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Fall-related concerns, balance and gait in older adults with osteoporosis

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THESIS FOR DOCTORAL DEGREE (Ph.D.)

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”Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning” - Winston Churchill

ABSTRACT

Aim: The overall aim of this thesis was to evaluate the short- and long-term effects of a specific and progressive balance-training programme, focusing on dual- and multi-task exercises, with respect to fall-related concerns, gait, balance performance and physical function in older adults with osteoporosis. Furthermore, to evaluate the reliability and validity of the Falls Efficacy Scale-International questionnaire, and to explore perceptions of fall-related concerns and balance after participating in the balance-training programme.

Methods: In a methodological study the relative and absolute reliability and convergent validity of the Falls Efficacy Scale –International (FES-I) for older adults with or without osteoporosis and an increased risk of falling was evaluated. In a randomized controlled trial including 3 groups (Training, Training + physical activity and Control), both the short- and long-term effects of a balance-training programme, focusing on dual- and multi-task exercises, for older adults with osteoporosis were evaluated with respect to fall-related concerns, walking speed with or without a supplemental cognitive task, balance performance, and physical function. Inductive qualitative content analysis was used to explore how older women with osteoporosis perceive fall-related concerns and balance in daily life after participating in the balance-training programme.

Results: The Swedish version of the FES-I showed acceptable values for relative and absolute reliability in older Swedish individuals with increased risk of falling. Moreover, the results showed low convergent validity for FES-I in correlation with balance performance and health-related quality of life in older women with osteoporosis and increased risk of falling. The balance-training programme had positive effects on fall-related concerns, gait, balance, and physical function. Both training groups showed positive effects from the balance-training intervention at the first follow-up. However, at 9 months follow-up, the effects for the Training + physical activity group had regressed to baseline values, and were even lower at the 15 months follow-up, one year after the end of the intervention. This was in contrast to the participants in the Training group, who maintained improved positive effects throughout the study period. After the balance-training the participants described perceived fall-related concerns and balance in daily life under the categories of empowerment, safety and menace, with an underlying theme of 'internalised risk perception related to experience of bodily fragility' that always was present. The analysis also identified a dynamic process, in which seasonal, environmental and personal factors influenced how participants perceived their fall-related concerns and balance.

Conclusion: The FES-I is a reliable questionnaire for older individuals with increased fall risk, but it has low convergent validity with balance performance tests and health-related quality of life among older women with osteoporosis. The specific and progressive balance-training programme, focusing on dual- and multi-tasks, positively influenced fall-related concerns, gait speed, and physical function in older adults with osteoporosis in both a short- and long-term perspective. To cope with the fragility caused by osteoporosis, the participants experience an internalised risk perception that protects against possible threats and harm. The participants improved their empowerment and self-efficacy, resumed activities, and became more active after participation in balance-training programme.

SAMMANFATTNING

Syfte: Det övergripande syftet med denna avhandling var att utvärdera kort- och långtidseffekter av ett specifikt och progressivt balansträningsprogram med fokus på övningar med delad uppmärksamhet, avseende fallrelaterade besvär, gång, balans och fysisk funktion hos äldre med osteoporos. Syftet var även att utvärdera reliabilitet och validitet av frågeformuläret Falls Efficacy Scale-International, och att beskriva upplevelser av fallrelaterade besvär och balans, efter deltagande i balansträningsprogrammet.

Metod: I en metodologisk studie utvärderades relativ och absolut reliabilitet och konvergent validitet av Falls Efficacy Scale-International (FES-I) för äldre med osteoporos och ökad fallrisk. I en randomiserad kontrollerad studie med tre grupper (Träning, Träning+fysisk aktivitet och Kontroll) utvärderades både kort- och långtidseffekter av balansträningsprogrammet avseende fallrelaterade besvär, gånghastighet med och utan samtidig kognitiv uppgift, balans och fysisk funktion. Induktiv kvalitativ innehållsanalys användes för att beskriva hur äldre kvinnor med osteoporos upplever fallrelaterade besvär och balans i dagliga livet efter att ha deltagit i balansträningsprogrammet.

Resultat: Den svenska versionen av FES-I har acceptabla värden för relativ och absolut reliabilitet för äldre individer med ökad fallrisk, men låg konvergent validitet i jämförelse med balans och hälsorelaterad livskvalitet för äldre kvinnor med osteoporos och ökad fallrisk. Båda träningsgrupperna förbättrades avseende fallrelaterade besvär, gång, balans och fysisk funktion till första uppföljningen. Vid 9 månaders uppföljning hade effekterna för en av träningsgrupperna (Träning+fysisk aktivitet) minskat. Vid 15 månaders uppföljning, ett år efter interventionen, hade effekterna återgått till värden liknande eller lägre än de vid studiens start. Däremot hade deltagarna i den andra träningsgruppen behållit de positiva effekterna av balansträningen under hela uppföljningsperioden. Efter att ha deltagit i balansträningen beskrev deltagarna upplevelsen av fallrelaterade besvär och balans i det dagliga livet i kategorierna egenmakt, trygghet och hot, med ett underliggande tema “internaliserad riskuppfattning relaterat till upplevelsen av kroppslig bräcklighet” som alltid var närvarande. Vidare identifierades en dynamisk process där säsongs-, miljömässiga- och personliga faktorer påverkade hur deltagarna upplevde fallrelaterade besvär och balans.

Konklusion: FES-I är ett reliabelt frågeformulär för äldre personer med ökad fallrisk, men har låg konvergent validitet med balanstest och hälsorelaterad livskvalitet för äldre kvinnor med osteoporos. Det specifika och progressiva balansträningsprogrammet, med fokus på övningar med delad uppmärksamhet, förbättrade fallrelaterade besvär, gånghastighet och fysisk funktion hos äldre med osteoporos även i det långsiktiga perspektivet. För att hantera den upplevda bräckligheten orsakad av benskörhet, erfor deltagarna en internaliserad riskmedvetenhet som skyddar mot eventuella hot och skador. Deltagarna förbättrade sin egenmakt och tilltro till sin förmåga, återupptog aktiviteter och blev därmed mer aktiva efter deltagande i balansträningen.

LIST OF SCIENTIFIC PAPERS

This thesis is based on the following original papers, which are referred to in the text using Roman numerals (Studies I-IV):

I. Halvarsson A, Franzén E, Ståhle A.
Assessing the relative and absolute reliability of the Falls Efficacy Scale-International questionnaire in elderly individuals with increased fall risk and the questionnaire´s convergent validity in elderly women with osteoporosis.
Osteoporosis International 2013; 24:1853-1858.

II. Halvarsson A, Franzén E, Ståhle A.
Balance training with multi-task exercises improves fall-related self-efficacy, gait, balance performance and physical function in older adults with osteoporosis: a randomized controlled trial.
Clinical Rehabilitation 2014; August 20. Epub head of print.

III. Halvarsson A, Oddsson L, Franzén E, Ståhle A.
Long-term effects of a progressive and specific balance-training programme with multi-task exercises for older adults with osteoporosis – a randomized controlled study.
Submitted.

IV. Halvarsson A, Ståhle A. Halén C, Roaldsen KS.
'Better safe than sorry' – a qualitative analysis of participants perspective of balance and fall-related concerns in older women with osteoporosis.
Submitted.

CONTENTS

LIST OF ABBREVIATIONS

ANOVA	Analysis of variance
BETA-study	Balance, elderly, training and activity study
BMD	Bone mineral density
CI	Confidence interval
DXA	Dual Energy X-ray Absorptiometry
FES	Falls Efficacy Scale
FES-I	Falls Efficacy Scale-International
HRQL	Health-related quality of life
ICC	Intraclass correlation coefficient
LLFDI	Late-Life function and disability instrument
LOA	Limits of agreement
MFE	Modified figure-of-eight
OLS	One-leg stance
SD	Standard deviation
SD_{diff}	Standard deviation of the difference
SEM	Standard error of measure
SEM%	Variance of standard error of measure
SF-36	Short form 36
SRD	Smallest real difference
SRD%	Variance of smallest real difference
WHO	World Health Organization

1 INTRODUCTION

1.1 AGEING POPULATION

The proportion of older adults in Sweden is growing. Today about 17% of the Swedish population is aged 65 years or older, a figure that is expected to gradually increase over the next 20 years to approximately 25%. (1) The definition of 'older adults' varies in different cultures and context. According to the World Health Organization (WHO) (2), most industrialised countries define older adults as persons with a chronological age of 65 years or more, the definition also used in this thesis.

Functional capacity, balance performance and mobility deteriorate with increasing age (3), thereby also increasing the risk of falling.

Each year, up to 30% of the older population experience a fall (4). A fall is defined as an unexpected loss of balance resulting in coming to rest on the floor, the ground or an object below knee level (5-7).

In Sweden, nearly 50,000 older adults aged 65 years or more were hospitalised due to falls in 2013, and nearly 1,600 older people died as a consequence of a fall: about four per day (8). Negative consequences of a fall include not only fall-related fractures and injuries but also impaired functional ability, decreased quality of life, fear of falling and depression (9).

There are several factors that increase the risk of falling among older people, including general muscle weakness (especially in the lower extremities), reduced reaction time, impaired vision and proprioception, and decrease of vestibular function. An increased tendency to fall is a major risk factor for falls among older people. (10)

1.2 OSTEOPOROSIS

Osteoporosis, literally *porous bone*, reduces the density and quality of bone. As the bones become more porous and fragile, the risk of fracture is greatly increased. The loss of bone occurs silently and progressively. Often there are no symptoms until the first fracture occurs (11). Osteoporosis is a systematic skeletal disease characterised by low bone mass and microarchitectural deterioration of the bone, leading to greater bone fragility and a consequent increase in fracture risk (12). The WHO defines osteoporosis as 'a condition in which the bone mineral density (BMD) is 2.5 SDs or more below the mean seen in young normal individuals measured in the hip, lumbal spine or forearm' (13). Osteoporosis is a silent disease, meaning that many individuals with the disorder are not aware that they suffer from it (8).

Osteoporosis can be divided into two types: *primary* and *secondary*. Primary osteoporosis is either postmenopausal or related to age or lifestyle factors such as lack of physical activity, smoking, alcohol consumption and inadequate nutrition. Secondary osteoporosis is caused by certain diseases or as a result of medical treatments. (14)

Some risk factors for osteoporosis are into unavoidable, such as ageing, a history of fractures, gender (female), early onset of menopause, hereditary factors, height and ethnicity. Others are avoidable, such as physical inactivity, smoking, alcohol consumption, low weight, inadequate nutrition and poor health. (14)

Osteoporosis is often a silent disease without specific symptoms and may only be detected in the connection with a fracture or bone density testing (Dual Energy X-ray Absorptiometry, DXA). The measurement value obtained from a DXA is compared to young reference material (T-score). A T-score lower than -2.5 standard deviations (SD) is classified as osteoporosis, a T-score value between -1 and -2.5 SD is classified as osteopenia, and a T-score value of -1 SD is considered normal (13).

Osteoporosis is treated using drugs, such as calcium and vitamin D, in combination with antiresorptive therapy. Today's medications are effective, particularly against vertebral compression fractures. Treatment of hip fracture or vertebral compression fracture with antiresorptive drugs that inhibit the breakdown of bone reduces the risk of new fractures. (15, 16) Treatment also involves changes in lifestyle, such as reducing physical inactivity, malnutrition and smoking (16).

Physical activity and training, especially weight-bearing exercises, can be used to prevent or postpone the development of osteoporosis (16-20).

As secondary prevention, strength training exercises have been found to reduce the loss of bone mass (17), increase bone density (21), improve health-related quality of life (18-20) and reduce pain (18, 19). Among older women with vertebral compression fracture, combining strength training exercise with training of balance and coordination has been found to improve health-related quality of life (22, 23). Balance-training in combination with individually designed strength training exercise has shown positive effects on falls and fall frequency in older adults with osteoporosis (24). Therefore, strength training, especially for the lower extremities, and balance-training (which stimulate the visual, vestibular and proprioceptive systems) can both decrease the risk of falls and fall frequency (25-29).

Osteoporosis is common in the older population globally, and Sweden has one of the highest rates in the world. Measures of bone density in the hip found that one out of every three women aged 70–79 years in Sweden has osteoporosis. The disease is more prevalent in women than in men, and every other woman and every fourth man will suffer from a fracture due to osteoporosis during their lifetime. (16)

Osteoporosis creates a major risk factor for fractures. In Sweden 107,000 new osteoporosis-related fractures were reported in 2010, of which 20,000 were hip fractures. Women accounted for 66% of those fractures. (8)

In 2010 the cost of osteoporosis in Sweden was estimated at 14 billion SEK, including the costs for first-year care for a fracture, long-term disability following a fracture and fracture prevention programmes (pharmacological costs account for only 2% of the total amount) (8).

Osteoporosis leads not only to restrictions in daily life, but also to an increased concerns about falls and fall-related injuries (30).

Preventing falls in people with osteoporosis provides benefits for both individuals, and society and can have a significant socio-economic impact.

1.3 FALL-RELATED CONCERNS

Fear of falling is common in the older population, with a prevalence rate of 20 to 60% for community-dwelling persons. The main risk factor for developing a fear of falling is having experienced at least one previous fall (31, 32). Fear of falling often leads to activity avoidance, which may cause decreased physical function, decreased quality of life and an increased risk of falling. Combined with resulting avoidance of activities of daily living, fear of falling also leads to a predicted number of falls per year (30).

Fear of falling increases with age, is more common among women (31) and is more common in elderly individuals with osteoporosis (33, 34). The consequences of a fall among older individuals with osteoporosis can be greater (35). It is also known that fear of falling is associated with decreased walking speed (36, 37) and balance performance (37).

Fear of falling may be warranted and justified as a protection mechanism — for example, as a means to avoid risky situations such as slippery surfaces. But when the fear is unwarranted, it can be socially dysfunctional (38, 39).

Cochrane's recent review on the effect of exercise in reducing fear of falling in older people living in the community found that there is weak evidence of success for various exercises, including Tai Chi, balance-training and strength and resistance training. This review concludes that exercise interventions may reduce fear of falling to some extent directly after the intervention but there is limited knowledge about long-term effects. Further well-designed randomized controlled trials are needed, and the authors encourage a core set of outcomes that includes fear of falling for all trials examining the effects of exercise interventions in older people living in the community. (40)

Fear of falling is one of several constructs that reflect the multifaceted phenomenon of fall-related psychological issues. One limitation in the literature is that authors do not refer to these different constructs but rather combined all the constructs under the terms of *fear of falling*. Thus, there is confusion regarding the best method of defining and measuring fall-related constructs. The most common and most studied fall-related constructs today are fear of falling, fall-related self-efficacy or falls efficacy (41), and balance confidence (42). Each of these constructs is a unique construct, although similar in nature, and should be measured and spoken of as unique, which unfortunately is not the case today (43). Furthermore, Jørstad et al. (44) also highlighted the inconsistency and confusion in this area regarding the application of various outcome measures.

In this thesis fall-related concerns are used as a generic term for fear of falling, fall-related self-efficacy (43), concerns about falling (45), balance confidence (43) and consequences of falling (46).

Fear of falling is defined as a 'lasting concern about falling that leads to an individual avoiding activities that he/she remains capable of performing' (47); it can be evaluated with single-item question regarding fall-related fear (46) and even with instruments such as the Survey of Activities and Fear of Falling in the Elderly (SAFFE) (43).

Fall-related self-efficacy is defined as 'the confidence in one´s ability to perform activities of daily living without falling' (41). This definition is based on Bandura's theory of 'self-efficacy', in which underlying cognitive processes control our emotions. According to this theory, people's beliefs affect their ability to perform and how they behave in certain situations (48). *Fall-related self-efficacy*, or *falls self-efficacy* or *falls efficacy* for short can be evaluated with the Falls Efficacy Scale (FES) (41).

Falls Efficacy Scale-International (FES-I) evaluates *concerns about falling* and was developed from the Falls Efficacy Scale. However, according to some authors fall-related self-efficacy can also be evaluated with FES-I and the questionnaire is used in a wide range of cultural contexts and languages (43). This confusion is highlighted by Jørstad et al.(44), as the FES-I was developed from a questionnaire that evaluates fall-related self-efficacy and that the authors retained the name of the questionnaire indicating that the FES-I also evaluates fall-related self-efficacy, when it is more correctly referred to measure *concerns about falling* (40, 45).

Balance confidence is defined as ‘confidence in one´s ability to maintain balance and remain steady’ and can be evaluated with the Activities-specific Balance Confidence scale (ABC) (42).

Consequences of falling is defined as the ‘loss of functional independence and damage to identity’ (46).

1.4 BALANCE CONTROL AND PERFORMANCE

Balance control is the foundation of our ability to move and function independently. Balance problems increase with age and increase the risk of loss of balance and falls. Balance control is based on a complex interaction among several systems (49-51).

Balance control can be defined as a task-specific multi-joint skill that relies on the interaction of several physiological systems, including musculoskeletal, neuromuscular, visual, vestibular and sensory (52).

To understand this complex system of balance control a model summarizing different underlying systems for postural or balance control can be used (52), i.e. biomechanical constrains, somatosensory information, stability limits, anticipatory postural adjustments, postural responses and stability in gait.

In the older population, balance control gradually decreases due to natural degenerative processes or pathological effects on any part of the balance system (10).

Systems involved in balance control deteriorate in the elderly (7). For example, posture is affected by reduced muscle strength and limited mobility, somatosensory information from the proprioceptive, visual and vestibular systems deteriorates, decreased functional stability limits and affects anticipatory postural adjustments, and reduced reactions to loss of balance may lead to impaired balance.

The deterioration in balance control among older people also reflects central changes in the brain that reduce the ability to integrate incoming information and compensate for incorrect or conflicting information (10, 53).

All this results in balance problems that may lead to physical inactivity, and thereafter to vicious circle of increased unsteadiness, reduced mobility and muscle weakness (54, 55), greater likelihood of falls and fractures and an increased risk for other diseases related to physical inactivity, such as diabetes and cardiovascular disease (14).

Balance performance has been found to be reduced in individuals with low bone mineral density (56) and osteoporosis (57, 58) , as altered body position due to increased kyphosis can lead to a greater postural sway.

1.5 GAIT

Walking speed is a strong independent predictor of self-perceived function in elderly (59, 60). Older people with the ability to walk faster than 1 m/s have generally good functional status, lower risk of health events and better survival (61).

Gait performance is negatively affected by increasing age. Older people reduce their gait speed and step length, which can lead to increased unsteadiness and thereby an increased risk of falling (62).

Individuals with low bone mineral density and osteoporosis experience not only reduced balance performance but also reduced gait performance (57, 58). However, studies on the impact on gait due to osteoporosis or low bone mineral are few and show ambiguous results (56, 63).

1.6 DIVIDED ATTENTION

Reduction of motor function following various types of attention-demanding cognitive stress and divided attention (i.e. dual- and multi-tasking) may be an indicator of future falls (64-66) and is a natural component in our daily activities (67). A growing body of research shows that both healthy older individuals and those with balance impairments show quite dramatic decreases in motor performance under simple cognitive stress (64). That is, dual-tasking affects balance, gait and fall risk (67).

Woollacott et al. (53) define attention as an individual's information processing capacity. This capacity is limited, and performing tasks requires a certain portion of that capacity; hence, if two tasks are performed simultaneously and together they require more than the total capacity, task performance will deteriorate on either or both (68).

Balance control also demands many cognitive resources, and the more difficult the postural task, the more cognitive processing is required (69). Balance control and other cognitive processing share cognitive resources, and therefore simultaneous performance of a secondary task affects stability in both healthy and balance-impaired older adults. Performance levels vary depending on the complexity and type of the secondary task. (53, 70).

If an older adult perform an added cognitive or motor task (dual-tasking) while walking and the brain's resources are insufficient, then one of the tasks will be prioritised (53).

1.7 PHYSICAL ACTIVITY AND TRAINING

Caspersen defines physical activity as 'any bodily movement produced by skeletal muscles that results in energy expenditure' and training or exercise as 'planned, structured, and repetitive bodily movements done to improve or maintain one or more components of physical fitness' (71).

Here, physical activity refers to the complementary intervention assigned to one of the intervention groups: i.e. physical activity in the form of walking.

1.8 BALANCE-TRAINING FOR OLDER ADULTS

Cochrane's review of the impact of exercise in improving balance in older people concluded that there is weak evidence that several exercises – such as gait, balance, co-ordination and functional tasks – are effective in improving balance in older adults and that additional research with high methodological quality is required (72).

Some authors have found positive effects of exercise (including balance-training), including reduction of the risk of falling (73), improvement in quality of life (74), and in improvement in balance, mobility and falling frequency in older women with osteoporosis (29). In contrast, Jensen et al. did not find any relation between reduced risk of falling and exercise as part of a fall prevention programme among frail older individuals living in residential care facilities (75). This indicates the need for specific balance-training and not only general exercise or strength training. Some studies do show that a specific balance-training programme may improve balance performance (76) and physical function (77) in older individuals.

As the Cochrane review above points out, there are limited studies evaluating the long-term effects of balance-training for older adults. However, our recent long-term evaluation of the current balance-training programme for healthy older participants with a fear of falling shows that the positive effects of the balance- training programme were maintained at the nine month follow-up (6 months after the intervention), as seen through improved fast walking speed, walking speed during a dual-task condition and decreased fear of falling. This decreased fear of falling was still present at the 15 month follow-up, i.e. one year post intervention (78). Furthermore, Melzer et al. (77), evaluated a similar balance-training programme among healthy older participants with no fear of falling and no known balance problems and found that the improvements in balance function witnessed immediately after the intervention were lost after 6 months. Bird et al.'s study of the long-term effects of balance-training found that participants who stayed physically active and performed regular physical training during the follow-up period were able to conserve the positive effects of the studied intervention (79).

1.9 MEASUREMENT PROPERTIES

When using measuring instruments for assessments it is important to use reliable and valid ones. Measurement properties include both reliability (relative and absolute) and validity.

Relative reliability evaluates the level of agreement or reproducibility between two or more measurements (80) and absolute reliability, on the other hand, examines the variability or measurement error caused by repeated measurements, such as standard error of measurement (SEM) and smallest real difference (SRD) (81, 82). It is of clinical importance to be aware of the measurement error when using measurements for evaluating the effects of a treatment or changes over time.

Validity is commonly referred to as the degree to which the assessment measures what it is designed to measure (83). This thesis evaluated convergent validity, which refers to the degree to which two measurements of a construct that theoretically should be related in fact are related.

A Rasch analysis approach can be used to further understand measurement properties; this approach gives a detailed analysis of item/person goodness-of-fit, evaluates the category and its function, detects items that do not contribute to the underlying construct and transforms raw scores to interval data based on the pattern of responses (84).

1.10 RATIONALE FOR THIS THESIS

Our research group has previously developed a specific, progressive and individually adjusted group balance-training programme for older adults with self-perceived balance problems and a tendency to fall. The balance-training programme has been successfully evaluated in both short- and long-term perspectives in healthy older adults, showing reduced fear of falling and improved gait ability as outcomes (78, 85). This intervention programme was further developed and modified for a more fragile group of older adults – those with osteoporosis and fall-related concerns – as this group has been shown to have an increased risk of falling and form whom the detrimental consequences of falls entail significant medical and societal costs and a great deal of individual suffering.

We hypothesised that this balance-training programme, which includes dual- and multi-tasks, would significantly improve fall-related concerns, walking speed while performing secondary cognitive task, fast walking speed, balance performance and physical function in older adults with osteoporosis and an increased risk of falling. Qualitative interviews were conducted in order to gain a greater understanding of the impact of the balance-training programme on the perception of fall-related concerns and balance in daily life. Furthermore, we hypothesised that the Falls Efficacy Scale-International would be a highly reliable instrument and would have a moderate correlation with balance performance and health-related measures for older women with osteoporosis.

2 AIM

The overall aim of this thesis was to evaluate the short- and long-term effects of a specific and progressive balance-training programme, focusing on dual- and multi-task exercises, with respect to fall-related concerns, gait, balance performance and physical function in older adults with osteoporosis. Furthermore, to evaluate the reliability and validity of the Falls Efficacy Scale-International questionnaire, and to explore perceptions of fall-related concerns and balance after participating in the balance-training programme.

Specific aims were:

Study I: To evaluate the relative and absolute reliability of the Falls Efficacy Scale-International for elderly people with increased fall risk, and the convergent validity of the Falls Efficacy Scale-International in a group of elderly women with osteoporosis.

Study II: To evaluate the effects of a balance-training programme including dual- and multi-task exercises on fall-related self-efficacy, fear of falling, gait and balance performance, and physical function in older adults with osteoporosis and an increased risk of falling, as well as to evaluate whether additional physical activity would further improve effects.

Study III: To evaluate long-term effects of balance-training, focusing on multi-task exercises and with supplementary physical activity, on concerns about falling, fear of falling, gait speed, balance performance and physical function in older adults with osteoporosis and an increased risk of falling.

Study IV: To explore how older adults with osteoporosis perceived fall-related concerns and balance in daily life after having participated in a balance-training programme.

3 METHODS

3.1 DESIGN

Study I is a reliability and validity study, while Study II and Study III are prospective randomized controlled trials (part of the BETA-study; NCT01417598). Study II evaluates short-term effects of the intervention for those who completed the period from baseline to the first month follow-up. Study III evaluates the long-term effects of the intervention for all randomized participants and for those who completed the entire study period. Study IV is an explorative cross-sectional study with a qualitative research approach. See Table 2.

3.2 PARTICIPANTS

Participants were recruited through advertisements in local newspapers in Stockholm County, through the Swedish Osteoporosis Society and through the Endocrinology Clinic at the Karolinska University Hospital.

To be included the candidate had to meet the following criteria: aged 65 years or older; osteoporosis objectively verified by Dual energy X-ray Absorptiometry (DXA) in the hip and lumbar back; independently ambulatory; and have a fear of falling and/or have experienced at least one fall in the last 12 months. Subjects were excluded if they had experienced fall-related fractures during the previous year; moderate or severe dementia (Mini-Mental score < 24 assessed with Mini mental state examination); severely decreased vision, or other diseases or constraints that might interfere with participation in the exercise programme.

A total of 96 older adults were included in this part of the BETA-study, randomized into three groups: two intervention groups, Training (n = 34) and Training + physical activity (n = 31), and to one Control group (n = 31). Randomization into the three groups was performed in blocks of nine, using online software (http://www.randomization.com/). Participants were over-recruited to ensure power and compensate for dropouts during the study period. Table 1 shows characteristics of the 96 randomized participants.

At baseline a significant difference was found among the three groups for frequency of heart failure ($p = 0.049$), where the Training + physical activity group differed from the two other groups. Furthermore, significant differences were found between the two training groups for fear of falling ($p = 0.043$), measured with the single-item question ‘In general, are you afraid of falling?’; the Training + physical activity group perceived more fear of falling and a higher frequency of previous cancer compared ($p = 0.037$) to the Training group. There was also a difference between the Training group and the control group ($p = 0.045$) regarding experience of falls during the previous year before inclusion, with the Control group reporting more falls, see Table 1.

During the entire study period a total of 41 participants dropped out. Sixty-nine participants were tested at the 3 months follow-up, 60 at the 9 months follow-up and 55 at the 15 months follow-up, see Figure 1.

There were no significant differences between the subjects who dropped out (n = 41) and those who completed the study (n = 55) in terms of baseline characteristics or measured variables, except for frequency of angina ($p = 0.040$), with a higher frequency among the drop-outs ($n = 6$ compared to $n = 1$).

Study I, the validity part, included all randomized subjects (n=81) who participated in the on-going study of balance-training for older adults with osteoporosis during 2010 and 2011. For the reliability subjects were also recruited from another on-going project on balance-training for healthy elderly people with a fear of falling and tendency to fall (85), resulting in 59 subjects, 32 from the on-going study among older adults with osteoporosis and 27 from the on-going study among healthy individuals.

Sample size for the reliability part in Study I was calculated using the $2c^2$ method (86), where 'c' stands for the number of categories in the questionnaire (i.e. 2×4^2), resulting in a minimum of 32 required subjects.

Study II included 69 participants that completed the period from baseline to the first follow-up at 3 months after the intervention.

Study III involved all the 96 randomized participants who were included in this part of the BETA-study.

Sample sizes for Study II and III were calculated based on the primary outcome measure, Falls Efficacy Scale- International (sum score), and results from a previous pilot study (85). For the sample size calculation power was set to 80% with a two-sided test at the alpha level of 5% for the primary outcome measure. This calculation resulted in a required sample size of 21 in each group.

In Study IV all participants that had participated in the balance-training programme from spring 2011 to spring 2012 were included, i.e. 25 informants.

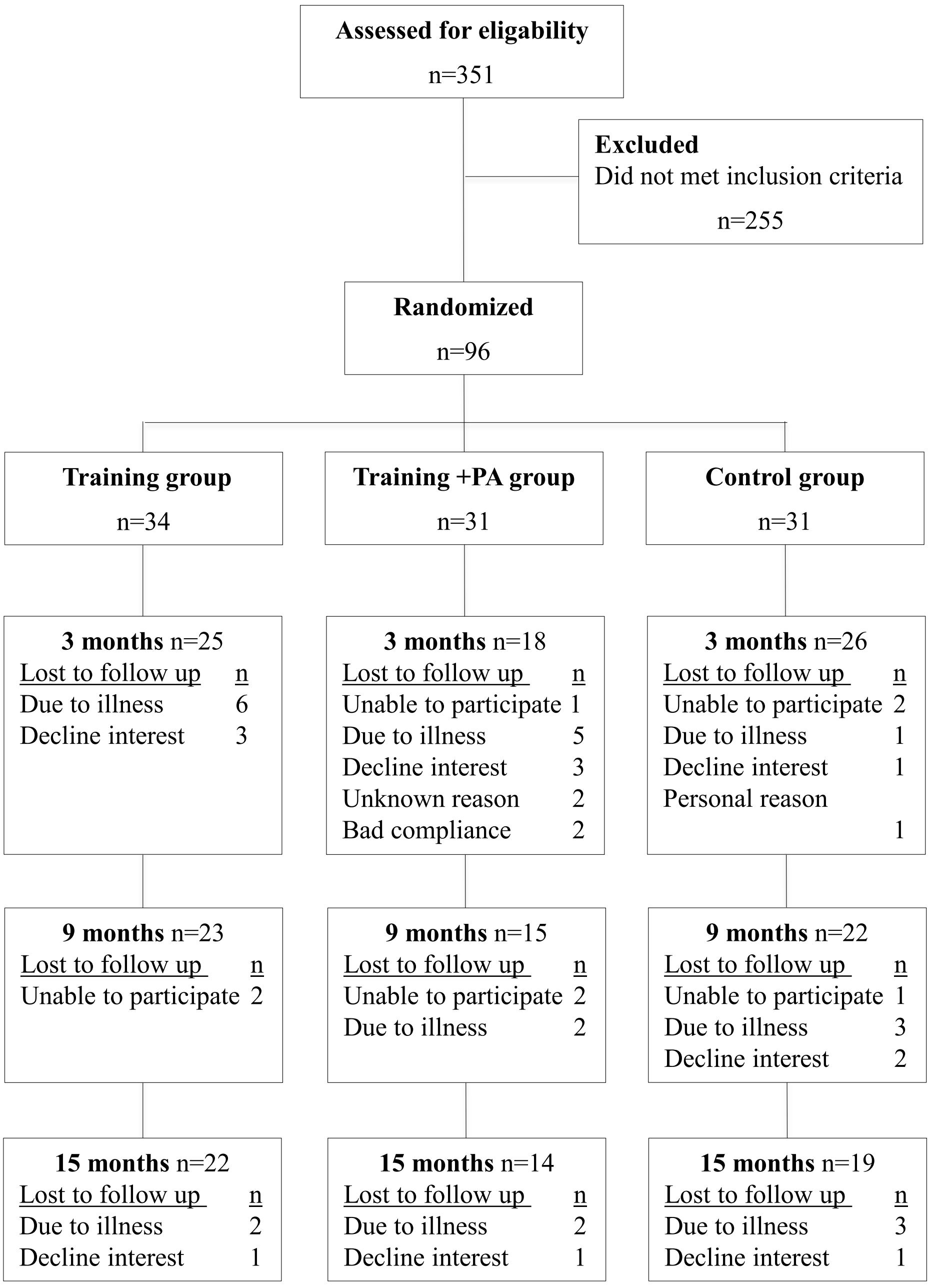

Figure 1. Flow chart of individuals reporting interest in the study and number of excluded candidates, assigned randomly to the Training, Training + physical activity (PA), and Control groups at baseline, and assessed at 3, 9 and 15 months follow-up.

Table 1. Baseline characteristics of the 96 individuals included in the randomized controlled trial and assigned to Training, Training + physical activity (PA) and Control groups.

Variable	Total n=96	Group		
		Training n=34	**Training+PA** n=31	**Control** n=31
Gender (female/male), n	94/2	34/0	30/1	30/1
Age, mean (min-max)	76 (66-87)	76 (67-86)	76 (67-87)	75 (66-84)
Body mass index (kg/m^2), median (min-max)	25 (16-35)	24 (19-31)	25 (16-35)	26 (17-33)
Height (cm), mean (min-max)	162 (141-189)	162 (153-171)	161 (141-180)	164 (149-189)
Mini Mental State Examination score, median (min-max)	28 (24-30)	29 (24-30)	28 (25-30)	28 (25-30)
Household status (living alone/together). %	59/41	53/47	64/36	61 /39
Living situation (house/apartment). %	21/79	27/73	19/ 81	16/84
Education level (primary school/high school/ college or university). %	22/33/45	24/32/44	26/29/ 45	16/39/45
Work (blue/white collar). %	54/46	59/41	48/ 52	55/ 45
Number of prescribed medications, median (min-max)	4.5 (1-15)[b]	4 (1-15)[a]	6 (1-13)[a]	4 (1-13)
Diabetes yes, %	3	6	3	0
Hypertension yes, %	46	50	48	39
Myocardial infraction yes, %	5	3	6	6
Heart failure yes, %	8	3	19	3
Angina yes, %	7	6	10	6
Stroke yes, %	6	9	6	3
Cancer yes, %	20	9	29	23
Lung disease yes, %	13	9	16	16
Experienced a fall during the last 12 months yes, %	78[a]	68[a]	77	90
Fear of falling[c] (not at all/a little/quite a bit/ very much). %	0/40/38/21	3/50/35/12	0/32/39/29	0/35/42/23
Physical activity level[d] 1/2/3/4/5. %	0/10/45/44/1	0/12/35/53/0	0/6/65/29/0	0/13/36/48/3

[a] One missing value
[b] Two missing values
[c] According to the single-item question 'In general, are you afraid of falling?' (46)
[d] According to the Frändin-Grimby activity scale (87)

3.3 DATA COLLECTION

3.3.1 Study I

Data for the reliability part of Study I were collected during the autumn of 2010 and spring of 2011 using a postal survey, see Table 2. The first postal survey was sent out and followed by a second survey two weeks later. To control for bias during the period between postal surveys, participants answered an additional question about whether anything had happened since they had answered the first survey, such as increased bodily pain, lumbago, cold including fever etc.

The first postal survey was sent to 72 subjects of whom 64 answered. Of these 64, two participants did not complete the Falls Efficacy Scale-International questionnaire and three answered that something had happen during the two weeks between the surveys that could influence how they answered the questionnaire and were therefore excluded from the study. In the end, 59 subjects were included in the reliability part of the study.

Data for the validity part of Study I were collected from the baseline testing from the on-going randomized controlled trial, which ran from late 2009 to spring 2011, regarding Falls Efficacy Scale-International, fear of falling (single-item question 'In general, are you afraid of falling?'), question about history of falls balance performance (one-leg stance and modified figure-of-eight test) and health-related quality of life (SF-36), see Table 2.

3.3.2 Study II and III

Data for Study II were collected at baseline and at the 3 months follow-up (directly after the intervention period). Study III data were also collected at 9 and 15 months after baseline testing (6 and 12 months after the intervention period) to evaluate the long-term benefits of the intervention, see Table 2.

The assessments were performed at a movement laboratory either at the Division of Physiotherapy at Karolinska Institutet or at the Department of Physiotherapy at Karolinska University Hospital. Baseline testing started with a learning session, where the participants performed all the physical measurements once. Subsequent testing sessions started randomly with either questionnaires or physical assessments. The sequence of questionnaire (Falls Efficacy Scale-International, single-item question 'In general, are you afraid of falling?', Late-Life function and disability instrument and Frändin-Grimby activity scale) and physical measurements (GAITRite®, one-leg stance and modified figure-of-eight test) followed a predetermined schedule. The participants were allowed to take breaks when needed. Each participant was allowed 90–120 minutes, divided equally between questionnaires and physical measurements.

All assessors were blinded for group allocation at baseline. However, after baselines testing all assessors were not blinded for group allocation since some of them were also involved in leading the balance-training sessions.

3.3.3 Study IV

Data for Study IV (qualitative interviews) was collected from spring 2011 to spring 2012, see Table 2. All participants in the balance-training programme during those three semesters of the balance-training programme were asked to participate in this study, and all of them gave their consent to participate, resulting in 25 informants (including three pilot interviews), nine informants from the two intervention groups and 16 from the control group who participated in the balance training following the 15-month end point of the randomized controlled trial.

Interviews were conducted one to two months after completion of the 12-week balance-training programme at the Division of Physiotherapy, Karolinska Institutet, or at the Physiotherapy Department at Karolinska University Hospital. Both locations were familiar to the informants, since they had performed the baseline and follow-up tests for the BETA-study at the Division of Physiotherapy, Karolinska Institutet, and underwent balance training at the Physiotherapy Department of Karolinska University Hospital.

Each interview was limited to 90 minutes, with individual interviews lasting 25–67 minutes. Interviews were taped with a digital voice recorder (Olympus WS-550M). Three pilot interviews were performed to test and adjust the interview guide and to practice interview techniques.

Table 2. Overview of study design, data sources, outcome measures, time of data collection, number of participants and analyses of the four studies included in this thesis.

Study	**I**	**II**	**III**	**IV**
Design	Methodological study (reliability and validity)	Randomized controlled trial	Randomized controlled trial	Explorative, cross-sectional
Data sources	Functional test and structured interviews from test-retest and cross-sectional from baseline values	Functional test and structured interviews from baseline to 3 months follow-up	Functional test and structured interviews from baseline, 3 -, 9 and 15 months follow-up	Semi-structured interviews, 1-2 months after completion of the balance-training
Outcome measures				
Fall-related concerns	x	x	x	
Falls	x	x	x	
Balance performance	x	x	x	
Gait speed		x	x	
Physcial function		x	x	
Physcial activity level		x		
Health-related quality of life	x			
Time of data collection	From late 2009 to spring 2011	From December 2009 to January 2012	From December 2009 to December 2012	From spring 2011 to spring 2012.
Participants	Reliability n=59, Validity n=81	n=69	Intention-to-treat n=96, Per protocol n=55	n=19
Analyses	Quantitative Intra-class coefficient, Cronbach´s alpha, standard error of measure, smallest real difference, Bland and Altman analyses and Spearman´s rank correlation coefficient	Quantitative Per protocol analysis. Mann-Whitney U-test, Wilcoxon signed-rank test, Kruskall-Wallis, independent t-test and repeated measure analysis of variance	Quantitative Intention-to-treat and per protocol analysis using a mixed model analysis with SIDAK´s post-hoc test	Qualitative Inductive qualitative content analysis

3.4 ASSESSMENTS

3.4.1 Fall-related concerns

The Falls Efficacy Scale-International (FES-I) and a single-item question ‘‘In general, are you afraid of falling?’ was used to measure fall-related concerns.

FES-I questionnaire consists of 16 items assessing concerns about falling during physical and social activities. Subjects estimate ‘how concerned’ they are when performing daily activities, answering each question on a four-point scale (1–4) indicating not at all concerned, somewhat concerned, fairly concerned and very concerned. A total score is calculated and ranges from 16 to 64 (45). In Study II the FES-I was referred to measure fall-related self-efficacy.

The questionnaire was translated into Swedish by Nordell et al. (88) and initially validated for older individuals who had experienced a fracture. Further investigation of the psychometric properties and summary scores of the FES-I has been transformed to linearly scaled scores (0–100) using a one-parameter Rasch model for values from older women with osteoporosis in the BETA-study, in order to allow use of parametric statistical methods (89).

The single-item question was used to measure fear of falling: ‘‘In general, are you afraid of falling?’,’ with possible responses being ‘‘not at all’’, ‘‘a little’’, ‘‘quite a bit’’ and ‘‘very much’’ (46).

3.4.2 Falls

At baseline testing, fall frequency was assessed by participant reports of whether they had fallen during the last year, and then at each follow-up by whether they had fallen during the time since the previous follow-up session. A ‘fall’ was defined as an unexpected loss of balance, resulting in coming to rest on the floor, the ground, or an object below knee level (6).

3.4.3 Balance performance

Balance performance was assessed with the modified figure-of-eight test and one-leg stance. The modified figure-of-eight test consists of participants walking a path of two circles (ø163 cm) laid out on the floor in tape, forming a figure-of-eight. The test leader measured the time taken to complete two figures-of-eight and observed the number of oversteps (occasions when no part of the shoe touched the taped line). (90) The modified figure-of-eight was performed three times, and the mean value was used for analysis.

For the one-leg stance, subjects stood alternately on the right and left leg with hip and knee slightly flexed, arms hanging and their eyes open, for as long time as possible (maximum 30 seconds) (90, 91); the test was performed three times for each leg. The mean value of all six measures was used for analysis.

3.4.4 Gait speed

The GAITRite® walkway system (CIR Systems, Inc., Haverton, PA, USA) (92, 93) was used to assess gait speed. Participants were assessed at their preferred speed while performing or not performing a secondary cognitive task, i.e. a dual-task condition. The task consisted of reciting every second letter of the Swedish alphabet aloud. Participants also walked at their maximal speed under the single-task condition. Six trials for each condition were performed, and the mean score for each condition was used for analysis. (63)

3.4.5 Physical function

The function component of the Late-Life Function and Disability Instrument (LLFDI) was used to assess self-reported physical function. The function component consists of an overall score for physical function that can be divided into three subscores: upper extremity function, basic lower extremity function and advanced lower extremity function. Summary scores were calculated by adding the item scores from each dimension and their subscales, and transformed to linearly scaled scores (0–100) based on a one-parameter Rasch model. (94)

The questionnaire has been translated and adopted to Swedish conditions, and both reliability and validity have been evaluated for an older Swedish population with good results (95).

3.4.6 Physical activity level

Physical activity level was assessed with the Frändin-Grimby activity scale (87), which includes physical activity, exercise and household activities, with scores ranging from 1 (hardly any physical activity) to 6 (hard or very hard exercise regularly and several times a week).

3.4.7 Health-related quality of life

The Short Form 36 (SF-36) was used to assess health-related quality of life (96). The SF-36 is a generic health survey that consists of 36 question (ordinal scale); it generates a health profile with two sub-domains, one regarding physical health (physical functioning, role limitations due to physical problems, bodily pain and general health) and the other one regarding mental health (vitality, social functioning, role limitations due to emotional problems and mental health) (97). In Study I a sum index score is presented for the two sub-domains; a high score indicates better health-related quality of life. The SF-36 has been found to be valid and reliable for measuring health-related quality of life in a general Swedish population (96).

3.4.8 Cognitive function

The Mini mental state examination test (MMSE) (98, 99) was used to screen participants to ensure that they did not have any suspicion of impaired cognition, and a sum score below 24 was a criterion for exclusion from the study.

3.5 INTERVENTION

The balance-training intervention in this thesis has been well described and published in Clinical Rehabilitation as a 'Rehabilitation in practice' article (100). That article provides a description of the theory and practical application of the programme.

The original framework for the balance-training concept was developed by Professor. Lars Oddsson (an Alumni of the Karolinska Institutet) and his group at the NeuroMuscular Research Center, Boston University (101). Professor Oddsson then initiated a collaborative effort on fall prevention with Professor Elisabeth Olson at the Division of Physiotherapy, Karolinska Institutet, which led to an expanded focus on this area of work. As further described below, the programme has since been subsequently theorised, developed and adapted to Swedish conditions and the specific population of participants (100).

3.5.1 Theory

3.5.1.1 Balance control

The balance -training programme was based on well-established principles of exercise physiology and on the knowledge that balance control relies on the interaction of several physiological systems, as well as interaction among environmental factors and the performed task (50, 101, 102).

A model summarising systems underlying postural or balance control was published during development of the programme (52). This programme addresses several systems: stability limits, anticipatory postural adjustments (APA), postural responses, sensory orientation (somatosensory, visual, and vestibular), and stability in gait (dynamic balance), see Figure 2.

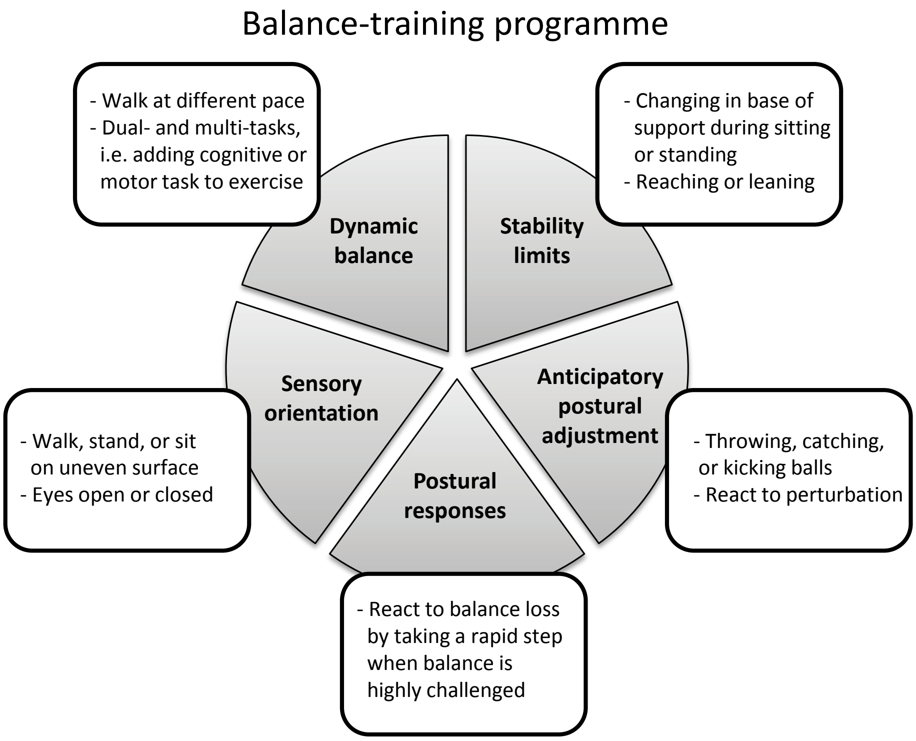

Figure 2. Illustration of the balance-training programme and the various components in the programme associated with the different systems that contribute to postural control.

3.5.1.2 Dual- and multi-task conditions

Dual- and multi-task performance (performance when a person's attention is divided between a motor and/or a cognitive task) is a natural component of daily activities, and this condition was not only included in the balance-training programme but given a central role. It is known that performing a secondary task affects stability in both healthy and balance-impaired older adults, and performance levels vary depending on the complexity and type of secondary task. (53, 70) Moreover, performing a secondary task affects balance, gait, and fall risk (67), especially in older adults.

3.5.1.3 Specificity and progression

This programme is based on basic exercise physiology principles of training adaptations and is specific for the system trained (101, 102). It complies with the principle of *specificity* in that it is based on exercises targeting various systems for postural control (see Figure 2) with the aim of improving balance performance in specific situations that may occur in daily life, such as regaining postural stability after perturbation or being able to suddenly avoid an obstacle, with retained balance, while simultaneously walking and answering a question.

The balance-training programme is progressively challenging for each individual, as the exercises are performed on different levels (basic, moderate and advanced). This progression follows both the taxonomy of tasks (103), which explains how each individual can improve his or her skills by performing training tasks of increasing complexity, and the basic concept of progression in exercise physiology, meaning that the intensity, difficulty or complexity of exercises needs to be increased as the body adapts to exercise over time. (101, 102) The following list outlines the progression of the balance-training:

- Basic level: one to two components are incorporated
- Moderate level: three to four components are incorporated
- Advanced level: more than four components are incorporated, almost always including both a motor task and a cognitive task (dual- or multi-task activities).

For example, at the basic level, participants walk on uneven surfaces (dynamic balance and sensory orientation), at the moderate level they walk a course with reduced step width (stability limits, dynamic balance and sensory orientation) and at the advanced level a simultaneous cognitive dual-task is added (stability limits, dynamic balance, sensory orientation, dual- and multi-task activities and postural responses).

3.5.2 Practical execution of the programme

The training was provided in 45-minute group sessions, with 6–10 participants in each group, three times per week over a 12 weeks period. Two or three physiotherapists were present at each session to ensure participant safety and to allow them to adjust and individually progress through the exercises to the point of loss of balance, avoiding external support from the physiotherapist, to allow their natural balance response to execute fully.

Each session started with a short (5–7 minute) warm-up (marching in place, one-leg standing, weight shifting, lunges, arm and neck movements), followed by exercises performed while sitting on balls (15 minutes) and exercises standing and walking (15–20 minutes). The sessions ended with stretching and breathing exercises. The sitting, standing and walking exercises differed across sessions to achieve variety, but every exercise was repeated later on in the programme, often in a more challenging form. Example of complementary cognitive tasks includes counting (adding or subtracting by 3 or 7 from a given start number), reading a newspaper silently or aloud, and reciting categories (such as flowers, animals, countries or cities). Motor tasks included moving the arm, leg, head or trunk (leaning, turning); juggling; throwing and catching a balloon/ball; kicking a balloon; carrying a glass of water, a tray with several glasses of water or a large ball; and closing the eyes and buttoning and unbuttoning clothing. See Figure 3 for illustrations of exercises in the programme.

3.5.3 Individual adjustments

Even though the balance-training was conducted in group sessions, the exercises were individually adjusted for each participant, with the aim of constantly challenging their postural control system. These examples demonstrate how the exercises were individually adjusted and made sufficiently challenging for each individual, see Figure 2:

- Using different arm and foot positions, such as arms hanging at the sides or crossed over the chest or placed in the lap while sitting. For changes in support area, the feet can be placed wide apart, near each other, close together, in a semi-tandem or tandem stance, or on balance-disc cushions.
- Performing exercises at different speeds, such as walking, and incorporating head, arm or leg movements.
- Varying the spacing between cushions or varying the number of cushions when walking on balance-disc cushions.
- Adding a motor or cognitive task. Adjusting the difficulty of the added task.
- Varying the density and size of uneven surfaces.

3.5.4 Physical activity

In addition to following the balance-training programme, one of the intervention groups (Training + physical activity) was also instructed to perform supplemental physical activity in the form of walking with or without poles during the 12 weeks intervention period, for at least 30 minutes, three times/week.

After the 12 weeks balance-training intervention period with and without supplemental physical activity, participants received no instruction about continued balance training or physical activity but were encouraged to live their regular lives.

The participants in the Control group were offered the same balance-training following completion of the study, i.e. after the 15 months follow-up.

Sitting in a circle, kicking a ball, with arms in different positions.

Walking, stepping on balance-disc cushions placed in a straight line, adjacent or apart.

Walking forwards at a fast speed, finishing with stepping up and down on two height-adjustable step platforms while performing an added motor task.

Slalom walking around balance-disc cushions, while performing an added motor task.

Individual adjustments while sitting on balls and passing round a small ball, i.e. different foot positions, base of support and posture.

Figure 3. Pictures illustrating examples of the exercises and equipment used in the balance-training programme.

3.6 DATA ANALYSES

Statistical calculations were performed using PASW Statistics version 18.0-22.0 (SPSS Inc., Chicago, IL, USA).

Descriptive statistics are presented as mean, median, minimum (min)-maximum (max), standard deviation (SD), 95% confidence interval (95% CI), number of (n) and percentages (%).

Significance level was set at $p \leq 0.05$.

3.6.1 Study I

The relative reliability, test-retest, was analysed by using the intra-class coefficient [1] (104). A one-way repeated-measures analysis of variance (ANOVA) was used to calculate ICC-values. Strength of agreement for ICC values was assessed following Bland & Altman (105), with < 0.20 = poor, 0.21–0.40 = fair, 0.41–0.60 = moderate, 0.61–0.80 = good, and 0.81–1.00 = very good.

[1] $ICC_{2.k} = (MS_s - MS_e) / MS_s + (k[MS_t - MS_e]/n)$,

where MS_s is the subjects mean square, MS_e the error mean square and MS_t the trials mean square, all obtained from the ANOVA, n is the number of subjects and k the number of trials.

Internal consistency reliability was evaluated by calculating Cronbach's alpha for the whole score. Values above 0.7 indicate acceptable internal consistency reliability (106).

To quantify measurement error the analysis used absolute reliability, standard error of measure (SEM) [2], variance of standard error of measure (SEM%) [3], smallest real difference (SRD) [4] and variance of smallest real difference (SRD%) [5] was used (81, 82).

[2] $SEM = \sqrt{WMS}$

Where WMS is the mean square error term from analysis of variance.

[3] $SEM\% = (SEM/mean \times 100)$

[4] $SRD = 1.96 \times SEM \times \sqrt{2}$

[5] $SRD\% = (SRD/mean) \times 100$

Equation 5 is the mean of all the data from the two test occasions.

In addition, Bland & Altman analyses were used to assess systematic changes of the mean (82). These include the following calculations:

[6] $\overline{d}$= mean difference between the two test sessions (test 2 minus test 1)

[7] SD_{diff} = the standard deviation of the difference between the two test sessions

[8] 95% confidence interval of $\overline{d}$ (95% CI)

[9] Limits of agreement (LOA) = $\pm 2SD_{diff}$

This analysis also includes the creation of a graph plotting the difference between the two tests against the mean for each subject, in order to visualise systematic variations around the mean difference between the two test occasions ($\bar{d}$).

Spearman's rank correlation coefficient (r_s) was used to evaluate the convergent validity between the FES-I and balance performance (modified figure-of-eight test, one-leg stance), health-related quality of life (SF-36), self-perceived fear of falling (single-item question 'In general, are you afraid of falling?') and self-reported history of falls. The strength of the correlation coefficient (r) was classified according to Munro (107) (0.00–0.25 = little if any; 0.26–0.49 = low; 0.50–0.69 = moderate; 0.70–0.89 = high; and 0.90–1.00 = very high correlation), and the significance level was set at $p \leq 0.05$.

3.6.2 Study II

Significant differences at baseline between groups were analysed using Cronbach's alpha, Fisher's exact test, Mann-Whitney U-test, Kruskall-Wallis test and independent t-test.

To analyse differences for ordinal variables or not-normally distributed variables the difference between the two test occasions was calculated, and the Kruskall-Wallis test and the Mann-Whitney U-test were used for comparisons between groups. For within-group comparisons the Wilcoxon signed-rank test was used. Normally distributed quantitative data were investigated with two-factor, repeated measures analysis of variance (ANOVA) as a mixed design (General Linear Model), with a main effect of factor 1 (time) and factor 2 (group), and interaction effects of factors 1 and 2. (105)

3.6.3 Study III

Differences between groups at baseline were analysed using Cronbach's alpha, Fisher's exact test, Mann-Whitney U-test, Kruskall-Wallis test and independent t-test. (105)

Analyses of statistical differences over time between groups were conducted on an intention-to-treat basis (n = 96) using a mixed model analysis, with SIDAK's post-hoc test if significant interactions were found. The analysis was supplemented with a per protocol analysis for those who completed the entire study period (n = 55). The mixed model was performed with covariance structure of compound symmetry or unstructured, depending on the model with the best fit for each variable (108). Linearly scaled Falls Efficacy Scale – International scores (89) were used in the analysis and log transformed values for the modified figure-of-eight test.

For the framework of this thesis, supplemental analyses were performed looking at long-term effects among participants who completed all follow-up sessions (n=47). Effect size for independent samples was calculated with Cohen's d (difference between sample means/pooled standard deviation) (109) between baseline and 15 months follow-up, and between 3 months follow-up and 15 months follow-up. Cohen's guidelines for interpretation of effect size are 0.20 = 'small effect', 0.50 = 'medium effect 'and 0.8 = 'large effect' (110).

3.6.4 Study IV

Based on the interviewer's logbook and multiple reviews of the interview audio files, the authors selected the 19 most information rich interviews for analysis. The interviews were transcribed verbatim (Olympus WS-550M transcription set). One pilot interview was excluded because the informant misunderstood the topic of the interview and the interviewer was not yet experienced enough to lead the conversation back to the topic in question. The remaining five interviews were audio reviewed, but no further information or useful contribution to the existing results was found.

The transcripts, consisting of 255 pages, were analysed using inductive qualitative content analysis (111, 112). The analysis sought both to identify manifest categories and to identify underlying, latent meanings.

All 19 transcribed interviews were read thoroughly several times with the aim of the study in mind, and reduced to meaning units: words and statements that relate to the central meaning. Two authors analysed nine of these interviews separately and reduced them to meaning units; a comparison showed agreement in the selection.

The meaning units were then condensed, and each meaning unit was given a code. During several meetings the coded meaning units were grouped into subcategories and categories in order to examine and ensure that the categories were mutually exclusive. Abstraction was used to identify the underlying latent meaning/content of how older women perceive fall-related concerns and balance in daily life after participating in balance-training.

During the analysis all authors took an active part both by performing analyses individually and together with the other authors in order to allow different interpretations to be captured; the results were discussed during several meetings to achieve consensus.

3.7 ETHICS APPROVAL

The project was approved by the regional board of ethics in Stockholm (Dnr: 2006/151-31, 2009/819-32). In 2012 the ethical application was expanded to allow recruitment of an additional 25 subjects to compensate for dropouts and to ensure the power of the study (Dnr: 2012/1829-32). An additional ethical review took place in 2013 to approve the interview-based qualitative study regarding participants' perception of fall-related concerns and balance function in daily life after completion of the balance-training (Dnr: 2013/1810-32).

All informants gave their written informed consent to participate.

4 RESULTS

4.1 STUDY I

In the first postal survey the median of the FES-I sum score was 26 (range 17–49), and in the second it was 25 (range 17–51), see Table 3.

The relative test-retest reliability for the FES-I was very good, with an ICC_2 value of 0.88 and a Cronbach's alpha of 0.94. Absolute reliability – i.e. measurement error (SEM) and smallest real change (SRD) – was SEM 2.9, SEM% 10.6%, SRD 7.9 and SRD% 29%, see Table 3.

As illustrated in the Bland & Altman graph (Figure 4), some outliers were evident, and a tendency for systematic change could be seen as a larger variation in the mean in individuals with higher mean scores on the FES-I compared with those with lower mean scores.

The sum score for the FES-I in the validity part of the study ranged from 18 to 45, with a mean value of 28 (median 26). There was 'little if any' to 'low' convergent validity between the FES-I and the modified figure-of –eight test ($r_s = 0.36$), one-leg stance right/left (r_s = -0.15/-0.16), health-related quality of life physical function ($r_s = -0.47$), health-related quality of life mental function ($r_s = -0.11$), single-item question regarding fear of falling ($r_s = 0.15$) and self-reported fall history ($r_s = -0.16$).

Supplemental results

Similar results were found for relative and absolute reliability of the FES-I when analysing only those subjects who had a diagnosis of osteoporosis (n = 32) compared to the whole group (n = 59), see Table 3.

Table 3. Number of participants, median, min-max, intra-class correlation (ICC_2), Cronbach's alpha, standard error of measure (SEM) and smallest real difference (SRD) for the Falls Efficacy Scale-International (FES-I) questionnaire for the 59 participants included in the reliability part of the study and for the 32 participants with an osteoporosis diagnosis.

	Falls Efficacy Scale-International					
	Test 1	**Test 2**				
	Median (min-max)	Median (min-max)	ICC_2	Cronbach's alpha	SEM	SRD
n=59	26 (17-49)	25 (17-51)	0.88	0.94	2.9	7.9
n=32	26 (18-49)	26.5 (18-48)	0.89	0.95	2.7	7.5

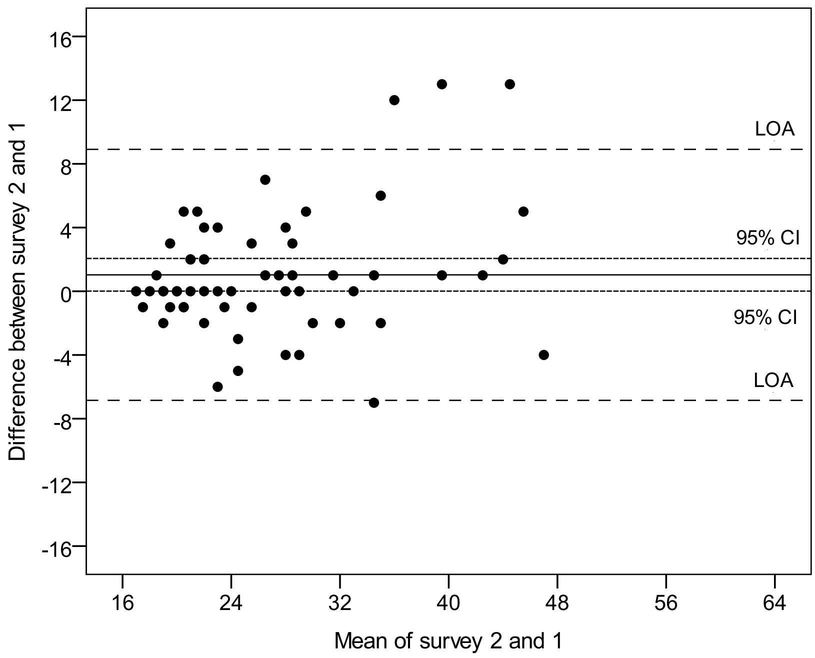

Figure 4. Bland & Altman graph presenting the Falls Efficacy Scale-International (FES-I) questionnaire results. The difference between the two tests is plotted against the mean of the two tests. The solid line represents the mean difference between the two tests, dotted lines the 95% confidence interval (95% CI) of the mean difference and dashed lines limits of agreement (LOA).

4.2 STUDY II

The adherence rates for the training sessions were 89%, with a range of 66–100%.

Regarding the supplemental physical activity intervention, all except one participant in the Training + physical activity group completed the added physical activity. In the Training group all participants were regularly physically active, and compare to the Training + physical activity group there were no differences in activity performed. Consequently, there were no differences between these two groups regarding balance-training and physical activity.

Significant difference was found in fall-related self-efficacy, as measured with the FES-I, between baseline and the 3 months follow-up ($p = 0.044$). All three groups significantly improved their fall-related self-efficacy during this interval ($p \leq 0.015$). Further analysis revealed that both training groups had a significantly larger change in FES-I scores compared to the control group (4 points versus 1.5 points, $p \leq 0.001$).

No significant changes from baseline to 3 months follow-up was found for fear of falling, measured with single-item question 'In general, are you afraid of falling?', between the three groups ($p = 0.243$). However, both intervention groups had a significant decrease in fear of falling from baseline to follow-up ($p \leq 0.046$).

No significant change was shown for preferred walking speed over time and between groups, ($p = 0.086$). However, both training groups increased their preferred walking speed from baseline to 3 months follow-up ($p = \leq 0.025$), while the control group remained unchanged ($p = 0.929$). At fast speed a significant change was shown over time and between groups ($p = 0.008$). The Training group increased their fast walking speed with 0.13 m/s ($p = < 0.001$) and Training + physical activity group 0.10 m/s ($p = 0.003$). During walking at preferred speed with a cognitive dual-task, a significant change was shown over time and between groups ($p = 0.003$). However, it was only the Training + physical activity group that increased their walking speed (0.14 m/s, $p = < 0.001$).

There were no significant differences between the three groups from baseline to 3 months follow-up for both one-leg stance and modified figure-of-eight test (see Table 4). However, within-group analysis revealed that both training groups increased their time in one-leg stance (from 5.5 s to 11.9 s, $p \leq 0.020$), and the Training + physical activity group significantly reduced oversteps in the modified figure-of-eight ($p = 0.035$).

Both training groups significantly increased their advanced lower extremity function scores from baseline to 3 months follow-up ($p \leq 0.034$), while the Control group scores remained unchanged. Within-group analysis comparing baseline and follow-up revealed significant improvement in overall score and in the basic lower extremity function sub-score for both training groups, and the Training group also increased upper extremity function. See Table 4.

Only the Training + physical activity group significantly increased their physical activity level from baseline to follow-up ($p=0.025$).

Table 4. Median, min-max, mean, standard deviation (SD) for the Falls Efficacy Scale-International (FES-I), one-leg stance (OLS), modified figure-of-eight test (MFE), gait speed during preferred speed with and without a cognitive dual-task, fast speed, physical function assessed with Late-Life Disability and Function Instrument at baseline and at 3 months follow-up for the three groups (Training, Training+physical activity, and Control). The Kruskall-Wallis test was used to analyse differences between groups over time for the FES-I, OLS, and MFE; a two-factor repeated-measures ANOVA was used for gait speed and physical function. Significance level at ≤ 0.05 is marked by bold type.

	Training group n=25		**Training + physical activity group** n=18		**Control group** n=26		
Variables	**Baseline** median (min-max)	**3 months** median (min-max)	**Baseline** median (min-max)	**3 months** median (min-max)	**Baseline** median (min-max)	**3 months** median (min-max)	p-value Kruskall-Wallis
Falls Efficacy Scale-International	26 (20-47)	22 (17-32)	26 (20-46)	22 (17-38)	27.5 (21-39)	25 (17-41)	0.044
One-leg stance, s	6.2 (1.8-30.0)	18.1 (1.7-30.0)	4.7 (0.5-30.0)	10.2 (1.9-30.0)	8.9 (1.1-30.0)	9.0 (0.6-30.0)	0.099
Modified figure-of-eight test							
Time, s	24.5 (18.0-59.6)	26.4 (16.4-58.0)	26.0 (17.9-62.2)	28.9 (20.0-56.0)	27.8 (15.3-89-2)	25.8 (18.6-55.5)	0.444
Oversteps, n	3 (0-9)	2 (0-13)	4 (0-24)	3 (0-8)	2 (0-50)	3 (0-46)	0.063
Gait speed, m/s	mean (SD)	mean (SD)	mean (SD)	mean (SD)	mean (SD)	mean (SD)	Interaction effect
Preferred speed	1.21 (0.21)	1.28 (0.22)	1.09 (0.21)	1.18 (0.19)	1.17 (0.21)	1.16 (0.21)	0.086
Fast speed	1.53 (0.26)	1.66 (0.26)	1.42 (0.28)	1.52 (0.29)	1.52 (0.34)	1.52 (0.34)	0.008
Preferred speed dual-task	1.15 (0.24)	1.19 (0.24)	1.00 (0.36)	1.14 (0.31)	1.09 (0.24)	1.06 (0.29)	0.003
Late-Life Function and Disability Instrument							
Overall	59.9 (8.2)	64.4 (6.8)	56.0 (6.1)	58.6 (8.6)	57.7 (6.6)	59.3 (8.9)	0.157
Upper extremity	71.5 (7.8)	76.3 (9.1)	68.4 (9.7)	69.0 (9.4)	71.6 (7.5)	74.4 (9.6)	0.216
Basic lower extremity	68.8 (11.9)	72.9 (9.7)	65.5 (8.9)	70.1 (13.5)	67.1 (10.3)	69.4 (12.2)	0.613
Advanced lower extremity	53.4 (13.3)	61.0 (11.6)	46.3 (10.4)	50.4 (13.6)	48.3 (12.1)	49.9 (13.6)	0.034

4.3 STUDY III

The intention-to-treat analysis (n=96) of the long-term effects of the intervention programme found statistically significant interaction effects were found for Falls Efficacy Scale-International scores, preferred gait speed with and without a cognitive dual task, fast gait speed, number of oversteps in the modified figure-of-eight test and advance lower extremity function assessed with the Late-Life function and disability instrument, see Table 5, Figures 5-8.

Post-hoc analysis revealed no significant differences between groups at any of the follow-up occasions for concerns about falling. However, within-group differences over time showed significant improvement for the Training group when comparing baseline to each follow-up ($p < 0.001$), with improvement being maintained over time ($p = 0.013$; 3 vs. 15 months follow-up). The Training + physical activity group significantly improved from baseline to 3 months follow-up ($p < 0.001$). However, after the 3 months follow-up there was a significant decline in concerns about falling, and at the time of the last follow-up this group had regressed to baseline values (3 vs. 9 months follow-up, $p = 0.003$, and 3 vs.15 months follow-up, $p = 0.026$, baseline vs. 15 months follow-up, $p = 0.132$). The Control group showed significant improvement from baseline to 3 months follow-up ($p = 0.038$) and remained stable over time.

For preferred gait speed, with and without a cognitive dual-task, and for fast gait speed, post-hoc analysis revealed no significant differences between groups at any of the follow-ups. Within-group analysis over time showed that after the intervention the Training group had significantly improved their preferred gait speed (baseline vs. 3 months, $p = 0.036$) and fast gait speed (baseline vs. 3 months, $p < 0.001$), maintaining this improvement over time ($p \geq 0.818$). No significant changes were found for preferred gait speed with a cognitive dual-task.

The Training + physical activity group showed significant improvement from baseline to 3 months follow-up in both preferred gait speed with ($p = 0.002$) and without dual-task ($p = 0.031$) and in fast speed ($p = 0.007$). No significant differences across test occasions were found for the Control group: i.e., this group remained stable over time in terms of gait speed.

The Training + physical activity group was the only group that showed significant changes for oversteps in the modified figure-of-eight test, showing a decreased number of oversteps between baseline and 3 months follow-up ($p = 0.035$).

Post-hoc analysis for advanced lower extremity function revealed that the Training group significantly improved after the intervention ($p < 0.001$) but returned to baseline values at the 9 months follow-up (3 vs. 9 months, $p = 0.027$). The Training + physical activity group showed no significant differences after the intervention. However, after the intervention, advance lower extremity function started to decline and was below baseline values at the 9 months follow-up (3 vs. 9 months follow-up, $p = 0.046$). At the last follow-up the Training group had significantly improved advanced lower extremity function compared to the Training + physical activity group ($p = 0.015$). No significant differences across test occasions were found for the Control group.

When analysing the data per protocol ($n = 55$), statistically significant interaction effects were found for concerns about falling, fast gait speed, preferred gait speed with a cognitive dual-task and number of oversteps in the modified figure-of-eight test. Post-hoc analysis of the per protocol analysis revealed similar results for the Training, Training + physical activity and Control groups for the intention-to-treat analysis regarding concerns about falling, preferred speed with and without dual-task, and fast speed. The post-hoc test of the modified figure-of-eight test revealed no significant differences for any group.

Fear of falling, evaluated with the single-item question ‘In general, are you afraid of falling?’, was reduced during the study period in all three groups, with a more pronounced effect in the two training groups.

At baseline 68% (n = 23) of participants in the Training group had experienced a fall during the previous year, with 77% (n = 24) in the Training + physical activity group and 90% (n = 28) in the Control group reporting a fall. Fall frequency between baseline and first follow-up (3 months) was 16% (n = 4) in the Training-group, 28% (n = 5) in the Training + physical activity group and 15% (n = 4) in the Control group. Between the three and 9 months follow-up the fall frequency was 39% (n = 9) in the Training group, 35% (n = 5) in the Training + physical activity group and 14% (n = 3) in the Control group, and between the nine and 15 months follow-up 41% (n = 9) in the Training group, 50% (n = 7) in the Training + physical activity group and 16% (n = 3) in the Control group. During the study period, 49 falls were reported across all follow-up occasions, 30 (61%) of which were reported as single falls. Two subjects reported experiencing more than 4 falls.

Supplemental results

When only analysing the subjects who completed all follow-ups (n = 47), interaction effects were found for fast gait speed, preferred speed with cognitive dual-task and number of oversteps in the modified figure-of-eight test.

Medium effect sizes were found for fast gait speed, one-leg stance, number of oversteps in the modified figure-of-eight test, overall function, basic lower extremity function and advanced lower extremity function when analysing effects from baseline to 15 months follow-up, see Table 6.

Both medium and large effect sizes were shown when analysing effects from 3 months to 15 months follow-up, for almost all variables, see Table 6.

Table 5. Median and min-max for Falls Efficacys Scale-International. Mean, standard deviation (SD) for preferred gait speed with and without dual-task, fast gait speed, one-leg stance, time and oversteps for modified figure-of-eight test, Late-Life Function and Disability Instrument overall, upper extremity, basic lower and advanced lower extremity function for Training, Training+physical activity (PA) and Control group at baseline, 3, 9 and 15 months follow-up for all randomized participants (n=96), for those who fulfilled the whole study period (n=55) and for those who completed all follow-up oaccsions (n=47). Mixed model analysis with SIDAK's post-hoc test were used to analyse interaction effects between groups over time. Significance level at p≤0.05 is marked by bold style.

Variables		Baseline		3 months		9 months		15 months		Interaction effect, p-value		
		n	median (min-max)	n	median (min-max)	n	median (min-max)	n	median (min-max)	n=96	n=55	n=47
Falls Efficacy Scale - International*	Training	34	27.5 (20-47)	25	22 (17-32)	23	22 (17-33)	22	23 (17-45)			
	Training +PA	31	26 (19-46)	18	22 (17-38)	15	24 (20-48)	14	26 (17-44)	**0.006**	**0.050**	0.103
	Control	31	27 (21-39)	26	25 (17-41)	22	23 (18-37)	19	24 (19-32)			
Gait speed			mean (SD)		mean (SD)		mean (SD)		mean (SD)			
Preferred, m/s	Training	34	1.19 (0.19)	25	1.28 (0.22)	23	1.28 (0.23)	22	1.28 (0.20)			
	Training +PA	31	1.12 (0.22)	18	1.18 (0.19)	14	1.12 (0.23)	14	1.10 (0.18)	**0.048**	0.144	0.230
	Control	31	1.20 (0.25)	26	1.16 (0.20)	22	1.18 (0.20)	19	1.23 (0.21)			
Fast, m/s	Training	34	1.51 (0.26)	25	1.66 (0.26)	23	1.64 (0.29)	22	1.65 (0.26)			
	Training +PA	31	1.44 (0.26)	18	1.52 (0.29)	14	1.48 (0.32)	14	1.47 (0.32)	**0.003**	**0.015**	**0.027**
	Control	31	1.55 (0.32)	26	1.52 (0.34)	22	1.59 (0.28)	19	1.64 (0.31)			
Preferred with cognitive dual-task, m/s	Training	34	1.10 (0.23)	25	1.19 (0.24)	23	1.21 (0.25)	22	1.21 (0.22)			
	Training +PA	30	1.02 (0.34)	18	1.14 (0.31)	14	1.00 (0.33)	14	1.06 (0.26)	**0.006**	**0.002**	**0.011**
	Control	31	1.12 (0.26)	26	1.06 (0.29)	22	1.12 (0.26)	19	1.14 (0.27)			
One-leg stance, seconds	Training	34	12.0 (9.1)	25	15.4 (9.7)	23	12.3 (9.9)	22	12.8 (8.6)			
	Training +PA	31	9.7 (8.9)	18	12.5 (9.9)	15	7.6 (6.4)	14	10.9 (10.4)	0.300	0.574	0.613
	Control	31	9.4 (8.5)	26	8.6 (8.0)	22	9.6 (9.7)	19	7.9 (8.9)			

Table 5. Continue

Variables		Baseline		3 months		9 months		15 months		Interaction effect, p-value		
		n	mean (SD)	n	mean (SD)	n	mean (SD)	n	mean (SD)	n=96	n=55	n=47
Modified figure-of-eight test												
Time in seconds**	Training	34	28.1 (9.0)	25	28.5 (9.8)	23	27.3 (8.8)	22	24.6 (7.0)			
	Training +PA	31	34.1 (19.7)	18	32.0 (10.4)	15	35.7 (14.3)	14	30.7 (10.6)	0.388	0.114	0.111
	Control	31	28.7 (13.9)	26	29.1 (10.7)	22	25.9 (10.7)	19	25.7 (9.2)			
Number of oversteps**	Training	34	3.9 (4.3)	25	3.1 (3.7)	23	3.0 (3.2)	22	4.0 (3.7)			
	Training +PA	31	6.5 (6.1)	18	3.2 (2.7)	15	4.7 (5.4)	14	3.7 (3.9)	**0.009**	**0.049**	**0.015**
	Control	31	6.3 (11.6)	26	8.1 (12.6)	22	7.1 (10.8)	19	5.0 (10.4)			
Late-Life Function and Disability Instrument												
Overall function	Training	34	59.1 (8.0)	25	64.5 (6.8)	23	61.4 (6.8)	22	62.0 (8.4)			
	Training +PA	31	56.8 (5.6)	18	58.7 (8.6)	15	55.5 (7.6)	13	54.3 (7.1)	0.101	0.295	0.658
	Control	31	58.7 (8.0)	26	61.0 (8.9)	22	60.5 (9.0)	19	60.7 (7.0)			
Upper extremity function	Training	34	71.2 (7.7)	25	76.3 (9.1)	23	74.0 (7.8)	22	73.5 (11.4)			
	Training +PA	31	70.3 (10.3)	18	69.0 (9.4)	15	67.5 (9.5)	13	66.7 (8.3)	0.524	0.741	0.874
	Control	31	71.7 (9.4)	26	74.4 (9.6)	22	73.4 (11.6)	19	73.1 (10.1)			
Basic lower extremity function	Training	34	67.6 (11.4)	25	72.9 (9.7)	23	70.5 (10.5)	22	70.6 (12.2)			
	Training +PA	31	65.6 (8.4)	18	70.1 (13.5)	15	64.7 (9.4)	13	62.2 (8.1)	0.201	0.229	0.785
	Control	31	68.4 (11.8)	26	69.4 (12.2)	22	67.3 (12.2)	19	72.0 (12.3)			
Advanced lower extremity function	Training	34	52.2 (12.7)	25	61.0 (11.6)	23	55.3 (10.5)	22	57.5 (12.9)			
	Training +PA	31	48.1 (9.2)	18	50.4 (13.6)	15	43.7 (17.8)	13	43.5 (14.3)	**0.015**	0.062	0.116
	Control	31	50.1 (13.0)	26	49.9 (13.6)	22	53.7 (13.3)	19	53.0 (12.3)			

* Mixed model analysis was performed on linearly scaled scores.

** Mixed model analysis was performed on logit values. Analysis of number of oversteps was performed on n=93

Table 6. Effect size according to Cohen's d, for Falls Efficacy Scale-International (FES-I), gait speed at preferred speed with and without cognitive dual-task and at fast speed, one-leg stance (OLS), performance time and number of oversteps for the modified figure-of-eight test (MFE), and physical function as measured with the Late-Life Function and Disability Instrument. Guidelines for interpretation of effect size according to Cohen (0.20 = small effect size, 0.50 = medium effect size and 0.8 = large effect size) (110).

	Effect size					
	Baseline - 15 months			3 months - 15 months		
	Training - Control	Training+PA - Control	Training - Training+PA	Training - Control	Training+PA - Control	Training - Training+PA
FES-I*	-0.2	-0.1	0.0	0.5	0.8	0.3
Gait speed						
Preferred	0.4	0.2	-0.2	0.0	-0.8	-0.8
Fast	0.6	0.4	-0.3	-0.3	-0.7	-0.5
Preferred with DT	0.2	0.2	0.0	-0.5	-1.0	-0.7
OLS	0.3	0.7	0.3	-0.3	0.1	0.3
MFE**						
Time	-0.1	-0.2	-0.1	-0.5	-0.1	0.3
Oversteps	-0.1	-0.5	-0.3	0.8	0.5	-0.4
LLFDI						
Overall	0.0	-0.5	-0.4	-0.4	-0.8	-0.3
Upper extremity	0.2	-0.1	-0.3	0.1	0.5	0.3
Basic lower extremity	-0.2	-0.6	-0.4	-0.2	-0.7	-0.7
Advanced lower extremity	0.2	-0.4	-0.5	-0.4	-1.0	-0.4

* Calculations of effect size were performed on linearly scaled scores.
** Calculations of effect size were performed on logit values.

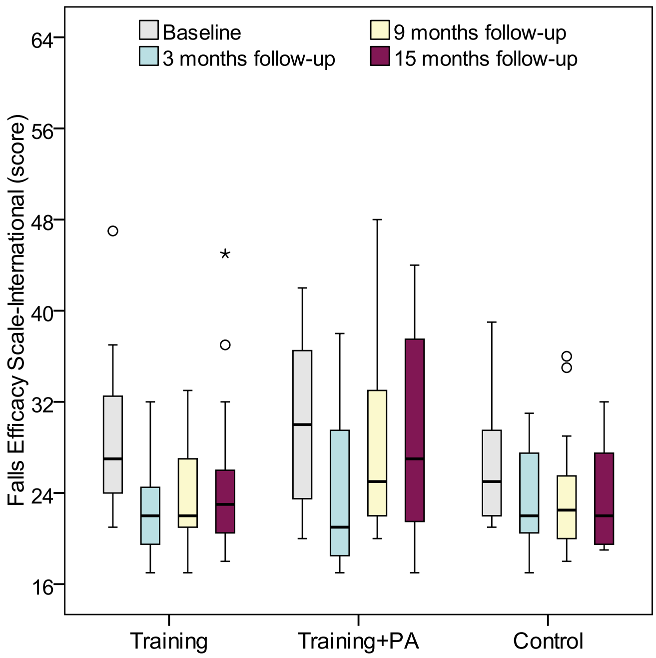

Figure 5. Concerns about falling measured with Falls Efficacy Scale-International (FES-I), illustrated with box plot, at baseline and 3, 9 and 15 months follow-ups for the three groups: Training, Training + physical activity (PA) and Control. The box plots represent median, quartiles, min-max and outliers.

Figure 6. Normalised frequency (%) of the single-item question related to fear of falling 'In general, are you afraid of falling?' with possible answers: 'not at all', 'a little', 'quite a bit', and 'very much' for the Training group, Training + physical activity (PA) group and Control group at baseline and at 3, 9 and 15 months follow-ups, respectively.
* One missing value.

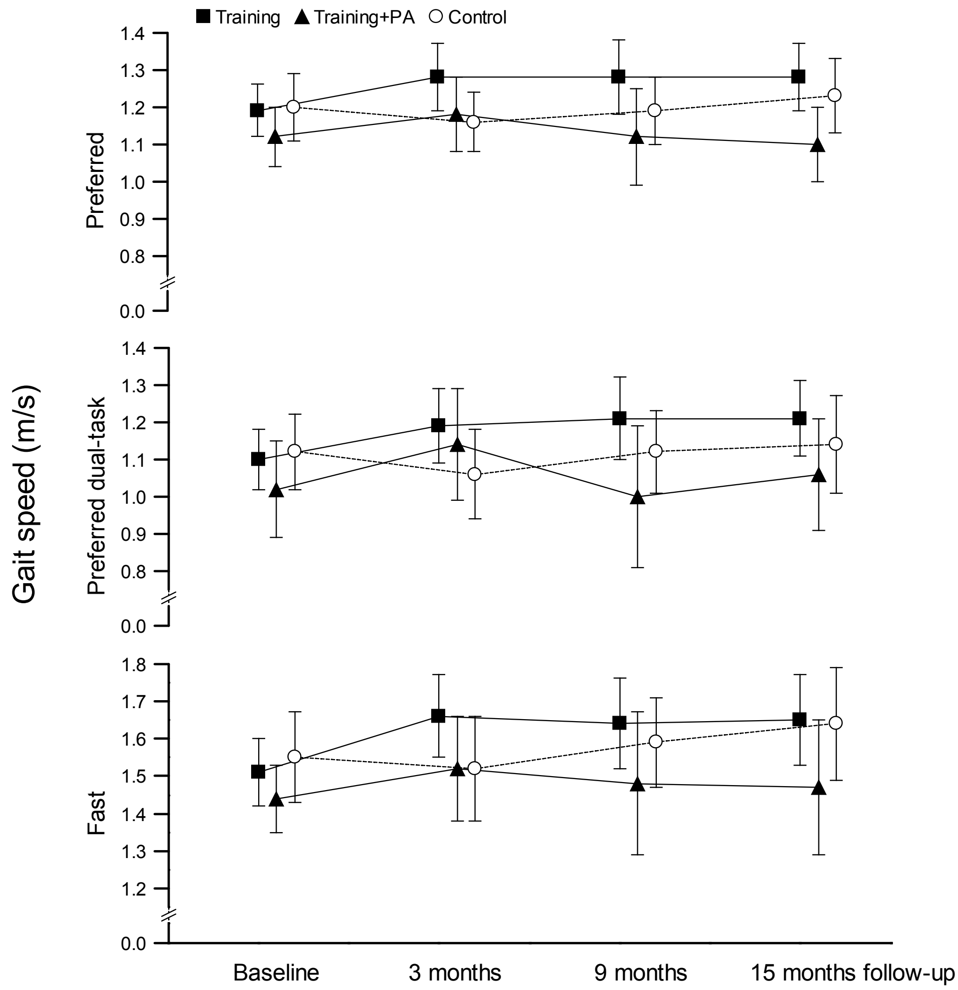

Figure 7. Means and 95% confidence intervals for gait speed (cm/s) shown for preferred, fast and preferred speed during dual-task condition, at baseline and at 3, 9 and 15 months follow-up for the Training, Training + physical activity (PA) and Control groups, respectively.

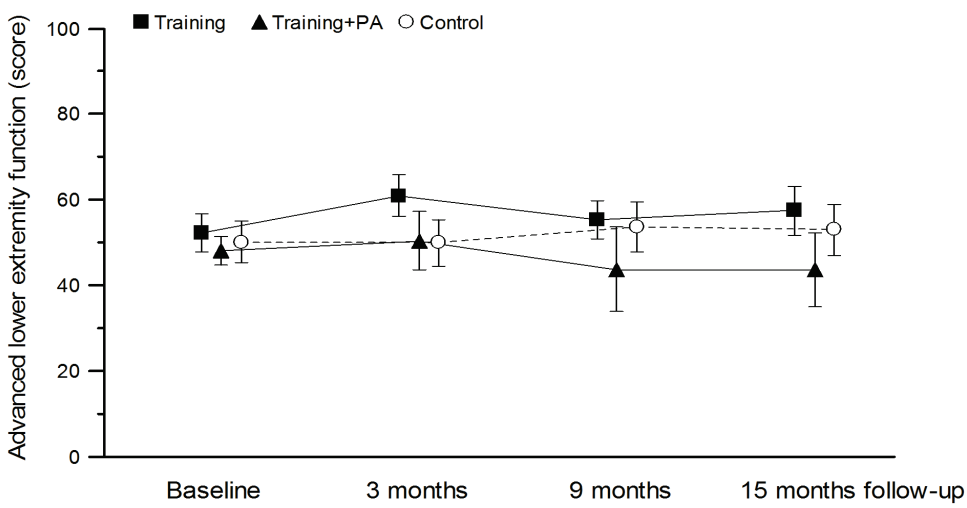

Figure 8. Means and 95% confidence intervals for advanced lower extremity function, assessed with the Late-Life Function and Disability Instrument function component, at baseline and at 3, 9 and 15 months follow-up for the Training, Training + physical activity (PA) and Control groups, respectively.

4.4 STUDY IV

The analysis from Study IV identified one underlying theme – *internalised risk perception related to experience of bodily fragility*. This theme was manifested in three categories – *empowerment* (feeling empowered and self-efficient), *safety* (trusting in safety precautions and fall-prevention strategies to avoid fall-related consequences) and *menace* (feeling at risk and avoiding threatening situations) – which reflected the essential meaning of the interviews with regard to how the informants experienced fall-related concerns and balance in everyday life.

In order to live with the fragility caused by osteoporosis and prevent fractures and declining health, the informants had an internalised risk perception related to the experience of bodily fragility. They were strongly aware of their fragility and were markedly concerned about hurting themselves. In order to live with osteoporosis-induced fragility, informants needed to protect their bodies against threats and harm. A fall is synonymous with fracture and impaired health. To protect their fragile bodies and prevent falls, informants had developed a high degree of risk perception. Though they did not always verbalise it, risk perception was always present as a backdrop of tacit knowledge built on awareness of their fragility and the risk of fractures, their dependence, and the potential for disability due to a fall. Many of the informants had lived with their fragile bodies for a very long time, and their on-going awareness and performance of impact analysis had become a part of whom they were and how they were supposed to react emotionally and physically in every situation.

The three manifest categories of empowerment, safety, and menace describe how the informants' experienced fall-related concerns and balance in everyday life, influenced by their fragile bodies. The analysis found an on-going negotiation between identification with the different categories, in which seasonal, environmental and personal factors influenced the dynamic of how informants perceived their fall-related concerns and balance, as shown in Figure 9. Environmental factors such as the winter season, and personal factors such as lack of wellbeing, may lead a person who is highly empowered or who uses active risk prevention strategies into a situation of menace and avoidance of activity.

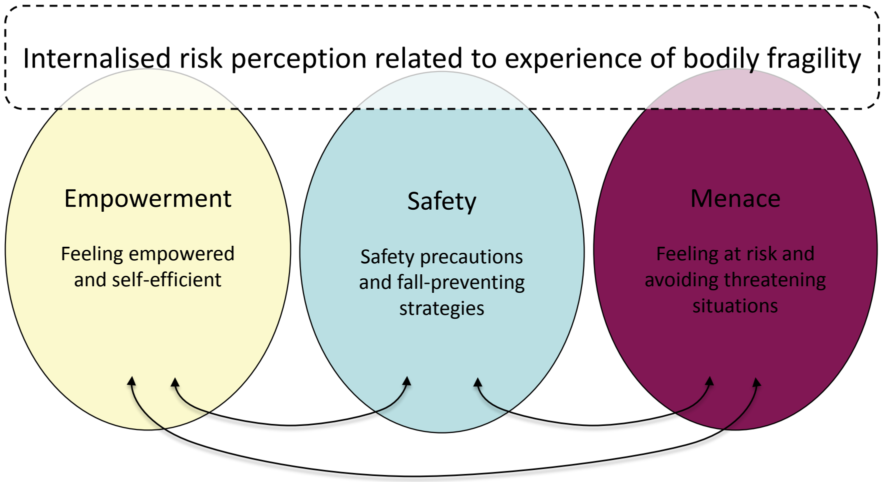

Figure 9. Dynamic process between the manifest categories: empowerment (feeling empowered and self-efficient), safety (trusting in safety precautions and fall-prevention strategies to avoid fall-related consequences) and menace (feeling at risk and avoiding threatening situations). These categories emerged in the latent part of the analysis, where seasonal, environmental and personal factors influenced the dynamic of how informants perceived their fall-related concerns and balance. Contextual factors may lead a person with high empowerment and/or active risk prevention strategies into a situation of menace and avoidance of activity.

Below are some quotations from the interviews to illustrate some supplemental information regarding perception of the balance-training programme:

> *”I've gone from terror to fear, to feeling relatively secure. That's because now I've trained my balance much better recently here. And I know about the risks. Okay, obviously I knew about the risks before, too, but then I hadn' thought in that way that I could train up my balance”*

> *” ... I dare ... I'm not frightened beforehand now. No, now I set off and how shall I put it I don't plan in the same way but now it's just to set off out and if it should happen. I think my fear has gone away. I don't know, I don't feel it's the same I don't know if I'm still afraid at all.”*

> *“There's no comparison on the same day, the difference is huge. It's .. My balance has improved and I think my fear of falling has just about gone away, perhaps if I was to take a great big step ... I don't know if it's fright, no I think it's more what shall I do to take a big step ... so I don't think I'm afraid of falling down but it's more a practical thing how to set about it”*

> *”It made me happier and more positive-thinking”*

> *”Many people with brittle bones, they should join in this kind of thing if they get the chance. That it's really good. In every way. You're more aware of how you move and you think of it more”*

5 DISCUSSION

This thesis comprises four studies, and the main findings from each study were:

- The Swedish version of the Falls Efficacy Scale-International (FES-I) is a reliable instrument in older Swedish individuals with increased risk of falling. Moreover, we found low convergent validity for the Falls Efficacy Scale-International correlated with balance performance and health-related quality of life in older women with osteoporosis and increased risk of falling.

- The specific and progressive balance-training programme focusing on dual- and multi-task exercises improved fall-related concerns in older adults with osteoporosis, as well as preferred walking speed with and without a cognitive dual-task, fast walking and self-reported physical function. However, it is unclear if added physical activity gives additional benefits to the balance-training programme, as all participants already were regularly physically active as recommended.

- The specific and progressive balance-training programme for older adults with osteoporosis, focusing on dual- and multi task exercises, had positive effects on concerns about falling, gait, balance and physical function when measured immediately after the training period (analysed with a intention-to-treat analysis based on all 96 randomized participants), as well as some long-term beneficial effects lasting up to 15 months. Both training groups gained positive effects from the balance-training programme measured at the first (3 months) follow-up. At the 9 months follow-up, however, effects in the training + physical activity group had dropped back to baseline values; values were even lower at the 15 months follow-up, one year after the end of the intervention. This is in contrast to participants in the Training group, who retained improved levels and maintained positive effects during the whole study period.

- A qualitative content analysis of the 19 interviews showed that informants' descriptions of their perceived fall-related concerns and balance in daily life after having participated in balance-training could be categorised in terms of empowerment, safety and menace. Furthermore, an underlying theme of 'internalised risk perception related to experience of bodily fragility' was always present. The analysis also identified a dynamic process in which seasonal, environmental and personal factors influenced how informants perceived their fall-related concerns and balance.

In the rationale for this thesis we hypothesised that this specific and progressive balance-training programme, focusing on dual- and multi-task exercises, would significantly improve fall-related concerns, walking speed during a cognitive dual-task, fast walking speed, balance performance and physical function in older adults with osteoporosis and with an increased risk of falling. By evaluating the results from Study II and III we can confirm that this balance-training programme was successful in improving fall-related concerns, walking speed during a cognitive task, fast walking and physical function for older adults with osteoporosis. However, we could not completely confirm the hypotheses for improvement in balance performance. We found significant improvement in number of oversteps in the modified figure-of-eight test but no difference in performance time for the same test, nor in performance time for the one-leg stance test.

Furthermore, we hypothesised that the Falls Efficacy Scale-International is a reliable instrument with moderate correlation with balance performance and health-related quality of life measures for older women with osteoporosis. In Study I we found that the Falls Efficacy Scale-International has a good relative reliability and acceptable absolute reliability, but it did not have more than moderate correlation with balance performance.

5.1 FALL-RELATED CONCERNS

At the beginning of the research project forming the base of this thesis, we defined fear of falling as 'a loss of self-efficacy to perform certain activities without falling' (41), After some time, as our knowledge of fall-related concerns increased, our understanding about different constructs involved in fall-related concerns changed and we became aware that Tinetti et al.'s definition did not refer to fear of falling but to fall-related self-efficacy. In Study II we used the Falls Efficacy Scale-International to assess fall-related self-efficacy. However, as our knowledge about the different constructs and the Falls Efficacy Scale-International were further developed, we refer to that the Falls Efficacy Scale-International assessing concerns about falling in Study III. In both Study II and III fear of falling was assessed with the single-item question 'In general, are you afraid of falling?'

Furthermore, awareness of the different constructs associated with fall-related concerns become more pronounced during Study IV, where we obtained good descriptions of informants' perception of fall-related concerns and gained greater understanding of how informants invoked all the various constructs (fear of falling, fall-related self-efficacy, concerns about falling, balance confidence and consequences of falling) when reflecting on their perception of fall-related concerns. With this new knowledge, it might have been interesting and beneficial to have supplemented the assessments we used with other assessments that reflect all the constructs associated with fall-related concerns, with the aim of achieving a broader understanding on how these various constructs are affected by this specific and progressive balance-training programme.

As mention above, the development of the constructs associated with fall-related concerns – fear of falling, fall-related self-efficacy, concerns about falling, balance confidence and consequences of falling – we found the term *fall-related concerns* to be an umbrella term for the five constructs, see Figure 10. Mostly influenced by Study IV but also incorporating the literature on the topic, we concluded that fear of falling, fall-related self-efficacy, concerns about falling, balance confidence and consequences of falling are five constructs that are of great importance, and all contribute to fall-related concerns among this group of older adults with osteoporosis.

We found that the balance-training programme had a positive effect on fall-related concerns. The interviews from Study IV markedly improved our awareness of informants' perception of fall-related concerns, and we obtained descriptions and improved our knowledge of the informants' internal dialogue about why they are afraid of falling and the consequences of falls, as well as whether that fear protects them from risky situations and hence is a necessary thing. With this knowledge in mind, for older adults with osteoporosis the aim of training interventions should not be a total reduction of fear of falling, since this population describes their fear of falling as being protective. However, it is not beneficial or healthful to have an excessive fear of falling that might lead to activity avoidance, isolation and withdrawal from social participation. An intervention that reduces fear of falling from an excessive level to a more appropriate one may be beneficial for participants. The programme under analysis had an impact on participants' concerns about falling according to results from the Falls Efficacy Scale – International, with lower sum-scores after the intervention indicating that participants were less concerned about falling in specific situations in daily life, such as walking on uneven and slippery surfaces. The programme was successful in improving participants' fall-related concerns, and made participants more confident and secure in their daily lives.

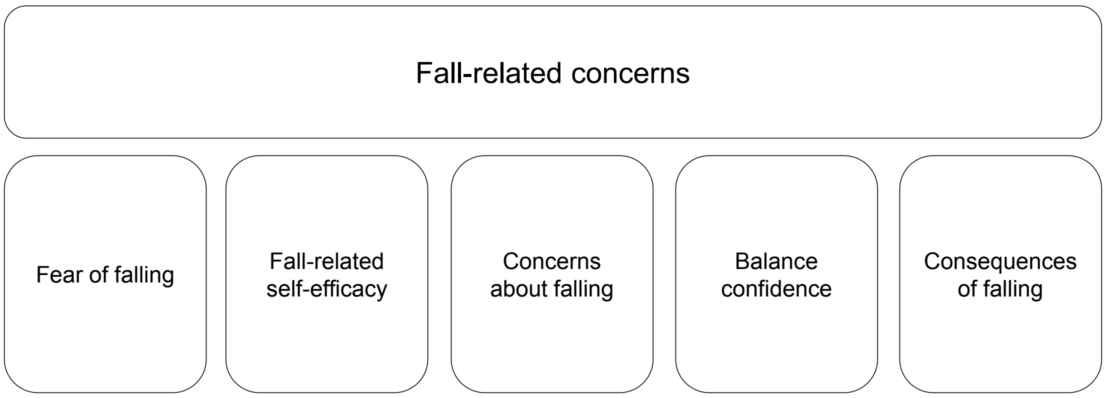

Figure 10. Fall-related concerns seen as an umbrella term for fear of falling, fall-related self-efficacy, concerns about falling, balance confidence and consequences of falling; all are of importance for older adults with osteoporosis.

5.2 FALLS

During the course of the study period, participants in the two training groups experienced more falls compared to the Control group; a similar pattern has also been found in a previous study by our research group among healthy older individuals with self-perceived balance deficits and a fear of falling (78). One explanation for this may be that participants in the two training groups gained a higher level of self-confidence in their physical function, decreased their fear of falling and thereby exposed themselves to more challenging situations in daily life, with a consequent greater risk of falls. One limitation in this study was that only fall frequency was reported, and not fall severity (whether falls required medical attention). However, we do know that the reported falls did not lead to any fractures during the study period.

5.3 BALANCE PERFORMANCE

As mentioned above, the balance-training programme was successful in reducing the number of oversteps in the modified figure-of-eight test but found no difference in performance time for this test or for the one-leg stance. We might speculate as to different explanations for this lack of improvement in balance performance. Could there be a limitation in the measurement instruments used to assess balance performance? Should we have included a balance assessment that addressed the different systems of balance control, according to the model we used to explain the theory behind the balance-training programme? For example, the BEST- or MiniBEST-test might have been an appropriate assessment to measure the different systems of balance control (52). However, the BEST- or MiniBest-tests had not yet been translated into Swedish or adopted for Swedish contexts when we started this research project.

Or could the lack of improvement in balance performance after the intervention have been due to the fact that the participants already had a good balance from the start? Recruitment for the research project forming the base of this thesis targeted older adults with self-reported balance deficits, and subjects were included in the study if they were afraid of falling and felt that their balance performance was affected. There were no exclusions after the baseline testing on the basis of performance on the balance assessments. Therefore, we could not say that all the participants had manifest balance deficits, which could be measured objectively, but only that this was a subjective experience.

Taking the results of these studies together, we might say that this group of older adults did not have balance problems as their main disability; in fact, they might have had relatively good balance control. Rather, their main difficulty was a lack of self-confidence and concern about the consequences of falling and the risk of seriously hurting themselves, leading them to have concerns related to falls and to be terrified of a loss of balance control.

As discussed above with respect to balance deficits and concerns about falling, this might also reinforce speculation regarding the connection between self-reported or perceived balance deficits and concerns about falling. There might be perceived deficits in balance control that are not captured with objectively measurements. One limitation that could occur when comparing and seeking correlation between questionnaires that capture participants' perception of a phenomenon that can be objectively measured is that perceptions and experiences are being compared against objective measures. What we perceive and experience does not necessarily correlate with measured functions and abilities. Therefore, in Study I it might not be surprising that we found a correlation between the FES-I and health-related quality of life as assessed with the SF-36, since both measures are based on subjects' self-reported perception of their function.

5.4 GAIT

Both training groups were able to increase their walking speed after the intervention for both preferred speed with and without a cognitive dual task and for fast walking speed. Moreover, the Training group were able to maintain the improvement during the entire follow-up period, while the Training + physical activity group regressed to baseline values.

It is known that persons with the ability to walk faster than 1 m/s generally have good functional status, a lower risk of health events and better survival (60, 61). The Training + physical activity group walked 1.02 m/s at baseline while performing a secondary cognitive task, while the other two groups walked ≥ 1.10 m/s. At 9 months the ability to walk while performing a secondary cognitive task was down to 1.00 m/s for the Training + physical activity group. This indicates that the participants in the Training + physical activity group had of lower level of function and therefore were more exposed to risks of negative health events.

5.5 PHYSICAL FUNCTION

The balance-training programme includes exercises that place demands on the lower extremities, and particularly on more advanced functions such as walking over varied terrains, over obstacles, and on different surfaces (slippery or uneven), situations in daily life that may be perceived as risky. Participants improved their self-rated physical function, as measured with the Late-Life Function and Disability Instrument with respect to advanced lower extremity function, which is evidence for the success of the balance-training programme in this regard. This conclusion is further confirmed by the statements from the informants in Study IV.

5.6 PHYSICAL ACTIVITY LEVEL

Physical activity level, as measured with the Frändin-Grimby activity scale, revealed that the Training + physical activity group was less physically active than the two other groups at baseline, a pattern that held steady at the first follow-up. This may also indicate that the Training + physical activity group had a lower level of function. However, as the research project forming the base of this thesis is a part of a larger study, the balance-training programme's effect on physical activity level over the long-term, as well as health-related quality of life, will be the main object of analysis in a forthcoming companion thesis.

5.7 LONG-TERM EFFECTS

Postive effects were found immediately after the training period, as well as some long-term beneficial effects lasting up to 15 months. Both training groups gained positive effects from the balance-training intervention measured at the first follow-up. At the 9 months follow-up, however, effects in the Training + physical activity group had returned to baseline values and were even lower at the 15 months follow-up, one year after the end of the intervention. This is in contrast to the participants in the Training group, who remained at improved levels during the whole study period.

In Study III we explored different explanations for this pattern: for example, the Training + physical activity group seemed to have lower physical function and higher morbidity compared to the two other groups. Also, participants in the Training group may have become more physically active during the intervention period and were simply better at maintaining their activity level during the follow-up period, thereby better conserving the positive effects of the balance-training intervention.

These findings may indicate that the two intervention groups needed different support following the balance-training intervention. Participants in the Training group were able to conserve the positive effects, which may indicate that the intervention was more effective for this group because they were able to remain physically active on their own. However, the positive effects for the participants in the Training + physical activity group started to decline six months after the intervention, i.e. at the 9 months follow-up. Participants in this group might have needed more support or a prolonged intervention in order to better conserve the positive effects: i.e., they may have benefited from an additional training period or other specifically prescribed physical activity after the initial balance-training period, preferably based on guidance from a physical therapist. All this is important to take in consideration when planning future studies and thinking about clinical implications. It may be important to identify participants that need more support and to individually adjust the intervention for them so that it is easier for them to remain physically active and engaged in daily life.

5.8 INTERVENTION

The balance-training programme was performed in 45-minute group sessions, with 6–10 participants in each group, three times per week over a 12 weeks period, with two or three physiotherapists present at each session. At the beginning of each semester participants stated their concern about performing the balance-training three times per week. Nevertheless, participants found the programme fun and enjoyable, and by the end of the intervention period they all were appreciated and wanted to continue with it. The qualitative interviews elicited additional information about these older women's thoughts about the importance of this type of balance-training and the lack of similar interventions in primary care. The high attendance rate (89%) for the balance-training programme leads us to conclude that participants did not find it difficult to complete balance-training sessions three times a week. However, some participants expressed that they would have preferred to do the sessions two times per week, spending at least one hour per session.

The balance-training programme has been successful in improving fall-related concerns. However, in the future the programme could be developed to include more components that specifically address these concerns. For example, therapists could discuss different concerns during the training sessions, allowing participants to explain their perceived concerns, and the situations in which they feel their fall-related concerns could be incorporated into the training programme.

The distribution of the exercises included in the programme should also be taken into consideration in the future. Exercises focused on standing and walking should be prioritised over sitting ones in order to make the programme more specific to balance performance while walking and standing and therefore a better reflection of balance tasks encountered in daily life.

The Training + physical activity group was instructed to also perform supplemental physical activity in the form of walking with or without poles during the 12-week intervention period, for at least 30 minutes, three times/week. Both intervention groups kept notes about their physical activity level during the intervention period. However, at the 3 months follow-up we noticed from these notes that the two intervention groups had been equally physical active, which meant that the Training + physical activity group in fact did not receive any supplemental intervention. This might be due to the researchers' lack of experience at the beginning of the study period regarding physical active levels among this group of older adults with osteoporosis.

Prescribing walking with poles, as a supplemental physical activity during a study to improve balance function may seem contradictory. However, given the difficult seasonal environment in Sweden, especially during the winter, poles were considered to be a way to ensure that participants could perform the supplemental physical activity. This was confirmed during one of the qualitative interviews when one informant gave a rich description of how the poles had helped her and also kept her more physically active. After reviewing participants' notes kept during the intervention we also found out that walking with poles was an activity that this group of older women already performed regularly.

5.9 INTERNATIONAL CLASSIFICATION OF FUNCTIONING

Applying the theoretical framework of the International Classification of Functioning (ICF) (113), see Figure 11, to the results of the randomized controlled trial (Studies II and III) and the qualitative study (Study IV) enables us to discuss the multi-faceted effects of the balance-training programme assessed in this thesis.

The balance-training programme focused on improving domains such as body function, structures and activity (i.e. gait, balance and physical function). The results of the randomized controlled trial show that balance-training was successful in improving gait and physical function, and the experiences of informants furthermore shows that participants experienced improvement in personal factors such as self-efficacy and confidence. The intervention furthermore had a perceived impact on activity levels and participation, as participants resumed activities that had previously been avoided and took up new activities. All this is influenced by environmental factors*,* as the informants became more perceptive of the environment and how it could affect them in safely performing activities of daily living.

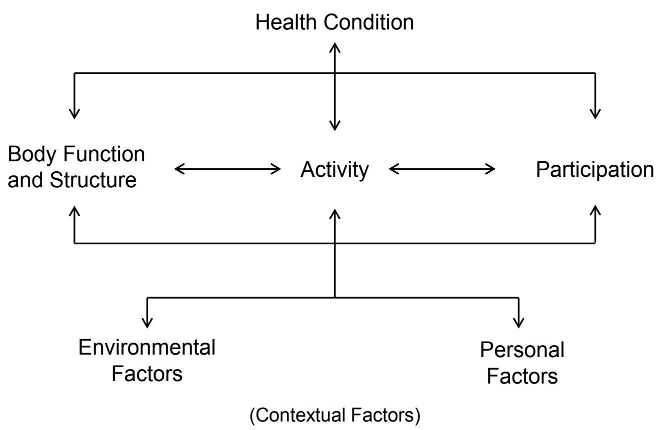

Figure 11. The International Classification of Functioning, Disability and Health (ICF) model. Interaction between functioning at the level of body (body functions and structures), the whole person (activity) and the whole person in a social context (participation), interacting with health conditions and contextual factors (113).

5.10 METHODOLOGICAL CONSIDERATIONS

5.10.1 Quantitative designs

The two empirical studies, Study II and III, were two randomized controlled trials with baseline testing and follow-ups at 3, 9 and 15 months. According to Domholdt, randomized controlled trials are the best design for evaluating whether or not the intervention under review has had any effect (83). Randomized controlled trials randomly assign participants into different groups and thereby reduce the risk of differences between groups at the beginning of the study. This makes the groups more equal, except for the intervention under investigation. All this makes it possible to determine that any difference between the groups at follow-up is caused by the intervention and not by differences between groups present at baseline: i.e., it allows researchers to determine the effect of the intervention.

5.10.1.1 External validity

In quantitative research it is important that samples be representative of the population being studied; this allows results to be generalised (83).

Participants were recruited into the research project forming the base of this thesis through advertisements in local newspapers in Stockholm County, through the Swedish Osteoporosis Society and through the Endocrinology Clinic at the Karolinska University Hospital, an approach known as convenience sampling (114). This approach might be considered the weakest recruitment method, since participants are self-selected and are interested in participating. By using this method, we may have included only motivated participants who were already aware of the importance of physical activity and training and not older adults with osteoporosis who really need this type of training but are isolated at home because of their excessive fear of falling. Although we involved the Endocrinology Clinic at the Karolinska University Hospital to broaden recruitment, unfortunately we only got a few subjects from this clinic.

Furthermore, the sample was highly skewed in gender distribution (containing only two men), which might be seen as a limitation for the generalizability of the results and which may invalidate the results for men. However, more women are diagnosed with osteoporosis (115), and they have a greater fear of falling (31), and may be more conscious of their balance deficits than men. Therefore, women may be more interested in participating in this type of study.

During the entire study period a total of 41 participants (43%) dropped out (Training group n = 12, Training + physical activity group n = 17 and Control group n = 12). No significant differences were found between the subjects who dropped out (n = 41) and those who completed the study (n = 55) regarding baseline characteristics or measured variables, except for frequency of angina ($p = 0.040$), which was higher among the dropouts (n = 6 compared to n = 1).

In this study we experienced a larger number of drop-outs compared to our previous long-term follow-up on healthy older adults, in which only 11% of participants dropped out after having participated in balance-training. This difference may reflect higher co-morbidity among older adults with osteoporosis, which would make it more likely for them to drop out.

And even if dropouts in this study did not differ from the other participants, it is possible that those with the most co-morbidity were the ones who dropped out.

5.10.1.2 Internal validity

In the randomized controlled trial, several assessors were involved in testing. To check for bias during data collection, all assessors were trained in the various measurements, and assessor learning sessions were held, with discussions on how to instruct participants and evaluate performance on the various assessments, in order to achieve consensus and ensure that the measurements were performed evenly. Written information with instructions was provided for each assessment.

One bias in these randomized controlled trials may be the lack of blinding of the assessors after the baseline testing. However, at the baseline testing all assessors and subjects were blinded for allocation, since the allocation was performed at the end of this test occasion. Based on experience in a previous randomized controlled trial on healthy older adults, significant resources were spent to try to keep the assessors blinded for group allocation at the follow-ups. Participants were repeatedly told not to disclose their group allocation, but despite all efforts at keeping assessors blinded the participants revealed their group allocation by expressing their gratitude and discussing perceived effects of the training with the assessors. Based on this experience, and because some of the assessors also were involved in the intervention, blinding for group allocation was not possible. However, there were always two assessors present during the physical tests in order to ensure that participants got the same standardised instructions and that the tests were performed in the same way.

All instructors for the balance-training programme were trained in objective of the research project, the theory behind the intervention and how to conduct the balance-training programme. Several instructors were involved in the training during the study period, but there was a core of instructors who were involved during the entire study period for both randomized controlled trials. During each training session two physiotherapists were present; one of them always had greater experience to ensure the quality of the balance training. All instructors followed a predetermined schedule for all the training sessions, with brief information about what type of exercises should be performed during each session. The aim was to ensure that all participants underwent the same balance-training programme during the different semesters of the trial. Instructors kept notes on progress in the training sessions, such as added tasks and so on. Comparing the different semesters, we noted that all participants ended up at advanced levels of training at approximately the same time. Yet during the sessions all exercises were individually adjusted following the participants' abilities so as to ensure progress during the training period.

The results also indicate that we had a high attendance rate at the balance-training programme (89%), with a range of 66–100%. Participants also kept notes on their physical activity or additional training outside the balance-training, both to ensure that the Training + physical activity group performed their additional intervention and to control for activity levels among the Training group during the study period. The programmes' high attendance rate should be considered a strength when drawing conclusions about the impact of the intervention.

5.10.1.3 Statistical considerations

This thesis used data from different sources, which creates data on different levels: nominal, ordinal and interval. All this may lead to challenges and limitations when evaluating the effects of an intervention by comparing baseline and follow-up measures and by comparing between groups. In Study I a non-parametric statistical correlation test, Spearman's, was used, since it involved data on different levels. In Study II, when evaluating the effects of the intervention from baseline to the 3 months follow-up, both non-parametric and parametric statistical tests were used depending on type of data. Study III entailed evaluating the long-term effects in Study III, including four test occasions and three groups, and there are limited statistical methods for analysing this type of data. The greatest limitation was the use of questionnaires that produce ordinal data, along with how to process that type of data as well as not normally distributed interval data. In order to use parametric statistical methods despite the presence of ordinal and not normally distributed data, we performed a Rasch analysis and transformed the ordinal scale of the Falls Efficacy Scale – International to a linear scale and log transformed the not normally distributed data (89).

A per protocol analysis was used in Study II in order to evaluate the actual effect of the intervention for those who completed the intervention period, without having taking into account dropouts. In Study III we used two types of analysis: intention-to-treat and per protocol. Intention-to-treat was used because it is the recommended and preferred analysis for this type of long-term follow-up study. Using a per protocol analysis which excludes participants from the analysis can lead to overestimation of treatment effects, whereas an underestimation may be present when using intention-to-treat analysis (116). An intention-to-treat analysis increases the generalizability to the general population, since it better reflects the clinical environment and expected results one would get in a clinical context.

The advantage of using a mixed-model analysis is that the model itself corrects for missing data and does not exclude participants if they have missing data. The model allows all randomized participants to remain in the model without having to impute data in correcting for missing values. Mixed-model estimates means and standard error are based on the data present at the different test occasions, between and within individuals (108).

According to the power calculation, 21 subjects were required in each group. Participants were over-recruited at baseline, since we noticed a higher dropout rate than expected and therefore also made an additional ethical application to compensate for dropouts and to ensure the power of the study (Dnr: 2012/1829-32). At the 3 months follow-up we already had a loss of power in one of the interventions groups (Training + physical activity group $n = 18$), which had decreased in size at the 9 and 15 months follow-ups, $n \leq 15$. In the Training and Control groups the number of participants was greater than 21 until the 15 months follow-up, when the Control group consisted of 19 participants.

5.10.2 Qualitative design

In Study IV we used an inductive qualitative content analysis, since the aim of the study was to explore how older women with osteoporosis perceived fall-related concerns and balance in daily life after participating in a balance-training programme. Other qualitative methods, such as phenomenography (describing differences and similarities in how individuals experience, understand and conceptualise a phenomena) and phenomenology (describing the essence of a phenomena) (117) were not considered suitable for the current research question, since the aim was not the get a description of differences, similarities or essences of the phenomenon. We wanted to obtain rich descriptions of informants' perception of fall-related concerns and balance, and therefore a qualitative content analysis was chosen.

An inductive approach was used, since we did not have a predetermined theory that we wanted to test or search for in specific data in the text, moving from the general to the specific, which would have called for a deductive approach. (111).

In qualitative methods, the three concepts of credibility, dependability and transferability are important in achieving trustworthiness (111, 112, 118).

Credibility concerns participant selection, data collection, data analysis execution (i.e., selecting the most suitable unit of meaning), and how well categories and themes cover data by, for example, presenting quotations from the interviews.

Dependability concerns factors that could cause instability in the data and whether the phenomenon or design induced changes: i.e., to what degree was there change over time and variations introduced by the researcher during the analysis process.

Transferability refers to whether the findings are transferable to other contexts. It is, therefore, valuable to give a description of the context, selection and characteristics of participants, data collection and analysis. (111, 112)

Pre-understanding refers to the researcher's existing knowledge about the context; it is important for researchers to have an open mind during analysis and to be aware of their pre-understanding (112).

The informants were recruited by appropriateness (119) in order to meet the objective of the study. We considered data collection through individual interviews to be an appropriate method within the aims of study. All the interviews were conducted by one co-author, who also had been involved in balance-training for ten of the informants. This may have produced bias, since the informants already knew the interviewer and might not have been comfortable disclosing negative thoughts or experiences with the balance-training. However, this interviewer was considered to be most suitable member of the research team, since she, as a physiotherapist, had extensive experience in meeting patients with different types of balance impairments in clinical settings and had good insight and knowledge of the aim of Study IV, as well as the larger randomized controlled study.

Four co-authors were involved in different steps of data analysis for the qualitative study, and triangulation was performed. All the authors took an active part, and during several meetings the different steps in the analysis were discussed and the results were supported by several quotations from the interviews.

To ensure stability in data collection, a semi-structured interview guide was used. All the interviews were transcribed after all interviews had been completed. Then the interviews were analysed over a limited period of time so as to reduce the risk of changes in data over time and/or variations in the authors' criteria during the analysis process.

To facilitate transferability, the characteristics of the informants were thoroughly described so as to give a rich description of the included participants. Similar results for these phenomena were also found in previous published studies for other groups (120, 121), and this may also facilitate transferability to a broader context or different populations. This might primarily apply to physically active older adults or to seniors who are well aware of the effect of exercise.

The pre-understanding for the four authors differed, ranging from extensive experience in treating and dealing with this group of informants, involvement in both test situations during the randomized controlled trial, responsibility for conducting the intervention with all the informants, extensive clinical experience in the rehabilitation of individuals with various balance problems and solid knowledge of different types of balance disorders and how they impact daily living; to have no connection to the informants but a good methodological knowledge and experience in conducting qualitative studies. All this was considered a strength when analysing the data from the study, since these authors were well equipped to connect with and understand the informants and their experiences.

6 CONCLUSION

The Falls Efficacy Scale-International is a reliable questionnaire for older individuals with increased fall risk, but it has low convergent validity with balance performance tests and health-related quality of life among older women with osteoporosis.

The specific and progressive balance-training programme, focusing on dual- and multi-task exercises, improves fall-related concerns, gait speed and physical function in older adults with osteoporosis and had positive long-term effects.

To cope with the fragility caused by osteoporosis, informants had an internalised risk perception that protected them against possible threats and harm. Informants perceived improved empowerment and self-efficacy after participation in balance-training. They resumed activities and became more active and independent in daily life using safety precautions and fall-prevention strategies. Depending on contextual factors, some situations still invoked fear and led to avoidance.

7 CLINICAL IMPLICATIONS

When evaluating or measuring fall-related concerns it is important to be aware of the different significant constructs and to choose the most appropriate assessment; it is also important to consider the use of different assessments to reflect several of the constructs.

This specific and progressive balance-training programme has positive short- and long-term effects in terms of improved fall-related concerns, gait and physical function. The participants found the programme fun and enjoyable.

It is important to identify participants that might need more support and to individually adjust the intervention, thereby making it easier for such participants to become more physically active and stay active in daily life.

Older women with osteoporosis perceived fragility, and their internalised risk awareness influences their perception of fall-related concerns and balance performance in daily life, depending on contextual and personal factors. Furthermore, in clinical settings, in training programmes and when trying to influence strategies for fall-related concerns in older women with osteoporosis, it is important to recall that contextual and personal factors have a major influence on how older women with osteoporosis perceive fall-related concerns and balance performance.

8 FUTURE RESEARCH

In the future we believe that interventions that have been tested and evaluated in randomized controlled trials with high-quality results should be the subject of research concerning their implementation in clinical settings, with the purpose to render the intervention available for the populations it was actually designed for. Therefore, the next step is to implement this type of balance-training for older adults in the community.

In this research project additional information was gained in the qualitative interviews concerning thoughts about the importance of this type of balance-training and the lack of such interventions in primary care.

Based on results from two randomized controlled trials, the lack of this type of intervention in primary care settings and the benefits both to older adults and to society from getting older adults more physically active and improving their fall-related concerns, balance and gait and thereby reduce the risk of falling and fall-related consequences that could lead to great costs for the society and for the individual, we think that the next step, i.e. the implementation of the programme, is highly merited.

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10 REFERENCES

1. Statistiska centralbyrån. Sveriges framtida befolkning 2013–2060. http://www.scb.se/Statistik/BE/BE0401/2013I60/BE0401_2013I60_SM_BE18SM1301.pdf2013 [2014-12-03].

2. World Health Organization. Definition of an older or elderly person. http://www.who.int/healthinfo/survey/ageingdefnolder/en/ [2014-12-03].

3. Spirduso W, Francis, KL, MacRae PG. Physical dimensions of aging. 2 ed: Champaign (IL): Human Kinetics; 2005.

4. Gillespie LD, Robertson MC, Gillespie WJ, Lamb SE, Gates S, Cumming RG, et al. Interventions for preventing falls in older people living in the community. The Cochrane database of systematic reviews. 2009(2):CD007146. Epub 2009/04/17.

5. Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. The New England journal of medicine. 1988;319(26):1701-7. Epub 1988/12/29.

6. Lach HW, Reed AT, Arfken CL, Miller JP, Paige GD, Birge SJ, et al. Falls in the elderly: reliability of a classification system. Journal of the American Geriatrics Society. 1991;39(2):197-202. Epub 1991/02/01.

7. Shumway-Cook A. Motor Control-translating research into clinical practise. 4 ed ed. Philadelphia: Lippincott Williams &Wilkins; 2011.

8. Hernlund E, Svedbom A, Ivergard M, Compston J, Cooper C, Stenmark J, et al. Osteoporosis in the European Union: medical management, epidemiology and economic burden. A report prepared in collaboration with the International Osteoporosis Foundation (IOF) and the European Federation of Pharmaceutical Industry Associations (EFPIA). Archives of osteoporosis. 2013;8(1-2):136. Epub 2013/10/12.

9. Murphy SL, Williams CS, Gill TM. Characteristics associated with fear of falling and activity restriction in community-living older persons. Journal of the American Geriatrics Society. 2002;50(3):516-20. Epub 2002/04/12.

10. Sturnieks DL, St George R, Lord SR. Balance disorders in the elderly. Neurophysiologie clinique = Clinical neurophysiology. 2008;38(6):467-78. Epub 2008/11/26.

11. International Osteoporosis Foundation. http://www.iofbonehealth.org/ [2014-12-03].

12. Consensus development conference: diagnosis, prophylaxis, and treatment of osteoporosis. The American journal of medicine. 1993;94(6):646-50. Epub 1993/06/01.

13. World Health Organization. Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. 1994.

14. Professional associations for physical activity (Sweden) and Swedish National Institutet of Public Health. Physcial activity in the prevention and treatment of diseases. Stockholm, Sweden: Elanders; 2010.

15. Reginster JY. Antifracture efficacy of currently available therapies for postmenopausal osteoporosis. Drugs. 2011;71(1):65-78. Epub 2010/12/24.

16. Socialstyrelsen. Nationella riktlinjer för rörelseorganens sjukdomar 2012 - Osteoporos, artros, inflammatorisk ryggsjukdom och ankyloserande spondylit, psoriasisartrit och reumatoid artrit - Stöd för styrning och ledning.

http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/18665/2012-5-1.pdf2012 [2014-12-03].

17. Karinkanta S, Heinonen A, Sievanen H, Uusi-Rasi K, Pasanen M, Ojala K, et al. A multi-component exercise regimen to prevent functional decline and bone fragility in home-dwelling elderly women: randomized, controlled trial. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2007;18(4):453-62. Epub 2006/11/15.

18. Wilhelm M, Roskovensky G, Emery K, Manno C, Valek K, Cook C. Effect of resistance exercises on function in older adults with osteoporosis or osteopenia: a systematic review. Physiotherapy Canada Physiotherapie Canada. 2012;64(4):386-94. Epub 2013/09/03.

19. Li WC, Chen YC, Yang RS, Tsauo JY. Effects of exercise programmes on quality of life in osteoporotic and osteopenic postmenopausal women: a systematic review and meta-analysis. Clinical rehabilitation. 2009;23(10):888-96. Epub 2009/09/01.

20. Hongo M, Itoi E, Sinaki M, Miyakoshi N, Shimada Y, Maekawa S, et al. Effect of low-intensity back exercise on quality of life and back extensor strength in patients with osteoporosis: a randomized controlled trial. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2007;18(10):1389-95. Epub 2007/06/19.

21. Kukuljan S, Nowson CA, Bass SL, Sanders K, Nicholson GC, Seibel MJ, et al. Effects of a multi-component exercise program and calcium-vitamin-D3-fortified milk on bone mineral density in older men: a randomised controlled trial. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2009;20(7):1241-51. Epub 2008/10/30.

22. Giangregorio LM, Macintyre NJ, Thabane L, Skidmore CJ, Papaioannou A. Exercise for improving outcomes after osteoporotic vertebral fracture. The Cochrane database of systematic reviews. 2013;1:CD008618. Epub 2013/02/27.

23. Dusdal K, Grundmanis J, Luttin K, Ritchie P, Rompre C, Sidhu R, et al. Effects of therapeutic exercise for persons with osteoporotic vertebral fractures: a systematic review. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2011;22(3):755-69. Epub 2010/12/17.

24. Giangregorio LM, Papaioannou A, Macintyre NJ, Ashe MC, Heinonen A, Shipp K, et al. Too Fit To Fracture: exercise recommendations for individuals with osteoporosis or osteoporotic vertebral fracture. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2014;25(3):821-35. Epub 2013/11/28.

25. Gillespie LD, Robertson MC, Gillespie WJ, Sherrington C, Gates S, Clemson LM, et al. Interventions for preventing falls in older people living in the community. The Cochrane database of systematic reviews. 2012;9:CD007146. Epub 2012/09/14.

26. Karlsson MK, Magnusson H, von Schewelov T, Rosengren BE. Prevention of falls in the elderly--a review. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2013;24(3):747-62. Epub 2013/01/09.

27. Perry SB, Downey PA. Fracture risk and prevention: a multidimensional approach. Physical therapy. 2012;92(1):164-78. Epub 2011/09/17.

28. Sherrington C, Whitney JC, Lord SR, Herbert RD, Cumming RG, Close JC. Effective exercise for the prevention of falls: a systematic review and meta-analysis. Journal of the American Geriatrics Society. 2008;56(12):2234-43. Epub 2008/12/20.

29. Madureira MM, Takayama L, Gallinaro AL, Caparbo VF, Costa RA, Pereira RM. Balance training program is highly effective in improving functional status and reducing the risk of falls in elderly women with osteoporosis: a randomized controlled trial. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2007;18(4):419-25. Epub 2006/11/08.

30. Delbaere K, Crombez G, Vanderstraeten G, Willems T, Cambier D. Fear-related avoidance of activities, falls and physical frailty. A prospective community-based cohort study. Age and ageing. 2004;33(4):368-73. Epub 2004/03/30.

31. Scheffer AC, Schuurmans MJ, van Dijk N, van der Hooft T, de Rooij SE. Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons. Age and ageing. 2008;37(1):19-24. Epub 2008/01/16.

32. Zijlstra GA, van Haastregt JC, van Eijk JT, van Rossum E, Stalenhoef PA, Kempen GI. Prevalence and correlates of fear of falling, and associated avoidance of activity in the general population of community-living older people. Age and ageing. 2007;36(3):304-9. Epub 2007/03/24.

33. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR. Balance disorder and increased risk of falls in osteoporosis and kyphosis: significance of kyphotic posture and muscle strength. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2005;16(8):1004-10. Epub 2004/11/19.

34. Arnold CM, Busch AJ, Schachter CL, Harrison L, Olszynski W. The relationship of intrinsic fall risk factors to a recent history of falling in older women with osteoporosis. J Orthop Sports Phys Ther. 2005;35(7):452-60. Epub 2005/08/20.

35. Kanis JA. Diagnosis of osteoporosis and assessment of fracture risk. Lancet. 2002;359(9321):1929-36. Epub 2002/06/12.

36. Chamberlin ME, Fulwider BD, Sanders SL, Medeiros JM. Does fear of falling influence spatial and temporal gait parameters in elderly persons beyond changes associated with normal aging? The journals of gerontology Series A, Biological sciences and medical sciences. 2005;60(9):1163-7. Epub 2005/09/27.

37. Reelick MF, van Iersel MB, Kessels RP, Rikkert MG. The influence of fear of falling on gait and balance in older people. Age and ageing. 2009;38(4):435-40. Epub 2009/05/20.

38. Zijlstra GA, van Haastregt JC, van Rossum E, van Eijk JT, Yardley L, Kempen GI. Interventions to reduce fear of falling in community-living older people: a systematic review. Journal of the American Geriatrics Society. 2007;55(4):603-15. Epub 2007/04/03.

39. Tennstedt S, Howland J, Lachman M, Peterson E, Kasten L, Jette A. A randomized, controlled trial of a group intervention to reduce fear of falling and associated activity restriction in older adults. The journals of gerontology Series B, Psychological sciences and social sciences. 1998;53(6):P384-92. Epub 1998/11/25.

40. Kendrick D, Kumar A, Carpenter H, Zijlstra GA, Skelton DA, Cook JR, et al. Exercise for reducing fear of falling in older people living in the community. The Cochrane database of systematic reviews. 2014;11:CD009848. Epub 2014/11/29.

41. Tinetti ME, Richman D, Powell L. Falls efficacy as a measure of fear of falling. Journal of gerontology. 1990;45(6):P239-43. Epub 1990/11/01.

42. Powell LE, Myers AM. The Activities-specific Balance Confidence (ABC) Scale. The journals of gerontology Series A, Biological sciences and medical sciences. 1995;50A(1):M28-34. Epub 1995/01/01.

43. Moore DS, Ellis R. Measurement of fall-related psychological constructs among independent-living older adults: a review of the research literature. Aging & mental health. 2008;12(6):684-99. Epub 2008/11/22.

44. Jorstad EC, Hauer K, Becker C, Lamb SE. Measuring the psychological outcomes of falling: a systematic review. Journal of the American Geriatrics Society. 2005;53(3):501-10. Epub 2005/03/04.

45. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age and ageing. 2005;34(6):614-9. Epub 2005/11/04.

46. Yardley L, Smith H. A prospective study of the relationship between feared consequences of falling and avoidance of activity in community-living older people. The Gerontologist. 2002;42(1):17-23. Epub 2002/01/30.

47. Tinetti ME, Powell L. Fear of falling and low self-efficacy: a case of dependence in elderly persons. Journal of gerontology. 1993;48 Spec No:35-8. Epub 1993/09/01.

48. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychological review. 1977;84(2):191-215. Epub 1977/03/01.

49. Woollacott MH, Shumway-Cook A. Changes in posture control across the life span--a systems approach. Physical therapy. 1990;70(12):799-807. Epub 1990/12/01.

50. Horak FB, Macpherson JM. Postural orientation and equilibrium. In: Smith JL, editor. Handbook of Physiology: Section 12: Exercise: Regulation and Integration of Multiple Systems. New York: Oxford University Press; 1996. p. 255-92.

51. Woollacott MH. Systems contributing to balance disorders in older adults. The journals of gerontology Series A, Biological sciences and medical sciences. 2000;55(8):M424-8. Epub 2000/08/22.

52. Horak FB, Wrisley DM, Frank J. The Balance Evaluation Systems Test (BESTest) to differentiate balance deficits. Physical therapy. 2009;89(5):484-98. Epub 2009/03/31.

53. Woollacott M, Shumway-Cook A. Attention and the control of posture and gait: a review of an emerging area of research. Gait & posture. 2002;16(1):1-14. Epub 2002/07/20.

54. Jensen J, Lundin-Olsson L, Nyberg L, Gustafson Y. Fall and injury prevention in older people living in residential care facilities. A cluster randomized trial. Annals of internal medicine. 2002;136(10):733-41. Epub 2002/05/22.

55. Lundin-Olsson L, Nyberg L, Gustafson Y. "Stops walking when talking" as a predictor of falls in elderly people. Lancet. 1997;349(9052):617. Epub 1997/03/01.

56. Lindsey C, Brownbill RA, Bohannon RA, Ilich JZ. Association of physical performance measures with bone mineral density in postmenopausal women. Archives of physical medicine and rehabilitation. 2005;86(6):1102-7. Epub 2005/06/15.

57. Lynn SG, Sinaki M, Westerlind KC. Balance characteristics of persons with osteoporosis. Archives of physical medicine and rehabilitation. 1997;78(3):273-7. Epub 1997/03/01.

58. Campbell AJ, Borrie MJ, Spears GF. Risk factors for falls in a community-based prospective study of people 70 years and older. Journal of gerontology. 1989;44(4):M112-7. Epub 1989/07/01.

59. Cress ME, Schechtman KB, Mulrow CD, Fiatarone MA, Gerety MB, Buchner DM. Relationship between physical performance and self-perceived physical function. Journal of the American Geriatrics Society. 1995;43(2):93-101. Epub 1995/02/01.

60. Studenski S, Perera S, Patel K, Rosano C, Faulkner K, Inzitari M, et al. Gait speed and survival in older adults. JAMA : the journal of the American Medical Association. 2011;305(1):50-8. Epub 2011/01/06.

61. Cesari M, Kritchevsky SB, Penninx BW, Nicklas BJ, Simonsick EM, Newman AB, et al. Prognostic value of usual gait speed in well-functioning older people--results from the Health, Aging and Body Composition Study. Journal of the American Geriatrics Society. 2005;53(10):1675-80. Epub 2005/09/27.

62. Maki BE. Gait changes in older adults: predictors of falls or indicators of fear. Journal of the American Geriatrics Society. 1997;45(3):313-20. Epub 1997/03/01.

63. Löfgren N, Halvarsson A, Ståhle A, Franzen E. Gait in older women with osteoporosis and fear of falling. European Journal of Physiotherapy. 2012;15(3):139-45.

64. van Iersel MB, Kessels RP, Bloem BR, Verbeek AL, Olde Rikkert MG. Executive functions are associated with gait and balance in community-living elderly people. The journals of gerontology Series A, Biological sciences and medical sciences. 2008;63(12):1344-9. Epub 2009/01/08.

65. Melzer I, Oddsson LI. The effect of a cognitive task on voluntary step execution in healthy elderly and young individuals. Journal of the American Geriatrics Society. 2004;52(8):1255-62. Epub 2004/07/24.

66. Melzer I, Kurz I, Shahar D, Oddsson LI. Predicting injury from falls in older adults: comparison of voluntary step reaction times in injured and noninjured fallers--a prospective study. Journal of the American Geriatrics Society. 2009;57(4):743-5. Epub 2009/04/28.

67. Segev-Jacubovski O, Herman T, Yogev-Seligmann G, Mirelman A, Giladi N, Hausdorff JM. The interplay between gait, falls and cognition: can cognitive therapy reduce fall risk? Expert review of neurotherapeutics. 2011;11(7):1057-75. Epub 2011/07/05.

68. Shumway-Cook A, Woollacott M. Motor Control: Theroy and Practical Applications. 2nd ed. Baltimore.: Lippincott, Williams and Wilkens; 2000.

69. Teasdale N, Simoneau M. Attentional demands for postural control: the effects of aging and sensory reintegration. Gait & posture. 2001;14(3):203-10. Epub 2001/10/16.

70. Alexander NB, Hausdorff JM. Guest editorial: linking thinking, walking, and falling. The journals of gerontology Series A, Biological sciences and medical sciences. 2008;63(12):1325-8. Epub 2009/01/08.

71. Caspersen CJ, Powell KE, Christenson GM. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. Public Health Rep. 1985;100(2):126-31. Epub 1985/03/01.

72. Howe TE, Rochester L, Neil F, Skelton DA, Ballinger C. Exercise for improving balance in older people. The Cochrane database of systematic reviews. 2011(11):CD004963. Epub 2011/11/11.

73. Karlsson MK, Gerdhem P, Ahlborg HG. The prevention of osteoporotic fractures. The Journal of bone and joint surgery British volume. 2005;87(10):1320-7. Epub 2005/09/29.

74. Malmros B, Mortensen L, Jensen MB, Charles P. Positive effects of physiotherapy on chronic pain and performance in osteoporosis. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 1998;8(3):215-21. Epub 1998/11/03.

75. Jensen J, Nyberg L, Rosendahl E, Gustafson Y, Lundin-Olsson L. Effects of a fall prevention program including exercise on mobility and falls in frail older people living in residential care facilities. Aging clinical and experimental research. 2004;16(4):283-92. Epub 2004/12/04.

76. Nitz JC, Choy NL. The efficacy of a specific balance-strategy training programme for preventing falls among older people: a pilot randomised controlled trial. Age and ageing. 2004;33(1):52-8. Epub 2003/12/30.

77. Melzer I, Oddsson L. Improving balance control and self-reported lower extremity function in community-dwelling older adults: a randomized control trial. Clinical rehabilitation. 2013;27(3):195-206. Epub 2012/07/28.

78. Halvarsson A, Franzen E, Faren E, Olsson E, Oddsson L, Stahle A. Long-term effects of new progressive group balance training for elderly people with increased risk of falling - a randomized controlled trial. Clinical rehabilitation. 2013;27(5):450-8. Epub 2012/11/02.

79. Bird M, Hill KD, Ball M, Hetherington S, Williams AD. The long-term benefits of a multi-component exercise intervention to balance and mobility in healthy older adults. Archives of gerontology and geriatrics. 2011;52(2):211-6. Epub 2010/04/27.

80. Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. Psychol Bull. 1979;86(2):420-8. Epub 1979/03/01.

81. Bland JM, Altman DG. A note on the use of the intraclass correlation coefficient in the evaluation of agreement between two methods of measurement. Comput Biol Med. 1990;20(5):337-40. Epub 1990/01/01.

82. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1(8476):307-10. Epub 1986/02/08.

83. Domholdt E. Rehabilitation research principles and applications. 3 ed: Elsevier Saunders; 2005.

84. Bond T, Fox C. Applying Rasch Model Fundemental Measurement in the Human Sciences. 2nd ed. New York, United State of America: Routledge; 2007.

85. Halvarsson A, Oddsson L, Olsson E, Faren E, Pettersson A, Stahle A. Effects of new, individually adjusted, progressive balance group training for elderly people with fear of falling and tend to fall: a randomized controlled trial. Clinical rehabilitation. 2011;25(11):1021-31. Epub 2011/08/19.

86. Norman GS, D. Biostatistics. The Bare Essentials. Second Edition.2000.

87. Frändin K, Grimby G. Assessment of physicak activity, fitness and performance in 76-year-olds. Scand J Med Sci Sports. 1994;4:41-6.

88. Nordell E, Andreasson M, Gall K, Thorngren KG. Evaluating the Swedish version of the Falls Efficacy Scale-International (FES-I). Advances in Physiotherapy. 2009;11(2):81-7.

89. Halvarsson A, Ståhle A. Psychometric properties of the Swedish version of the Falls Efficacy Scale-International for older adults with osteoporosis, self-reported balance deficits and fear of falling. Submitted. 2014.

90. Jarnlo GB, Nordell, E. Reliability of the modified figure of eight- a balance performance test for elderly women. Physiotherapy Theory and Practice. 2003;19:35-43.

91. Frandin K, Sonn U, Svantesson U, Grimby G. Functional balance tests in 76-year-olds in relation to performance, activities of daily living and platform tests. Scandinavian journal of rehabilitation medicine. 1995;27(4):231-41. Epub 1995/12/01.

92. Webster KE, Wittwer JE, Feller JA. Validity of the GAITRite walkway system for the measurement of averaged and individual step parameters of gait. Gait & posture. 2005;22(4):317-21. Epub 2005/11/09.

93. Menz HB, Latt MD, Tiedemann A, Mun San Kwan M, Lord SR. Reliability of the GAITRite walkway system for the quantification of temporo-spatial parameters of gait in young and older people. Gait & posture. 2004;20(1):20-5. Epub 2004/06/16.

94. Haley SM, Jette AM, Coster WJ, Kooyoomjian JT, Levenson S, Heeren T, et al. Late Life Function and Disability Instrument: II. Development and evaluation of the function component. The journals of gerontology Series A, Biological sciences and medical sciences. 2002;57(4):M217-22. Epub 2002/03/23.

95. Roaldsen KS, Halvarsson A, Sarlija B, Franzen E, Stahle A. Self-reported function and disability in late life - cross-cultural adaptation and validation of the Swedish version of the late-life function and disability instrument. Disability and rehabilitation. 2014;36(10):813-7. Epub 2013/08/16.

96. Sullivan M, Karlsson J, Ware JE, Jr. The Swedish SF-36 Health Survey--I. Evaluation of data quality, scaling assumptions, reliability and construct validity across general populations in Sweden. Soc Sci Med. 1995;41(10):1349-58. Epub 1995/11/01.

97. Sullivan M, Karlsson, J., Ware, J. . Hälsoenkät. Manual och Svensk Tolkningsguide [SF-36 Health Survey. Swedish manual and Interpretation guide] (In Swedish). Göteborg1994.

98. Folstein MF, Luria R. Reliability, validity, and clinical application of the Visual Analogue Mood Scale. Psychol Med. 1973;3(4):479-86. Epub 1973/11/01.

99. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975;12(3):189-98. Epub 1975/11/01.

100. Halvarsson A, Dohrn IM, Stahle A. Taking balance training for older adults one step further: the rationale for and a description of a proven balance training programme. Clinical rehabilitation. 2014. Epub 2014/09/10.

101. Oddsson L, Boissy P, Melzer I. How to improve gait and balance function in elderly individuals- compliance with principles of training. European Review of Aging and physical activity. 2007;4(1):15-23.

102. Garber CE, Blissmer B, Deschenes MR, Franklin BA, Lamonte MJ, Lee IM, et al. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. Medicine and science in sports and exercise. 2011;43(7):1334-59. Epub 2011/06/23.

103. Gentile A. Movement science: Foundations for physical therapy in rehabilitation. In: Carr JH SRE, editor. Skill acquisition: action, movement and neuromotor processes. Rockville: Aspen1987.

104. Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. J Strength Cond Res. 2005;19(1):231-40. Epub 2005/02/12.

105. Altman DG. Practical statistics for medical research. London: Chapman & Hall; 1991.

106. Cronbach LJ. Coefficient alhpa and the internal structure of tests. Psycometrika. 1951;16:297-334.

107. Munro BH. Statistical Methods for Health and Care Research Baltimore: Lippincott Williams & Wilkins; 2001.

108. Brown H, Prescott R. Applied mixed models in medicine. 2nd ed: Chichester John Wiley & Sons, Ltd.; 2006.

109. Kotrlik J, Williams H. The incorporation of effect size in information technology, learning, and performance research. Inf Technol, Learn Perform J 2003;21:1-7.

110. Cohen J. Statistical Power Analysis for the Behavioral Sciences. . 2nd ed. Hillsdale: Lawrence Erlbaum; 1988.

111. Elo S, Kyngas H. The qualitative content analysis process. Journal of advanced nursing. 2008;62(1):107-15. Epub 2008/03/21.

112. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurse education today. 2004;24(2):105-12. Epub 2004/02/11.

113. World Health Organization. International classifications of functioning, disability and health. http://www.who.int/classifications/icf/en2001 [2012-10-04].

114. Polit DF, Beck CT. Nursing research : generating and assessing evidence for nursing practice. 8 ed. Philadelphia: Lippincott Williams & Wilkins; 2008.

115. Kannus P, Uusi-Rasi K, Palvanen M, Parkkari J. Non-pharmacological means to prevent fractures among older adults. Ann Med. 2005;37(4):303-10. Epub 2005/07/16.

116. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. Int J Surg. 2012;10(1):28-55. Epub 2011/11/01.

117. Patton MQ. Qualitative Research & Evaluation Methods. 3rd ed: Sage Publications; 2002.

118. Elo S, Kääriäinen M, Kanste O, Pölkki T, Utriainen K, Kyngas H. Qualitative Content Analysis: A Focus on Trustwirthiness. SAGE open. 2014(January-March):1-10.

119. Krippendorff K. Content Analysis. An introduction to its methodology: SAGE Publications; 2013.

120. Roe B, Howell F, Riniotis K, Beech R, Crome P, Ong BN. Older people's experience of falls: understanding, interpretation and autonomy. Journal of advanced nursing. 2008;63(6):586-96. Epub 2008/09/24.

121. Reventlow SD, Hvas L, Malterud K. Making the invisible body visible. Bone scans, osteoporosis and women's bodily experiences. Soc Sci Med. 2006;62(11):2720-31. Epub 2005/12/17.