneficial effect of CGC was found for gait speed and three out of the four key gait variables, including double support time, walk ratio and single support asymmetry at both four and 12 months. Step velocity variability was not significantly different at either four or 12 months. The complete case analysis provided significant group differences at 12, but not at four months. Effect sizes for the key characteristics and gait speed were in the range 0.15-0.22. A higher proportion of participants in the CGC-group than in the OC group reported independence in outdoor mobility and use of public transportation. Participants in the CGC group had significantly higher score on the mobility subscale of the Nottingham Extended ADL scale.

Table 7 Group differences in gait speed and the four key gait variables

	Ordinal scale Mean rank		Ordinal scale analysis				Gait characteristics Median (IQR)		Complete case analysis
	CGC	OC	U	z	*p*	*Effect size*	CGC	OC	*p*
Four months:	n=139	n=143			n=282		n=132	n=122	n=254
speed(m/sec)	154.2	129.2	8180.5	-2.632	.008*	0.17	0.65(0.38)	0.57(0.38)	.142
Pace/Rhythm:									
Double support time (msec)	156.2	127.3	7900.5	-3.053	.002*	0.19	461(294)	538(285)	.135
Variability:									
SD step velocity (cm/sec)	150.6	132.7	8673.0	-1.894	.058	0.20	4.19(1.78)	4.25(1.91)	.735
Postural control:									
Walk ratio (steps/cadence)	153.3	130.1	8304.0	-2.448	.014*	0.16	0.46(0.20)	0.44(0.16)	.266
Gait Asymmetry:									
Single support asymmetry (%)	157.5	126.0	8276.0	-2.493	.013*	0.16	8.2(12.7)	9.2(13.7)	.247
Twelve months:	n=131	n=120			n=251		n=124	n=104	n=228
Speed (m/sec)	140.9	111.6	6130.0	-3.271	.001*	0.22	0.72(0.36)	0.59(0.32)	.011*
Pace/Rhythm:									
Double support time (msec)	140.5	112.0	6182.0	-3.180	.001*	0.21	422(216)	469(227)	.016*
Variability:									
SD step velocity (cm/sec)	139.2	113.5	7638.0	-0.603	.547	0.04	4.58(2.2)	4.35(2.14)	.668
Postural control:									
Walk ratio (steplength/cadence)	136.4	115.6	6728.0	-2.209	.027*	0.15	0.48(0.14)	0.45(0.17)	.039*
Gait Asymmetry:									
Single support asymmetry (%)	139.2	113.5	6364.0	-2.848	.004*	0.19	5.5(9.0)	7.9(11.2)	.037*

CGC= Comprehensive Geriatric Care, OC= Orthopaedic Care., SD= within-subject standard deviation.* Group differences are tested using the non-parametric Mann-Whitney U-test reporting the group mean rank, test statistic U and z. Effect size is calculated as $r = \frac{z}{\sqrt{N}}$

Unpublished results

Twelve months after the fracture 17percent of participants in the THF trial had died. Eight percent were wheelchair users and 9percent were not able to perform the GAITRite protocol. Two thirds of the participants who performed the 4m gait speed test had a gait speed below the cut-off for frailty 0.8 m/sec. Figure 12 shows the percentage of participants using walking aids before the fracture, and at four and at 12 months. Twelve months following the fracture, about half of the participants were dependent on assistance in outdoor mobility and only 10percent reported walking as well as they did before the fracture. Both groups had a decline in gait function from before the fracture to 12 months after measured in terms of self-reported mobility, use of walking aids, and perceived recovery of pre-fracture gait, and both groups had improved gait function from four to 12 months. Characteristics of the patients indicate both physical and cognitive impairment, and about 70percent presented with a combination of reduced physical and cognitive function four months following the fracture. Ninety percent would be classified as frail or pre frail using common cut-off scores for physical frailty at four months.

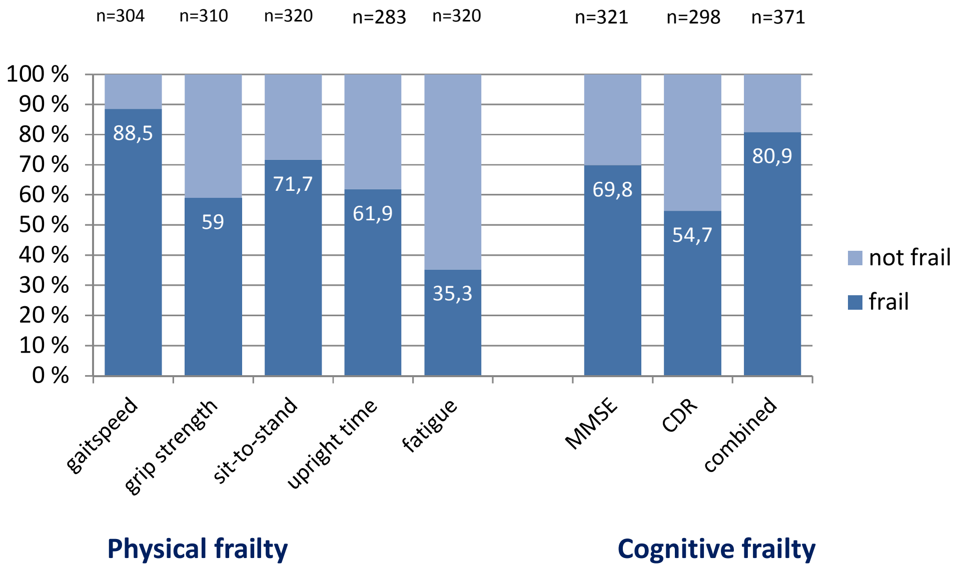


Figure 11. Physical and cognitive frailty four months post-surgery. Percentage above the cut off value for frailty for each indicator. Cut off values: gait speed <0.8 m/sec, grip strength men < 30, grip strength women <20, sit-to-stand unable or > 16.7 sec, upright time <262 min, fatigue: do you feel full of energy: yes/no. MMSE score <27, CDR >1.

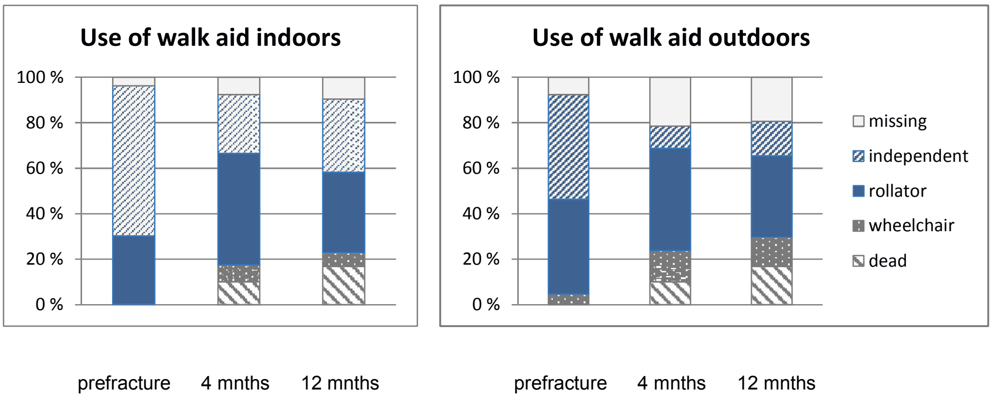


Figure 12 Use of walking aids during the first year following the fracture

Pain levels were in general low (Figure 13), with significant higher levels of pain among those with extra capsular fractures at four months, compared to twelve months. Interquartile range for the MMSE score were 20-28 points, with a median of 25 points. Four months post-surgery, the interquartile range for grip strength for women was 14-22 kg, median 18 kg (mean (SD): 16.6 (5.7) kg), and for men 24-34 kg, median 28 kg (mean (SD): 29.4 (7.8) kg).

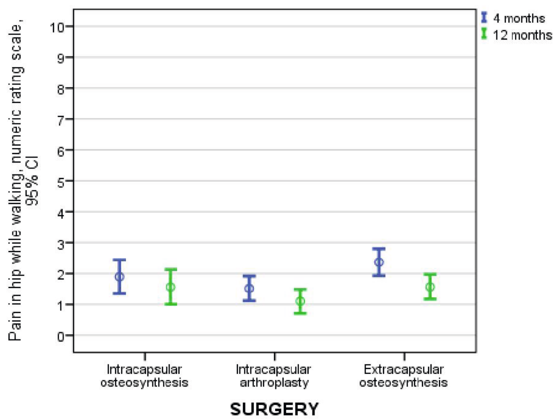


Figure 13 Pain level at four and 12 months according to fracture type and surgery

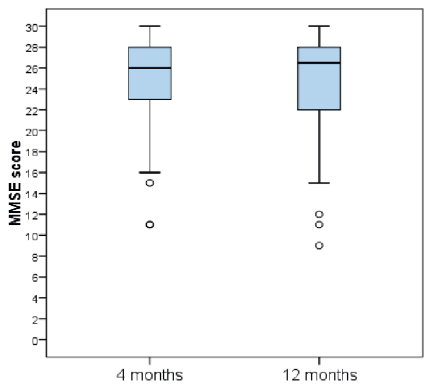


Figure 14 MMSE score at four (n=321) and 12 months (n=284)

Paper IV: Inclusion and retention rate in the EvaHip trial

Figure 10 shows the flow chart for the EvaHip trial. Eighth hundred and twenty two hip fracture patients underwent surgery during the inclusion period between February 2011 and April 2013. Two hundred and fifty met the inclusion criteria and 90 percent (223/250) of these patients were included and had their pre-fracture function registered. Four months following the fracture 82 percent (183/223) of the included participants performed baseline registration. Of these, 78percent (142/183) were randomised. From the 142 participants who were randomised 79percent (112/142) completed the 12 months follow-up. In total, 33percent (64/196) of those initially included and still alive at 12 months were lost to follow up during the trial. Table 8 present group differences in pre-fracture function and patients characteristics for those who were randomised, refused further participation or were dead or excluded at the four months assessment. Pre-fracture cognitive function was lower among participants who refused further participation in the exercise intervention (p=.051) while physical function was similar in terms of use of walking aids (p=.880).

Table 8. EvaHip, pre-fracture function and patient characteristics according to status at baseline

	Total (n=223)	**Randomised** (n=142)	**Refusal** (n=50)	***p-value***	**Dead or excluded** (n= 31	***p-value***
Age (year)(mean (SD))	83.5 (6.2)	83.4 (6.2)	82.7 (6.0)	.828	85.2 (6.0)	.304
	n (%)	**n (%)**	**n (%)**		**n (%)**	
Women	161 (72)	110 (78)	32 (64)	.250	19 (61)	.205
Living alone	157 (70)	106 (75)	32 (64)	.362	19 (61)	.356
Hip fracture fall indoor	178 (80)	113 (72)	33 (70)	.253	26 (87)	.717
Walk aid/assistance indoor	59 (26)	32 (23)	10 (20)	.880	16(52)	.016*
Walk aid/assistance outdoor	104 (47)	63 (45)	19 (38)	.659	21 (68)	.054*
Intracapsular fractures	131 (59)	82 (58)	32 (64)	.716	17(55)	.954
Arthroplasty [a)]	114 (87)	66 (80)	25 (78)	.949	13(76)	.949
	Mean (SD)	**Mean (SD)**	**Mean (SD)**		**Mean (SD)**	
Barthel Index (0-20)	18.5 (2.1)	18.7 (2.0)	18.6 (2.0)	.976	17.7 (2.8)	.175
Nottingham E- ADL (0-66)	42.1 (16.7)	45.1 (16.0)	39.2(16.7)	.079	33.4 (16.4)	.002*
CDR [b)] (0-18)	1.7 (3.2)	1.2 (2.5)	2.6 (3.9)	.051*	2.9 (4.0)	.058

[b)]CDR=Clinical Dementia scale, [a)]proportion of intracapsular),*One way Anova with Games Howell posthoc test*

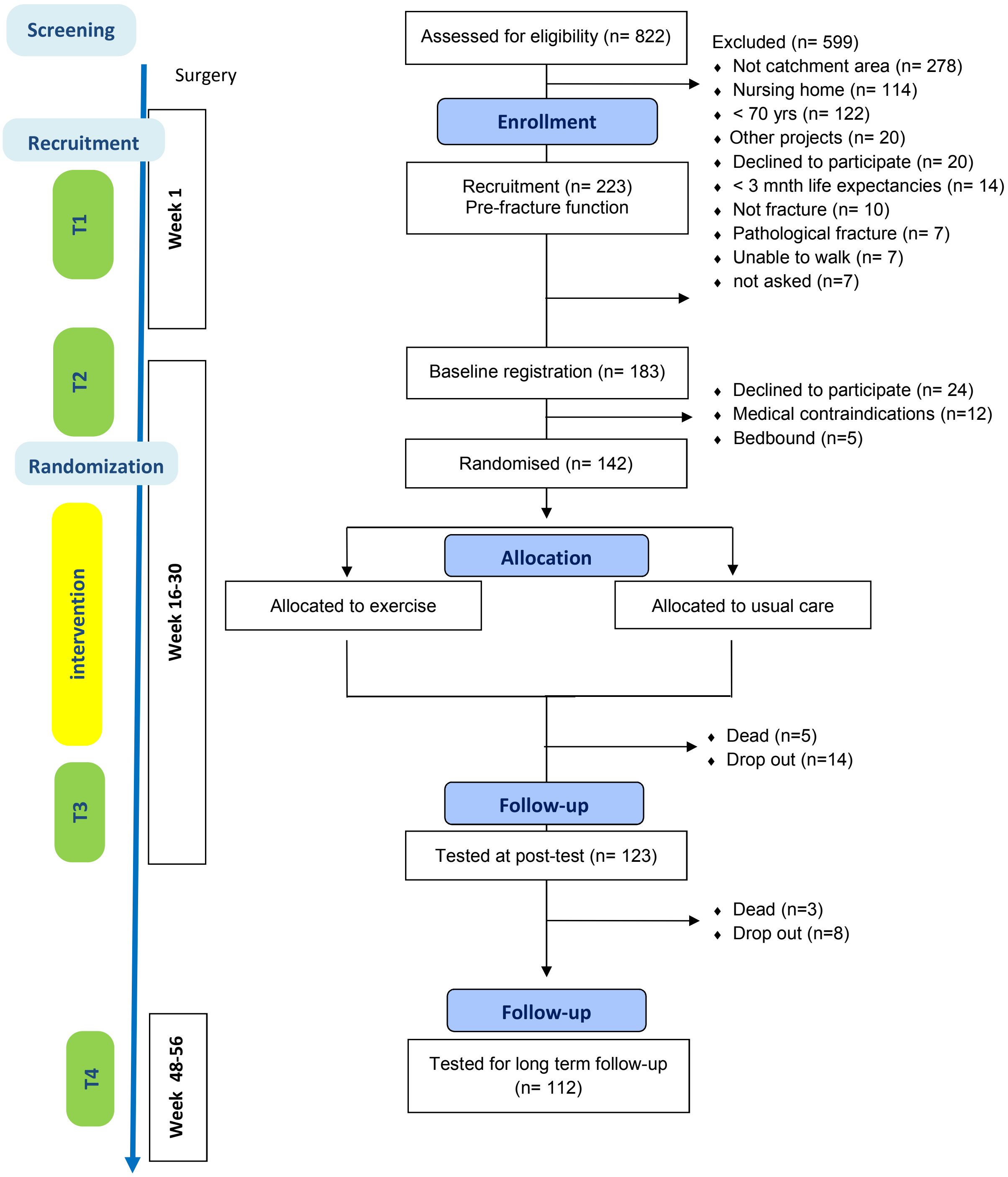


Figure15. Flow chart of the EVAHIP trial

Discussion

The main conclusion from this work is that gait following hip fracture could be described in terms of four relatively independent gait domains which are represented by four key gait characteristics; double support time, walk ratio, step velocity variability and single support asymmetry. Long double support time, low walk ratio, high gait variability and high levels of asymmetry were found to characterise gait four and 12 months following the fracture, suggesting high energy costs of walking and increased fall risk. In patients who had received CGC in the early pre- and post-surgery phase, double support time was shorter, walk ratio higher and asymmetry lower four and 12 months following the fracture, suggesting that these participants had more efficient and safe gait as a result of the intervention.

Despite the effect of early intervention, gait decline following the hip fracture was substantial, suggesting that further intervention is required to optimise gait recovery. The EvaHip- trial was designed to work specifically on gait control. Patient characteristics and attrition rate in the EvaHip trial suggest that a large proportion of elderly with hip fracture are able to attend an individually tailored exercise programme targeting gait and balance delivered four months following the fracture. Reduced cognitive function was more pronounced among those who declined participation, suggesting that cognitive decline can be a barrier for participation.

In this chapter methodological issues regarding internal and external validity of the work in this thesis will be discussed, followed by a general discussion of the main findings, and how these findings may add to existing knowledge and could guide development of more targeted interventions to maximise gait recovery in the future.

Methodological considerations

Internal validity

Study design and risk of bias

The study design, using randomisation, is strength of this work. Randomised controlled trials are regarded a gold standard for experimental design in clinical studies. Potential sources for bias like confounding variables, selection bias and learning effects from repeated testing are handled by the randomisation procedure. There are however sources for biases that are not handled by the randomisation procedure, where the most obvious for the THF trial is the risk of tester bias and attrition bias. Blinding of testers during the hospital stay was not possible, and some patients were assessed by the same tester both during the hospital stay and at the four and twelve months follow-up We found the same trend for results based on data collected from records and more objective measurements like the activity monitoring, suggesting that tester bias is of minor importance.

Differences in amount and pattern of missing data between groups suggest that there is a genuine risk of attrition bias. In the THF trial, there was more missing gait data for participants in the OC group due to poorer gait function. A general rule for selection of outcomes in clinical trials is that the measurements can be performed in all or most participants. The primary outcome for the THF trial was the SPPB which allows for testing in the home setting. Also, participants unable to perform the measurements got a test score, thus providing relatively complete data sets. The GAITRite variables were secondary outcomes in the THF trial and it was expected that the gait tests could not be performed in all participants, as some were tested in their homes and some would not be able to walk the required distance. Furthermore, the intervention had a potential to affect ability to walk and the ability to attend the testing in the outpatient clinic, and the risk of bias due to missing data is therefore significant.

The exercise programme in the Eva-Hip trial was developed in close cooperation between clinicians and researches, and was conducted within ordinary clinical practice by physiotherapists in the municipality. This raises another source for bias, namely a diffusion of treatment effect, spread from the experimental to the control group. If possible, physiotherapist that took part in the trial did not treat participants in the control group and the exercise programme was not presented outside the group of physiotherapists responsible for the training. However, an increased focus on the patient group, awareness of the trial and discussions about standard care could have increased the interest and competence among the physiotherapists and thereby also the standard care and content of physiotherapy provided to the control group.

Handling missing data

Authorities, including the Consolidated Standards of reporting Trials (CONSORT) and the Cochrane Collaboration, recommend Intention to treat (ITT) principle as the preferred strategy to analyse data from randomised controlled trials in order to avoid selection and attrition bias. However, there is no consensus on how to carry out an ITT analysis in the presence of missing outcome data.[178] Missing data represents a severe risk of bias[179] and the rate of missing data on the gait assessment was high, as described in figure 10. Missing data is a special challenge in ageing research as older people have more functional and health problems than younger people and complete data are seldom possible to achieve.[177] Analyses of patterns of missing data in the THF trial suggest that gait data were missing not at random (MNAR), and thus, common methods for imputation could not be used. This was the rationale for transforming data into an ordinal scale. However, the primary analysis was not accounting for participants who performed a reduced protocol, the higher number of participants in the OC-group using walking aids during the assessment, or participants lost to follow-up. However, recommendations for handling of missing data in ageing research were followed.[177] Precaution was taken to prevent missing data, by adapting data collection procedures including transportation, home visits and using a broad set of outcome measures that allowed for describing function in those unable to perform the gait assessments. Extent and type of missing data was closely monitored and described according to reason for missing and by allocation, and multiple analytic approaches were used to assess the effect of missing data on the result. In this manner, the risk of attrition bias is transparent. This approach represents both the main limitation of the study in terms of internal validity, but also the strengths of the study in terms of external validity. Moreover, this approach provides new knowledge on groups that would normally have been excluded from research due to these challenges.

In the EvaHip trial, baseline data will be available. This was not the case in the THF trial. This allows for analysis of the EVA-Hip data based on the assumption that data are missing at random (MAR) or completely at random (MCAR), which allows for use of common methods like multiple imputation and mixed models to deal with missing data.

Gait test protocol and reliability of measurements

Standardisation and a clear rational for selection of gait protocol is a prerequisite for interpretation of results from gait assessments. Longer continuous walks have been recommended to achieve stable state walking and provide sufficient number of steps to get reliable measurements.[180] However, gait protocols including long continuous walks would exclude a large proportion of hip fracture patients because of limited capacity. Continuous walking is more likely to reflect outdoor mobility and half of the hip fracture patients in this study were not walking outdoors without being accompanied. Most falls resulting in hip fracture occur in the home, and indoor walking is characterised by short abrupt walks that require frequent shifts in attention. For this population of frail older hip fracture patients, a gait protocol including short abrupt walks appears to have higher external validity and was selected before continuous walking.

The chosen gait protocol however, provided a limited number of steps, which potentially could have affected the reliability of the measurements. It has been argued that continuous walks and a high number of steps are needed to get reliable data, and less consistent results has been demonstrated from short interrupted walks as compared to continuous walks.[181] Ten to 20 strides are suggested needed to estimate velocity and cadence accurately,[182] while between 15[183] to > 300 strides have been suggested necessary to get robust gait variability data.[182]

Calculation of gait variables in the THF trial was based on a mean of 25 steps per subject, with a range between eight to 83 steps. Despite a limited number of steps, the ICC's based on the back and forth walks for the mean variables were similar or higher than what has been found in earlier studies. [158, 159, 161, 182, 184] However, ICC's for the variability measures were relatively low, and is in line with earlier findings,[162] while asymmetry measures were slightly lower than what has been found in stroke patients.[185] There were no systematic differences between the two walks (back and forth), indicating that there was no learning effect or effect of fatigability. ICCs for the average of two measurements (ICC1.2) were higher than for single measurements, suggesting that taking the average of the back and forth walk is a preferable approach. In summary, the findings suggest that reliability is not a severe concern for other variables than variability.

Measures of gait variability are commonly reported and there is increasing evidence from cross sectional and longitudinal studies for the clinical relevance of variability as predictor falls and cognitive impairment despite inconsistent finding for reliability. [162] Thus, variability was included in the factor analysis. However, the low reliability or higher measurement error related to these variables in the present study may have given less clear results.

Broad inclusion criteria resulted in a very heterogeneous population concerning walking capability, which represented a challenge for standardisation of the test protocol. Participants who were unable to walk unsupported were allowed to use walking aids. We did additional analysis excluding these participants in the factor analysis without observing any effect on the factor solution. However, it could still be a source of bias in the THF trial as more participants in the OC-group walked with support, possibly improving their gait performance.

Gender

The number of females who sustain hip fracture is higher than for males, while treatment effects are reported to be poorer for male hip fracture patients[58]. These observations may indicate different gender risk profiles and suggest that a different response to intervention among men and women is to be expected. Gender was included in the regression analysis in paper II, but no subgroup analysis were performed in the THF trial, nor is it planned for the EvaHip trial, which could limit the generalisability for gender.

The factor analysis

Factor analysis is a method requiring that there is a certain pattern of correlation among variables included in the analysis, but without too high or too low correlation. High correlations among gait variables collected from the same walks are to be expected, but very high correlation may indicate that the variables represent the same construct and are redundant. Strengths of the present study were the initial selection procedure performed to avoid including redundant variables and the use of oblique rotation, which assume that factors are correlated. The overall KMO statistics was above .7 for the variables included in the analysis, and may thus indicate that patterns of correlations were relatively compact and should yield relatively distinct and reliable factors. This strengthens the view that factor analysis was a suitable method for the data. The correlation matrix determinant indicated multicollinarity, which could suggest that the model is unstable. However, supplementary analyses using different data sets provided similar factor solution, thus confirming that the model was relatively robust.

The THF trial and the EvaHip trial were effectiveness trials with designs not appropriate to reveal causal relations[186]. The underlying mechanisms for the effect on gait characteristics of the intervention would need to be explored in trials with a more explanatory design. Such studies would require more strict inclusion criteria, test protocols and more targeted outcome measures. The present approach allowed for a thorough description of gait within a relatively representative sample and thus forms a basis for more explanatory trials in the future.

External validity

The THF trial and the EvaHip trial are both described as pragmatic effectiveness trials. They were performed in a setting close to real life, and aimed at evaluating the added effect of introducing new routines to standard care. In effectiveness trials, the generalisability of results is fundamental, and routines for recruitment and follow-up are designed to secure a representative sample. Sham interventions are not used in pragmatic trials, as the intention is to compare the new intervention to the current practice. Clinician and patient bias are not viewed as detrimental, but accepted as part of the response to treatment. In pragmatic trials, outcome measures should represent the full range of health gains. Drop-outs provide important information and are not necessarily to be regarded as undesirable.[187, 188]

Effectiveness studies are designed to secure high external validity. The results from the present trial are however not generalizable outside the target population of community-dwelling older adults, such as for example nursing home residents or younger patients. However, within the target population, there is reason to assume that the included participants are representative: In the EvaHip trial pre-fracture function was registered in 90 percent of eligible patients, while 75 percent of eligible patients were included in the THF trial. St. Olav's Hospital is the only hospital within the catchment area receiving these patients, and only occasionally are patients sent to other hospitals because of capacity problems. There were no exclusion criteria on cognitive impairment and few patients were excluded due to medical reasons. This increases the generalisability of results to a broader group than has been subject to evaluation in earlier work.

In line with requirements for an effectiveness trial, the personnel involved were not picked or trained specifically for the trial and represented a variety both concerning age and experience as would be the case in a real life setting. However, both trials were single centre studies and the results are not necessarily generalizable across hospitals and municipalities, and certainly not across countries with different health care systems.

Ethical consideration

Research ethics means protecting the individual's autonomy and privacy but also doing research of high quality and clinical relevance. Reduced capacity to provide informed consent due to cognitive impairment, safety concerns due to health problems and challenges due to data collection are reasons why frail older people often are excluded from clinical trials. The consequence is that the evidence base for care of older people is derived from studies including younger and less complex populations. Frail older people will not necessarily react in a similar way to treatment as healthier populations, and frail people could in the worst case sustain harm from treatment that is beneficial in other populations. Inclusion of a representative sample of the target population is of outmost importance in ageing research in general and in hip fracture patients in particular. Careful planning of how information is provided to ensure informed consent and how to optimise the benefit/burden ratio is a prerequisite for doing ageing research of high ethical standards.[189]

Barriers for retention in studies on frail older adults include lack of perceived benefits and relevance of the study, difficulty in understanding and reading consent forms, fatigue, comorbidity and mobility problems, length and number of sessions, and that cognitive assessment is demanding or intrusive.[190] Most of these barriers were addressed in the THF trial and the EvaHip trial.

Neither the THF nor the EvaHip intervention was controversial in the way that new treatments or methods were delivered. The novelty was mainly a more structured, high quality and systematic approach than in most former intervention studies in the same population. Potential harms were therefor restricted to the extra burden associated with assessments.

Special attention was paid to ensure informed consent without excluding eligible patients. For participants where capacity to provide informed consent was questionable, next of kin were approached, and they could reserve against participation on behalf of the patients. Repeated information was provided at each follow-up including purpose of the study and option to withdraw from all or parts of the assessment without consequences. Special arrangements were performed to reduce the discomfort associated with the assessments. Transportation was provided, using the same taxi driver for all assessments. Precaution was also taken to avoid waiting time, and all assessment were performed by one or maximum two testers. All testers were trained and experienced within geriatrics. Assessment at home was offered to participants unable to attend the outpatient clinic, and all appointments for assessment were delivered both in writing and by telephone contact with the participant, next of kin or home care services.

There is no routine control of hip fracture patients who has undergone surgery at St.Olavs hospital. In the THF, a geriatrician was available for consultation and participants could be referred for consultation by orthopaedic surgeons by the test personnel, while in the EvaHip trial a medical examination was routine. No adverse advents were reported during or related to the assessments.

Discussion of results

Identification of relevant gait characteristics using instrumented walkways

A basic assumption for this work has been that gait is not a unitary concept and that different gait characteristics provide information beyond gait speed. Instrumented walkways provide information restricted to footfall parameters and conclusions from this work are therefore limited to spatial and temporal gait characteristics. The gait assessment was performed using a standardised protocol in a laboratory setting. Therefore, the generalisability to gait in real life settings could be questioned. However, there is relatively robust documentation for the association of spatial and temporal gait characteristics collected during similar conditions, and aspects of health, function and fall risk in older people, which justifies focusing on spatial and temporal gait characteristics.[180] In addition, electronic walkways are relevant for use in clinical practice, assessments are time efficient, and represent minimal burden on the participants.

Level of agreement between PKMAS® and GAITRite® software

The level of agreement between the newly developed PKMAS® and the well-established GAITRite® software for processing raw data from gait sequences assessed by the electronic gait mat was found to be high and to allow for interchangeable use, as long as systematic differences related to different algorithms are taken into consideration. Deviating and overlapping footsteps is a challenge when processing data from samples including frail individuals, and there is a risk of rejecting footfalls that represents important information. The new PKMAS® software is developed to resolve some of these problems and thereby provide more valid data. However, further research is needed to claim that the PKMAS® is superior to the GAITRite® in processing raw data.

A four domain model of gait following hip fracture

The close association between gait and aspects of health suggest that gait is a reflection of both muscle-skeletal factors like strength and power but also age related and pathological mechanisms related to the central nervous system. It has been suggested that gait is a window into understanding cognitive function, dysfunction and fall risk in older people in the clinic.[136, 191-193] Gait speed is a well-established and robust outcome measure recommended to use as part of routine examination in older adults[99] and there is increasing evidence that gait variability is a more sensitive marker than gait speed when it comes to fall risk, future mobility disability and cognitive impairment. Number and type of gait variables needed to provide a full description of gait in general and in hip fracture patients in particular is however not established.

The factor analysis resulted in four separate clusters of gait variables suggesting that gait following hip fractures could be described by these four. The factor solution was comparable to previous work in community-dwelling older people, and the domains were therefore named in concordance with the work by Lord et al;[180] pace/rhythm, postural control, variability and asymmetry.

One variable with high factor loading and no cross loading was selected for each domain; double support time, walk ratio, step velocity variability and single support asymmetry. In previous work, increased double support has been found to predict falls,[194] and to discriminate between different levels of frailty ,[126] Furthermore, it has been found to be associated with presence of white matter intensity and brain infarctions,[195] with reduced grey matter volume in frontoparietal and sensorimotor regions of the brain in well-functioning older adults, [129] and has also been found to be an indicator of fear of falling.[131] We found that well known predictors for poor outcome after hip fracture, including impaired cognitive function, reduced muscle strength, male gender and extra-capsular fractures were associated with double support, thus confirming that this is a relevant outcome following hip fracture.

In healthy older adults, the step length/cadence relationship is kept constant over age, independent of changes in speed and step length, suggesting that lower walk ratio reflects pathological mechanisms.[196] The walk ratio has been found to discriminate between disability levels and between healthy controls and people with disease.[197] Low walk ratio and a large reduction in walk ratio from slow to fast speed condition has been found to predict multiple falls and to be associated with cognitive impairment and physical function.[198] We found the walk ratio to be associated with grip strength, an indicator of sarcopenia and frailty[169], confirming that the walk ratio is a relevant outcome following hip fracture.

We found the domains pace/rhythm and postural control, represented by double support time and walk ratio, to be related. Cross loadings between these two domains for gait speed, step length and percentage single support, suggest that the pace variables; gait speed and step length measure overall gait performance not specific to gait rhythm or postural control.

Previous work provides some empirical support for a distinction between these two domains. One hypothesis is that gait rhythm, represented by temporal gait variables, reflects impairments in higher cortical functions while walk ratio and step width represents strategies to compensate for these impairments. Reduced walk ratio has been suggested to reflect less automatic and more conscious gait control.[134] Shorter and faster steps combined with wider steps has been identified as a strategy to cope with balance perturbations[130] at the cost of higher energy demands for walking [112], and older people with fear of falling broaden their step width when gait control is challenged.[123, 199, 200] Further, step width has been associated with reduced grey matter volume in other brain structures than the temporal variables indicating that step width represents different aspects of gait than the temporal variables.[129]

We found no cross loadings for the variability domain and no correlation with the other domains suggesting this is a distinct domain not related to the others. The evidence for the value of using gait variability is rather extensive: Gait variability has been associated with degenerative changes in the hippocampus and the anterior cingulus gyrus, areas related to memory and executive functions.[201] Step length variability and stance time variability have been shown to discriminate between functional status, physical activity level and health status,[164] and step width variability to discriminate between frailty statuses.[126] Furthermore, stride time variability has been found to be associated with reduced executive functions and to predict cognitive impairment and falls.[136] Stance time variability has been found to be predictor of future mobility disability independent of gait speed.[138] Finally, the effect of task specific gait training compared to traditional training has been demonstrated on double support time variability.[202] There was not a significant difference in gait variability between groups as a result of the intervention in the THF trial. This could be related to lower reliability compared to the other key variables, but could also indicate that gait variability is a more relevant outcome in more healthy populations with less severe gait impairments.

We found that spatial and temporal variability loaded on different domains. These findings are in line with previous results suggesting that spatial and temporal variability represent different constructs and that both should be represented.[140, 142] In a responsiveness study, only decreased step length variability was associated with improvement in gait while stance time variability was associated with gait decline.[163] These findings suggest that gait variability is a relevant outcome, but that further research is needed to improve interpretation.

Temporal asymmetry loaded high on the asymmetry domain without cross loadings, suggesting this is a domain clearly distinct from the three other domains. Significant predictors were extra-capsular fractures and male gender, but not cognitive function or grip strength, suggesting that asymmetry is related to other aspects of health and function than double support and the walk ratio. For the twelve months data and in the model including variables similar to the model by Lord et al (supplementary data) we found cross loadings for step length asymmetry on the postural control domain. The same findings has been reported in healthy populations and in older people with Parkinson's disease by other authors[176, 180] and suggest that step length asymmetry could be closer related to aspects of postural control than asymmetry in temporal characteristics.

Based on the factor analysis we have suggested a minimum four key characteristics to cover different aspects of gait recovery following hip fracture. However, the highest explained variance was for gait speed. This confirms the recommendation of gait speed as a summary measure for gait, and as a good indicator of overall health and function.[99]

The relevance of the four key characteristics is supported by previous findings, but further research is needed to decide if there is an added or complementary value to gait speed. Previous work suggest that gait variability is a more sensitive measure than gait speed and a precursor for cognitive impairments and gait instability in healthy older adults, but less is known about the added value of measuring gait variability in frail groups with established gait impairments.

Interventions to maximise gait recovery

Our findings from the THF trial of the long-term effect on gait of in-hospital CGC is in line with earlier research, confirming the importance of a broad and multidisciplinary approach both in geriatric patients in general and in hip fracture patients.[69] The novelty of the THF trial is that the effect is related to relatively short intervention early after the fracture (mean 11.5 days). Thus, the long term effect on gait most likely is related to what happens in the early pre- and post-surgery phase and not the rehabilitation provided after the acute phase. These results suggest that targeting frailty and optimising health condition in the very early stage is important to prevent decline in gait, to allow for a faster gait recovery, and to prevent permanent gait impairments.[59]

Results from the THF trial show that participants receiving CGC were mobilised more effectively.[203] More participants were able to leave directly for their homes, and use of rehabilitation services and nursing home residency was lower the first year following the fracture.[149] However, the high proportion of participants who were unable to walk, and who reported use of walking aids and dependency in outdoor mobility one year following the fracture suggest that gait recovery was far from optimal and thus indicate a need for further rehabilitation.

Frail older people need longer time to recover from illness and injury compared to more robust individuals, thus suggesting that ordinary rehabilitation tends to end while there still is a potential for further gait recovery. Paper IV, the protocol paper, describes a municipality based exercise programme delivered four months following the fracture. While there is evidence for a beneficial effect of extended rehabilitation on gait and mobility[204] and specifically from progressive strength training,[205] there is a lack of evidence for the effect of structured municipality based exercise programmes in older people with cognitive impairments. Considering the high prevalence of cognitive impairments in older people with hip fractures, the effect of exercise in samples including also these patients are warranted, as is knowledge about what characterises those who refuse to participate or are not included in exercise programmes.

The run in period in the EvaHip trial allowed for a description of pre-fracture function in 90percent of eligible patients who underwent surgery within the inclusion period. Lower pre-fracture cognitive function, but no difference in pre-fracture use of walking aids indicates that cognitive impairment is a more important barrier to participation in exercise programmes after hip fracture than mobility limitations.

The selection of exercises for the Eva-Hip trial was based on the findings of gait characteristics indicating fall risk and reduced gait efficiency in the THF-trial. There is increasing support for the view that exercises that aim to improve gait control and efficiency should be based on principles of motor learning and motor control.[98, 206-208] In older people with gait impairments in the form of gait variability and reduced gait speed, exercise programmes with a specific focus on gait control have been shown to improve gait efficiency, activity and participation,[97, 202, 208] but so far few exercise programmes targeting gait control have been evaluated following hip fracture. There is evidence for progressive strength training following hip fracture.[205] The EvaHip programme was designed to combine principles of progressive strength training and exercises relevant for gait control. The five chosen exercises were all variations of tasks focusing on control of body CoM over a shifting base of support, based on the assumption that impaired gait control and not strength alone is the main cause for gait limitations following hip fractures. The exercises included stepping up, stepping in different directions, sit-to-stand, lounge and walking. The programme has some similarities to functionally oriented strength exercise programmes e.g. by Sherrington[83-86] and Latham[87], but there are, to our knowledge, no programmes with a similar explicit focus on gait control that has been evaluated in hip fracture patients.

Conclusion

This is to our knowledge the first work to present data on gait characteristics beyond gait speed for a relatively large and representative group of community-dwelling hip fracture patients. This work presents a description of gait at different levels of function including number of patients who lose the ability to walk, self-reported walking, change in walking behaviour and temporal and spatial gait characteristics the first year following the fracture. It is suggested that at least four key gait variables; double support time, walk ratio, step velocity variability and single support asymmetry should be reported in addition to gait speed to cover the most important aspects of gait. Results show that gait is severely impaired after a hip fracture and that gait characteristics indicate reduced gait control and increased fall risk, high energy costs of walking due to compensating strategies, and high levels of asymmetry, suggesting suboptimal recovery of function.

This work suggests that gait characteristics following hip fracture can be separated into relatively independent gait domains which are similar to what has been found in other populations. Four key characteristics are suggested to represent these domains and should be the minimum set of variables to report to cover the most important features of gait. Psychometric properties, especially responsiveness of the different gait characteristics and association with clinical features have to be explored further before there is sufficient evidence to recommend the use of gait characteristics beyond gait speed as outcome measures in clinical trials.

Results from the Trondheim hip fracture trial support earlier findings, emphasising the close relationship between gait and health, the vulnerability characterising this patient group and the importance of optimising health status to reduce permanent gait impairments and loss of independence in the long term. Gait characteristics indicating fall risk and high energy costs of walking suggest that exercises to maximise gait recovery should combine progressive strength training and task specific exercises. The results show that when targeted to the specific needs of these frail older adults, a majority of participants were able to attend a relatively demanding exercise programme. Characteristics of those lost to follow up suggest cognitive impairment is a barrier to participation in interventions and requires special attention in hip fracture rehabilitation.

Both the THF trial and the EvaHip trial were pragmatic effectiveness studies developed in close collaboration between researcher and clinicians. Both studies had few exclusion criteria, included use of ordinary clinical staff, and were performed in a routine clinical setting. The generalisability is therefore regarded as high, and the implementation of similar models in comparable settings could be relatively easy. Future research should focus on development of integrated care pathways allowing for a more structured follow-up, including longer intervention and follow-up period, individualised and tailored interventions with specific focus on critical stages, especially the very early pre- and postoperative stage and early after returning to home.

Future directions

The factor analysis revealed four domains and four key gait characteristics. It is suggested that these cover relatively independent and distinct features of gait following hip fracture and should be used in addition to gait speed as outcome measures in interventions targeting gait recovery after hip fracture. Further work is needed to explore the how these key gait characteristics relate to clinical features and respond to interventions and provide information beyond gait speed. Increased knowledge about how specific gait characteristics are related to cognitive impairment, physical frailty, depression and fatigue could help reveal underlying mechanisms for gait decline following hip fracture and help target interventions to maximise gait recovery. There are few studies reporting responsiveness of gait characteristics in hip fracture patients. Further research should examine the responsiveness of the key characteristics before they could be recommended for use as outcome measures in intervention trials.

Future development of interventions to maximise gait recovery should focus on development of integrated care pathways. Findings from the THF trial of the long-term effect on specific gait characteristics from a general intervention targeting frailty in the early stages suggest that gait recovery is closely related to overall health, that structured exercise to improve gait should be part of multicomponent interventions, and that individualised interventions are important in this heterogenic population. Special attention should be paid to the large group with subtle or mild cognitive impairment which is probably an especially vulnerable group, with potential for prevention of further decline in function, and to the subgroups of patients known to be at higher risk of poor outcome, including male hip fracture patients, those with extra-capsular fractures and the oldest ones.

Clinical implications

Findings of gait characteristics related to fall risk, cognitive impairment and frailty confirms that the observed gait decline following hip fractures is complex and closely related to the vulnerability of these patients. Independence in basic ADL, but limitations in instrumental ADL prior to the fracture, support the notion that these patients are vulnerable and at high risk of further decline in function following the fracture. The proportion of participants with cognitive impairment was found to be high. Cognitive impairment is a well-known risk factor for falls, and the attrition rate in the EvaHip suggest that despite the exercise programme being home based and supervised, cognitive impairment was a barrier for participation. Increased focus and more structured assessment of cognitive impairment, especially of cognitive functions related to motor control and mobility, like executive functions and spatial navigation, could help target and individualise intervention to maximise gait recovery in older hip fracture patients.

The findings of four gait domains suggest that information beyond gait speed could be gained from more extensive gait assessments, especially by collecting data on gait asymmetry and gait variability. For routine clinical practice however gait speed is an accessible and robust measure of gait performance covering the most important aspects of gait. In research, exploring the effect of interventions targeting specific aspects of gait and underlying mechanisms, assessment of different aspects of gait should still be included. The use of gait protocols including stress tests like fast speed and dual task should be explored further, and could be a more sensitive measure of reserve capacity and flexibility in gait.

Two assumptions for intervention were explored: First that gait decline following hip fractures is related to the high prevalence of secondary complications like delirium, new falls, infections and detrimental effects of immobilisation. Findings of more efficient and safe gait in participants who received CGC during the hospital stay suggest that targeting this vulnerability to optimise health condition have an impact on long term gait outcome. These findings highlight the need for integrated care pathways based on geriatric assessment, multidisciplinary approaches and multicomponent interventions. The second assumption was that frail older adults need time to recover before being able to benefit from high-intensity, specific gait training. Results from the EvaHip trial do suggest that a large proportion of community dwelling older hip fracture patients are able to complete a home-based, supervised exercise programme delivered four months after the fracture, however the effectiveness of the programme remains to be evaluated.

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Paper I

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Comparison of programs for determining temporal-spatial gait variables from instrumented walkway data: PKmas versus GAITRite

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Abstract

Background: Measurement of temporal-spatial gait variables is common in aging research with several methods available. This study investigated the differences in temporal-spatial gait outcomes derived from two different programs for processing instrumented walkway data.

Method: Data were collected with GAITRite® hardware from 86 healthy older people and 44 older people four months following surgical repair of hip fracture. Temporal-spatial variables were derived using both GAITRite® and PKMAS® processing programs from the same raw footfall data.

Results: The mean differences between the two programs for most variables were negligible, including for Speed (mean difference 0.3 ± 0.6 cm/sec, or 0.3% of the mean GAITRite® Speed). The mean absolute percentage difference for all 18 gait variables examined ranged from 0.04% for Stride Duration to 66% for Foot Angle. The ICCs were almost perfect (≥0.99) for all variables apart from Base Width, Foot Angle, Stride Length Variability, Step Length Variability, Step Duration Variability and Step Width Variability, which were all never-the-less above 0.84. There were systematic differences for Base Width (PKMAS® values 1.6 cm lower than GAITRite®) and Foot Angle (PKMAS® values 0.7° higher than GAITRite®). The differences can be explained by the differences in definitions and calculations between the programs.

Conclusions: The study demonstrated that for most variables the outcomes from both programs can be used interchangeably for evaluation of gait among older people collected with GAITRite® hardware. However, validity and reliability for Base Width and Foot Angle derived by PKMAS® would benefit from further investigation.

Keywords: Gait, GAITRite, PKMAS, Reliability, Aging

Background

Gait analysis provides highly relevant outcomes for the older population. It reflects both impairment-level deficits and functional status [1-3]. Temporal-spatial gait variables have repeatedly been shown to be important for identification of injury/disease [4-6], prediction of falls [7,8], and quantification of the effect of interventions [9,10]. In particular, gait speed has been associated with health status, activity levels and quality of life, and is predictive of future morbidity and mortality [11-14].

The GAITRite® system is a well established method of quantifying gait. Over 200 papers have been published since 2000 using data collected and processed with the GAITRite® system. The measurement properties of a large number of temporal and spatial outcomes derived from GAITRite® data have been reported (eg. [15-17]). Recently, a new program has been developed in order to solve some of the problems with processing difficult footstep patterns, for example overlapping steps and turns. The PKMAS® software purports to accurately derive temporal-spatial outcomes from raw GAITRite® data. However, in order to interpret clinical and research findings from PKMAS® processed gait data, and to be able to draw comparisons with published data that has used the GAITRite® system, the inter-program reliability

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of the two processing algorithms needed to be examined. A direct comparison of outcomes from the same walk trials would enable the degree of variability caused by the processing program alone to be determined, irrespective of other sources of noise in the data.

This study examined the level of agreement and inter-program variability between the two processing programs, using data from older people walking at self-selected, preferred speed, on a GAITRite® mat. Very high levels of agreement for an outcome variable would indicate the variable is interchangeable regardless of the program used to process it. Systematic differences, if known, can be taken into consideration during comparisons. Lower levels of agreement due to random spread of differences would suggest the outcome may have important differences when processed with PKMAS®, and the reliability and validity of the variable should not be assumed to be the same as with GAITRite®.

Methods

Participants

Data from two groups of participants were used for this study. The first group consisted of 100 healthy older people from the community in Trondheim, Norway. They were recruited for the Generation 100 study, an exercise intervention study (ClinicalTrials.gov identifier: NCT01666340). The second group included 50 older people, who were tested four months after surgical repair of hip fracture. The hip fracture patients were all part of the Trondheim Hip Fracture Trial [18]. All participants gave written informed consent to participate in their respective studies. Ethical approvals for the studies, which included the use of their data for purposes of cross-sectional and methods analyses, were granted by the Norwegian Ethical Review Board for Medical and Health Research (REK) – South East Region (2013/787b) and the Regional Committee of Ethics in Medical Research (Mid-Norway) (REK4.2008.335) respectively.

Procedures

For the healthy group, the baseline GAITRite® (CIR Systems Inc, Havertown, PA) raw data was collected using a 5.5 m mat (active length). Participants were asked to walk along the walkway at their preferred (usual) speed starting and stopping at least 1 m outside the ends of the mat (total walkway length at least 8.7 m). The hip fracture group were similarly asked to walk along a 4.7 m GAITRite® mat (total walkway at least 7.7 m) at their preferred speed. Only the first pass was used for this study.

The raw data was processed with both GAITRite® (v3.8E) and PKMAS® (v507C4I3) (ProtoKinetics, Havertown, PA) software and exported to Excel. After processing, all walks were checked to ensure the same steps, as well as the same number of steps, were used in both processing methods. Thirteen healthy participants and six hip fracture participants were excluded because during the processing of the walk files, a different number of steps were retained. A slight variation in which footfalls are retained would lead to small differences in the outcome variable values. This difference is likely to be clinically insignificant, but we wanted to exclude all sources of variation apart from those caused by the different software algorithms. It was noted that when the walk had two or fewer footfalls with one foot, PKMAS® does not calculate standard deviation (SD) for ipsilateral Stride Length, Step Length, Stride Duration, Step Duration and Base Width. In GAITRite®, SD of Stride Length, Stride Duration and Base Width are not calculated. When there is no SD calculated, PKMAS® exports a blank cell to Excel, however GAITRite® exports a zero. This creates an error when the right and left values are averaged. For this reason we excluded walks where there were less than six footfalls in total. One healthy participant was excluded for this reason.

Outcome variables

There are many gait variables that can be derived from data collected with GAITRite® mats. The outcome variables compared in this study were chosen as those previously reported in validity and/or reliability studies using the GAITRite® system (eg. [15-17], further information is provided in Additional file 1: A). The included variables were those that are calculated from the footfalls themselves, rather than variables that are derived from other gait variables. Thus symmetry variables and composite scores were not examined. Exceptions to this are Speed which is combines Stride Length and Stride Duration, and the 'percentage of gait cycle' variables. For all variables apart from Speed and Cadence, the mean of the left and right values were calculated and used as a single data point for the variable.

Statistical analyses

Mean difference between values for each outcome variable from the two programs, and the percentage error (mean of the *absolute* difference expressed as a proportion of the GAITRite® value) were obtained for each group to identify the magnitude of the differences between the processing algorithms. The mean percentage difference underestimates the variability at individual level if differences are both positive and negative. The mean *absolute* percentage differences were therefore calculated to better indicate the size of the error at individual level. The mean differences for the total cohort are also presented with this difference expressed as a percentage of the mean GAITRite® value. Intraclass correlation coefficients (ICC) for absolute agreement (2,1) and consistency (3,1) were calculated for each pair of outcomes to determine inter-program reliability [19]. Absolute agreement indicates how close individual data points are to each other using the two programs, while consistency indicates the relative agreement or agreement regardless of systematic error [20]. The Bland-Altman method was used to calculate the 95% limits of agreement (LOA) to demonstrate the spread of differences [21], and mean versus difference plots were inspected in order to identify heteroscedasticity in the differences over the range of values.

Results

The final cohort consisted of 86 healthy and 44 hip fracture participants who had mean age ± SD of 72.0 ± 1.3 years and 82.7 ± 6.0 years respectively. Fifty-six percent of the healthy group and 82% of the hip fracture group were women. Table 1 presents the group means for each group, each program and each variable, plus the mean difference between the values generated by each processing program and mean absolute percentage differences. The mean differences between programs were similar for both groups of participants, although the mean absolute percentage difference was sometimes higher among the healthy group for the variability measures because the SD values tended to be lower among the healthier older people.

Table 2 presents the results of the ICCs, differences for the total cohort, and LOA. The inter-program reliability was very high (both ICCs ≥ 0.99, $p < 0.001$) for Speed, Cadence, Stride Length, Step Length, Stride Duration, Step Duration, Stance Duration, Swing Duration, Double Support Duration, Stance%, Double Support% and Stride Duration Variability. ICC(2,1) showed absolute agreement above 0.95 for all others except Base Width (0.86) and Step Length Variability (0.84). ICC(3,1) was similar to absolute agreement for all measures except Base Width where consistency was very high at 0.97. High consistency but lower absolute agreement indicates that there was a systematic difference in the Base Width values.

The magnitudes of the mean differences between the two programs were very small relative to the magnitudes of the variables themselves for all measures apart from Base Width (mean difference −1.6 cm, or 17.4% of mean GAITRite® value) and Foot Angle (mean difference 0.7°, or 9.7% of mean GAITRite® value). Mean absolute percentage differences showed individual differences could be quite large for all of the variability measures except

Table 1 Data for each outcome variable

	Healthy group			*Hip fracture group*		
	GAITRite® (mean ± SD)	**PKMAS® (mean ± SD)**	**Mean difference* ± SD (% error)**	**GAITRite® (mean ± SD)**	**PKMAS® (mean ± SD)**	**Mean difference* ± SD (% error)**
Speed (cm/s)	129 ± 21	129 ± 21	0.3 ± 0.6 (0.4%)	60 ± 22	61 ± 23	0.4 ± 0.5 (0.9%)
Cadence (steps/min)	110 ± 10	110 ± 10	−0.1 ± 0.2 (0.1%)	93 ± 15	92 ± 15	−0.0 ± 0.1 (0.1%)
Stride length (cm)	140 ± 16	140 ± 16	−0.0 ± 0.2 (0.1%)	78 ± 25	78 ± 25	0.1 ± 0.6 (0.3%)
Step length (cm)	70 ± 8	70 ± 8	−0.1 ± 0.4 (0.5%)	39 ± 13	39 ± 13	0.2 ± 0.3 (0.7%)
Stride duration (s)	1.1 ± 0.1	1.1 ± 0.1	0.00 ± 0.00 (0.04%)	1.3 ± 0.2	1.3 ± 0.2	0.00 ± 0.00 (0.1%)
Step duration (s)	0.55 ± 0.05	0.55 ± 0.05	0.000 ± 0.003 (0.5%)	0.67 ± 0.11	0.67 ± 0.11	−0.001 ± 0.004 (0.5%)
Stance duration (s)	0.69 ± 0.07	0.69 ± 0.07	0.003 ± 0.006 (1.2%)	0.93 ± 0.18	0.94 ± 0.18	0.011 ± 0.019 (1.4%)
Swing duration (s)	0.41 ± 0.03	0.41 ± 0.03	−0.002 ± 0.004 (0.5%)	0.40 ± 0.08	0.40 ± 0.08	−0.004 ± 0.007 (1.3%)
Double support duration (s)	0.28 ± 0.04	0.28 ± 0.05	0.004 ± 0.008 (1.5%)	0.53 ± 0.16	0.53 ± 0.16	0.009 0.013 (1.8%)
Stance time as a percentage of cycle time (%)	62.6 ± 1.3	62.8 ± 1.4	0.17 ± 0.35 (0.3%)	69.6 ± 4.5	69.9 ± 4.5	0.30 ± 0.46 (0.5%)
Double support time as a percentage of cycle time (%)	25.3 ± 2.6	25.7 ± 2.8	0.39 ± 0.84 (2.1%)	39.3 ± 8.9	39.8 ± 9.1	0.52 ± 0.98 (1.9%)
Base width (cm)	8.7 ± 2.5	7.1 ± 2.8	−1.64 ± 0.71 (21.4%)	10.4 ± 3.7	8.9 ± 3.9	−1.58 ± 1.00 (19%)
Foot angle (°)	6.8 ± 3.8	7.5 ± 3.7	0.65 ± 1.02 (66%)	7.7 ± 5.7	8.5 ± 5.6	0.76 ± 0.82 (40%)
Variability (SD) in Stride Length (cm)	2.4 ± 1.2	2.6 ± 1.2	0.17 ± 0.50 (28%)	4.1 ± 1.9	4.1 ± 1.8	0.00 ± 0.43 (9%)
Variability (SD) in Step Length (cm)	1.6 ± 0.7	1.7 ± 0.8	0.03 ± 0.55 (32%)	2.7 ± 1.1	2.7 ± 1.0	−0.08 ± 0.56 (17%)
Variability (SD) in Stride Duration (s)	0.02 ± 0.01	0.02 ± 0.01	0.001 ± 0.003 (7%)	0.07 ± 0.04	0.07 ± 0.04	0.000 ± 0.002 (2.3%)
Variability (SD) in Step Duration (s)	0.01 ± 0.01	0.01 ± 0.01	−0.001 ± 0.005 (20%)	0.04 ± 0.02	0.04 ± 0.02	−0.001 ± 0.004 (8%)
Variability (SD) in Step Width (cm)	1.9 ± 0.9	2.0 ± 0.9	0.05 ± 0.18 (9%)	1.8 ± 0.8	2.0 ± 0.9	0.12 ± 0.23 (11%)

*Negative differences indicate GAITRite® higher than PKMAS®.
SD = standard deviation.
Mean ± SD, mean difference ± SD and mean absolute percentage error, for each group, each system and each variable.

Table 2 Intraclass correlations and limits of agreement

Gait variable	Absolute agreement: ICC(2,1) (95% CI)	Consistency: ICC(3,1) (95% CI)	Mean difference* (SD,% difference)	Limits of agreement 95% CI	
				Lower	Upper
Speed (cm/s)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.34 (0.59, 0.3%)	−0.82	1.50
Cadence (steps/min)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	−0.05 (0.19, 0.0%)	−0.42	0.33
Stride length (cm)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.02 (0.38, 0.0%)	−0.73	0.76
Step length (cm)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.02 (0.42, 0.0%)	−0.79	0.84
Stride duration (s)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.000 (0.001, 0.0%)	−0.002	0.003
Step duration (s)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.000 (0.004, −0.1%)	−0.008	0.007
Stance duration (s)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.005 (0.009, 0.7%)	−0.012	0.022
Swing duration (s)	0.99 (0.99-1.00)	1.00 (0.99-1.00)	−0.003 (0.005, −0.7%)	−0.013	0.007
Double support duration (s)	1.00 (0.99-1.00)	1.00 (1.00-1.00)	0.005 (0.010, 1.5%)	−0.014	0.025
Stance time as a percentage of cycle time (%)	1.00 (0.99-1.00)	1.00 (0.99-1.00)	0.22 (0.39, 0.3%)	−0.56	1.00
Double support time as a percentage of cycle time (%)	0.99 (0.99-1.00)	1.00 (0.99-1.00)	0.43 (0.89, 1.4%)	−1.31	2.17
Base width (cm)	0.86 (−0.03-0.96)	0.97 (0.95-0.98)	−1.62 (0.82, −17.4%)	−3.22	−0.02
Foot angle (°)	0.97 (0.89-0.99)	0.98 (0.97-0.98)	0.69 (0.95, 9.7%)	−1.18	2.56
Variability (SD) in Stride Length (cm)	0.95 (0.93-0.97)	0.96 (0.94-0.97)	0.01 (0.48. 3.6%)	−0.84	1.06
Variability (SD) in Step Length (cm)	0.84 (0.78-0.89)	0.84 (0.78-0.89)	−0.01 (0.56, −0.5%)	−1.10	1.08
Variability (SD) in Stride Duration (s)	1.00 (0.99-1.00)	1.00 (0.99-1.00)	0.001 (0.003, 1.6%)	−0.006	0.007
Variability (SD) in Step Duration (s)	0.98 (0.97-0.98)	0.98 (0.97-0.98)	−0.001 (0.005, −2.7%)	−0.009	0.008
Variability (SD) in Step Width (cm)	0.97 (0.95-0.98)	0.98 (0.97-0.98)	0.08 (0.20, 3.9%)	−0.32	0.47

ICC = Intraclass Correlation, CI = confidence interval, SD = standard deviation.
*Negative differences indicate GAITRite® higher than PKMAS®.
ICC (2,1) absolute agreement, ICC(3,1) consistency (with 95% CI), mean difference (with SD and mean difference as a percentage of the mean GAITRite® value), and 95% limits of agreement for the total cohort. All ICCs were significant at $p < 0.001$.

Stride Duration Variability. Mean absolute percentage differences were also large for Base Width (around 20%, differences ranged from −4.1 to 0.4 cm) and Foot Angle (range −2.6 to 3.5°). The magnitude of the differences was especially high for Foot Angle with mean absolute percentage difference for the cohort of 57%.

Scatter plots and Bland-Altman plots are shown for Speed, Base Width, Step Length Variability and Stride Duration Variability in Figure 1. The plot for Base Width shows >95% of differences were negative indicating that PKMAS® Base Width values were systematically lower than the GAITRite® values. The plots for Stride Duration Variability (not shown) and Step Duration Variability showed greater differences for lower values of variability which affected only a small number of healthy participants. Apart from these two variables the plots showed even spread of differences over the range of values.

Discussion

This study demonstrated high levels of absolute agreement and consistency between the new and the established algorithms for most of the temporal and spatial gait variables we examined using electronic walkway data from healthy and gait impaired older people. All ICC values were greater than 0.84 and, with the exception of Base Width and Step Length Variability, greater than 0.95. However, the study identified several variables that should be considered with some caution at group level, and a few more that could be problematic at individual level if comparing GAITRite® to PKMAS®.

Base width

The ICC(2,1) absolute agreement for Base Width was 0.86 but the ICC(3,1) for consistency was 0.97, which suggests that while absolute agreement with GAITRite® values may be lacking, and both individual and group level comparisons not recommended, the variable processed by PKMAS® may be itself reliable and as good at detecting change over time as GAITRite®. PKMAS® values are approximately 1.6 cm, or about 17%, lower than GAITRite® values. The systematic and random differences between the two programs can be explained by differences in how they define and calculate Base Width (see Additional file 2: B1). In essence, an outward foot angle greater than zero degrees, will lead to the GAITRite® Base Width measure being larger than the PKMAS® base width measure. The greater the amount of Foot Angle, the larger the difference between the two Base Width values. It should be noted, however, that previous studies have questioned the reliability of GAITRite® Base Width as an

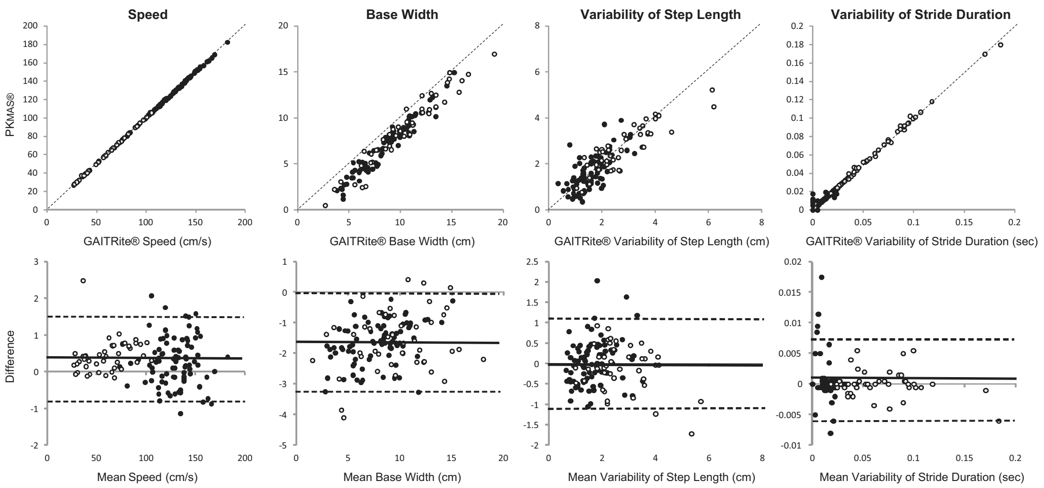

Figure 1 Associations between GAITRite® and PKMAS® data. Scatter plots showing the associations between GAITRite® and PKMAS® data, and Bland-Altman plots showing mean difference and 95% limits of agreement for Speed, Base Width, Step Length Variability and Stride Duration Variability. ● = healthy older people, ○ = post hip fracture patients.

outcome measure. Menz et al. found the test-retest ICC using the average from three walks was only 0.49 for a group of older people [16]. This suggests the within-individual variation can be close to the between-individual variability.

Step length variability

The lower ICCs for absolute agreement and consistency for Step Length Variability suggest that the output from the two processing methods should not be considered equivalent at individual level, and considered with caution at group level. One reason is that the magnitude of the variable itself is quite small so that even small differences between the programs can result in *relatively* large values for the differences between the values. In addition, step spatial calculations are different in the two processing methods (Additional file 2: B2). These small differences that do not noticeably affect the resulting values for Step Length if the walk is reasonably straight, can result in relatively larger differences in the SD of Step Length. If the direction of progression of the walk is not parallel to the mat, the values, and SDs of the values, can differ between the two programs even more.

Foot angle

The ICCs indicated that Foot Angle was acceptable at group and individual level although values appeared to be consistently about 0.7° higher with PKMAS®. The upper level of the 95% limit of agreement was 2.6°. These differences could be considered unacceptably large. Values for individuals were on average 57% different which also appears unacceptably large. It is important to note here that, as with Base Width, the reliability of the Foot Angle as an outcome measure has been questioned because the variability within individuals is relatively large compared with the magnitude of the variable [16]. The difference between the programs can again be explained by the different methods of calculation (Additional file 2: B3). It is not possible from this study to say which method is more valid or reliable.

All variability measures

The agreement for variability of both the temporal and spatial stride and step values appeared to be good at group level but there were some unacceptably high absolute differences, in particular among individuals with very low variability. This seems to be due to the resolution of the standard deviation calculation when the values are close to zero. Some small values are exported as zero by GAITRite® but as greater than zero by PKMAS®. The small differences in the calculation of spatial measures of Stride and Step Length can also be explained by differences in the location of the heel reference point (Additional file 2: B1). There are also differences in the calculations of temporal measures (Additional file 2: B4).

Prior studies have determined the validity and reliability for variables derived from the GAITRite® system (Additional file 1: A). GAITRite® data has been compared with paper and ink techniques, video-based systems, in-shoe stride analysers and 3-dimensional motion analysis systems [15-17,22,23]. The measurement error between the PKMAS® and GAITRite® algorithms was found to be smaller than errors reported in these other comparisons. The clinical meaning of the magnitude of the differences needs to be considered in the light of the purpose of the measurement. The impact of the slight differences in definitions and calculations used by PKMAS® for some of the variables may affect (improve or reduce) the validity of the variable in terms of its association with disease status, function and fall risk. Such studies are recommended for future research.

We chose to take the average of the values from left and right sides, rather than the average of all the steps. For most of the variables there will be negligible difference between the mean of the left and right sides and the mean of all the footfalls. However, for the variability measures, this decision is clinically important because mean SD is a better indication of the within-individual variability than the SD of all steps which will also be related to the degree of asymmetry [24]. There were also practical reasons for this approach as GAITRite® only exports left and right means and not the mean of all the footfalls. To derive the mean of all the footfalls, the individual footfalls would need to be exported. PKMAS® exports right, left and grand means. Other considerations regarding the two programs include:

1. We found that PKMAS® can indeed process difficult walks that include overlapping, double or backward steps more easily than GAITRite®.
2. GAITRite® exports a zero when a value cannot be calculated, for example due to insufficient steps. This affects the SD of many variables when there are five or fewer footfalls. While only one of our healthy participants needed only five steps to cover the active walkway (5.5 m), our participants were all over 70 years and walking at preferred speed. Researchers interested in the standard deviation of walks from younger participants or people walking at faster speeds should use caution with the data exported from GAITRite®, especially with shorter mats. We also found that SD values close to zero are exported as zero by GAITRite® but as a small value by PKMAS®.
3. PKMAS® purports to be able to process data recorded with GAITRite® hardware, however we encountered a few problems. In particular, PKMAS® periodically reads a single active sensor as a footfall and careful checking is required to identify these 'extra' footfalls. In addition, PKMAS® occasionally had difficulty determining the duration of stance phase for the final step. This may be because both our mats have 'seen a lot of action', but we recommend careful checking of each walk during processing of GAITRite® data with PKMAS®.

This study did not directly investigate the reliability or validity of PKMAS® derived data, however for the variables with good absolute agreement and consistency and minor differences from GAITRite® derived variables, validity and reliability can be assumed to be the same as for GAITRite®. For the remaining variables, it is not possible to know from this study whether validity and reliability are better or worse than for the GAITRite® derived variables. The study aimed to directly compare the two programs and a strength of the study is that the same footsteps were used by both processing algorithms and therefore the differences found can only be explained by the processing. We included participants with a range of gait ability (preferred gait speed ranged between 27-182 cm/s) and included participants with and without gait impairment. In addition, the study used testing procedures typical of those used in research studies with this population. However, the findings cannot be generalised to all populations and testing procedures.

Conclusions

GAITRite® is a widely used clinical and research tool and this report is an important step in determining the utility of PKMAS® as an alternative processing method. We conclude that Speed, Cadence, Stride Length, Step Length, Stride Duration, Step Duration, Stance Duration, Swing Duration, Double Support Duration, Stance%, Double Support% and Stride Duration Variability values are interchangeable with GAITRite® values. Base Width and Foot Angle have systematic differences of 1.6 cm lower with PKMAS® and 0.7° higher with PKMAS® respectively. The relatively large, randomly spread differences found for Base Width, Foot Angle, and variability of Stride Length, Step Length, Step Duration and Step Width mean that we recommend values are not comparable at individual level. The findings from this study will help inform clinicians and researchers wishing to interpret data processed using PKMAS®, and compare individual or group level data with published data that was processed using GAITRite®.

Additional files

Additional file 1: A.pdf – **Terminologies and definitions.**

Additional file 2: B.pdf – **Differences in calculations to derive variables between GAITRite® and PKMAS®.**

Competing interests
All authors declare that they have no competing interests. The work was carried out independently of either of the program developers.

Authors' contributions

TE participated in data processing, designed and carried out the study analysis, and wrote the manuscript. PT and JLH contributed to study design and to the drafting of the manuscript. PT also participated in data processing. All authors read and approved the final manuscript.

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Paper II

Title page:

Identification of gait domains and key gait variables following hip fracture

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Abstract

Title: Identification of gait domains and key gait variables following hip fracture

BACKGROUND: Restoration of gait is an important goal of rehabilitation after hip fracture. Numerous spatial and temporal gait variables have been reported in the literature, but beyond gait speed, there is little agreement on which gait variables should be reported and which are redundant in describing gait recovery following hip fracture. The aims of this study were to identify distinct domains of gait and key variables representing these domains, and to explore how known predictors of poor outcome after hip fracture were associated with these key variables.

METHODS: Spatial and temporal gait variables were collected four months following hip fracture in 249 participants using an electronic walkway (GAITRite®). From the initial set of 31 gait variables, 16 were selected following a systematic procedure. An explorative factor analysis with oblique (oblimin) rotation was performed, using principal component analysis for extraction of factors. Unique domains of gait and the variable best representing these domains were identified. Multiple regression analyses including six predictors; age, gender, fracture type, pain, global cognitive function and grip strength were performed for each of the identified key gait variables.

RESULTS: Mean age of participants was 82.6 (SD= 6.0) years, 75% were women, and mean gait speed was 0.6 (SD= 0.2) m/sec. The factor analysis revealed four distinct gait domains, and the key variables that best represented these domains were double support time, walk ratio, variability of step velocity, and single support asymmetry. Cognitive decline, low grip strength, extra capsular fracture and male gender, but not pain or age, were significant predictors of impaired gait.

CONCLUSIONS: This work proposes four key variables to represent gait of older people after hip fracture. These core variables were associated with known predictors of poor outcome after hip fracture and should warrant further assessment to confirm their importance as outcome variables in addition to gait speed.

Keywords: Gait, Hip fracture, Factor analysis, Rehabilitation

Introduction

Safe and efficient gait is a prerequisite for independent living in old age. Worldwide there are 1.6 million hip fractures annually [1]. The majority of hip fracture patients never regain prefracture function [2]. Gait impairment is an important reason this group faces long-term disability [3], loss of independence in activities of daily living (ADL), and increased fall risk [4].

The underlying mechanisms for gait decline following hip fractures are poorly understood and there are few reports on gait characteristics beyond gait speed in this group. Gait speed has been recommended as an overall measure of health and function in older adults [5]. However gait is not a unitary concept, and different gait variables have demonstrated discriminate and predictive ability for cognitive function [6] and for falls [7] suggesting there are complementary information to gain from gait variables beyond gait speed.

With the advent of electronic walkways, a large number of gait variables can be easily measured and reported, even in frail populations such as hip fracture patients. Identification of which gait variables capture the most important properties of gait impairment after hip fracture would aid future research targeting gait.

Factor analysis can be used to explain the underlying structure of a set of variables and thereby reduce a large dataset to a more manageable size, while retaining as much of the original information as possible [8]. Previous studies deriving gait domains by use of factor analysis in relatively healthy community-dwelling older adults have demonstrated three to six distinct domains of gait [6, 9, 10]. However, it is not known if the same domains are representative for gait in frailer older people following hip fracture. The present study aimed to identify a set of gait variables to describe gait in hip fracture patients and to explore how known risk factors for poor outcome after hip fracture are associated with these gait variables.

Method

Participants

Data were collected between April 2008 and December 2011 from participants included in the Trondheim Hip Fracture Trial [11]. Inclusion criteria for that trial were community-dwelling prior to the fracture, aged ≥ 70 years, and having undergone surgery for intra- or extra-capsular hip fracture (ICD 72.0-72.2). Exclusion criteria were pathological fractures and life expectancy shorter than 3 months. For the present study, data from the assessment carried out four months post-surgery were used.

The Trondheim Hip Fracture Trial was approved by the Regional Committee of Ethics in Medical Research (REK4.2008.335), the Norwegian Social Science Data Services (NSD19109), and the Norwegian Directorate of Health (08/5814). Patients or their next-of-kin gave informed written consent to be included in the study before participation.

Procedure

Gait assessment was carried out using a GAITRite® mat (CIR systems Inc. Sparta, US). Data were collected from a 4.88 m active area in the middle of an 8.0 m walkway. Participants walked back and forth at self-selected preferred speed, with each walk starting from a standing position approximately 1.5 m outside the active area. Walking aids were permitted only when the participant was unable to walk without one. Where two walks were available, the values from each walk were averaged.

Outcomes

Global cognitive function was assessed using the Mini Mental State Examination (MMSE) [12]. Grip strength was measured by the Jamar® handheld dynamometer, using the maximum value of two attempts by the strongest hand. Level of pain in the affected hip while walking was measured using an eleven-point numeric rating scale. Fracture type was dichotomised into intra- and extra-capsular fractures.

Data processing and statistical analysis

Data from the GAITRite mat were processed using the PKmas® software, which is a new programme developed to improve the processing of difficult footstep patterns, such as overlapping steps. Outcomes derived from the PKmas and GAITRite softwares have been shown to be comparable at group level for most variables [13]. Mean, within subject standard deviation (SD), coefficient of variance (CV (SD/mean*100)), and left/right ratio of spatial and temporal gait variables were calculated by the software and exported to Microsoft Excel® for further calculations of walk ratio (step length/cadence) and asymmetry: 100x(|ln(left/right)|) [14]. For the variability measures, the standard deviations for left and right sides were calculated separately and then averaged to avoid the effect of asymmetry on the values.

Selection of gait variables

Thirty-one commonly reported gait variables were initially considered for the factor analysis. These included three broad categories of variables; the mean temporal and spatial values measured over multiple steps, variability over these steps measured as both SD and CV, and left-right step asymmetry. CV is preferred when increase in SD is proportional to the within subject mean value. If SD is unrelated to the within subject mean value SD should be used as the measure of variability [15]. Steps instead of strides allow for calculation of left/right asymmetry and were therefore chosen.

The pattern of correlation among variables within a dataset determines if factor analysis is a suitable method. The correlation matrix determinant was checked for indications of multicollinearity (should be >0.00001) and the Kaiser-Meyer-Olkin statistics (KMO) for sampling adequacy (should be >0.5 for individual variables and >0.7 for overall KMO) [8]. Variables with a correlation higher than .9 and with KMO below 0.5 were considered removed from the analysis.

Each gait variable was inspected for normal distribution by Q-Q plots. As factor analysis is not very sensitive to deviations from the normal distribution [8], minor deviations were accepted. Based on the Q-Q plots, double support time, step time and all the variability variables except SD step width, were log transformed.

Factor analysis

An exploratory factor analysis was conducted in SPSS (IBM statistics 21). The extraction method was principal component analysis and the number of factors based on Eigenvalues > 1. Factors were expected to be correlated, and therefore oblique rotation used [8]. Criteria for selection of key variables were high factor loading in combination with low levels of cross loading. Factor loadings higher than 0.3 was set as the limit for cross loadings [8].

In order to assess the robustness of the results, we performed additional analyses using gait data collected twelve months following the fracture and also after exclusion of participants who walked with walking aids during the assessment. We also performed an additional factor analysis using a similar set of variables as Lord et al. [9], in order to compare with findings in healthy older adults.

Multiple regression analyses

Multiple regression analyses were carried out with gait speed and each of the identified key gait variables as dependent variables. Six known risk factors for poor outcome after hip fracture (age, gender, fracture type, pain level, grip strength and MMSE score) were entered as predictors. We used log transformed values for skewed variables (double support time and step velocity variability).

Results

Two hundred and forty nine participants were included in the analysis. Seventy-five percent were women. Time since fracture was 16.2 (SD 1.8 weeks). Sixty-four percent had intracapsular fractures, and of these the majority (67%) were operated with arthroplasty. Sixty percent of the participants used walking aids indoors. Twenty-five percent were not able to walk without walking aids during the gait assessment and therefore used either a rollator or a stick. Table 1 shows clinical characteristics of the participants four months post-surgery, while Table 2 shows means, standard deviations and the range for the gait variables included in the factor analysis.

- Insert Table 1. Clinical characteristics four months post-surgery -

Initial selection of variables

The procedure for selection of variables is presented in Appendix 1. Based on inspection of the correlation matrix and KMO statistics for individual variables, seven variables were removed including cadence, all stance time parameters, percentage double support, and single support time. Variability was reported as SD based on inspection of degree of proportionality between SD and means, and CV not included.

The selection procedure resulted in 16 variables remaining to be included in the factor analysis (Table 2). For this model the overall KMO was 0.79 and the Bartlett's test of sphericity was significant (p<0.0001).

- Insert Table 2. Gait characteristics -

Factor analysis

The factor analysis (Table 3) yielded four domains explaining 79% of the variance. These domains were labelled in line with earlier published models [9]. Domain 1: Pace/rhythm, Domain 2: Postural control, Domain 3: Variability, and Domain 4: Asymmetry. Forty-seven percent of the variance was explained by the pace/rhythm domain which also contained the highest number of variables and was dominated by mean and variability of temporal variables. Postural control explained 15%, variability 11% and asymmetry 7%. The pace/rhythm, postural control and asymmetry domains had about 10% overlap in variance between factors, thus supporting the use of oblique rotation. Cross loadings for single variables above 0.3 were found for step velocity, step time, single support percentage, step length and SD step length.

- Insert Table 3. Factor loadings -

Four variables with high loadings without cross loading were found for the pace/rhythm domain; double support time and SD of single support time, double support time and step time. For the other three domains walk ratio, variability in step velocity and asymmetry of single support time were the variable with highest loading and with no cross loadings.

Double support time were selected above measures of variability to represent the Pace/Rhythm domain due to previous work indicating the clinical relevance of this variable [7, 16-19] and as mean of temporal gait variables more consistently has demonstrated good reliability as compared to measures of gait variability [20].

Additional analyses firstly excluding participants using walking aids during the assessments and secondly using the data from the 12-month assessments, revealed the same domains and similar loadings as for the primary analysis (appendix 3). Using the variables similar to Lord et al. [9], the factor analysis revealed almost the same factor structure as found in healthy older adults, except that with our hip fracture patients' data the pace and rhythm domains were combined (appendix 2).

Multiple regression analyses

Results from the multiple regression analyses are presented in Table 4 showing that male gender and extra capsular fractures were associated with lower gait speed, increased double support time and higher asymmetry. Reduced global cognitive function were associated with lower gait speed and increased double support time, and low grip strength with reduced gait speed, increased double support time and lower walk ratio. Age and pain were not significantly associated either of the key variables.

- Insert Table 4. Multiple linear regressions -

Discussion

This study aimed to find domains that characterise gait in hip fracture patients and the key gait variables that best represent each of these domains. As expected we found high correlations among gait variables captured from the same walk. Despite this, the factor analysis revealed four relatively distinct domains and at least one variable for each domain with high factor loading and minimal cross loadings. The relevance of the four key gait variables was supported by the regression analysis, showing associations with established predictors for poor outcome following a hip fracture.

The main structure of the factor solution found in the present work was similar to that found in a previous sample of community-dwelling older people, supporting the notion of a more universal gait model [21]. As a result we choose to name domains revealed from the factor analysis in our study according to the previous models; pace/rhythm, postural control, variability and asymmetry.

In line with earlier work we found that temporal variables, mean step width, asymmetry in temporal variables, and spatial variability loaded to distinct gait domains. However we did not find pace (velocity and step length) and rhythm (temporal variables) separated onto distinct domains. Cross loadings were found for step velocity, step length and percentage single support. These are variables highly related to gait speed suggesting that these variables represent overall gait performance similarly to gait speed.

We found temporal and spatial variability loaded onto separate domains. This was the same finding as in healthy older adults [9]. Previous work has also demonstrated low correlation between these gait characteristics and suggested that variability in temporal and spatial gait characteristics represent different constructs [15].

As in most previous studies, the regression analysis demonstrated that gait speed might be a robust indicator of gait. However, gait speed did not have a high loading in the variability and the asymmetry domains, suggesting that these domains represented by the key variables step velocity variability and single support asymmetry have added value beyond gait speed.

The clinical correlates of the four domains cannot be implied from the factor analysis, but has to be interpreted in view of empirical evidence and earlier findings. Pace and rhythm in gait have been suggested to reflect central gait control mechanisms, with ‘pace’ being related to higher cortical mechanisms and ‘rhythm’ to spinal and brain stem mechanisms [6]. The ratio of step length to cadence (walk ratio) in normal gait is highly consistent across speeds and has been suggested to reflect higher order automatic control of gait [22]. Low walk ratio has been associated with cautious gait [23] and falls [24]. A combination of shorter step length, increased cadence and broader step width, rather than simply reducing gait speed, has been described as a strategy to cope with medio-lateral balance perturbations and increased medio-lateral margins of stability during walking [25, 26]. Hip fracture is a unilateral injury associated with pain [27], changes in biomechanics and muscle function of the hip abductors [28]. Asymmetric weight loading is a persistent characteristic of gait after hip fracture [29], and high levels of gait asymmetry were also found in this study.

The regression analyses indicated an association between gait impairments and known predictors of poor functional outcome after hip fracture including cognitive function, male gender, fracture type, and grip strength which is associated with sarcopenia and frailty [30]. This suggests that the identified key gait variables are relevant to outcome following hip fracture and can thus be recommended for the assessment of gait following a hip fracture. Further work should explore more specific hypotheses including how cognitive functioning, physical frailty and muscle function related to hip stability are associated with the different key gait variables and look specifically at how each of the key gait variables respond to interventions.

The study has some limitations. A factor solution is the result of the selection of variables entered into the analysis. Therefore, it is possible that other gait variables than those included in our model are important for outcome after hip fracture. Further this work included a heterogenic sample with regards to physical and cognitive function. This should make results generalizable but could also hide differences between subgroups. Never-the-less our gait model was found to be robust as demonstrated by similar findings with the 12-months post-fracture data and if participants walking with walking aids were excluded. Furthermore, the structure of the factor solution and loading of variables is also very similar to the model previously described in healthy older adults [9].

Conclusion

The present work suggests four key gait variables: double support time, walk ratio, SD of step velocity and single support time asymmetry to represent domains of gait in older hip fracture patients. It is suggested that the findings may facilitate the selection and interpretation of gait variables in future clinical trials.

Further work is needed to determine how these variables are associated with clinical features, or can be used to provide insight into the improvement in gait performance achieved by different interventions. In the longer term in-depth knowledge about gait characteristics could help to guide the development of more targeted and effective interventions to maximise gait recovery and to understand underlying mechanisms of gait impairments in older hip fracture patients.

Author's contribution: All authors were involved in conception and design of the study. P.T and K.T were responsible for data collection. P.T performed the data analysis and drafted the manuscript. All authors have been involved in critically revising the manuscript and have given final approval of the version to be published.

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Table 1. Clinical characteristics four months post-surgery

Sample characteristics	**N**	**Mean (SD)**
Age (years)	249	82.6 (6.0)
Barthel Index (0-20)	249	17.4 (3.0)
Nottingham E-ADL Index (0-66)	248	35.9(17.0)
Mini Mental State Examination (0-30)	247	24.3 (5.2)
Grip strength women	185	18 (5)
Grip strength men	61	30 (8)
Pain while walking (0-10)	240	1.8 (2.0)
	n/N	**%**
Women	191/249	77
Intracapsular fractures	158/249	64
Arthroplasty*	107/158	68

E-ADL: Extended activities of daily living, *proportion of intracapsular fractures

Table 2. Gait characteristics four months post-surgery (n=249)

Mean gait characteristics	**Mean**	**SD**	**range**
Steps (number)	25.2	10.2	8-83
Speed (m/sec)	0.62	0.25	0.20-1.42
Cadence (steps/min)	91	16	55-132
Walk Ratio (step length/cadence)	0.45	0.13	0.11-0.81
Step length (m)	0.40	0.12	0.13-0.81
Step width (cm)	8.93	3.9	0.35-22.0
Step time (s)	0.682	0.128	0.455-1.099
Single support (%)	30.8	4.6	17.4-38.9
Double support (s)	0.536	0.197	0.210-1.159
Variability gait characteristics	**Mean**	**SD**	**range**
SD step velocity (m/sec)	0.05	0.02	0.02-0.11
SD step length (m)	0.03	0.01	0.01-0.08
SD step width (cm)	1.9	0.7	0.6-4.1
SD step time (s)	0.047	0.039	0.007-0.319
SD single support (s)	0.036	0.018	0.007-0.126
SD double support (s)	0.060	0.067	0.008-0.627
Asymmetry gait characteristics %	**Mean**	**SD**	**range**
Step length asymmetry	15	21	0-163
Step time asymmetry	10	10	0-46
Single support time asymmetry	14	15	0-76

SD = standard deviation; CV = coefficient of variation (SD/mean x 100); Asymmetry = 100 x (|ln(left/right)|)

Table. 3 Factor loadings and proportion of variance explained by each domain for the 16 gait variables included in the analysis. Factor loadings above 0.3 are in bold.

Pace/Rhythm:	**Pace/Rhythm 47%**	**Postural control 15%**	**Variability 11%**	**Asymmetry 7%**
Gait speed	**-.721**	**-.353**	.218	-.110
Step time	**.978**	**-.394**	-.224	-.052
Single support %	**-.495**	**-.473**	.161	-.224
Double support time	**.857**	.108	-.194	.100
SD step time	**.888**	.057	.162	.066
SD single support time	**.847**	.031	.168	.028
SD double support time	**.855**	.108	.129	.048
Postural control:				
Walk ratio	-.135	**-.900**	.019	-.177
Step length	-.436	**-.653**	.155	-.148
Step width	.051	**.635**	.122	-.078
Variability:				
SD step velocity	.036	.237	**.820**	.095
SD step length	**.508**	.149	**.660**	.028
SD step width	-.159	-.163	**.666**	-.013
Asymmetry:				
Step length asymmetry	-.062	.215	-.070	**.725**
Step time asymmetry	.028	-.121	.089	**.935**
Single support asymmetry	.024	-.109	.016	**.953**

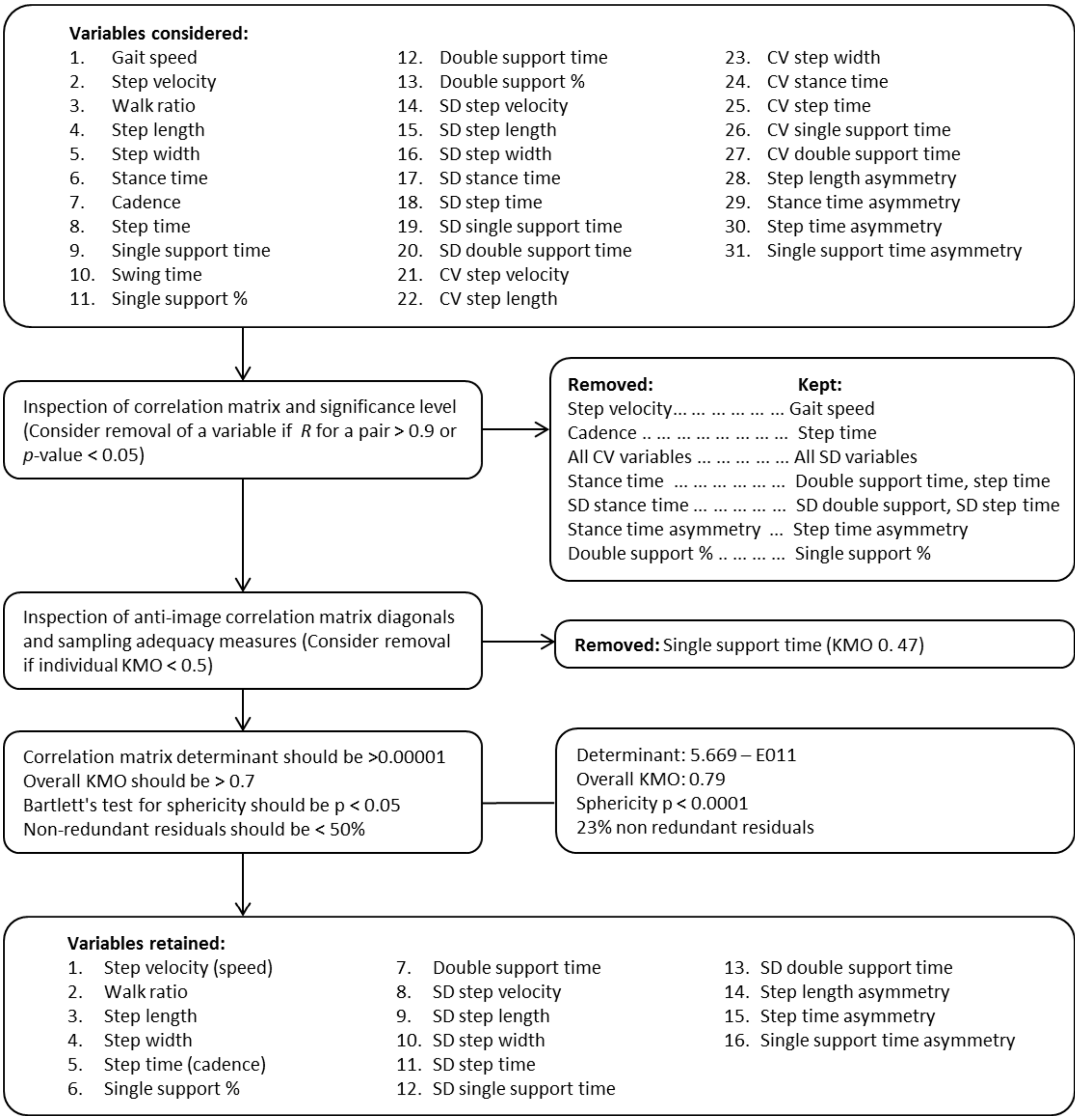
SD= standard deviation

Table 4. Multiple linear regression analysis with the key gait variables and gait speed as dependent variable

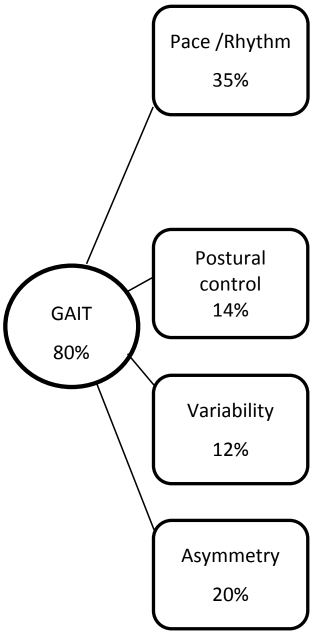
4 months	**Double Support**		**Walk Ratio**		**SD step velocity**		**SS Asymmetry**		**Speed**	
Adjusted R^2	0.150		0.182		.008		.074		.240	
	B	p	B	p	B	p	B	p	B	p
age	..087	.186	-.113	.080	.114	.107	.048	.481	.113	.070
gender	-.227	**.007**	-.087	.288	.031	.735	-.200	**.022**	.201	**.011**
fracture	.160	**.008**	.008	.892	-.063	.330	.199	**.002**	-.190	**.001**
pain	.026	.672	-.076	.199	-.024	.718	.115	.070	-.060	.296
MMSE	-.208	**.001**	.100	.104	-.125	.067	.014	.827	.205	**.001**
grip strength	-.267	**.003**	.296	**.001**	.100	.309	-.094	.320	.374	**<.001**

MMSE mini mental state examination, SS=single support

Appendix 1 Flow chart describing the process for initial selection of variables for the factor analysis

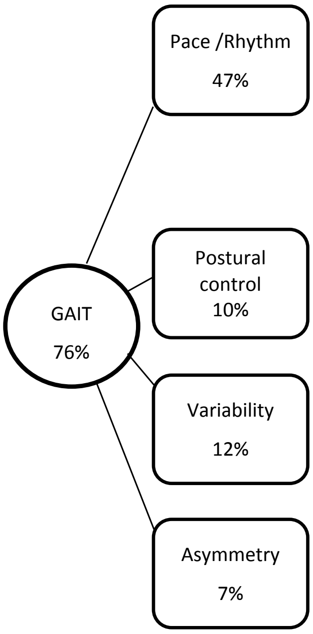


Appendix 2. Replication of the Sue Lord Model. The rotated component matrix of the varimax rotated solution showing factor loadings and proportion of variance explained by each domain. Factor loadings above 0.3 in bold. Dataset: 4 months assessment



	Pace/ rhythm	**Postural control**	**Variability**	**Asymmetry**
Step velocity	**-.848**	**.367**	.187	-.246
Step time (cadence)	**.870**	**.339**	-.252	.034
Stance time	**.917**	.123	-.222	.127
Single support time	**.326**	**.832**	-.167	-.229
Double support time	**.855**	.049	-.154	.142
SD step time	**.870**	**.339**	-.252	.034
SD single support time	**.853**	-.082	.175	.155
SD double support time	**.737**	.081	.123	.135
SD stance	**.889**	-.141	.137	.173
Step length	**-.637**	**.632**	.101	-.277
Step width	.183	**-.631**	.129	.022
SD step velocity	.071	**-.335**	**.824**	.115
SD step length	**.514**	-.239	**.661**	.124
SD step width	-.282	.149	**.652**	.048
Step length asymmetry	.147	**-.437**	-.076	**.626**
Step time asymmetry	.145	-.150	.072	**.851**
Single support time asymmetry	.179	-.110	.037	**.936**
Stance time asymmetry	.163	.066	.073	**.915**

Appendix 3. The pattern matrix of the oblimin rotated solution showing factor loadings and proportion of variance explained by each domain. Factor loadings above 0.3 in bold. Dataset: 12 months assessment



	Pace/ rhythm	Postural control	Variability	Asymmetry
Step velocity	**-.799**	**.331**	.049	.009
Step time (cadence)	**.932**	**.401**	-.152	.129
Single support %	**-.688**	**.348**	.092	-.075
Double support time	**.855**	.049	-.154	.142
SD step time	**.819**	-.066	.281	.085
SD single support time	**.685**	-.081	**.308**	.138
SD double support time	**.737**	.081	.123	.135
Walk Ratio	-.083	**-.885**	-.033	.004
Step length	**-.605**	**.593**	.025	.001
Step width	-.135	**-.644**	.051	.167
SD step velocity	.045	-.202	**.851**	-.083
SD step length	**.410**	-.125	**.737**	-.092
SD step width	-.243	.284	**.609**	.123
Step length asymmetry	.139	**-.379**	-.054	**.486**
Step time asymmetry	.080	.005	-.028	**.901**
Single support time asymmetry	.055	-.032	.006	**.896**

Paper III

Title page:

The long term effect of Comprehensive Geriatric Care on gait after hip fracture: The Trondheim Hip Fracture Trial - a randomized controlled trial

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ABSTRACT:

Purpose: Hip fracture patients are frail and the fracture usually followed by substantial decline in gait function. Few studies have assessed gait characteristics other than gait speed in hip fracture patients and knowledge about the effect of early intervention on long term gait outcome is sparse. The purpose of this study was to evaluate the long term effect of pre- and post-surgery Comprehensive Geriatric Care (CGC) on gait control and gait efficiency in hip fracture patients.

Methods: Two armed, parallel group, randomized controlled trial comparing Comprehensive Geriatric Care (CGC) to conventional Orthopaedic Care (OC) in pre- and early post-surgery phase. Hip fracture patients (n=397), community dwelling, age >70 and able to walk at time of the fracture were included. Spatial and temporal gait characteristics were collected using an instrumented walkway (GAITRite® system) four and 12 months post-surgery.

Results: Participants who received CGC had significantly higher gait speed, less asymmetry, better gait control and more efficient gait patterns, more participants were able to walk, and participants reported better mobility four and 12 months following the fracture as compared to participants receiving OC

Conclusion: Pre- and post-surgery CGC showed an effect on gait control and efficiency as long as one year after hip fracture. These findings underscore the importance of targeting the vulnerability of these patients at an early stage to prevent gait decline in the long term. As presently most hip fracture patients are treated in orthopaedic wards without geriatric involvement these results are important to inform new models for hip fracture care.

ClinicalTrials.gov (NCT00667914)

Key words: Hip fracture, gait, frailty, comprehensive geriatric care

Mini abstract:

At present most hip fracture patient are treated in orthopaedic wards. This study showed that a relatively short hospital intervention based on principles of comprehensive geriatric assessment resulted in safer and more efficient gait as long as one year following the fracture.

Introduction

Safe and efficient gait is crucial for autonomy and quality of life in old age. Hip fractures are associated with a substantial decline in gait and represent a severe threat to health and wellbeing for older people. Hip fracture incidence rises exponentially with increasing age, with a reported residual life time risk in women older than 60 years of 44% [1,2]. With advances in surgical techniques almost full recovery could be expected following a hip fracture, however less than half of hip fracture patients return to their prior level of function and the reduction in health-related quality of life is considerable and long lasting [3]. Two years after a hip fracture gait speed is considerably lower than that of community dwelling women of the same age [4], having had a hip fracture is associated with an increased risk of new falls and injuries [5] and up to ninety percent lose independence in daily tasks involving walking [6]. It remains unclear why there should be such a disproportionately large decline in gait function, and there is a lack of consensus about content and timing of interventions to maximize recovery of gait [7].

Falls that lead to hip fractures are rarely genuine accidents, and most falls happen during indoors activities that are not normally associated with fall risk [8,9]. Hip fractures are closely related to reduced health and function [10-13] and in a recent study about two thirds of hip fracture patients were classiefied with moderat or high levels of frailty [14]. Frailty is defined as a state of vulnerability, an age-related increased risk of functional decline due to global deficiency of physiological reserves and reduced ability to respond adequately to stressors [15]. This suggests older people who sustain hip fractures are especially vulnerable and at high risk of functional decline due to an inability to respond adequately to the strain the injury represent. Comprehensive geriatric care is a multidimensional and multidisciplinary approach targeting frailty. The long-term effect on function in geriatric patients is well documented [16], and similar approaches have shown to improve outcome in hip fracture patients [17]. However, most hip fracture patients around the world receive conventional orthopaedic care, and knowledge is sparse concerning the long-term effect of early comprehensive geriatric care on the recovery of gait.

Few intervention studies have included measures of gait characteristics beyond gait speed in hip fracture patients. However gait is not a unitary concept. Relatively independent domains of gait (pace, rhythm, variability, postural control and asymmetry) have been identified [18], and age related changes in spatial and temporal gait characteristics have been linked to reduced gait control and efficiency of gait in older people [19]. Increased knowledge on the effect of various interventions on specific gait characteristics may contribute to the development of better targeted and more effective treatment and rehabilitation models in the future.

The aim of the present study was to compare the long-term effect of pre- and post-surgery Comprehensive Geriatric Care (CGC) versus conventional Orthopaedic Care (OC) on gait.

Method

Design Overview:

Data on spatial and temporal gait characteristics were collected as part of the Trondheim Hip Fracture Trail, a single centre, prospective, two-armed, block randomized, parallel group, controlled trial [20].

Setting and Participants:

The study took place at St.Olav University Hospital from April 2008 to December 2010. St. Olav is the regional hospital for the population of Sør-Trøndelag with 302 000 inhabitants, and performs about 400 surgical procedures related to hip fractures each year. The geriatric department has existed since 1994 and has developed a geriatric evaluation and management unit which has shown to be effective in reducing mortality and increasing number of patients living at home in acutely sick and frail older adults [21-23]. Between 2008 and 2011, five out of 15 beds in the department were dedicated to hip fracture patients, in order to evaluate the effect of the new service delivery model. In Norway length of hospital stay after a hip fracture is restricted to the acute and sub-acute phase and patients are typically transferred to a rehabilitation institution or a nursing home within few days after surgery.

This study was powered to detect group difference in the primary outcome of the Trondheim Hip Fracture trial, the Short Physical Performance Battery. Expecting a drop-out rate of 20%, with α level of 0.05 and 80% power, 380 patients were needed to confirm a clinically meaningful difference of 1 point between groups on the Short Physical Performance Battery four months after the fracture [24].

Inclusion criteria were confirmed hip fracture (ICD-10 72.0-72.2), age 70 years or older, able to walk 10m prior to the hip-fracture and being community-dwelling at time of the fracture. Exclusion criteria were life expectancy less than three months, pathological fractures and high energy trauma.

Randomization and Interventions:

Randomization was performed using a web-based computerized randomization service developed by, and administrated from the Unit of Applied Clinical Research at the Norwegian University of Science and Technology (NTNU). The computer generated sequence was prepared by the Unit of Applied Clinical research and kept sealed until inclusion was closed and the data analysis plan finalized.

All patients with a confirmed hip fracture were approached by a nurse in the emergency room. If confirmed eligible, informed written consent was collected from the patient or the next of kin. Once included in the trial, the staff in the emergency room accessed the web-based computer program. The program randomly assigned patients to receive pre- and post-surgery CGC or orthopaedic care OC in a ratio of 1:1. Patients were transferred directly to the allocated ward for pre-operative care.

Patients were allocated to either conventional OC in an orthopaedic ward or CGC in a geriatric ward. Both pre- and postoperative care was provided at the allocated ward. Details of the intervention are described elsewhere [25]. In short, CGC is based on multidimensional assessment of somatic and mental health, mobility, ADL and social situation using standardized assessment protocols resulting in an individualized treatment and rehabilitation plan. The intervention was delivered by a multidisciplinary team consisting of geriatricians, physiotherapists, occupational therapists and registered and assistant nurses specialized within geriatric medicine. Short and long term goals were set for each patient in collaboration between the patient, next of kin and the team based on prefracture function, home conditions, cognitive function and current medical condition with a focus on early mobilization and rehabilitation.

Evaluation of progress and adjustment of goals and treatment plan were performed continuously during formal meetings in the team. Discharge planning was focused from day one post-surgery and involved next of kin and primary health care if necessary. Physiotherapy within two weeks or a homebased rehabilitation team following the patient from discharge were arranged for all patients who left directly home. All patients discharged to rehabilitation institutions or nursing homes were followed by a report including the results of the geriatric assessment, description of progress and expected prognosis.

In the geriatric ward, the hip fracture patients were clustered in a separate unit with five single-bed rooms dedicated to older fracture patients and staffed with dedicated personnel. Physical environments were facilitated with regards to delirium prophylaxis. Ward routines were developed to enhance physical activity with a specific focus on splitting up long periods of sitting and lying. Meals were served in the dining room instead of the patient rooms and patients were encouraged to use the communal areas.

Daily evaluations of need for physiotherapy were part of the routine. Patients that did not progress as expected according to the care plan were given higher priority as were patients with special challenges like restrictions on weight bearing. Exercises performed during the hospital stay, instructions for a home exercise program and written information provided by the physiotherapist were based on procedures from the orthopaedic department. In addition, goals and plans for mobilization and training of daily life activities, including progression, were described as part of the care plan and evaluated continuously. Mobilization and practicing relevant daily activities were a common responsibility for the team, commonly performed in collaboration between physiotherapists and nurses in the beginning, and then managed by the care personnel as routines and methods were established. Beyond this there was no additional focus on specific exercises aimed to improve gait control.

Patients in the orthopaedic ward received conventional orthopaedic care according to national and international standards including mobilization within 24 hours post-surgery [25]. Hip fracture patients stayed in a mixed unit with orthopaedic trauma patients. Geriatricians acted as consultants on request in a few patients. Physiotherapy was routinely requested for all patients and delivered by physiotherapists who were organized in a separate unit serving several departments. There was no structured multidisciplinary collaboration or regular meetings for common goal setting and information about individual patients was passed informally. Physiotherapy included the same exercise program, instruction in home exercises and written information as in the geriatric ward. The physiotherapists had the main responsibility for practicing walking and adjusting walking aids. Prioritizing of patients was based on the individual physiotherapist's evaluation of the patient's potential. Discharge planning was mainly the responsibility of the nurse. Patients discharged directly to their homes were provided a requisition for physiotherapy and had to arrange for appointments on their own. Patients discharged to institutions were followed by a short medical report.

Number of staff per patient bed was higher in the geriatric ward as compared to the orthopaedic ward; nurses 1.67 vs 1.48, doctors 0.13 vs 0.11, physiotherapists 0.13 vs 0.09 and occupational therapist 0.13 vs 0.0 [20].

Outcomes and follow-up

Assessments at four and 12 months were performed at the geriatric outpatient clinic at the hospital. Assessments were performed by assessors not involved in the patient care. Blinding was not possible for staff that provided the intervention, study participants, or assessors during the hospital stay. Assessments performed after discharge were performed without knowledge of group allocation, but with some assessments performed by the same assessors both in-hospital and at follow-ups. A standardized test battery, fixed protocols, procedures and instructions were used to minimize the influence of the assessor. Data processing and the first data analysis were performed blinded for group allocation.

Gait characteristics were measured over an 8 m (4.88m active area) instrumented walkway, the GAITRite® mat (CIR systems Inc. Havertown,PA). Participants walked back and forth at self-selected preferred speed, starting from a standing position. Walking aids were permitted only when the participants were unable to walk without.

A large number of gait variables can be extracted from the GAITRite system. Gait speed is regarded an indicator of overall health and function, sensitive to change in function and recommended to use as outcome in frail populations [26]. To cover aspects of gait beyond gait speed the following gait variables were selected; speed and step length to represent pace; cadence, double support time and percentage single support to represent rhythm; step width and walk ratio (step length/cadence) [27,28] to represent postural control; standard deviation of step velocity to represent gait variability; and single support asymmetry to represent gait asymmetry.

A relatively large proportion of patients were expected to either die, loose their ability to walk, or be unable to perform a full gait assessment during the follow-up period. It was deemed important to be able to describe the full range of participants according to gait function and therefore participants who were not able or unwilling to attend the outpatient clinic were offered a home visit with a reduced test protocol including a four-meter gait speed test, but not the GAITRite assessment. Accordingly, five participant categories would be present at each follow-up: 1) Those performing the GAITRite assessment, 2) Those performing a reduced protocol including the 4 meter gait speed test, 3) Those unable to walk, 4) Those deceased within the follow-up period, and 5) Drop outs.

Pre-fracture function was assessed through recall from the patient or next of kin using the Barthel Index [29], the Nottingham E-ADL scale [30] and the Clinical Dementia Rating scale [31]. Independence in mobility four and 12 months post-surgery was assessed by the mobility subscale of the Nottingham E-ADL scale.

Statistical analysis

Data from the GAITRite mat was processed using the PKmas® (ProtoKinetics, Havertown, PA) software, which is a new program developed to improve the processing of difficult footstep patterns from electronic gait mats. Outcomes derived from the PKmas and the GAITRite software have been shown to be comparable at group level for most variables [32]. Means, standard deviations and left/right ratio of steps were calculated by the software and exported to Microsoft Excel® for further calculations of walk ratio (step length/cadence) and single support asymmetry: 100x|ln(left/right)| [33]. For the variability measures, standard deviations of the gait variables for left and right sides were calculated separately and then averaged to avoid an effect of asymmetry on the variability outcomes.

The intervention had the potential to affect number of patients who ended up in each of the five predefined categories, and consequently, it was important to investigate to which extent missing data were informative or not. Our approach was to first characterise the differences in pre-fracture function between the five participant categories. We then conducted two analyses: a primary analysis where we transformed the data into ordinal scaled data and included participants who had lost their ability to walk, and a secondary complete case analysis based on the continuously scaled data. In the primary analysis, continuously scaled data were transformed into a 1-4 point ordinal scale using cut points based on quartiles for the OC-group. Participants unable to walk were provided a value of zero which resulted in a five point scale, with higher scores indicating better function. We then performed a sensitivity analysis where people who died during follow-up were added to the category of zero.

All statistical analyses were performed using SPSS Inc. (SPSS Statistics for Windows, Version 21.0. Chicago: SPSS Inc.). Descriptive statistics are reported as mean and standard deviation. Normality of gait variable distributions was checked by inspection of Q-Q plots and Kolmogorov-Smirnov tests. Most gait variables had a skewed distribution and the nonparametric Mann-Whitney U-test was used to test for group differences. Outcomes are reported as median rank, median and interquartile range. Differences in outcomes between participants with complete and missing data were tested with a one-way ANOVA, using the post-hoc Gams-Howell test. Group differences for categorical variables were tested by Pearson's Chi square test.

Ethics

This study complies with the ethical rules for human experimentation as stated in the Declaration of Helsinki and has been approved by the Regional Committee of Ethics in Medical Research (REK 4.2008.335), the Norwegian Social Science Data Service (NSD19109), and the Norwegian Directorate of Health (08/5814).

Role of the founding source

The research was supported by Norwegian Research Council, The Liaison Committee between the Central Norway Regional Health Authority (RHA) and the Norwegian University of Science and Technology (NTNU), the Norwegian Women's Health Association and the Norwegian Extra Foundation for Health and Rehabilitation through the EXTRA funds and The Norwegian Fund for Post-Graduate Training in Physiotherapy.

RESULTS

A total of 397 participants were randomized between 18th April, 2008 and 30th of December, 2010. Prefracture function and sample characteristics according to allocation are presented in Table 1 and show that treatment arms were comparable. Length of stay was slightly longer in the geriatric ward: 12.6 (SD 0.4) vs 11.0 (SD 0.5) days in the orthopaedic ward. Preoperative waiting time (29.0 (SD 23.3)) hours was similar for the OC and the CGC group. More patients in the CGC group were discharged directly home: 25% as compared to 11% in the orthopaedic group [20].

Insert table 1. Prefracture function and sample characteristics according to allocation

Patient flow through the study is described in Figure 1. At four months 254 participants (64%) underwent gait assessment with the GAITRite system and 228 participants (57%) at 12 months.

Insert fig 1. Patient flow chart

Table 2 shows pre-fracture function according to the five participant categories present at 12 months follow-up, and illustrates that participants who performed a reduced protocol, were unable to walk or had deceased, had poorer prefracture function as compared to participants who performed the GAITRite assessment. Prefracture function for those unable to walk at 12 months and prefracture cognitive function among drop-outs tended to be lower in the OC-group as compared to the CGC-group, indicating that data were not missing at random.

Insert Table 2. Prefracture function stratified by subgroups of missing data

Significantly more participants in the CGC-group were able to perform either the GAITRite or 4m-gait speed test both at four months (p=.049) and at 12 months (p=.005). At 12 months, 63% (124/198) of participants in the CGC-group and 52% (104/199) in the OC-group performed the GAITRite assessment (p=.037). In the CGC-group, 80% (99/124) were able to walk without walking aids during the test, while 69% (72/104) walked unsupported in the OC-group, (p= 0.065). Among those unable to perform the GAITRite assessment, 10% (20/198) in the CGC-group and 7% (14/199) in the OC-group were still able to perform a 4m-gait speed test (p=.275). In the OC-group 8% (16/199) were unable to walk and in the CGC-group 5% (9/198), (p=.152). In the OC-group 19% (37/199) had deceased within 12 months compared to 15% (29/198) (p= .291). In the OC-group 14% (28/199) had withdrawn compared to 8% (16/198) in the CGC group (p=.057).

At four months the proportion unable to walk was 4% (7/198) in the CGC-group and 11% (21/199) in the OC-group, p=.006. The proportion able to walk without walking aids during the test was 81% (107/132) in the CGC-group and 66% (80/122) in the OC-group, p=.006.

The primary analysis showed better gait characteristics at both four and 12 months in the CGC group compared to the OC-group, for all gait variables except variability (Table 3). These results did not change when including the deceased in the analysis. A complete case analysis provided similar results as for the primary analysis for the 12 months data, but did not reach significance level at four months.

Insert Table 3. Group differences in gait characteristics

Table 4 shows higher scores on the mobility sub-scale of the Nottingham E-ADL scale at 12 months and a tendency towards more participants reporting walking independently both in- and outdoor in the CGC group as compared to the OC-group.

Insert Table 4. Self-reported mobility 12 months following the fracture

Adverse events

Mortality rates were closely monitored according to predefined criteria [24]. No adverse events were reported.

Discussion

This study aimed to evaluate the long term effect of comprehensive geriatric care (CGC) on gait characteristics related to gait control and efficiency of gait four and 12 months following hip fracture. To our knowledge this is the first clinical trial assessing the effects of intervention on other gait characteristics than gait speed in hip fracture patients. We found that more participants in the CGC-group preserved their ability to walk, that gait characteristics indicated better gait control and efficiency, and that participants reported better mobility as compared to the OC-group as long as one year following the fracture as a result of a relatively short intervention focusing on interdisciplinary management.

Group differences in pace and rhythm, i.e. lower gait speed, shorter steps and longer double support time indicate reduced gait control and higher fall risk [34] in the OC-group four and 12 months following the fracture. Reduced walk ratio and increased step width further suggest that participants in the OC-group have reduced postural control and use more compensating strategies to secure gait as compared to the CGC-group [35,36]. These compensating strategies are associated with higher energy costs of walking [37,38]. High energy costs of walking are related to activity avoidance and reduced function [39] and could be part of the explanation why participants in the CGC-group reported better quality of life and more independence in daily life activities [20]. Persistent asymmetry in weight loading and in quadriceps strength has been found in hip fracture patients [40] and has been used as an argument for the relevance of early and high dose progressive strength training in hip fracture patients [41]. Our results suggest that targeting frailty in an early stage has a long-term effect on gait asymmetry.

The mean group difference of 0.08 m/sec in gait speed at12 months is below the 0.1 m/sec that is regarded as a clinically meaningful difference in gait speed [42]. However, a higher proportion of participants in the CGC-group performed the gait assessment at 12 months and prefracture function indicate that it was the participants with low prefracture function that were lost to follow-up in the OC-group, probably resulting in an attrition bias. In addition, more participants in the OC-group were using walking aids as they were not able to walk unassisted. The group difference is therefor most likely underestimated which also may explain the relatively low effect sizes. Clinical relevance of the group differences is supported by the findings of higher number of participants who preserved ability to walk and higher self-reported mobility in the CGC-group.

CGC is a complex multicomponent intervention and a combination of factors can possibly explain the effects. Results from activity monitoring on day four post-surgery have been published earlier and show higher activity level and activity being more spread throughout the day in the geriatric ward [43]. These findings indicate that patients were more easily mobilized due to better medical care, but also that mobilization procedures were more successful as a result of CGC. The comprehensive assessment and the team approach likely provided more structured and individualized mobilization and care of the patients, and allowed for more well-founded and planned prioritizing of patients that needed special attention, especially those with cognitive decline. Lower prefracture cognitive function and ADL function in the OC-group among participants who lost ability to walk is an indication that this strategy was successful and that CGC resulted in more of the most vulnerable participants being able to preserve ability to walk. The organization of physical therapy as an external service in the orthopaedic ward may not have allowed for the same systematic and coordinated approach and likely resulted in more ad hoc prioritizing of patients and less total activity and less walking integrated in daily life activities during the stay as compared to the geriatric ward.

Returning home after a hip fracture is a critical phase associated with lack of confidence and reduced participation [44]. A higher percentage of participants in the CGC-group were able to return directly home. It is likely that patients receiving CGC were more prepared for the home-setting due to an explicit focus on progressive ADL training throughout the stay and systematic early discharge planning that involved relatives and primary care.

A limitation of this study is the lack of formal blinding. However, the use of standardized tests and instructions should reduce the risk of tester bias and there were no indications of such, the same trends were found for data collected through registers and from more objective data like the activity monitoring. Another limitation is the amount of participants not able to perform the GAITRite assessment, which could question the suitability of data from instrumented walkways used as outcome in frail populations with an expected high rate of loss to follow up. Our approach was to carefully register reasons for inability to perform the test and invest effort to obtain a minimum of data on gait offering a home-based test protocol for those unable to attend the outpatient clinic. These procedures allowed for a relatively comprehensive and detailed description of gait following hip fracture which has not been presented earlier.

The strengths of this trial are the randomized controlled design, the large sample size, few exclusion criteria, high retention rate when taking the population into consideration, and a relatively long follow-up period.

Missing data is a general challenge in research on frail populations, but it is important to recognize that patterns of missing data could be informative as demonstrated in this study. Our analysis of patterns of missing data indicated that data were not missing at random and common methods like multiple imputation could not be applied. Our analysis strategy partly solved this problem by including a category of zero for those unable to walk, but we were not able to account for those performing only the reduced gait protocol, the drop outs, or the higher percentage in the OC- group who were unable to walk without walking aids. Nevertheless, we believe we have accounted for the most influential causes of bias, and if any should remain, rather underestimated than overestimated the treatment effect.

Conclusion

This randomized controlled trial demonstrates that CGC including a team-based, structured and individualized approach to mobilization, resulted in better gait control, gait efficiency and self-reported mobility as long as one year following the fracture. These results underscore the close association of health and gait functions and raises important issues concerning how to maximize gait recovery after hip fracture. Targeting the frailty of these patients in a very early stage seems to reduce the initial decline in gait function and perhaps make them more susceptible to rehabilitation and exercise at a later stage. Further research is needed to evaluate the added effect of exercises programs designed to target gait control specifically.

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Pernille Thingstad, Kristin Taraldsen, Ingvild Saltvedt, Olav Sletvold, Beatrix Vereijken, Sarah E. Lamb, and Jorunn L Helbostad declare that they have no conflict of interest.

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Table 1. Prefracture function and sample characteristics according to allocation

		CGC			OC		
		N	n (%)	Mean (SD)	N	n (%)	Mean (SD)
Demographics:							
Age at baseline (years)		198		83.4(5.4)	199		83.2(6.4)
Women		198	145 (73)		199	148 (74)	
Living alone		198	115 (58)		199	124 (62)	
Hip fracture fall indoors		186	135 (73)		188	140 (75)	
Fracture /surgery:							
Intracapsular		198	119 (59)		199	127 (64)	
Intracapsular arthroplasty[a)]		118	76 (64)		127	88 (69)	
Extracapsular		198	78 (39)		199	70 (35)	
No surgery		198	2 (1)		199	2 (1)	
Weight restrictions		198	17 (9)		195	20 (10)	
Prefracture gait function:							
Indoor	Independent	190	140 (73)		192	151(79)	
	Rollator	190	50 (26)		192	41 (21)	
Outdoor	Independent	185	119 (64)		182	116 (64)	
	Rollator	185	57 (31)		182	56 (31)	
	Wheelchair	185	9 (5)		182	10 (6)	
Prefracture function:							
Nottingham E-ADL (0-66)		195		42.5 (17.7)	192		41.9 (17.5)
Barthel Index (0-20)		195		18.3 (2.3)	192		18.1 (2.8)
Clinical Dementia Rating Scale (0-18)		184		2.7 (3.9)	173		2.7 (3.9)

CGC=Comprehensive Geriatric Care, OC = Orthopedic Care [a)]Proportion of intracapsular fractures with arthroplasty

Table 2. Prefracture function stratified by subgroups of missing data at twelve months. Comparing participants performing the GAITRite assessment at 12 months to subgroups with missing data (One-way Anova, post-hoc Games-Howell), and comparing treatment arms (Student's t-test) within each subgroup.

	GAITRite assessment n=228			**Reduced protocol** n=34			**Inability to walk** n=25			**Dead** n=58[1)]			**Drop-outs** n=42		
	mean(SD)			mean(SD)		p	mean(SD)		p	mean(SD)		p	mean(SD)		p
Nottingham EADL (0-66)	48.28(15.7)			36.98(15.4)		.001	23.0(12.5)		<.001	27.2(13.6)		<.001	46.2(14.2)		.914
Barthel Index(0-20)	18.9(1.8)			17.4(2.8)		.015	15.8(3.8)		.004	16.6(3.1)		<.001	18.7(2.0)		.979
CDR (0-18)	1.8(3.2)			4.0(5.1)		.036	4.4(3.8)		.050	5.5(4.9)		<.001	1.3(2.3)		.730
	CGC n=124	OC n=104	p	CGC n=20	OC n=14	p	CGC n=9	OC n=16	p	CGC n=29	OC n=37	p	CGC n=15	OC n=27	p
Nottingham E-ADL (0-66)	48.4(16.4)	48.1(15.0)	.898	33.2(15.9)	39.3(16.7)	.286	29.9(13.0)	20.2(11.4)	.075	25.2(12.3)	29.0(14.6)	.337	44.9(13.1)	46.9(14.9)	.836
Barthel Index (0-20)	19.0(1.6)	18.7(2.1)	.215	16.4(3.0)	18.3(2.3)	.056	17.3(1.7)	15.0(4.4)	.064	16.1(3.0)	16.9(3.2)	.297	18.8(1.4)	18.7(2.3)	.657
CDR (0-18)	2.0(3.5)	1.7(2.7)	.459	4.6(4.5)	4.8(6.4)	.904	1.1(1.1)	6.1(3.7)	.001*	6.5(4.5)	4.7(5.2)	.143	0.3(0.7)	1.8(2.7)	.017*

CGC=Comprehensive Geriatric Care, OC = Orthopedic Care, CDR: Clinical Dementia Rating Scale [1)] Missing data on 8 persons, died before data were collected.

Table 3. Group differences in Gait Characteristics

		Ordinal scale Mean rank[a]		Ordinal scale analysis				Gait characteristics Median (IQR)		Complete case analysis
		CGC	OC	u	z	*p*	*Effect size*	CGC	OC	*p*
Four months:		n=139	n=143			n=282		n=132	n=122	n=254
Pace:	Speed(m/sec)	154.2	129.2	8180.5	-2.632	.008*	0.17	0.65(0.38)	0.57(0.38)	.142
	Step length (cm)	152.5	129.7	8272.0	-2.495	.013*	0.16	42.48(17.96)	38.12(18.9)	.113
Rhythm:	Cadence(steps/min)	150.4	132.9	8702.0	-1.850	.064	0.11	92.3(26.4)	89.2(25.9)	.469
	Double support time (msec)	156.2	127.3	7900.5	-3.053	.002*	0.19	461(294)	538(285)	.135
	Single support (%)	157.5	126.0	7718.5	-3.328	.001*	0.21	32.7(6.8)	30.1(7.8)	.057
Variability:	SD step velocity (cm/sec)	150.6	132.7	8673.0	-1.894	.058	0.20	4.19(1.78)	4.25(1.91)	.735
Postural control:	Step width(cm)	155.7	127.7	7969.5	-2.952	.003*	0.19	8.3(5.4)	8.8(5.0)	.129
	Walk ratio (step length/cadence)	153.3	130.1	8304.0	-2.448	.014*	0.16	0.46(0.20)	0.44(0.16)	.266
Gait Asymmetry:	Single support asymmetry (%)	157.5	126.0	8276.0	-2.493	.013*	0.16	8.2(12.7)	9.2(13.7)	.247
Twelve months:		n=131	n=120			n=251		n=124	n=104	n=228
Pace:	Speed (m/sec)	140.9	111.6	6130.0	-3.271	.001*	0.22	0.72(0.36)	0.59(0.32)	.011*
	Step length (cm)	141.9	110.5	5997.0	-3.509	<.0001*	0.23	44.53(16.5)	39.0(17.2)	.007*
Rhythm:	Cadence (steps/min)	137.0	115.9	6650.0	-2.347	.019*	0.16	95.0(21.5)	91.6(19.8)	.230
	Double support time (msec)	140.5	112.0	6182.0	-3.180	.001*	0.21	422(216)	469(227)	.016*
	Single support (%)	143.1	109.2	5844.0	-3.787	<.001*	0.25	34.1(4.8)	31.7(5.5)	.002*
Variability:	SD step velocity (cm/sec)	139.2	113.5	7638.0	-0.603	.547	0.04	4.58(2.2)	4.35(2.14)	.668
Postural control:	Step width (cm)	135.8	117.2	6806.0	-2.071	.038*	0.14	7.7(5.4)	8.6(5.4)	.153
	Walk ratio (step length/cadence)	136.4	115.6	6728.0	-2.209	.027*	0.15	0.48(0.14)	0.45(0.17)	.039*
Gait Asymmetry:	Single support asymmetry (%)	139.2	113.5	6364.0	-2.848	.004*	0.19	5.5(9.0)	7.9(11.2)	.037*

CGC=Comprehensive Geriatric Care, OC = Orthopedic Care

*Group differences are compared by Mann-Whitney test. [a] Mean rank is reported for the five point ordinal scale data and median (IQR) for the GAITRite data

Table 4. Self-reported mobility 12 months following the fracture

	Intervention (CGC)			Control (OC)			*p*
	N	n (%)	Mean(SD)	N	n (%)	Mean(SD)	
Walking aids:							
Independent indoor	156	81(55)		136	61(45)		.125
Independent outdoor	137	66(48)		116	43(37)		.075
Nottingham Mobility subscale (0-18)	158		9.4(6.4)	149		7.5(6.3)	.013
Independence in:							
Outdoor mobility	158	89(56)		149	60(40)		.015
Stairs	158	93(59)		149	73(49)		.195
Public transportation	158	55(35)		149	34(23)		.040

CGC=Comprehensive Geriatric Care, OC = Orthopedic Care

Effect of CGC on gait after hip-fracture

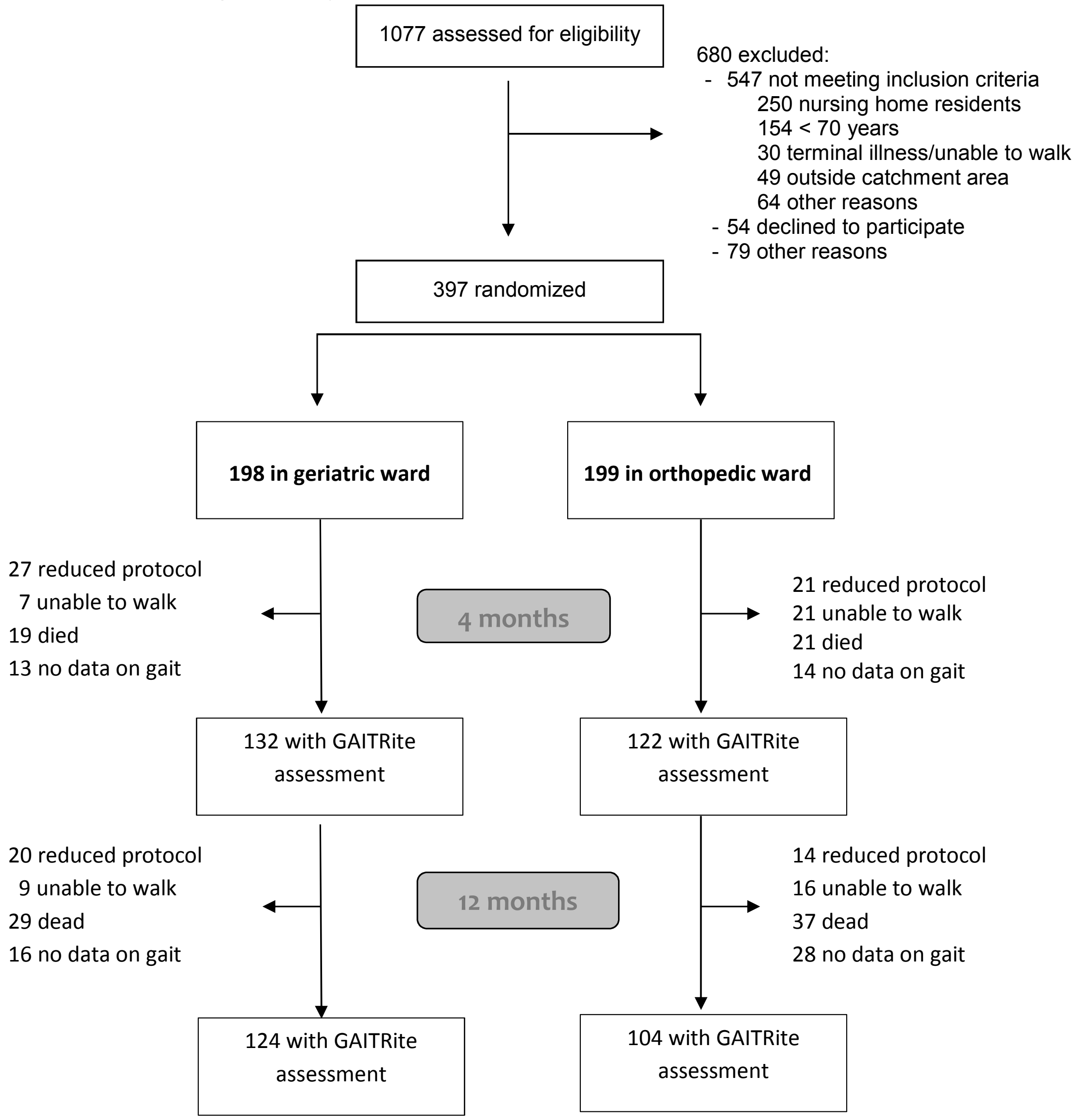

Figure 1. Flow chart. Gait assessment

Paper IV

RESEARCH ARTICLE

Effectiveness of Task Specific Gait and Balance Exercise 4 Months After Hip Fracture: Protocol of a Randomized Controlled Trial — The Eva-Hip Study

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Abstract

Background and purpose. Regular rehabilitation is not sufficient for regaining function after a hip fracture, and more targeted interventions for home-dwelling elderly hip-fracture patients are needed. This paper describes the protocol of a study assessing the effectiveness and cost effectiveness of a task specific progressive gait and balance exercise programme for hip-fracture patients, performed 4 months after the fracture. **Methods/design.** A single blind two-arm pragmatic randomised controlled trial was conducted with 142 hip-fracture patients randomized to a 10-week home-based exercise programme or to practice as usual 4 months following the surgery. Inclusion criteria were age >70 years and being home dwelling prior to the fracture. Exclusion criteria are life expectancy <3 months and inability to walk 10 m prior to the fracture. The content and organization of the programme was developed in collaboration between physiotherapy researchers and primary health-care physiotherapists. Participants were followed for 1 year post-surgery, evaluating short-term and long-term effects of the programme. The primary outcome is gait speed, and the secondary outcomes are spatial and temporal gait parameters, free living physical behaviour by activity monitoring, mobility performance, activities of daily living, fear of falling, cognitive function, depression and health-related quality of life. Cost-effectiveness analysis is planned. **Discussion.** This paper describes a task specific exercise programme aimed to improve gait and balance after a hip fracture. Inclusion started in February 2011, and the last 1-year follow-up is performed in March 2014. Broad inclusion criteria and physiotherapy-guided home-based exercises may facilitate the participation from frail patients and thereby increase the generalizability of the findings. Development and completion of the intervention within routine clinical practice will enlighten the implementation of results into clinical practice. Results may add new insight into how physiotherapy can improve gait and thereby activity and functioning in everyday life and have implications on future content and organization of physiotherapy after a hip fracture.

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Keywords

accelerometry; ageing; exercise; gait; hip fracture

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Background

Hip fractures are associated with high age, frailty and permanent disability (Bertram *et al.*, 2011) including increased risk for new falls and fractures (Lloyd *et al.*, 2009), fear of falling, severely reduced quality of life (Ziden *et al.*, 2008b; Rohde *et al.*, 2010; Jellesmark *et al.*, 2012) and low levels of physical activity (Resnick *et al.*, 2011). Obtaining efficient and safe gait following a hip fracture could mean the difference between a home-dwelling, active and independent life and dependency and need for residential care. Despite evidence for the beneficial effect of early physiotherapy and exercise after hip fracture, there is insufficient evidence for best practice (Handoll *et al.*, 2011) and even less is known about the effect of extended exercise interventions and long-term effects of exercise interventions. The current knowledge base is mostly based on a few efficacy driven studies performed under highly controlled conditions or including participants that are relatively homogenous compared with the general home-dwelling hip fracture population (Orwig *et al.*, 2011; Sylliaas *et al.*, 2012; Latham *et al.*, 2014). It is not obvious that exercise programmes proven effective in efficacy studies will produce the same effect during real-world conditions (Flay *et al.*, 2005)

Earlier studies have usually evaluated the effect using mobility tests and self-reported measures of activity. To our knowledge, there are few studies that have evaluated the effect of exercise intervention on specific gait characteristics in combination with objective measures of activity after hip fracture. Such knowledge could be important to be able to develop more targeted and effective exercise programmes.

Gait and balance are the key aspects of mobility in daily life. It may be hypothesized that exercises for balance and gait especially for frail older persons with limited capacity will be more effective if they are performed under conditions similar to those encountered during daily life. Task specific exercises that aim to improve motor control represent a different approach from traditional exercise programmes, where strength, balance and endurance are trained as separate components (Sherrington and Henschke, 2013). This has been supported by VanSwearingen *et al.* (2011) who found that task specific exercises improved gait efficiency and activities of daily living (ADL) and increased the amount of physical activity in elderly people with impaired gait more than traditional impairment-oriented exercises (VanSwearingen *et al.*, 2011).

Basic mobility tasks of daily life involve frequent shifts between positions, such as sitting down or getting up, short walks, turns, stepping sideways or backwards or climbing stairs, all involving weight bearing over a changing base of support. Inadequate weight transfer, and reduced ability to adjust the body's centre of mass in relation to a changing base of support, is associated with balance impairments, falls (Robinovitch *et al.*, 2013) and hip fractures (Singer *et al.*, 2013; Winter, 1995). The association between impaired executive function, gait impairments and fall risk is well established, and there is increasing evidence for the effect of dual task training to improve gait and balance in elderly people with increased fall risk (Hsu *et al.*, 2012; Liu-Ambrose *et al.*, 2013; Montero-Odasso *et al.*, 2012).

Hip-fracture patients tend to be old and frail, and rehabilitation is often too short for gait performance to recover. Cognitive decline (Seitz *et al.*, 2011), depression (Holmes and House, 2000), fear of falling (Visschedijk *et al.*, 2010; Visschedijk *et al.*, 2013) and fatigue (Folden and Tappen, 2007) may restrict participation in community-based exercise programmes or even in home exercise programmes that are based on exercises that are not supervised. Patients that are vulnerable to deterioration in health and to functional decline may thus not receive sufficient follow-up after returning to their own homes, and may therefore not regain optimal functional abilities. A systematic review and meta-analysis suggested that exercise programmes initiated after the end of standard rehabilitation are promising strategies to improve independence in daily life activities after hip fracture but marked the lack of cost-effectiveness studies of extended programmes (Auais *et al.*, 2012).

This paper describes the protocol of a study that aims to evaluate the effectiveness and cost effectiveness of a task specific, home-based exercise programme initiated 4 months after the surgery. A specific focus has been on including a representative sample, to run the trial within real-world conditions and to include a broad spectrum of outcomes.

Methods

Participants were recruited between February 2011 and February 2013, at St Olav University Hospital, the regional hospital for the municipality of Trondheim (180,000 inhabitants and approximately 300 hip fractures annually). Randomization and intervention were finished by June 2013, and the last follow-up will be performed in March 2014.

Context

The standard path for home-dwelling hip-fracture patients in Trondheim is to be transferred from the hospital to a rehabilitation facility within the first week after surgery. Time spent at the rehab facility varies from 2 to 8 weeks. The frailest and most dependent patients are discharged to nursing homes. A small number of patients are discharge directly to their own homes. There are no standards for content, intensity or length of physiotherapy offered to hip-fracture patients after they have returned home. Available services are home-based physiotherapy as a single service, physiotherapy as part of an ambulatory rehabilitation team or treatment in private physiotherapy clinics.

Overview of the study

This trial intends to evaluate the effectiveness of a late-phase exercise intervention. Participants were included within the first 5 days after the fracture, whereas baseline registrations and randomization took place 4 months following the fracture and the last assessment was 12 months after the fracture.

Design

The study is a two-arm pragmatic, single blind, block randomised controlled trial with even the distribution of patients in each arm.

Participants

The evaluation of eligibility was performed in two steps, first during the index stay and then as part of the baseline registrations at 4 months. Eligible participants were home dwelling prior to the fracture, lived in the municipality of Trondheim, were 70 years or older, diagnosed and underwent surgery for intra-capsular or extra-capsular hip fractures International Classification of Diseases (ICD-10 S72.0-S72.2)[1] resulting from a low trauma incident. Patients were excluded if the fracture was pathological, life expectancies were less than 3 months, they were unable to walk 10 m (with or without walking aids) prior to the fracture or were participating in one of two defined conflicting research projects. Patients who were bedridden or had medical contraindications for training as evaluated by a geriatrician at the time of baseline registration 4 months post-surgery were excluded before randomization.

Inclusion and randomization

Informed consent was obtained within the first 4 days after the surgery. For patients deemed non-competent in giving informed consent by a subjective evaluation by the case nurse, a next of kin was approached for a preliminary consent. After the completion of the baseline assessment at 4 months, participants were randomized to task specific exercise or usual care. The randomization was performed using a web-based computerized randomization service developed at the Unit for Applied Clinical Research, Norwegian University of Science and Technology. A stratified block randomization technique was used to ensure balanced group concerning intra-capsular versus extra-capsular fractures and pre-fracture use of walking aid (rollator indoor or not). All details concerning the solution were undisclosed to the research staff until end of inclusion. Group assignment through the web programme was performed by an administrative coordinator in the community health service who was not involved in any contact with participants. This person received identification number and name of participants for randomization from the research staff, ran the computer programme and noticed the physiotherapist who was to follow the patient.

Blinding

Assessors and personnel performing statistical analyses were blinded to participants' group allocation. Participants were instructed not to provide information that could reveal group allocation to the researchers or the assessors during the study period.

Intervention

The exercise programme was developed in collaboration between physiotherapy researchers and clinical physiotherapists working in home-based rehabilitation. By combining theoretical foundation with clinical expertise, we aimed at developing a task specific exercise programme that was standardized but could be tailored to individual needs and capabilities. The programme was intended to be feasible for routine clinical work.

[1]International Classification of Diseases, World Health Organization.

Patients randomized to the new exercise intervention received a home-based programme starting 4 months post-surgery, supervised by a physiotherapist twice weekly for 10 weeks, each session lasting approximately 45 minutes. The programme consisted of the following five weight-bearing exercises, all entailing change in base of support (Appendix): 1) walking; 2) stepping in a grid pattern; 3) stepping up on a box; 4) sit-to-stand; and 5) lunge. Each exercise is described at five difficulty levels to allow for the standardized registration of individualization and progression.

Progression was obtained by introducing variations in the task to challenge weight transfer, increasing movement speed, adding weight by using weight-vests, introducing more complex combinations of movements, and by adding secondary tasks (dual task condition). Exercises were meant to be performed without compensating strategies such as hand support or asymmetric weight bearing. Ten physiotherapists with varying background and experience were responsible for administering the exercise programme, as part of their ordinary work in the municipality.

Patients allocated to the control group received treatment as usual, which included a variety of different approaches, from no follow-up at all to quite extensive interdisciplinary rehabilitation in their homes or in an institution. Patients in the intervention group were given a choice whether to continue the treatment they already received in addition to the exercise programme they were randomized to, or to postpone this too after completing the exercise intervention.

Study assessments

Assessment was performed at four time points: (T1) during the hospital stay, (T2) 4 months post-surgery, (T3) within 2 weeks after conclusion of the intervention and (T4) 1 year post-surgery. During (T1) the hospital stay, only data on pre-fracture ADL and cognitive function were collected, whereas the full test battery, including 4 days activity monitoring, was performed at T2, T3 and T4. At T2, after baseline registrations, participants were randomized to take part in a 10-week home-based exercise programme or to receive usual care. Patients who were reluctant to participate in the exercise programme or dropped out during the follow-up period were still encouraged to meet for study assessments. All trial registrations were performed by experienced physiotherapists who were blind to group allocation and not involved in the exercise programme. Information on pre-fracture ADL and cognitive function collected at T1 were based on information from the patient, next of kin and medical record. Information on cognitive function was collected routinely from next of kin. (T2) Baseline, (T3) post-intervention and (T4) 1-year assessments were performed at the outpatient clinic and the movement laboratory at the hospital. Patients who were unable or reluctant to attend were offered a home visit with a modified protocol not including GAITRite® mat (CIR systems Inc. Sparta, US) or measures of knee extension muscle strength but otherwise the same battery. For the intervention group, level of progression, number of repetitions, time spent on each exercise and fatigability following each training session were reported on standardized forms.

Outcomes

The primary outcome measure is preferred gait speed. Secondary outcome measures are spatial and temporal gait parameters, physical activity, mobility performance, ADL, cognitive function, depression, health-related quality of life, falls efficacy, fatigue and fall rate during the follow-up period.

Preferred gait speed is regarded as a robust and sensitive measure of overall health and function and has been recommended as an outcome in interventions on elderly populations (Abellan van Kan *et al.*, 2009). Other outcomes were chosen to cover a broad spectrum of health-related aspects relevant in frail populations, and to include both performance-based measures of physical function, objective measures of free living physical behaviour and self-reported health. Outcomes commonly used within geriatric research were chosen for the purpose of comparison with other trials.

Gait variables were measured by means of an electronic walkway (GAITRite®) (Kressig *et al.*, 2006). Participants walked back and forth across a 10-m walkway, where the middle 4.88 m were recorded by the gait mat, in preferred, slow and fast self-administered speeds, and at preferred speed while counting backwards, for a total of eight walks. Gait variables include mean and variability of spatial variables, step length and step width and temporal variables, and the proportion of time per gait cycle in single support during preferred speed. Walk ratio is calculated as the ratio between step length and cadence at fast gait speed (Rota *et al.*, 2011). Dual task effects are expressed as the percentage differences between single and dual task conditions (Plummer-D'Amato *et al.*, 2012). Asymmetry in step length and single support is calculated as the ratio between the affected and the non-affected leg during preferred speed (Yogev *et al.*, 2007).

Assessment of other outcomes

Basic and instrumental ADL (I-ADL) was measured by the Barthel Index (Mahoney and Barthel, 1965) and the Nottingham Extended I-ADL Scale (Nouri and Nb, 1987). Mobility was assessed by the Short Physical Performance Battery (Guralnik *et al.*, 1994) and the Timed Up-and-Go test (Podsiadlo and Richardson, 1991). Physical activity was measured by single-axis accelerometers over 4 days (activPALs from PAL Technologies ltd, Glasgow, UK), attached to participant's non-affected thigh (Taraldsen *et al.*, 2014). Outcome measures are mean upright time and mean number of upright events. Isometric knee extension strength was measured by a dynamometer (MIE limited edition, LTD) with the subject seated.

Health-related quality of life was measured using the EuroQol-5D-3L (Rabin and de Charro, 2001). The Mini Mental State Examination (Folstein *et al.*, 1975; Strobel and Engedal, 2008) and the Clinical Dementia Rating Scale (Hughes *et al.*, 1982) were used for the evaluation of cognitive status. Depression was assessed by the Geriatric Depression Scale (Sheikh and Yesavage, 1986) and falls efficacy by the 7-item Short Falls Efficacy Scale International (Hauer *et al.*, 2011; Helbostad *et al.*, 2010). The Chalder Fatigue Questionnaire (Chalder *et al.*, 1993) was used to assess chronic fatigue and an 11-point numeric scale to evaluate fatigability following each exercise session. The number of falls and fall circumstances during the follow-up period is registered on the basis of retrospective reports from participants, next of kin and physiotherapists. The outcome measures are the same as used in previous studies on hip-fracture patients from our research group (Sletvold *et al.*, 2011).

Utilization of health services

Costs will be calculated applying a broad health-care perspective. Data on use of hospital services (inpatient, day patient or outpatient services) and medications will be collected from the participants' hospital medical records. Data on use of health services delivered by the municipality units will be collected from the participants' municipality records, for example, home-based services and short-term nursing home stay. The use of services from general practitioners and private physiotherapists will be collected from the Norwegian Directorate of Health.

Sample size calculations and statistical analysis

Previous studies in otherwise healthy hip-fracture patients have reported meaningful difference in preferred gait speed in the range of 0.08 (Perera *et al.*, 2006) and 0.12 m/sec (Kwon *et al.*, 2009), whereas other studies suggest that meaningful change in gait speed is population dependent and probably higher for less healthy populations (Alley *et al.*, 2011). We expected our sample to be less healthy and with a larger within as well as between subject variance compared with the sample referred in the previous studies. Therefor a meaningful difference of 0.15 m/sec were selected for the power calculations. With a power of 90% and $p = 0.05$, a sample size of $n = 54$ in each arm are necessary to detect a difference in gait speed between groups of 0.15 m/sec. On the basis of the data from a previous study in hip-fracture patients with similar inclusion criteria performed by our research group, we expect about 20% to refuse to participate in the intervention, further 15% to have die during the follow-up period, 10% to be excluded because of medical contraindications or lost of ability to walk and about 10% to be expected to withdraw (Sletvold *et al.*, 2011). On the basis of these assumptions, we estimated the number of patients needed to be included during the index stay to be 220.

Statistical methods

All data will be analysed and presented according to the updated CONSORT guidelines for reporting parallel group trials including intention to treat and per-protocol analysis (Schulz *et al.*, 2010). Descriptive statistics will be used to describe patient characteristics and drop out during the follow-up period. As a first choice, primary and secondary outcomes will be analysed using the analysis of covariance (ANCOVA) (Vickers and Altman, 2001), adjusting for age, gender, pre-fracture I-ADL and baseline cognitive function (Mini Mental State Examination < 28).

Cost effectiveness will be analysed by calculating the incremental cost-effectiveness ratio (ICER) as the difference in costs between the two treatment groups, divided by their difference in effects measured as the quality-adjusted life years. We will use the time trade off tariff values from the United Kingdom to value the EQ-5D-3L health states (Dolan, 1997). Where there are incomplete benefits or cost data due to loss to follow-up, we will use non-parametric methods to infer cumulative costs and benefits. To derive confidence intervals for the ICER, non-parametric bootstrap methods will be applied. Uncertainty in the ICER estimates will be presented as scatterplots on the cost-effectiveness plane and as cost-effectiveness acceptability curves.

Adverse events

Significant adverse events are defined as falls during exercise sessions, falls during the exercise period, musculoskeletal injuries, medical complications, hospital admissions and deaths. Significant adverse events during the exercise period are reported to the study administration.

Ethical considerations

The test battery consists of well-known and commonly used assessment tools in geriatric populations. Participants received an individual evaluation and adjustment of the programme to secure challenging but safe training. Each session was closely supervised by an experienced physiotherapist who also secured the participant by manual support if needed. The intervention is structured and targeted, but not fundamentally different from what could be given as part of normal clinical practice. Thus, the exercise programme is not regarded to be experimental or potentially harmful to the patients. Patients in the control group will receive today's best practice. The study has been approved by the regional ethics committee (REK 2010/3265-3).

Results

Inclusion was finalized in February 2013 with a total of 223 patients included, representing 90% of home-dwelling patients over the age of 70 years admitted for hip fracture within the catchment area during the inclusion period. Four months after the fracture, baseline registrations were performed on 183 (73%) participants, and 142 of the 250 eligible hip-fracture patients (57%) were randomized to the exercise intervention. The drop-out rate was 10% at T3 post-intervention and 15% at T4 1-year follow-up; in addition, eight participants died within the follow-up period. Twenty-seven of the 41 participants who were not randomized still met for assessments at T3 and 19 at 1-year follow-up (Figure 1).

Table 1 compare pre-fracture function and demographics for participants who were randomized to those who refused to participate in the exercise trial and those who were excluded or had died before baseline assessment. The results indicate that demographics and type of surgery did not differ between participants who were randomized or not, whereas those who refused to participate had poorer cognitive function, and those who were excluded on the basis of medical reasons or died had a reduced physical function prior to the fracture.

Discussion

This paper describes the protocol of a randomised controlled trial aimed to evaluate the effectiveness and cost effectiveness of a home-based exercise trial delivered at a time when regular rehabilitation is usually ended.

The described study can answer some of the limitations of previous studies. Strict inclusion criteria, especially on medical conditions and cognitive function in previous studies, have resulted in very low proportions of patients being considered eligible and included (Latham *et al.*, 2014; Orwig *et al.*, 2011). Further, hip-fracture patients participating in extended exercise programmes performed in an outpatient setting tend to have better cognitive function (Sylliaas *et al.*, 2011) than would be expected from prevalence studies on hip-fracture patients (Seitz *et al.*, 2011).

A strength of the present study is that patients are identified from daily screenings of operation lists and included already during the hospital stay. All hip fractures within the catchment area of the study are operated at the same hospital. Thus, this procedure ensures that the study sample is drawn from the population of interest, and the flow chart represents all potentially eligible hip-fracture patients within the catchment area.

A further strength is the collection of data on pre-fracture function shortly after the fracture and assessment of participants who are reluctant to participate in the exercise intervention that starts 4 months after

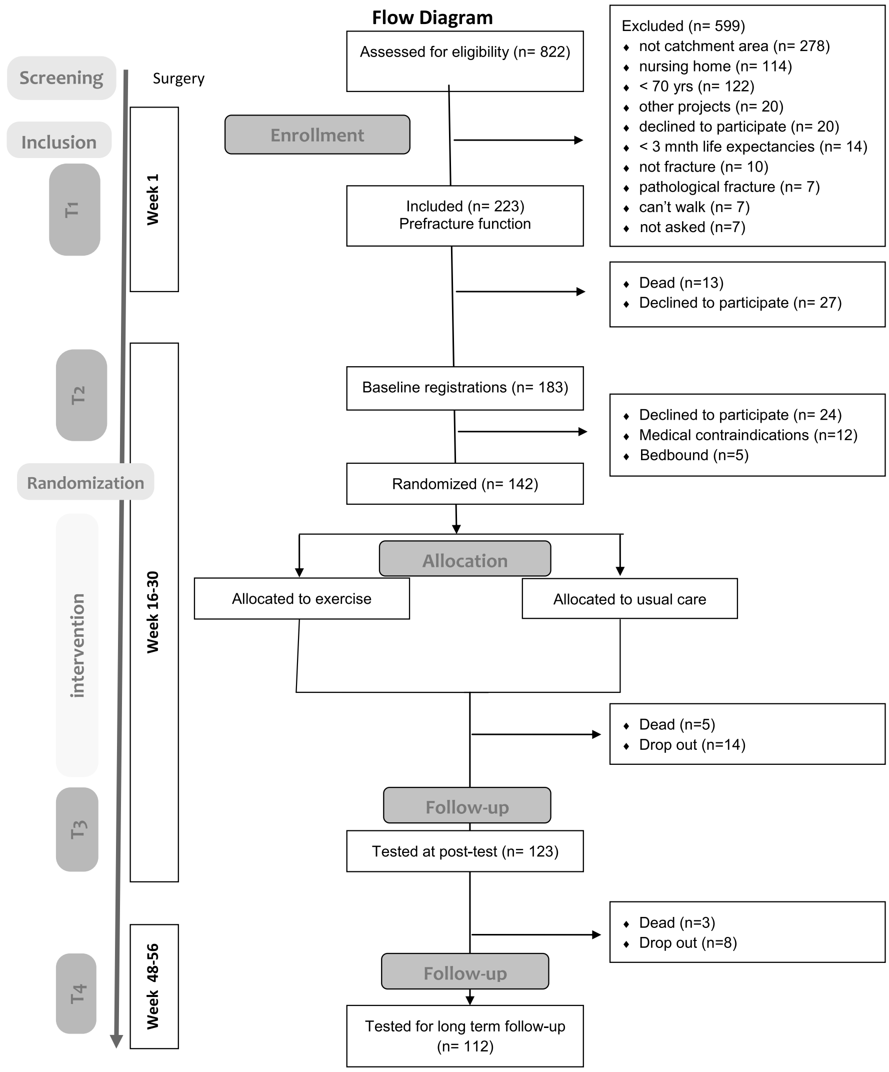

Figure 1. Study flow chart

inclusion but still willing to attend study assessments. Together, this provides a quite unique material for comparing characteristics of those who do participate and those who drop out during the follow-up period at different stages. Such knowledge is lacking and is of outmost importance when interpreting results of intervention trials in frail populations.

Inclusion criteria are broader than in most comparable trials. The excluded number of patients due to medical reasons are few (7%) taken into consideration the characteristics of the population and is, lower than in most comparable trials. The study has no exclusion criteria on cognitive impairment. Cognitive impairment is common within this population, and it is therefore of special interest to develop interventions that are effective in persons with impaired cognitive function. Still, results on pre-fracture function indicate that those who refuse to participate in the exercise

Table 1. Group differences in patient characteristics, pre-fracture function, fracture type and surgery between randomized participants and those who refused participation or were excluded or died before randomization

	Total (*n* = 223)	Randomized (*n* = 142)	Refusal (*n* = 50)	*p*	Dead or excluded (n = 31 (15+16))	*p*
Age (year) (mean (SD))	83.5 (6.2)	83.4 (6.2)	82.7 (6.0)	.828	85.2 (6.0)	.304
n (%)						
Women	161 (72)	110 (78)	32 (64)	.250	19 (61)	.205
Living alone	157 (70)	106 (75)	32 (64)	.362	19 (61)	.356
Hip fracture fall indoor	178 (80)	113 (72)	33 (70)	.253	26 (87)	.717
Walk aid/assistance indoor	59 (26)	32 (23)	10 (20)	.880	16 (52)	.016
Walk aid/assistance outdoor	104 (47)	63 (45)	19 (38)	.659	21 (68)	.054*
Intra-capsular fractures	131 (59)	82 (58)	32 (64)	.716	17 (55)	.954
Arthroplasty (proportion of intra-capsular)	114 (87)	66 (80)	25 (78)	.949	13 (76)	.949
Mean (SD)						
Barthel Index (0–20)	18.5 (2.1)	18.7 (2.0)	18.6 (2.0)	.976	17.7 (2.8)	.175
Nottingham extended activities of daily living (0–66)	42.1 (16.7)	45.1 (16.0)	39.2 (16.7)	.079	33.4 (16.4)	.002*
Clinical Dementia Rating Scale (0–18)	1.7 (3.2)	1.2 (2.5)	2.6 (3.9)	.051*	2.9 (4.0)	.058

*Significant group differences (One way Anova with Games Howell posthoc test assuming unequal variance).

programme have poorer cognitive function than those who have been randomized, despite that special care was taken to include this group, both in the design of the intervention and concerning study assessments procedures. These results underscore the need for more knowledge and targeted approaches towards these patients in future trials.

Few studies on exercise after hip fracture report the total number of patients who underwent surgery for a hip fracture during the inclusion period. Studies providing this information report inclusion rates between 14% and 44% (Orwig *et al.*, 2011; Sipila *et al.*, 2011; Ziden *et al.*, 2008a) suggesting that an inclusion rate of 57% 4 months after the surgery in the present study is relatively high.

There are good arguments for a more task specific approach to exercise after hip fractures and a lack of knowledge concerning the potentially beneficial effects of exercises on safety and effectiveness of gait after a hip fracture. In general, the effect of exercise interventions on physical performance such as muscle strength is better documented than the effect on more patient relevant outcomes (Auais *et al.*, 2012) underscoring that what persons can do is not the same as what they do. Assessment of gait characteristics beyond speed and extensive collection of data on physical activity by body-worn sensors provide new information on hip-fracture patients that may be important to evaluate the effect of the intervention on future fall risk and on everyday life function.

The study can also bring new information about cost effectiveness extending the rehabilitation period for hip-fracture patients. As standard rehabilitation in hip-fracture patients is usually finalized 4 months after surgery, an extended exercise programme such as this would represent new and extra costs. Cost effectiveness is therefore of special importance to assess but is so far lacking (Auais *et al.*, 2012).

Limitations of the study are the use of practice as usual for the control group instead of a sham intervention with comparable intervention time as for the exercise group. However, in this setting, it was regarded as important to be able to assess the gain of an extra effort compared with what these patients usually are offered. This is also relevant when calculating cost effectiveness of the programme. Another question is to which extent the results can be generalizable outside the municipality of Trondheim. Trondheim has a well-developed health-care and rehabilitation service, and it is expected that a substantial part of the participants in the control group will receive physiotherapy as part of usual care, which represents a danger of underestimating the effect a similar programme would have in another setting.

Implications for physiotherapy practice

This study can add new and important knowledge concerning the effectiveness and cost effectiveness of a physiotherapy-lead progressive gait and balance exercise programme for home-dwelling hip-fracture patients, intended to improve gait and activity. This may guide the development of more effective physiotherapy interventions for improving the outcome after hip fracture in frail, older patients and allow for a larger proportion remain independent in their homes for a longer time.

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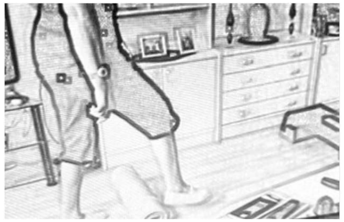
Appendix A

	Equipment	Level 1	Level 2	Level 3	Level 4	Level 5
Walking 	3- to 10-m walking path, no walking aid, supported by physiotherapist if necessary	Needs substantial support during walking: mostly forward walking at slow speed, short sessions	Needs moderate support while walking: simple instructions on increased step length/ walk the path in fewer steps and higher speeds.	Walks without support: Increased step length, speed variations, start/stop, turns. Simple dual task (e.g. talk while walking, counting and naming children) obstacle negotiation. Minimum of 10 minutes active walking	Variations in speed. Obstacle negotiation, narrow path walking and more challenging dual task. (calculating, birthdays of grandchildren, detailed road descriptions and shift keys from left to right pocket)	High speed, frequent, turns. Combinations of additional tasks. Outdoor walking in natural terrain or urban setting
Stepping 	Anti-slip mat with a 3 × 3 grid pattern. (grid 40 × 40 cm) If necessary, supported by hand	Standing with support, weight transfer without stepping	With support: short steps forward and sideways	Without support, but with close supervision: steps in all directions in a predictable pattern. Slow speed. Minimum of 10 minutes active stepping	Without support: steps towards the edge of the mat, with higher speed than Level 3 and with variable patterns	High speed, unpredictable stepping patterns (instructed), weight vest

Step-Up 	Adjustable step-box, weight vest	With support: tapping onto the step but not stepping up	With substantial support: able to do some of the four following exercises: 1) stepping up; 2) stepping up and over; 3) stepping sideways, one foot on each side of the step; and 4) lowering one foot at a time while standing on the step ('checking the water')	Little support, close supervision: exercises 1–4. Sessions of 3 × 15–20.	Without support: all four exercises. Series of 3 × 15–20	Increased height of the step-up box, weight vest. Higher speeds, longer sessions
Chair rise 	Chair 45–47 cm, pillows for adjusting height and weight vest	Raising/lowering on heightened chair with support	Raising/lowering on heightened chair without support	Raising/lowering on normal chair without support. 3 × 10–15 rep	Raising/lowering on normal chair with asymmetrical foot placements, and at higher speeds. Emphasis on controlled lowering	Raising/lowering on normal chair with weight vest
Lunge 	Weight vest	With substantial support: short forward lunges	With moderate support: short forward lunges	Without support: short forward lunges 3 × 8–12 rep	Lunges with 90° hip and knee flexion	Lunges with weight vest