SAIJA KARINKANTA

# To Keep Fit and Function

## Effects of three exercise programs on multiple risk factors for falls and related fractures in home-dwelling older women

ACADEMIC DISSERTATION
To be presented, with the permission of
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To my loved ones

# Contents

# LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, which are referred to in the text by the Roman numerals I-IV:

I Karinkanta S, Heinonen A, Sievänen H, Uusi-Rasi K, Kannus P (2005): Factors predicting dynamic balance and quality of life in home-dwelling elderly women. Gerontology 51:116-121.

II Karinkanta S, Heinonen A, Sievänen H, Uusi-Rasi K, Pasanen M, Ojala K, Fogelholm M, Kannus P (2007): A multi-component exercise regimen to prevent functional decline and bone fragility in home-dwelling elderly women: randomized, controlled trial. Osteoporosis International 18:453-462.

III Karinkanta S, Heinonen A, Sievänen H, Uusi-Rasi K, Fogelholm M, Kannus P (2009): Maintenance of exercise-induced benefits in physical functioning and bone. Osteoporosis International 20:665-674

IV Karinkanta S, Nupponen R, Heinonen A, Pasanen M, Sievänen H, Uusi-Rasi K, Fogelholm M, Kannus P (2011): Effects of exercise intervention on health-related quality of life and fear of falling among home-dwelling older women: 12-month randomised, controlled trial and a one year follow-up. Journal of Aging and Physical Activity, *in press.*

# ABBREVIATIONS

| | |
|---|---|
| ADL | activities of daily living |
| AGS | American Geriatrics Society |
| ANCOVA | analysis of covariance |
| BMI | body mass index |
| BGS | British Geriatrics Society |
| BMC | bone mineral content |
| BMD | bone mineral density |
| BMU | basic multicellular unit |
| BSI | bone strength index |
| CI | confidence interval |
| CNS | central nervous system |
| CoA | cortical bone area |
| CoD | cortical bone density |
| CoM | centre of mass |
| CV | coefficient of variation |
| DXA | dual-energy X-ray absorptiometry |
| FoF | fear of falling |
| GEE | generalized estimating equation |
| GLM | generalized linear model |
| GRF | ground reaction force |
| HRQoL | health-related quality of life |
| HRT | hormone replacement therapy |
| HSA | hip structure analysis |
| ITT | intention-to-treat |
| MET | metabolic equivalent |
| MU | motor unit |
| pQCT | peripheral quantitative computed tomography |
| PRT | progressive resistance training |
| $R^2$ | square of the sample coefficient of determination |
| RaR | rate ratio |
| REML | restricted maximum likelihood estimation |
| RCT | randomized controlled trial |

| | |
|---|---|
| 1 RM | one repetition maximum |
| RPE | rated perceived exertion |
| RR | risk ratio |
| RT | reaction time |
| SD | standard deviation |
| SE | standard error |
| SEE | standard error of the equation |
| SMD | standardized mean difference |
| TrD | trabecular bone density |
| VAS | visual analogue scale |
| Z | section modulus, an index for bending strength |

# ABSTRACT

The thesis and its original publications are based on the randomized, controlled KAAMU exercise intervention study of the UKK Institute, Tampere, Finland. The intervention was conducted 2002-2004.

The purpose of the study was to evaluate the effects of two exercise programs and their combination on multiple risk factors for falls and fall-related fractures in home-dwelling older women. The feasibility of the exercise programs and maintenance of the training effects after cessation of the exercise intervention were also assessed.

One hundred and forty-nine women aged 70 to 78 years were randomly assigned to the four groups: 1) a resistance training group (RES), 2) a balance-jumping training group (BAL), 3) a combination group doing resistance and balance-jumping training (COMB), and 4) a control group (CON). The supervised training was three times a week for 12 months. One hundred and forty-four women (97%) participated in the 12-month assessment. Of these, 120 women (81%) continued to the subsequent one-year follow-up measurements (24-month assessment).

Muscle performance, balance, reaction time (RT), bone mass and structure, health-related quality of life (HRQoL) and fear of falling (FoF) were assessed at baseline, and at 12 and 24 months. Changes in health status, and falls and fractures during the intervention and the subsequent one-year follow-up were elicited by monthly questionnaires.

Main statistical analyses included ANCOVA, general linear models and generalized estimating equations (GEE models) and were primarily done on an ITT basis. In addition, the baseline data were used to assess the factors associated with dynamic balance and HRQoL in home-dwelling older women.

High lower limb extension force, brisk physical activity, small number of diseases, younger age, and better postural stability were associated with good performance of dynamic balance at baseline. Furthermore, good dynamic balance together with low number of diseases and daily walking at least 3 kilometers were associated with better HRQoL of the women.

Training compliance with the programs was found to be good. Attendance (calculated as percentage of all training sessions offered) was 67% (individual range 0 to 100%), being highest in the RES group (74%), followed by the COMB group (67%) and the BAL group (59%). No severe adverse events were reported and no differences in the numbers of monthly reported health problems were found between exercisers and controls ($p=.955$).

After the end of the intervention at 12 months, isometric lower limb extension force was 13-14% higher in the RES and COMB groups ($p=.001$), and the dynamic balance 6-8% better in the BAL and COMB ($p<.001$) groups than in the CON group. In addition, a 10% treatment effect was found in self-rated physical functioning between the COMB and the CON groups ($p=.047$). Further, the per protocol analysis indicated that the tibial shaft bone strength index (BSI) decreased 2% less in the COMB than in the CON group ($p=.032$). Concerning HRQoL, exercise intervention resulted in minor gain in General Health scale score. No between-group differences were seen in bone mineral content of the femoral neck, postural stability, RT, FoF or reported falls and fractures.

At 24 months, about half of the exercise-induced gains in dynamic balance and the tibial shaft BSI were seen in the COMB compared to CON ($p=.005$ and $.065$ respectively). The other beneficial effects had been lost.

In conclusion, high-to-moderate intensity resistance and balance-jumping training were safe and feasible exercise modalities for relatively healthy older women. Twelve-month resistance and balance-jumping training, especially in combination, prevented functional decline by improving muscle performance and dynamic balance as well as self-rated physical functioning. A positive effect found in the structure of the loaded tibia suggested that training could also prevent bone fragility. Some exercise-induced benefits were partially maintained one year after the cessation of the exercise intervention. However, to maintain the gains achieved, especially in muscle force and self-rated physical functioning, continued training seemed necessary.

# TIIVISTELMÄ

Väitöskirja perustuu UKK-instituutissa vuosina 2002-2004 tehtyyn ikäihmisten liikuntatutkimukseen (KAAMU). Tutkimus oli asetelmaltaan satunnaistettu, kontrolloitu koe, jossa arvioitiin kahden eri liikuntaharjoitteluohjelman sekä näiden yhdistelmän vaikutuksia kotona asuvien iäkkäiden naisten kaatumisten ja niihin liittyvien murtumien vaaratekijöihin. Lisäksi väitöskirjassa arvioitiin harjoitusohjelmien soveltuvuutta kyseiselle kohderyhmälle sekä saavutettujen harjoitusvaikutusten pysyvyyttä.

Sataneljäkymmentäyhdeksän 70–78 –vuotiasta tamperelaisnaista satunnaistettiin yhteen neljästä ryhmästä: 1) voimaharjoitteluryhmä (RES), 2) tasapaino-hyppelyharjoitteluryhmä (BAL), 3) yhdistetyn harjoittelun ryhmä, joka teki sekä voima- että tasapainohyppelyharjoitteita (COMB) ja 4) verrokkiryhmä (CON). Ohjattu ryhmäharjoittelu oli 3 kertaa viikossa 12 kuukauden ajan. Sataneljäkymmentäneljä naista (97 %) osallistui intervention päätyttyä 12-kuukauden mittauksiin. Lisäksi 120 naista (81 %) osallistui vuosi liikuntaintervention päättymisen jälkeen tehtyihin 24 kuukauden mittauksiin.

Tutkittavien henkilöiden lihasvoima, tasapaino, reaktioaika, luun massa ja rakenne, terveyteen liittyvää elämänlaatu sekä kaatumispelko arvioitiin tutkimuksen alussa sekä 12 ja 24 kuukauden kuluttua. Lisäksi tutkittavat vastasivat sekä intervention että seurannan aikana kuukausittaiseen kyselyyn koskien terveydentilaa sekä mahdollisesti sattuneita kaatumisia ja murtumia.

Ajan myötä tapahtuneiden muutosten tarkasteluun käytettiin tilastollisina analyysimalleina kovarianssianalyysia (ANCOVA), lineaarisia sekamalleja (GLM) sekä yleistettyjä estimointiyhtälöitä (GEE-mallit). Lisäksi tutkimuksen aloitusvaiheen osallistuneilta analysoitiin dynaamiseen tasapainoon sekä elämänlaatuun liittyviä tekijöitä.

Aloitusvaiheen analyysi osoitti, että hyvä alaraajojen ojentajien lihasvoima, reipas liikunta, vähäinen sairauksien määrä, alhaisempi ikä sekä vähäinen huojunta seisoma-asennossa olivat yhteydessä hyvään suoriutumiseen dynaamista tasapainoa mittaavasta testistä. Lisäksi hyvä dynaaminen tasapaino, vähäinen sairauksien määrä ja vähintään 3 kilometrin päivittäinen kävely olivat yhteydessä parempaan terveyteen liittyvän elämänlaatuun.

Intervention aikana tutkittavat osallistuivat harjoitteluryhmiin varsin hyvin. Osallistumisprosentti, laskettuna kaikista tarjotuista harjoituskerroista, oli 67 % (yksilöllinen vaihteluväli 0-100 %). Voimaharjoitteluryhmäläiset harjoittelivat ahkerimmin (74 %). Yhdistetyn harjoittelun ryhmässä ja tasapaino-hyppelyharjoitusryhmissä harjoitteluprosentit olivat 67 ja 59 %. Tutkittavat eivät raportoineet harjoittelun aikana vakavia haittavaikutuksia. Myöskään harjoitusryhmäläisten ja verrokkien kuukausittain raportoimat terveysongelmat eivät poikenneet toisistaan (p=.955).

12 kuukauden harjoitteluintervention päätyttyä oli alaraajojen ojentajalihasten isometrinen voima 13–14 % suurempi RES- ja COMB -ryhmissä (p=.001) ja dynaaminen tasapaino 6-8 % parempi BAL- ja COMB -ryhmissä (p<.001) kuin verrokeilla. Myös COMB-ryhmäläisten itsearvioitu fyysinen toimintakyky oli noin 10 % parempi verrokkiryhmään verrattuna (p=.047). Lisäksi aktiivisesti harjoitelleiden COMB-ryhmäläisten sääriluun lujuusindeksi heikkeni noin 2 % vähemmän kuin verrokeilla (p=.032). Elämänlaatua arvioitaessa harjoittelulla näytti oleva pientä positiivista vaikutusta tutkittavien kokemaan terveyteen. Sen sijaan harjoittelu ei vaikuttanut reisiluun kaulan mineraalimassaan, reaktioaikaan, seisoma-asennossa tapahtuvaan huojuntaan, kaatumispelkoon eikä raportoitujen kaatumisten tai murtumien määrään.

Vuosi harjoittelun lopettamisen jälkeen noin puolet harjoittelun avulla saavutetuista hyödyistä oli nähtävissä kehon dynaamista tasapainoa arvioivassa testissä (p=.005) sekä sääriluun lujuutta kuvaavassa indeksissä (p=.065). Muu harjoittelun avulla saavutettu hyöty oli kuitenkin menetetty seurannan aikana.

Johtopäätöksenä voitiin todeta, että vähintään kohtuullisesti rasittava voimaharjoittelu ja tasapaino-hyppelyharjoittelu olivat turvallisia ja käyttökelpoisia harjoitusmuotoja kotona asuville suhteellisen terveille iäkkäille naisille. Etenkin voima- ja tasapaino- ja hyppelyharjoitteita yhdistävä harjoittelu näytti ehkäisevän naisten toimintakyvyn heikkenemistä lisäämällä alaraajojen lihasvoimaa sekä parantamalla tasapainoa ja itsearvioitua fyysistä toimintakykyä. Harjoittelusta saattoi olla hyötyä myös luun lujuudelle. Vaikka joitakin harjoitteluvaikutuksia oli vielä nähtävissä vuosi harjoittelun lopettamisen jälkeen, tutkimus viittasi siihen, että harjoittelun jatkaminen on tarpeellista etenkin alaraajojen lihasvoiman ja fyysisen toimintakyvyn säilyttämiseksi.

# 1. INTRODUCTION

Most societies in the world are going grey due to longer life expectancy and lower birth rate. In Finland, the number of working aged people (15-64 yrs.) started to decrease last year since the first age class of the baby boom generation, those born after the Second World War, in 1945-1950, achieved official retirement age (Statistics Finland 2009). Moreover, it has been estimated that the proportion of Finns aged 65 or more will rise from the current 17% to 23% by the year 2020, and to 27% by 2040 (Statistics Finland 2010).

The time after the retirement, the so-called third age, is typically associated with many positive things, such as freedom, personal space and self-fulfillment. However, aging also predisposes to functional limitations, disability and dependence, especially after the eighth decade (Guralnik et al. 1996). This has negative consequences for both the individual and society. One such consequence is a tendency to fall and be injured. For example, in Finland over 7,000 hip fractures are reported annually, more than 90% of them are caused by a fall. Unfortunately, functional ability after hip fracture quite often remains below the pre-injury level resulting in increased need for long-term care. (Parkkari et al. 1999, "Care of patients with hip fractures" 2006, Kannus et al. 2006)

Aging is associated with several physiological changes in tissue, organ and function level. Because a part of these changes is suggested to be caused by decreased physical activity, not the aging process *per se,* regular exercise is currently highly recommended to all older adults. (Nelson et al. 2007, *Physical Activity Guidelines for Americans* 2008, Chodzko-Zajko et al. 2009)

However, the exercise recommendations have been based on studies with some variations in terms of the type, intensity, frequency and duration of the exercise and the study populations of older adults have been heterogeneous. Measured outcomes have also varied considerably.

For all these reasons, it is essential to compare potentially beneficial exercise programs with each other and use well-defined aspects of health and functioning as the outcome. Considering primary prevention, the possibilities of an exercise regimen should be considered in the early stages of the aging process; that is, when the functional ability of the individuals still is fairly good.

This thesis focuses on assessing the effects of two different exercise programs, alone or in combination, on multiple risk factors of falls and related fractures in relatively healthy home-dwelling older women. It also provides information about the feasibility of the exercise programs and the maintenance of the achieved benefits.

# 2. REVIEW OF THE LITERATURE

## 2.1 Aging and physical functioning

Proper physical functioning and mobility are essential for older adults' independence. Functional decline predisposes to the need for home services, hospitalization and even death (Kemper 1992, Guralnik et al. 1994, Penninx et al. 2000, Gill et al. 2004).

Functional decline may develop progressively. According to a commonly used model of the disablement process by Verbrugge and Jette (1994), chronic and acute conditions (e.g. disease or injury) may result in impairments of specific body systems, such as decreased muscle strength and impaired balance. Impairments, in turn, typically cause functional limitations in basic physical and mental actions, and are seen for example in mobility problems. Disability ensues when functional limitations cause difficulties in activities of daily life and thus limit older adults' independence. In addition, different predisposing risk factors and extra- and intra-individual factors, such as medical care, rehabilitation and lifestyle and behavior changes, may either accelerate or decelerate the individual disablement process.(Verbrugge and Jette 1994) In the early stages of functional decline, called preclinical disability, older people may also compensate and modify their task performance by changing the method, frequency, or time used for it (Fried et al. 1991, Fried et al. 2000, Wolinsky et al. 2005).

Regular physical activity is considered essential for healthy and active aging, since it can prevent and treat many common diseases, as well as preserve and restore good physical functioning (Nelson et al. 2007, *Physical Activity Guidelines for Americans* 2008, Chodzko-Zajko et al. 2009).

### 2.1.1 Effects of aging on physical performance

With advancing age, several physiological changes in different tissues, organ systems and functions occur affecting physical performance of older adults (Figure 1) (Chodzko-Zajko et al. 2009).

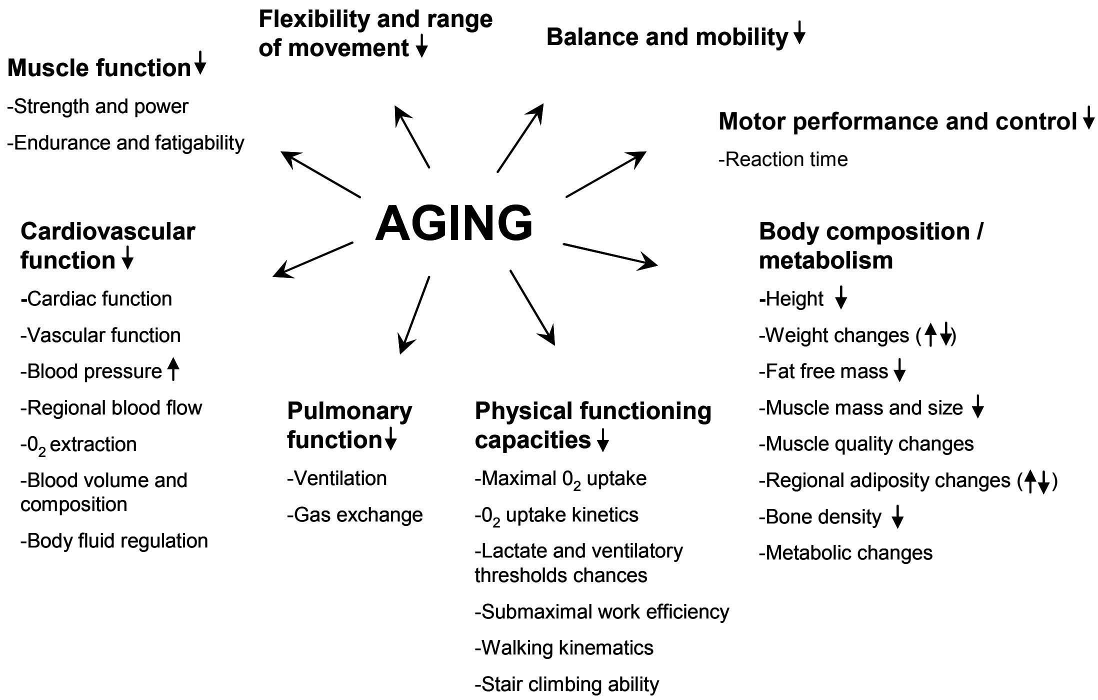



Figure 1. Schematic summary of typical changes in physiological systems and functions with advancing age in healthy people. Adapted from Chodzko-Zajko et al. (2009).

Of these physiological changes, the effects of aging on three important functions related to physical functioning (muscle function, balance, and motor performance and control) are presented in more detail in the following paragraphs. In addition, the role of exercise is discussed.

#### *2.1.1.1 Muscle function*

Aging is associated with the progressive decline of muscle mass, strength, quality and power (Vandervoort 2002, Thompson 2009, Aagaard et al. 2010). Peak musculoskeletal function is achieved in young adulthood -the 20s and early 30s. In middle age some slowing of contractions occurs, but changes in absolute muscle strength are minor until about the sixth decade. (Vandervoort 2002)

Maximum muscle strength, power, and rate of force development decrease with aging even in highly trained champion athletes (Korhonen 2009, Aagaard et al. 2010). From the sixth decade isometric muscle strength begins to decline approximately 1-1.5% per year, and therefore, healthy people in the seventh and eighth decades produce, on average, about 20-40% lower isometric strength than young adults. The age-related reductions in strength are most notable in weight-bearing lower limb muscles. Moreover, muscle power output and the ability to develop force quickly declines more rapidly than strength with aging. In addition to age, other factors, such as a sedentary lifestyle, inadequate nutrition, and diseases in the later years of life have deleterious effects on muscular capacity (Figure 2). (Vandervoort 2002, Hunter et al. 2004, Aagaard et al. 2010) In women, the changes in muscle mass and strength are also associated with menopause and related hormonal status (Maltais et al. 2009).

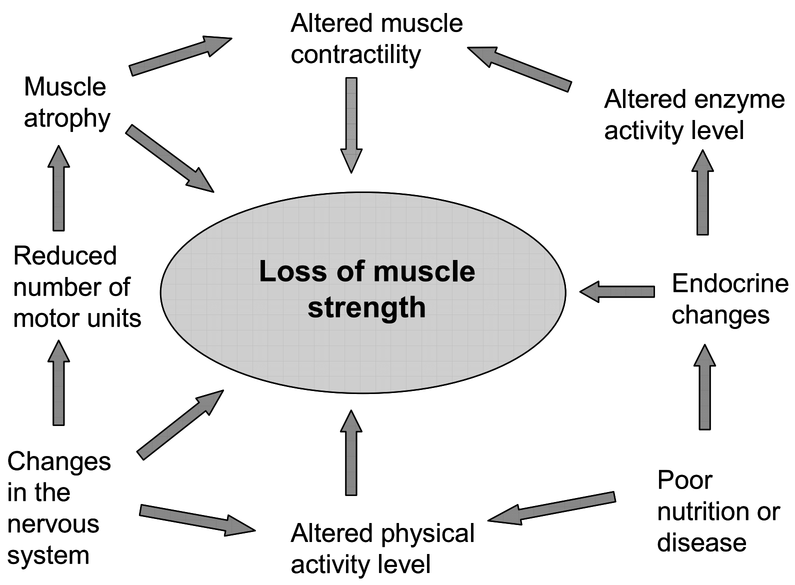



Figure 2. Proposed mechanisms leading to the loss of muscle strength with advancing age. Adapted from Porter et al. (1995) and Taylor and Johnson (2008).

Age-related decrease in muscle mass is mainly due to reduced number of type I and type II muscle fibers, size of type II muscle fibers, and increased amount of fat and connective tissue within the muscle (Vandervoort 2002, Maltais et al. 2009, Aagaard et al. 2010). Decrease in muscle strength and power is, in addition to muscle atrophy, caused by changes in nervous system. These changes are clearly seen in the motor unit (MU) function including loss of MUs, enlarged MUs and impaired ability to recruit MUs. Reduction in sarcoplasmic reticulum activity and actin sliding speed on myosin combined with type II muscle fiber atrophy also affects muscle quality by slowing especially lower limb muscle contractile properties.(Vandervoort 2002, Thompson 2009, Aagaard et al. 2010)

The clinical problems begin when the loss of muscle mass and strength are extensive, causing frailty, mobility problems, and loss of function and independence (Vandervoort 2002, Aagaard et al. 2010). In 1989, Irwin Rosenberg proposed the term sarcopenia to describe age-related decrease of muscle mass (Rosenberg 1989, Rosenberg 1997). There after, the term has been extended to cover the loss of muscle strength that occurs with advancing age. Recently the European Working Group on Sarcopenia in Older People defined sarcopenia as "a syndrome characterized by progressive and generalized loss of skeletal muscle mass and strength with a risk of adverse outcomes such as physical disability, poor quality of life and death" (Cruz-Jentoft et al. 2010). The degree of muscle mass and strength loss dictates whether or not an individual is considered sarcopenic (Hunter et al. 2004, Jones et al. 2009). However, since definitions and measurement protocols of sarcopenia have varied, the exact prevalence of this condition is not known. Estimates of studies from United States and Europe have varied from 5 to 13% and 11 to 50% for people aged 60-70 and older than 80 respectively (Waters et al. 2010).

Several mechanisms have been suggested to be involved in sarcopenia, including the aforementioned changes in muscle fiber quantity and quality, motor neurons and muscle fat content. In addition, decreases in protein synthesis rates, anabolic and sex hormone production, and basal metabolic rate, as well as increased dietary protein need and exposure to oxidative stress and inflammation are associated with sarcopenia (Cruz-Jentoft et al. 2010, Waters et al. 2010).

*Effects of exercise.* Physical activity can retard the loss of skeletal muscle and function. The clearest evidence comes from resistance training. (Chodzko-Zajko et al. 2009) Since the study by Frontera and co-workers in the 1980s showing large increases in both muscle strength and muscle fiber size after high-intensity resistance training in older men (Frontera et al. 1988), numerous studies have been conducted to replicate the results in different older populations.

Recently, a systematic Cochrane review of 121 randomized, controlled trials showed that progressive resistance training (PRT) has a large positive effect on muscle strength of lower limbs in older adults (standardized mean difference (SMD) 0.84, 95% confidence interval (CI) 0.67-1.00). In addition, beneficial effects were seen in physical ability and functional limitations, but these effects were modest to moderate in size (e.g. physical ability SMD 0.14, 95% CI 0.05-0.22). (Liu and Latham 2009) However, less is known about how long the beneficial effects of resistance training can be maintained among older adults after the cessation of training. Some evidence suggests that muscle strength can be maintained to some extent from 5 to 27 weeks (Lexell et al. 1995, Sforzo et al. 1995, Taaffe and Marcus 1997), but especially information regarding maintenance of the functional benefits is lacking (Liu and Latham 2009).

Even very old people can benefit from PRT (Fiatarone et al. 1990, Harridge et al. 1999). In fact, similar changes have been seen in response to heavy resistance training in both young and older adults (Macaluso and De Vito 2004). During the first two weeks improvements in the ability to perform a training exercise are mainly due to a learning effect. After that, during the next 3-4 weeks, the improvements are attributed to neural adaptations including increased number of recruited MUs, increased firing rate and synchronization of the individual MUs, a better coordination of synergistic and antagonist muscles, and an increased neural drive of the central nervous system. Most likely, the phase of learning effect includes similar adaptations. After 6 weeks of training, muscle size increases are also seen. It seems that both type I and type II muscle fibers retain their capacity for hypertrophy in response to resistance training. (Macaluso and De Vito 2004). It has been perceived, however, that given the same relative training stimulus, the hypertrophic response is lesser in older women than in older men (Hunter et al. 2004).

Given the positive effects of numerous prospective training studies (Liu and Latham 2009), resistance training is highly recommended to older adults. Recently done, or updated, physical activity recommendations of the American College of Sports Medicine, the American Heart Association and the U.S Department of Health and Human Services all highlight the importance of regular muscle strengthening exercises (Nelson et al. 2007, *Physical Activity Guidelines for Americans* 2008, Chodzko-Zajko et al. 2009). The recommendations state that, in addition to almost daily aerobic exercise, all older adults should include muscle strengthening activity or exercises for a minimum of twice a week. To maximize strength development, progressively advanced moderate-to-high intensity resistance training [~50-80% of 1 repetition maximum (RM)] for major muscle groups has been deemed as an advisable method (Nelson et al. 2007, *Physical Activity Guidelines for Americans* 2008, Cruz-Jentoft et al. 2010).

#### *2.1.1.2 Balance*

Balance is a commonly used term among health professionals, especially in clinical practice. It has no universally accepted definition, but it is typically used in association with such terms as stability and postural control. (Pollock et al. 2000) Good balance is associated with independence in instrumental activities of daily living, such as housework, cooking, shopping, and travel (Judge et al. 1996, Judge 2003). Impaired balance, instead, is a major risk factor for falls, fractures and admissions to nursing homes (Tinetti et al. 1988, Guralnik et al. 1994, Judge 2003, Wagner et al. 2009).

Postural control is defined as the act of maintaining, achieving or restoring a state of balance during any posture or activity (Pollock et al. 2000). Previously, postural control was considered an automatic task, kind of a summation of reflexes (Woollacott and Shumway-Cook 1990, Woollacott and Shumway-Cook 2002, Horak 2006). However, especially during this millennium the understanding of the complexity of postural control has substantially increased. Today, we realize that postural control is a complex skill based on the interaction of multiple sensory-motor processes (Pollock et al. 2000, Horak 2006). The role of the central nervous system (CNS) and attentional demands of balance control especially have been better understood (Pollock et al. 2000, Woollacott and Shumway-Cook 2002, Seidler et al. 2010). Therefore, the ability to stand, to walk and to interact with the environment safely requires many resources from different physiological systems (Figure 3). However, with advancing age substantial declines in these systems occur. (Horak 2006)

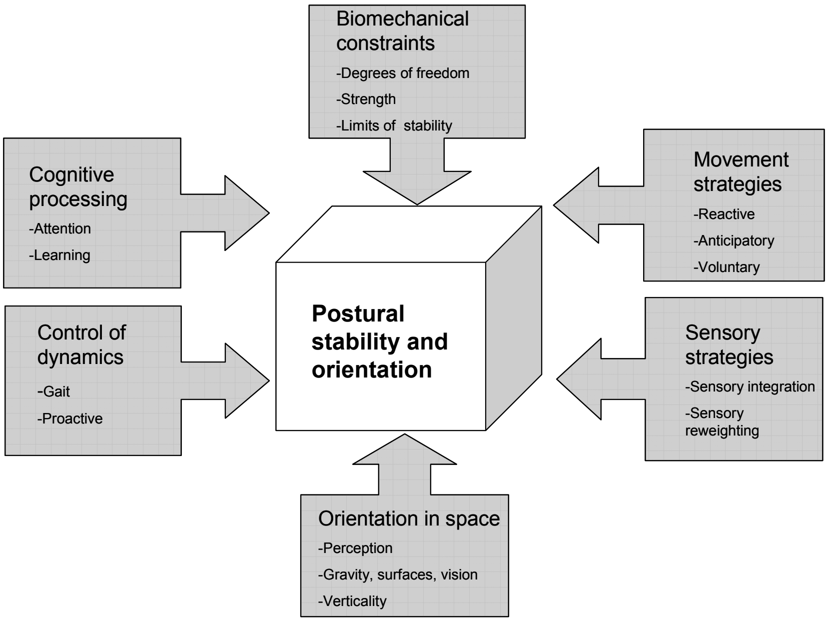



Figure 3. Important resources required for postural stability and orientation based on Horak's theoretical framework (2006).

Biomechanical constraints affecting postural stability include muscle strength and limits of stability (Horak 2006). Thus, age-related decreases in muscle function have deleterious effects on older adults' balance.

Three main types of movement strategies can be used to return the body to balance in a standing position. Ankle and hip strategies are used to keep the feet in place and only move the body's center of mass (CoM). Instead, reaching or stepping to recover balance changes the base of support. However, even when a person steps in response to an external perturbation, she or he first attempts to return the CoM to the initial position by exerting angle torque. (Pollock et al. 2000, Horak 2006) Before any voluntary movements, anticipatory (also called predictive) postural strategies are used to maintain stability, for example by increasing muscle activity (Woollacott and Tang 1997, Pollock et al. 2000, Horak 2006). With aging the tendency to use hip strategy or take a step when balance is threatened increases. In addition, older adults more often take multiple steps or use less demanding stepping patterns and thus avoid crossover steps. (Maki et al. 2000, Horak 2006, Maki and McIlroy 2006)

Sensory strategies play a major role in controlling balance (Woollacott and Shumway-Cook 1990, Horak 2006). Sensory information from somatosensory, visual and vestibular systems needs to be integrated to interpret complex sensory environments. Since these environments frequently change, relative dependence on each sense has to be re-weighted. (Horak 2006) For example, in a well-lit environment with a firm base of support, healthy people mainly rely on somatosensory inputs (~70%). However, when the surface becomes unstable, we need to increase sensory weighting to vestibular and vision information and decrease dependence on surface somatosensory inputs. (Peterka 2002, Horak 2006) Healthy older adults have measurable declines in each of sensory system related to balance, such as reduced touch and pressure sensation on plantar surfaces, joint position sense, visual acuity, visual edge detection, and vestibular input (Alexander 1994, Judge 2003). In addition, many diseases and disorders impair sensory systems and thus complicate the ability to re-weight postural sensory dependence further predisposing older people to falls in particular sensory contexts (Horak 2006).

Orientation in space; that is, the ability to orient the body parts with respect to gravity, the support surface, visual surrounding and internal references, is needed for postural control. Healthy people can identify gravitational vertical position in the dark to within 0.5° degrees. However, inaccurate internal representation of verticality will result in automatic postural alignment that is not aligned with gravity, and thereby rendering a person unstable. (Horak 2006)

Compared to quiet stance, the control of balance during gait and while changing from one posture to another is more challenging, since the body's CoM is not within the base of foot support (Woollacott and Tang 1997, Horak 2006). Proactive control mechanisms mainly relying on visual system and attention, are used to detect potential threats to stability during gait (Woollacott and Tang 1997). Frank and Patla (2003) describe walking as "a state of controlled falling in which we always are only one step away from disaster". In response to the high requirements of walking, older adults seem to assume a rigid posture, to narrow step lengths and widths, and to use more conservative strategies when negotiating obstacles. (Woollacott and Tang 1997)

In addition to the above mentioned systems, postural control requires many cognitive resources. The more difficult the postural task, the more cognitive processing is required. (Woollacott and Shumway-Cook 2002, Horak 2006) Furthermore, postural control appears to be more attentionally demanding in older adults than in young adults (Woollacott and Shumway-Cook 2002, Seidler et al. 2010). This is caused by age-related changes in brain structure, function and biochemistry. It has been suggested that central control mechanism is even more important to maintaining postural stability than the peripheral sensory-motor system in older adults. (Seidler et al. 2010) Therefore, the performance of a secondary task that is attentionally demanding is more deleterious to postural control in older adults than in younger people (Woollacott and Shumway-Cook 2002, Seidler et al. 2010).

*Effects of exercise*. Since balance control is considered a fundamental motor skill by the CNS, it is possible, like any other motor skill, to train and practice postural control strategies to become more efficient and effective (Pollock et al. 2000). Different types of exercise have been used to improve balance among older adults. A Cochrane review of 34 RCT-studies and 2883 participants concluded that interventions involving gait, balance, co-ordination and functional exercises or muscle strengthening exercises, as well as those including multiple exercise types have the greatest impact on balance. The effects were more clearly seen in indirect, that is, functional measures of balance, than in direct force platform indicators. Limited evidence, however, was found that the effects were long-lasting. (Howe et al. 2007)

On the other hand, Orr and colleagues (2008) found in their systematic review that PRT alone did not consistently improve older adult's balance performance – only about 20% of the balance tests used in 29 studies showed significance improvements compared to controls after PRT. Variation of the method used to assess balance, and length and intensity of the training programs may partly explain the results.

Instead, meta-analyses of fall prevention interventions clearly suggest that balance exercises or retraining, alone or in combination with other exercise modalities, are needed to prevent the most unwanted consequences of impaired balance – falls and fall-related injuries (Robertson et al. 2002, Sherrington et al. 2008, Gillespie et al. 2009). Therefore, all recent physical activity recommendations and guidelines recommend regular balance exercises, especially for fall-prone older adults (Nelson et al. 2007, *Physical Activity Guidelines for Americans* 2008, Chodzko-Zajko et al. 2009, "Summary of the Updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons" 2011).

To be effective, balance exercises should be physically challenging, frequently performed and long-lasting (Province et al. 1995, Li et al. 2005, Sherrington et al.

2008, Karinkanta et al. 2010). Moreover, in complexity of the postural control and especially its dependence on the environment and task, exercise should be diverse in nature and cover the wide range of situations that community-dwelling older adults may face in their daily lives (Frank and Patla 2003).

#### *2.1.1.3 Reaction time*

When a person meets a postural or other challenge or threat, the ability to react quickly and appropriately is needed (Lord and Sturnieks 2005). Therefore, it is no surprise that slow reaction time (RT) is associated with balance and mobility problems, increased risk for falling, and, for example, for unsafe driving in older adults (Lord and Ward 1994, Lord et al. 1996a, Sakari-Rantala et al. 1998, Lord and Menz 2002, Anstey et al. 2005, Sakari et al. 2010).

RT can be assessed by measuring the time taken to react to a stimulus. This reaction consists of decision and movement times, that is, time to initiate a movement and time to carry out the required response respectively. (Lord and Sturnieks 2005) RT tests can be simple, in which typically the same stimulus and response are used or choice-based in which stimulus, response or both vary (Era et al. 1986, Lord and Fitzpatrick 2001, Lord and Sturnieks 2005). Most commonly RT is measured by using the dominant hand or foot. However, more functional responses, such as stepping, jumping and whole-body responses are also used (Lord and Fitzpatrick 2001, Kalapotharakos et al. 2006, Shigematsu et al. 2008, Sasai et al. 2010).

From the age of twenty to the age of seventy, the simple dominant hand RT increases about 20%, and further decline is also seen thereafter (Fozard et al. 1994). In the Finnish Evergreen study initially 75 and 80-year-old men and women were followed-up for five years. Men showed a higher speed in a simple RT test compared to women. For both sexes, the declines, an average of 30 to 50%, were seen after five years. In addition, a slow performance in baseline measurements was a powerful predictor of death during the next five-year period. (Era and Rantanen 1997)

The changes in RT are caused by age-related deficit of peripheral sensory-motor functions and CNS (Birren and Fisher 1995, Seidler et al. 2010). Moreover, the interdependence of these systems seems to become stronger with aging (Li and Lindenberger 2002, Yordanova et al. 2004). It has been also suggested that aging is accompanied by a functional dysregulation of motor cortex excitability during sensory-motor processing, this deficit becoming progressively evident with greater task complexity (Yordanova et al. 2004). Recently, Godefroy and Roussel (2010) showed that the majority of simple RT slowing after the age 40 is due to perceptuomotor slowing, but after 60 years decline in attention is also seen.

*Effects of exercise.* Active older adults have faster RT than their inactive counterparts, indicating that exercise may have beneficial effects on reaction and movement speed (Baylor and Spirduso 1988, Emery et al. 1995, Era et al. 1995, Hatta et al. 2005). However, in RCT studies the results have been inconsistent in showing that reaction time can be improved by exercise intervention (Table 1). Half of the studies yielded no response (Panton et al. 1990, Roberts 1990, Whitehurst 1991, Hassmèn and Koivula 1997, Barnett et al. 2003, Liu-Ambrose et al. 2004a, Oken et al. 2006, Smiley-Oyen et al. 2008). It seems that the positive effects in simple hand or foot RT are seen when multiple exercises (balance, strength and aerobic) are combined, and the training is continued over 6 months (Rikli and Edwards 1991, Lord et al. 1995, Williams and Lord 1997, Lord et al. 2003). Nevertheless, positive outcomes are also seen after short-term square-stepping or aerobic exercise if functional responses, such as vertical jump or whole-body movements, are used (Table 1) (Kalapotharakos et al. 2006, Shigematsu et al. 2008).

*Table 1.* Effects of exercise on reaction time (RT) in RCT studies among older adults

| Study | Participants | Intervention | Reaction time outcome | Between-group difference |
|---|---|---|---|---|
| Panton et al. 1990 | n=49 healthy untrained men and women, 70-79 yrs, mean age 72y., USA | walking/jogging 3xwk vs. strength training 3xwk vs. CR, **6 months** | a simple hand RT (total RT, fractionated RT and speed of movement were measured) | no difference in any outcomes |
| Roberts 1990 | n=52 independent-living men and women, 65-87 yrs, mean age 72 y., USA | walking 3xwk vs. CR, **6 weeks** | a simple hand RT, a choice RT (also movement times (MT) were reported) | no difference in RTs or MTs |
| Rikli & Edwards 1991 | n=34 sedentary women, 57-85 yrs., mean age 70 y., USA | aerobic, balance, coordination and strengthening exercises (EX) 3xwk vs. CR , **3 years** | a simple hand RT, a choice RT | a simple RT improved in EX compared to CR (p=.014), a choice RT improvement was ns* |
| Whitehurst 1991 | n=14 healthy, sedentary women, 61-73 yrs, mean age 66 y., USA | cycling exercise 3xwk vs. CR, **8 weeks** | a simple hand RT, a choice RT | no difference in either RTs |
| Lord et al. 1995 | n=197 independent-living women, 60-85 yrs, mean age 72 y., Australia | balance, coordination, strengthening and endurance exercises 2xwk vs. CR, **8 weeks** | a simple foot RT | a simple foot RT improved in exercise group compared to CR (p<.01) |
| Hassmèn & Koivula 1997 | n=40 healthy men and women, 55-75 yrs., mean age 66 y., Sweden | walking 3xwk vs. control (mental tasks 3xwk), **3 months** | a simple hand RT, a choice RT | no difference |
| Rooks et al. 1997 | n=131 independent-living men and women, 65-95 yrs, mean age 73 y., USA | resistance training (RES) 3xwk vs. supervised walking 3xwk vs. CR, **3 months** | a simple foot RT | RES group improved compared to controls (p<.05) |
| Williams & Lord 1997 | n=187 community-dwelling women over 60 yrs, mean age 72 y., Australia | group (aerobic, balance and strength) exercise (EX) 2xwk vs. CR, **42 weeks** | a simple foot RT | RT improved in EX compared to CR (p=.022) |
| Barnett et al. 2003 | n=163 over 65 yrs men and women at risk of falling, mean age 75 y., Australia | balance-, coordination-, aerobic- and muscle exercises 1xwk + home exercises vs. CR , **6 months** | a simple foot RT | no difference |
| Lord et al. 2003 | n=551 older adults living in retirement villages, 62-90 yrs, mean age 80 y., Australia | weight-bearing group exercise (EX) 2xwk vs. combined CR (flexibility and relaxation 2xwk or no exercise), **12 months** | a simple hand RT, a choice stepping RT | Both improved in EX compared to combined CR (p<.05, p<.01) |

Continued overleaf

Table 1 continued

| Study | Participants | Intervention | Reaction time outcome | Between-group difference |
|---|---|---|---|---|
| Liu-Ambrose et al. 2004 | n=98 community-dwelling women with low bone mass, 75-85 yrs, mean age 79 y., Canada | resistance training 2xwk vs. agility training 2xwk vs. sham (stretching) exercise 2xwk, **6 months** | a simple hand RT, a simple foot RT | no difference either RT ($p=.09$, $p=.08$) |
| Kalapotharakos et al. 2006 | n=22 inactive men and women, 60-75 yrs, mean age 65, Greece | aerobic exercise (EX) 3xwk vs. CR, **12 weeks** | a choice whole-body RT | 20% improvement ($p<.05$) in the EX compared to CR |
| Oken et al. 2006 | n=135 relatively healthy men and women, 65-85 yrs, mean age 72 y., USA | yoga 1xwk + home exercises vs. walking outdoor tract 1xwk + home exercises vs. CR, **6 months** | a simple visual RT, a choice visual RT | no difference ($p=.76$, $p=.52$) |
| Shigematsu et al. 2008 | n=68 community-dwelling men and women, 65-74 yrs, mean age 69 y., Japan | square-stepping exercise (SSE) 2xwk vs. supervised walking (W) 1xwk, **12 weeks** | a vertical jump after a light signal (simple RT)<br>weight transfer time while stepping in different directions after a light signal (choice RT) | Both improved in SSE group compared to W ($p<.001$) |
| Smiley-Oyen et al. 2008 | n=57 independent-living men and women 64 y. or over, mean age 70 y., USA | cardiovascular exercise (CARDIO) 3xwk vs. flexibility exercises and weight-training (FLEX-TONE) 3xwk, **10 months** | a simple hand RT,<br>several choice RT tests | no difference |

CR=Control group (no exercise), ns=statistically non-significant, *$p=.034$, significance level was set at .01

## 2.2 Aging and bone

Bone is dynamic connective tissue whose structure and composition reflect a balance between the two major functions: provision of mechanical integrity for locomotion and protection, and involvement in the metabolic pathways associated with mineral homeostasis (Morgan et al. 2008). The responsibility to support loads that are imposed on bone during locomotion demands the bone to be strong and resilient, while at same time it must be lightweight and adaptive so that transportation does not become a metabolic burden (Khan et al. 2001a). The properties of bones do not remain constant with age. Instead, bone properties change throughout life; either improving or deteriorating (Boskey and Coleman 2010). With advancing age the latter option becomes more evident.

### 2.2.1 Bone structure and properties

The skeleton has two major parts: the axial and appendicular skeleton. The former comprises the bones of the head and trunk and the latter the bones of the upper and lower extremities. The macrostructure of long bones, such as tibia, femur and humerus, is divided into epiphysis, metaphysis and diaphysis parts (Morgan et al. 2008) (Figure 4).

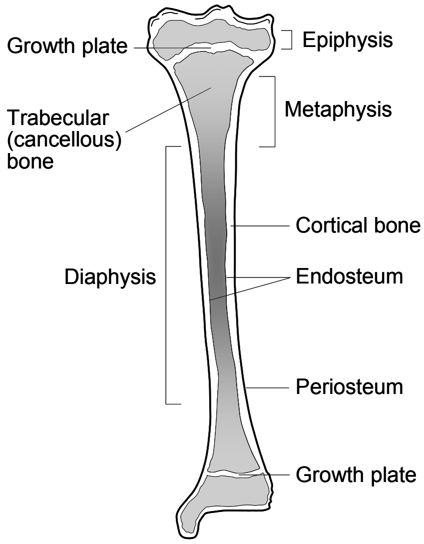



Figure 4. Schematic view of a growing long bone (tibia). Adapted from Khan et al. (2001a).

Bone tissue is organized into trabecular (also called cancellous or spongy) and cortical (compact or dense) bone. Trabecular bone, which is highly porous in structure, is principally found in the axial skeleton and in the epiphyses and metaphyses of the long bones. In contrast to trabecular bone, cortical bone is dense and highly calcified (~80% of volume), and forms primarily the rigid shaft of long bones. Both the epiphyses and metaphyses also have a thin shell of cortical bone surrounding the trabecular compartment. Cortical bone has two surfaces: endosteum and periosteum. Of these endosteum is metabolically active and heavily involved in bone formation and resorption. Periosteum, instead, contains of two layers and contributes, for example, to appositional bone growth during bone development and is responsible for increasing the diameters of the long bones with aging. (Khan et al. 2001a, Morgan et al. 2008) (Figure 4)

Bone tissue consists of inorganic (~60-70% by weight) and organic (~20-30%) materials and water (~5-10%). The inorganic phase comprises mainly an impure form of hydroxyapatite, a naturally occurring calcium phosphate. The organic phase is composed predominantly (98%) of type I collagen and a variety of noncollagenous proteins. The rest is made up of cells: osteoblasts, osteocytes and osteoclasts. These specialized bone cells are involved in the regulation of bone metabolism, by responding to multiple environmental signals including chemical, mechanical, electrical, and magnetic stimuli. (Khan et al. 2001a, Morgan et al. 2008)

Two different mechanisms are involved in bone turnover – modeling and remodeling. Modeling mainly occurs in the course of growth, and during the modeling process bone is added without previous bone resorption. (Forwood 2001). Instead, the adult skeleton is continuously remodeled (Chan and Duque 2002). During remodeling, old bone is removed by osteoclasts and replaced by osteoblasts. The teams of osteoclasts and osteoblasts constitute distinct anatomical structures: basic multicellular units (BMU). BMUs move in tandem with osteoclasts always in the front and osteoblasts following in rear. In healthy adult, the remodeling cycle lasts 6-9 months. All osteoclasts and 60-80% of osteoblasts die via apoptosis (that is, programmed cell death), and the remaining osteoblasts become either lining cells or osteocytes. In the past few years the function of osteocytes has been better understood. According to Manolagas and Parfitt (2010) osteocytes are the choreographers of the remodeling process on the bone surface by virtue of their ability to sense effete bone and direct the homing of osteoclasts to the site that is in need of remodeling. In addition, osteocytes produce factors that influence osteoblast and osteoclast generation as well as mineral homeostasis, mediate the homestatic adaptation of bone to mechanical loading, and control and modify mineralization of the matrix produced by osteoblasts. (Manolagas and Parfitt 2010)

*Mechanical properties.* The mechanical properties of bone are determined by material properties and bone structure (Morgan et al. 2008). Based on biomechanical principles, bone responds to forces such as gravity, ground reaction, and muscle contraction. When a force or load is applied to bone, an internal resistance develops – this is called stress. Stress (as force per unit) can be tensile, compression or shear in nature. Most forces applied to bone are a combination of the three stresses, resulting in bending, torsion or impact. The resulting deformation of the applied force is called strain. There is a linear relationship between stress and strain until the yield point of the curve is reached. After this point, called the plastic region, the stress-strain curve becomes nonlinear and the slope decreases. Stressing a bone beyond the plastic region will result in failure, that is, fracture. From the stress-strain curve, other mechanical properties of bone, such as stiffness (resistance to deformation) and toughness (absorption of the energy), can also be defined. (Downey and Siegel 2006, Morgan et al. 2008)

### 2.2.2 Effects of age on bone

During growth, skeletal ossification, which starts in the uterus, continues, and long bones increase their length and width inducing coordinated change of shape, size, and material of bone. Bone width increases by periosteal expansion, with new bone forming on already existing surfaces. The growth plates close at puberty, and longitudinal bone growth essentially stops (Riggs et al. 2008, van der Meulen et al. 2008, Boskey and Coleman 2010). By this time 90-95% of the eventual bone peak mass is reached (Riggs et al. 2008). However, appositional bone growth continues after puberty, and this accounts for the further changes in bone shape, and consequent mechanical changes. (van der Meulen et al. 2008, Boskey and Coleman 2010) This process brings the skeleton to its peak level within a few years; that is, at the end of the second or not later than the beginning of the third decade (Riggs et al. 2008). In women, smaller bones are results of earlier termination of longitudinal growth and lower rate of periosteal apposition (Riggs et al. 2002).

At some stage in young adulthood, the volume of bone formed in the formation phase of a remodeling cycle is less than the volume of bone resorptive phase of the cycle. This produces a net negative BMU balance, bone loss, structural decay and bone fragility. Some trabecular bone is lost before the age of 50 years in both women and men. Instead, cortical bone loss is minimal by the 50s. (Seeman 2008)

With advancing age, however, the bone loss accelerates, especially in women (Figure 5). After menopause, remodeling increases, negative BMU balance deteriorates, and periosteal apposition declines. All these accelerate cortical bone thinning and porosity, as well as trabecular bone thinning and loss of connectivity. In addition, rapid remodeling impairs the stiffness of the bone and predisposes it to microdamage because more densely mineralized bone is replaced with younger, less densely mineralized bone. Bone toughness, instead, is reduced since interstitial (deep) bone, which is not exposed to remodeling, becomes more densely mineralized. (Seeman 2008) The most rapid bone loss in women lasts for 4-8 years, and after that, period of constant rate of loss continues to the end of life. In men, only constant rate of bone loss occurs. (Riggs et al. 2008)

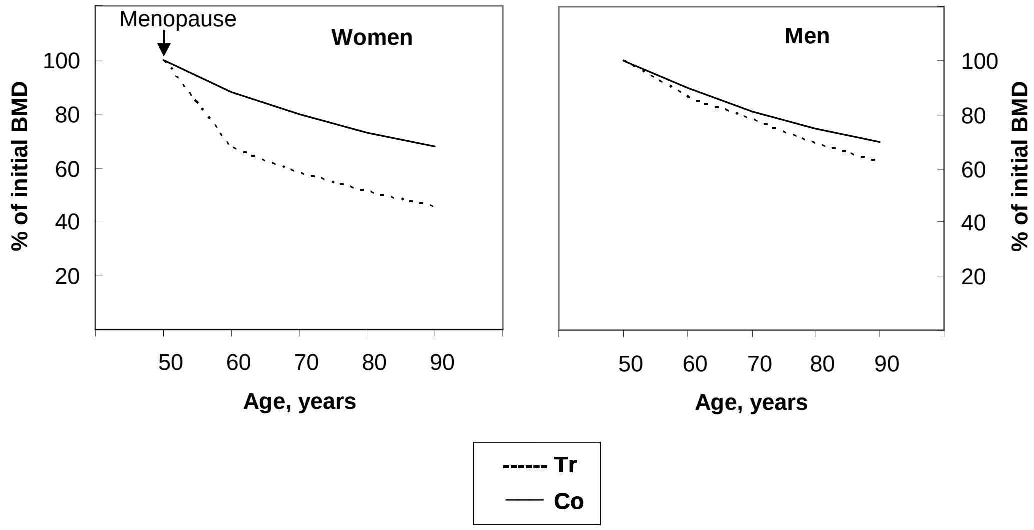



Figure 5. Patterns of age-related trabecular (Tr) and cortical (Co) bone loss after 50 years in women and men. Adapted from Khosla and Riggs (2005) and Clarke and Khosla (2010).

*Osteoporosis.* Osteoporosis is defined as a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture ("Osteoporosis prevention, diagnosis, and therapy" 2001). Moreover, osteoporosis is considered to be a consequence of a stochastic process, in which multiple genetic, physical, hormonal, and nutritional factors act alone or in concert to diminish skeletal integrity. (Marcus and Bouxsein 2008)

Since 1994 osteoporosis has been diagnosed for individuals whose bone mineral density (BMD) value, measured by Dual-energy X-ray absorptiometry (DXA), is 2.5 standard deviation (SD) below the average value for healthy young adult (T-value or T-score). In addition, BMD values of 1-2.5 SD below the young adult mean are defined as osteopenic indicating low bone mass, which is not yet considered osteoporotic. (Kanis et al. 1994, Marcus and Bouxsein 2008) BMD-based measures, thus, have wide clinical relevance.

However, since there has been a clear need to better understand the nature of skeletal bone loss, the limitations of BMD measurement, such as inability to separate cortical and trabecular bone from each other and the strong effect of bone size on BMD values, have become more evident. The ability of bone to resist fracture depends on both bone mass and its spatial distribution, and the intrinsic properties of the materials that comprise it. (Sievanen 2000, Khan et al. 2001b, Griffith and Genant 2008, Marcus and Bouxsein 2008) Thus, alternative methods to measure bone structure and strength (e.g. quantitative computed tomography, magnetic resonance imaging and quantitative ultrasound) have been used increasingly in bone and osteoporosis research.

With age, the incidence of osteoporosis increases. Using T-score -2.5 as a cutpoint, 30% of all postmenopausal Caucasian women and 70% of those aged 80 years would be defined as osteoporotic. (Marcus and Bouxsein 2008, Compston 2010) However, it has been also suggested that despite a strong age association, osteoporosis is not a disease of aging *per se* (Boskey and Coleman 2010).

The main focus in the management of osteoporosis is to reduce the risk of osteoporotic fractures, thus treatment comprises strategies to increase or maintain bone strength and to prevent falls (Kannus et al. 2005a, Jarvinen et al. 2008). In older adults evidence-based strategies to reduce fracture risk include exercise training, calcium and vitamin D supplementation and anti-osteoporotic agents. (Wilkins and Birge 2005, Rizzoli et al. 2009, Sweet et al. 2009, Sinaki et al. 2010)

In the prevention of osteoporosis lifelong physical activity and proper nutrition have an essential role ("Osteoporosis prevention, diagnosis, and therapy" 2001, Bonaiuti et al. 2002, Heaney 2008, Uusi-Rasi et al. 2008). Bone tissue deposition, maintenance, and repair are the result of cellular processes, and the bone cells responsible for these functions are dependent on nutrition. The most important nutrients are calcium and phosphorus. The skeleton also serves as very large nutrient reserve for these two minerals. The size of the reserve is dependent in part on the daily balance between absorbed intake and excretory loss of these minerals. Further, vitamin D is essential for calcium absorption. Thus intake of calcium and vitamin D especially are considered to be important for a healthy skeleton. Vitamin D deficiency can result from inadequate exposure to sunlight and/or low intake of sources from food and calcium typically from low intake from food. (Heaney 2008) The Nordic Nutrition Recommendations (2004) states that daily intake of calcium should be from 600-700 mg in children, 900 mg in adolescents, and 800 mg in adults. The vitamin D intake recommendations for different age groups vary from 7.5 to 20 µg/d, being highest for small children and older adults (*Nordic Nutrition Recommendations* 2004, National Institute for Health and Welfare 2011). Milk products are the best source for proper calcium intake, and fish and fortified food products for vitamin D. The vital role of physical activity for healthy bones is discussed in details in the next chapter (2.2.3 Mechanical loading).

### 2.2.3 Mechanical loading

A number of stimuli affect bone turnover, as noted earlier. One important stimulus is mechanical loading. At the end of the 19th century it was already realized that mechanical loading affects the architecture of bone. Under proper loading a bone remodels itself to become stronger, and when the loading is decreased, the bone will lose strength. This is called Wolff's law after the German anatomist Julius Wolff. Nowadays, the mechanisms behind this law are better understood. (Frost 2004, Robling et al. 2006)

According to the mechanostat theory of Harold Frost, bone adapts its mechanical properties to keep the highest habitual stresses to which it is subjected within a range of safety. If higher than normal strain occurs, bone improves its properties until the strain induced by the load is within the safe range. In the same way, when peak strains decreased, bone adapts by decreasing its excessive structural rigidity through the remodeling. This latter adaptation is clearly seen in disuse situations. (Frost 1987, 2003, Robling et al. 2006). It seems that to be most efficient, the strains should be high, dynamic and unusual in nature, but short in duration (Robling et al. 2006). In other words, the strain rate should be high.

Mechanical loading, physical activity and exercise are currently deemed vital for healthy bones throughout the lifespan. Both cross-sectional and clinical trials have shown that high physical activity during childhood produces stronger bones with greater bone mass, higher mineral density and beneficial changes in structural properties (Uusi-Rasi et al. 2008, Nikander et al. 2010). In addition, weigh-bearing (e.g. jumping, stepping, aerobics and running) and resistance exercises seem beneficial to prevent or reverse bone loss in premenopausal women (Wolff et al. 1999, Wallace and Cumming 2000, Martyn-St James and Carroll 2010).

However, the effect of exercise to prevent bone loss seems to be lesser and somewhat inconsistent in postmenopausal women (Bonaiuti et al. 2002, Kelley et al. 2002, Kelley and Kelley 2006, Martyn-St James and Carroll 2006, 2008, 2009), especially if the structural properties of the bone are considered (Hamilton et al. 2010, Nikander et al. 2010). Moreover, very little is known about the effects of exercise on older adults' bone health, since only few RCT studies have included people aged 70 years or older (McCartney et al. 1995, Lord et al. 1996b, Liu-Ambrose et al. 2004b, Villareal et al. 2004, Englund et al. 2005, Korpelainen et al. 2006b). Of these studies, Liu-Ambrose (2004b), McCartney (1995), Lord (1996b), and Villareal (2004) did not find any exercise effect on BMD at lumbar spine, femoral neck, trochanter or total hip in response to 6-12 months' resistance, agility or multi-component training. Englund (2005), instead, found 8% exercise effect on BMD at Wards triangle, but not at the femoral neck or trochanter, after 12-month combined weight-bearing training in older Swedish women. Similarly, in the study by Korpelainen (2006b) there was no exercise effect on femoral neck and trochanter BMD, although some positive effect was seen in the trochanter BMC after 30-month multi-component training of older Finnish women with low bone mass.

On the other hand, two recent studies have shown positive response at femoral neck BMD after 8 and 18 months' multi-component training among slightly younger German and Portuguese women (mean age 69 and 69.9 years) respectively (Kemmler et al. 2010, Marques et al. 2011). Of these, Kemmler et al. (2010) also found positive effect at the lumbar spine, but Marques et al. (2011) did not.

Considering bone structural properties, only one exercise RCT study has been done among older adults (Liu-Ambrose et al. 2004b). In this Canadian study agility training slightly increased cortical bone density at the tibial shaft, and resistance training at the radial shaft, measured by pQCT in older women with low bone mass. Thus more studies are needed to ascertain whether exercise training can prevent loss of bone strength also during last decades of our lives. Furthermore, the suitability of the exercise types recommended for other age groups (as bone-enhancing exercise) for older people must be evaluated.

## 2.3 Preventing falls and fractures among community-dwelling older adults

Falls and fall-related injuries, such as fractures, are a growing global health problem in older adults, as they often lead to pain, functional limitations, disability, excess health-care costs and increased mortality (Johnell 1997, Kannus et al. 2005a, Johnell and Kanis 2006, Stevens et al. 2006). Thus, research on preventive measures for falls and fractures has become popular, especially in recent decades. Unfortunately, bone and fall-related studies have most often been conducted separately.

### 2.3.1 Incidence and consequences of falls

The main reason why falls and fall-related injuries have become a major health problem is that falls are very common among older adults. Every third community-dwelling person aged 65 or more falls at least once a year (Blake et al. 1988, Tinetti et al. 1988, Tinetti 2003). Of those who have fallen once, half fall again within the year (Nevitt et al. 1991, Tinetti 2003). Falls are most common among people aged 80 years and older (Luukinen et al. 1994, Tinetti et al. 1995) and women fall more often than men (Chu et al. 2005).

*Fractures.* Only about 5% of all falls cause fractures (Kannus et al. 2005a). However, more than 90% of hip fractures and almost all wrist fractures are caused by a fall, likewise about one third of vertebral fractures (Cooper et al. 1992, Myers and Wilson 1997, Parkkari et al. 1999, Palvanen et al. 2000). It has been estimated that the worldwide prevalence of fragility fractures in adults aged 50 years or more was 9 million in 2000. Of these 1.6 million were hip, 1.7 forearm and 1.4 vertebral fractures. (Johnell and Kanis 2006) In Finland, over 7,000 hip fractures are reported annually, and of these 70% occur in women and two thirds in community-dwelling older adults ("Care of patients with hip fractures" 2006, Kannus et al. 2006).

*Fear of falling*. One consequence of falls is fear of falling (FoF). FoF has been defined as an ongoing concern about falling that ultimately limits the performance of daily activities (Tinetti and Powell 1993). It has been recognized as a specific health problem among older adults since the post-fall syndrome, also called ptophobia, was identified in the early 1980s. At first, FoF was considered to develop only as a consequence of falling. (Legters 2002, Scheffer et al. 2008) However, FoF also occurs in those older adults who have not fallen (Tinetti et al. 1988, Myers et al. 1996, Lawrence et al. 1998). Moreover, a recent cohort study indicated that when comparing physiological and perceived fall risk, one third of older people underestimate or overestimate their fall risk. Interestingly, people with low FoF but high physiological fall risk seemed to be protected against falling. (Delbaere et al. 2010)

In community-dwelling older adults, the prevalence rates for FoF range from 20 to 85%. In a large cross-sectional study of over 4,000 community-living Dutch people aged 70 years or more, half reported FoF and over one third associated avoidance of activity (Zijlstra et al. 2007a). Higher age, female gender, poor perceived general health and multiple falls especially seem to be main risk factors for developing FoF (Zijlstra et al. 2007a, Scheffer et al. 2008).

The main consequences of FoF are impaired physical and mental performance, restricted social participation, increased risk of falling and progressive loss of health-related quality of life (Zijlstra et al. 2007b, Scheffer et al. 2008). Thus, FoF may propel an older person into a vicious circle consisting of loss of confidence, restricted activity, impaired mood and physical functioning, falls, and loss of independence (Zijlstra et al. 2007b).

Exercise is seen as a promising intervention to reduce FoF and break the vicious circle since it may directly prevent the decline in physical functioning and mobility. However, only few studies have evaluated the effect of exercise intervention on FoF. (Zijlstra et al. 2007b). So far, the best exercise-based evidence comes from Tai Chi training (Zijlstra et al. 2007b, Sjosten et al. 2008, Logghe et al. 2010).

### 2.3.2 Risk factors for falls and fractures

Traditionally, risk factors for falls have been defined as intrinsic and extrinsic factors. Major intrinsic risk factors include previous fall, muscle weakness, gait and balance disorders, visual impairment, functional and cognitive impairment, dizziness, depression, urinary incontinence, orthostatic hypotension, low body mass index (BMI), female sex and being over age 80. Extrinsic risk factors include polypharmacy, psychotropic medications, and environmental hazards (e.g. poor lighting, loose carpets, uneven surfaces, doorsteps, and slippery floors and roads). ("AGS/BGS Clinical Practice Guideline: Prevention of falls in Older Persons" 2010) Recently, Close (2009) categorized fall risk factors slightly differently using the acronym DAME, which include Drugs and Alcohol, Age-related Physiological Changes, Medical Problems, and Environment as the main categories. Regardless of the classification used, risk factors vary and interact individually, and the risk a fall increases rapidly as the number of risk factors rises (Close 2009, "AGS/BGS Clinical Practice Guideline: Prevention of falls in Older Persons" 2010).

It is notable that a large number of risk factors for falls, such as advanced age, female sex, low BMI, muscle weakness and functional limitations are also related to reduced bone strength (Figure 6). The occurrence of a fracture, instead, depends on the force of the fall and the strength of the bone (Woolf and Akesson 2003, Kannus et al. 2005b, Sambrook et al. 2007, Silva 2007). It has to be remembered, however, that the strongest determinant of a fracture is the actual fall rather than bone fragility (Kannus et al. 2005b, Jarvinen et al. 2008, van Helden et al. 2008), and the majority of fractures occurs in people with normal or only slightly lowered BMD (Marcus and Bouxsein 2008). Furthermore, abnormalities in gait and balance are recognized as the most frequent and sensitive risk factors that predispose to both falls (Shaw et al. 2003, Davison et al. 2005, Ganz et al. 2007, "AGS/BGS Clinical Practice Guideline: Prevention of falls in Older Persons" 2010) and fractures (Wagner et al. 2009). In addition to manifest mobility limitations, preclinical mobility limitations, such as slowed 2 km walking, have also recently been suggested to predispose to falls, especially among older women with history of falling (Manty et al. 2010). Thus, people of advanced age and with multiple other risk factors for falls can be defined as the high-risk population for falls and fractures (Karinkanta et al. 2010).

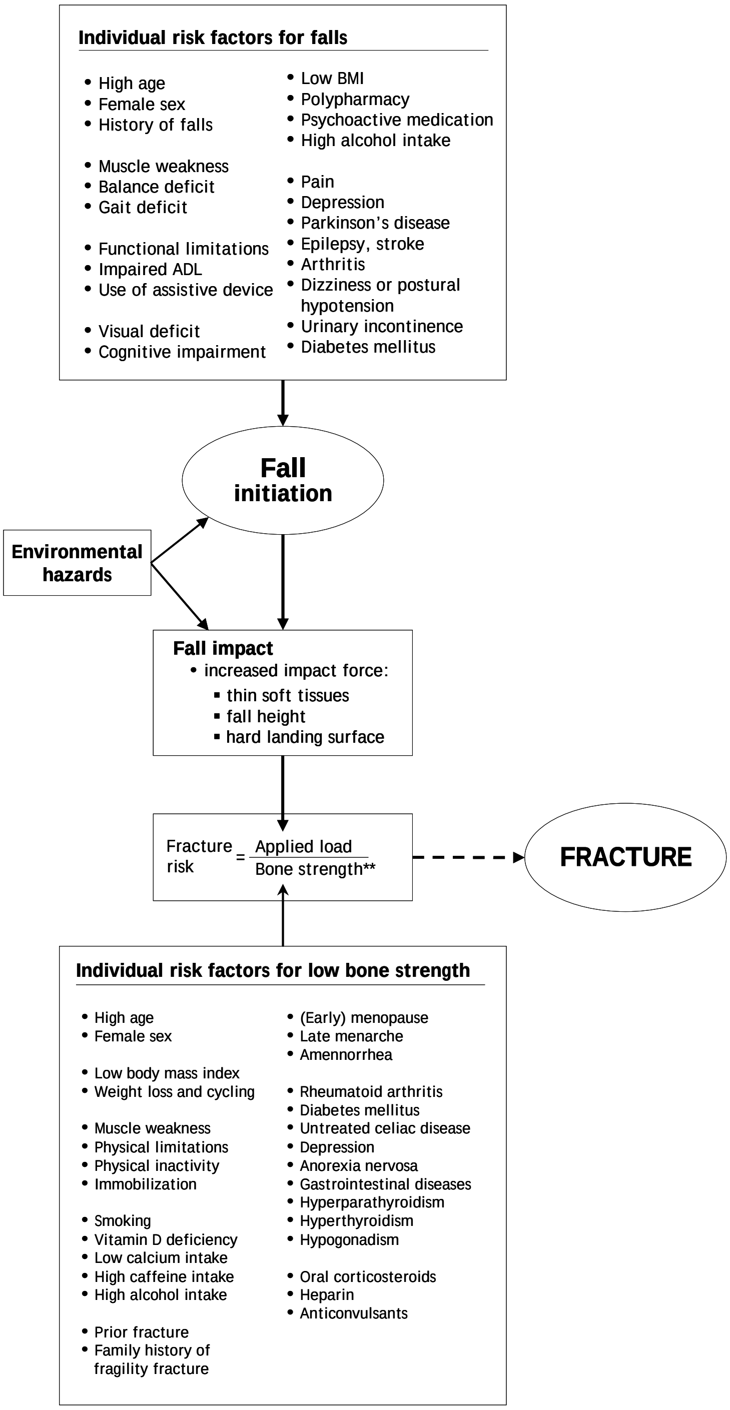



Figure 6. Risk factors of falls and reduced bone strength that result in fractures. **Bone strength is determined by bone geometry (size and shape) and structure (architecture) and material properties. Bones break when the applied load is greater than the bone strength. Adapted from Karinkanta et al. (2010).

### 2.3.3 Interventions preventing falls and fractures

Several studies on preventive interventions that aim to reduce falls and fall-related fractures among community-dwelling older people have been conducted, especially in recent years. Studies have focused either unselectively on older adults in general or selectively on specific high-risk subpopulations, such as individuals with multiple falls or those aged 80 years or over. In addition, both single and multifaceted interventions have been used. Multifaceted interventions have been based on individually tailored fall risk assessment and prevention measures (called multifactorial intervention), or a similar combination of two or more preventive measures has been offered to all participants (multiple intervention). (Gillespie et al. 2009)

#### *2.3.3.1 Fall prevention*

Given the complexity of fall-related risk factors, intervention programs that simultaneously cover and treat a multitude of risk factors are theoretically considered to be most effective (Tinetti 2003, 2008, Tinetti and Kumar 2010). However, the evidence from RCT studies does not totally support this theory. (Campbell and Robertson 2007, Gillespie et al. 2009). In a Cochrane review (2009) of 111 RCT studies and 55,303 participants multifactorial interventions reduced the rate of falls in community-dwelling older adults [Rate Ratio (RaR) 0.75, 95% CI 0.65-0.86], but not risk of falling (that is, number of fallers). Also, single interventions using vitamin D supplement, home safety assessment, gradual withdrawal of psychotropic medication, anti-slip shoe devices, first eye cataract surgery or pacemakers (for people with carotid sinus hypersensitivity) were unable to reduce both rate and risk of falling. (Gillespie et al. 2009)

Instead, exercise as a single intervention seemed to be most effective in reducing both rate and risk of falling in the Cochrane review (Gillespie et al. 2009). This means that the number of older adults who experience a fall is reduced by exercise intervention, and furthermore, those who fall do not fall as often. In addition, exercise interventions may be more cost-effective than multifactorial interventions (Petridou et al. 2009, Davis et al. 2010).

However, not all forms of exercise are equally effective in the reduction of falls. The clearest evidence comes from combined balance and muscle training carried out in a group or individually in a home-based setting. (Gillespie et al. 2009, Karinkanta et al. 2010) In a Cochrane review (2009), group-based multi-component exercise decreased the rate of falls by 22% (RaR 0.78, 95% CI 0.71-0.86) and risk of falling 17% [Risk ratio (RR) 0.83, 95% CI 0.71-0.97]. In home-based multi-component exercise the corresponding values were 0.66 (0.53-0.82) and 0.77 (0.61-0.97) respectively. Furthermore, *a priori* subanalysis indicated a multi-component group exercise to be effective for both unselected and high-risk older adults. (Gillespie et al. 2009)

Contrary to multi-component exercise, evidence is somewhat lacking that exercise interventions that merely contain balance or muscle strength exercises can reduce falls; only Tai Chi training has been shown to be effective for both rate and risk of falling (Gillespie et al. 2009). On the other hand, a meta-regression of effective exercise components for fall prevention by Sherrington et al. (2008), emphasize in particular the role of high dose of challenging balance training. However, only few studies have been conducted to study the effect of single component exercise training other than Tai Chi (Wolf et al. 1996, McMurdo et al. 1997, Latham et al. 2003, Liu-Ambrose et al. 2004a, Woo et al. 2007), and of these only one study used PRT as a single intervention (Liu-Ambrose et al. 2004a). Furthermore, only the study of Liu-Ambrose (2004a) compared different training methods with each other. Both agility and resistance training had positive effects on fall risk profiles among older women with low bone mass compared with sham (stretching) exercise. However, no statistically significant differences in falls were seen. Moreover, Liu-Ambrose (2004a) did not include multi-component exercise in the trial. Further studies comparing different single and multi-component exercise interventions are therefore clearly needed.

#### *2.3.3.2 Fracture prevention*

In contrast to fall prevention, evidence to show that exercise can reduce fractures is somewhat inconclusive. Epidemiological evidence indicates that physical activity is associated with a reduced risk of fall and osteoporosis-related fractures (Sievanen and Kannus 2007, Moayyeri 2008). However, the experimental evidence is more controversial (Gillespie et al. 2009, Kemmler et al. 2010).

In a meta-analysis of 13 prospective cohort studies, moderate to vigorous physical activity was associated a 38% and 45% reduction of hip fracture risk among women and men, respectively (Moayyeri 2008). In particular, in the Nurses' Health Study with a follow-up period of 12 years, each increase in physical activity equivalent to 1 hour's walking per week at normal pace, reduced hip fracture by 6% among postmenopausal American women aged 40-77 years. Moreover, women who walked at least 4 hours per week had a 41% lower risk of hip fractures than sedentary women who walked less than one hour per week. (Feskanich et al. 2002) In the Uppsala Longitudinal Study of Adult Men, Swedish middle-aged men were followed-up over 35 years until the age of 82 years. Sedentary men had a 2.5-fold increased risk of hip fracture and a 1.5-fold higher risk of other fractures than men with high physical activity. The researchers estimated that if all the men had participated in regular sporting activities for at least 3 hours per week, one third of hip fractures could have been prevented. (Michaelsson et al. 2007) In addition, both studies indicated that the risk of hip fracture decreased if a sedentary person became physically active, and, conversely, giving up a physically active lifestyle led to increased hip fracture risk (Feskanich et al. 2002, Michaelsson et al. 2007).

RCT studies, however, do not totally confirm the epidemiological evidence. In the Cochrane review by Gillespie et al. (2009) exercise resulted in a 64% reduction of fracture risk compared with no exercise (RR 0.36, 95% CI 0.19-0.70). However, this favorable result was obtained on the basis of only five randomized studies, including published and unpublished data, predominantly from a study by Korpelainen and co-workers (Korpelainen et al. 2006b). In this Finnish study, after 30 months of group and home-based exercises that included jumping, balance and muscle strengthening, older women (70-73 years) with low bone mass who exercised sustained fewer fall-related fractures than did study participants who did not exercise (6 versus 16 fractures). In the other two published studies (McMurdo et al. 1997, Ashburn et al. 2007) also included in the Cochrane review and in a novel study by Kemmler et al. (2010), the total number of fractures was lower than in the study by Korpelainen (2006b), and the beneficial effect of exercise on fracture risk was thus less obvious. Recently published 7-year follow-up data of an RCT study by

Korpelainen (2010), however, supports the notion that exercise may have positive long-term effects on hip fracture risk in older women with low bone mass.

## 2.4 Health-related quality of life and physical activity in older people

There is no universal definition for quality of life. Clearly, quality of life means different things to different people. (Fayers and Machin 2007). For example aspects of physical, social, psychological and spiritual well-being are associated with quality of life. At the same time, quality of life can also be seen as cognitive judgment of satisfaction with one's life (McAuley and Morris 2007). In medicine especially, quality of life is typically seen as health-related. Health-related quality of life (HRQoL) refers to the impact of a person's health on his or her functioning and well-being. In contrast to the global concept of life-satisfaction, self-rated HRQoL encompasses the subjective experience of one's body and emotions as well as the perception of the level of functioning. The core of the concept is not the objective level of functioning or health status but the person's perception and appraisal of these (Hays and Morales 2001, Fayers and Machin 2007, Halvorsrud and Kalfoss 2007)

Both generic and disease specific instruments have been developed to assess HRQoL. The most widely used generic HRQoL instrument in different populations and settings is the Medical Outcome Study Health Survey Short Form (SF-36) (Ware and Sherbourne 1992, McHorney et al. 1993) and its parallel survey RAND-36 (Hays et al. 1993, Hays and Morales 2001). In the surveys eight scale scores of different aspects of HRQoL are achieved. The scale scores are Physical Functioning (PF), Role Limitations due to physical problems (RLP), Role Limitations due to emotional problems (RLE), Mental Health (MH) (Emotional Well-Being in RAND-36), Energy (E), Pain (P), Social Functioning (SF), and General Health (GH).

A number of observational studies have reported beneficial associations between physical activity and well-being in both younger and older adults (Netz et al. 2005, Wolin et al. 2007). Regular exercise is associated with enhanced global satisfaction and improved mood and bodily or emotional well-being among late middle-aged and older adults. It seems, however, that objectively measured improvement of fitness is not necessitated (Arent et al. 2000, Rejeski and Mihalko 2001, Netz et al. 2005). On the other hand, several studies suggest that a perceived improvement in functioning or well-being may reinforce the adoption of regular exercise and thus serve as a personal incentive for continuing activity (Rejeski and Mihalko 2001, McAuley et al. 2005).

The evaluation of the effect of exercise intervention on HRQoL has increased in recent years, even if it is typically assessed as a secondary outcome. A favorable HRQoL response to exercise interventions has been observed in many clinical and healthy adult samples (Gillison et al. 2009). However, there is inconsistent evidence that exercise can improve HRQoL among older adults. In single RCTs both positive response and no response have been reported among healthy and medically stable older adults, as well as in clinical older samples (Table 2). Besides, no single exercise type has been found to be superior to others. Two recent meta-analyses also indicate the heterogeneity in the HRQoL outcomes after exercise intervention. Li et al. (2009) found improvements in P, E, PF and RLP scores in the meta-analysis of four RCTs in older women with osteoporosis and osteopenia. However, in a meta-analyses of 11 RCT studies among community-dwelling older adults, only a modest increment in PF score was observed (Kelley et al. 2009).

*Table 2.* Effects of exercise on Health-Related Quality of Life (HRQoL) assessed with the Medical Outcome Study Health Survey Short Form (MOS SF-36) or RAND-36 Survey. Only those studies in which mean age of participants is at least 70 years are included.

| Study | Participants | Intervention | HRQoL outcome | Main results |
|---|---|---|---|---|
| Cress 1999 | n=56 independently living 70+ with relatively good health, mean age 76 y., USA | Supervised endurance and strength training in gym (EX) 3xwk vs. CR , **6 months** | MOS SF-36 (PF as primary outcome, other scales as secondary outcomes) + SIP | **at 6-mo:** no between-group differences in SF-36 scales or SIP |
| Greendale 2000 | n=62 aged 60+ recruited from community sites, mean age 74 y. (females 74%), USA | Weighted vest (3 or 5% of body weight) during weight-bearing activities 2 hours per day, 4xweek vs. CR, **27 weeks** | MOS SF-36 + 5-item MOS Pain Scale | **at 27-wk:** No between-groups differences in any HRQoL scales |
| Helbostad 2004<br><br>Randomized clinical study | n=77 physically frail 75+ living at home, mean age 81 y. (females 80%), Norway | Unsupervised home training (HT) (balance and strength exercises) 2xday + 3 meetings by groups leading by PT vs. Supervised combined training (CT) (progressive functional strength and balance training) 2xwk + same home-exercise as in HT group, **12 weeks** | MOS SF-36 (version 2.0, Norwegian) | **at 3-mo:** RLE and MCS ↑ in CT compared with HT (p=.003 and .01, respectively), ns trend that PF ↑ in CT compared with HT (p=.07)<br>**at 9-mo:** no between-group differences, overall improvements in RLE and MCS (p=.001 and .032) and trend for PCS (.057) |
| Stiggelbout 2004 | n=386 independently living aged 65-80 yrs, mean age 71 y. (females 63%), the Netherlands | Gymnastic program (light aerobic, muscle strengthening and coordination exercises) (EX) 1-2xwk vs. Health education program 1xmo (CR),<br>**10 weeks** | RAND-36 (4 scales: E, P, MH, GH + 1 item: change in health status)<br><br>+ VPS and TAAQOL (2 scales) | **at 10-wk:** No between-group differences in any QoL scales (EX vs. CR or EX1 vs. EX2 vs. CR)<br>*Only 277 (72%) were included to analysis.* |
| Devereux 2005 | n=50 community-dwelling women 65+ with osteopenia or osteoporosis, mean age 73 y., Australia | Water-exercise (EX) + self-management education 2xwk vs. CR,<br>**10 weeks** | MOS SF-36 | **at 10-wk:** PF, E, SF and MH ↑ in EX compared with CON, other scales: ns |
| Oken 2006 | n=135 relatively healthy men and women aged 65-85, mean age 73 y. (females 75%), USA | Supervised walking + home exercise (EX) 5xwk vs. supervised yoga (YOGA) 1xwk + daily home exercise vs. CR,<br>**6 months** | MOS SF-36 | **at 6-mo:** E, RLP, P, SF and PCS ↑ in YOGA compared with EX and CR (↓ or remain stable), other scales: ns |

Continued overleaf

Table 2 continued

| Study | Participants | Intervention | HRQoL outcome | Main results |
|---|---|---|---|---|
| de Vreede 2007 | n=98 community-living, medically stable women >70 yrs, mean age 74 y., the Netherlands | Functional task exercise (FUNC) 3xwk vs. Resistance exercise 3xwk (RES) vs. CR, **12 weeks** | MOS SF-36 (Dutch version, validated) | **at 3-mo**: PF↑ in RES compared with FUNC and CR, other scales: ns<br>**at 9-mo:** PF and PCS ↓ in FUNC compared with CR |
| Eyigor 2009 | n=40 healthy older women over 65 y., mean age 72 y., Turkey | Turkish folklore dance in group 3xwk + walking 30 min. ≥ 2xwk (EX) vs. CR, **8 weeks** | MOS SF-36 | **at 8-weeks:** PF, GH and MH ↑ in EX compared with CR |
| Grahn Kronhed 2009 | n=73 women aged 60-81 yrs. with osteoporosis and fragility fracture, mean age 71 y., Sweden | Supervised group exercise by PT (EX) (strengthening exercises for back, leg, arm and abdominal muscles, and balance exercises) 2xwk vs. CR, **4 months** | MOS SF-36<br>+ QUALEFFO | **at 4-mo:** PF, P, GH, SF and MCS ↑ in EX compared with CR, other SF-36 scales and QUALEFFO: ns |

CR=Control group (no exercise), ns=non significant
PF=Physical Functioning, E=Energy, P=Pain, SF=Social Functioning, MH=Mental Health, GH=General Health, RLP=Role Limitations/Physical RLE=Role Limitations/Emotional, PCS=Physical Component Summary, MCS=Mental Component Summary, VPS=Vitality Plus Scale, TAAQOL=TNO Leiden Academic Hospital Adult Quality of Life questionnaire, SIP= Sickness Impact Profile, QUALEFFO=Quality of life questionnaire of the European Foundation for Osteoporosis, PA=Public health physical activity recommendation

## 2.5 Summary of the literature review

Aging is associated with numerous of changes in the human body and its functioning. Decreased muscle function and impaired balance and motor control may cause functional limitations, such as mobility problems and impaired physical functioning. Proper physical functioning, however, is needed for independent living in advanced age.

The probability of falls increases with age. Every third person aged 65 years or older falls at least once a year. The majority of falls does not cause injuries but may result in other harmful outcomes, such as fear of falling and restricted activity. Every twentieth fall breaks a bone. It is noteworthy that many risk factors are the same for falls and reduced bone strength, including e.g. female gender, high age, low body mass index, muscle weakness, and physical and functional limitations.

Exercise has a potential to improve physical functioning and maintain bone strength, and thus to reduce falls and related fractures. Exercise may also improve health-related quality of life and reduce fear of falling among older adults, but evidence based on RCTs is lacking. Furthermore, since research on fall prevention and bone research have mainly been conducted separately, the effects of exercise in their entirety remain unclear.

Thus, we do not know whether generally-recommended bone-enhancing exercise is also feasible and effective for adults aged 70 years of more, and, furthermore, whether this exercise is beneficial in fall prevention. Therefore, there is a clear need to evaluate and compare various exercise programs to identify the modalities of exercise which are most beneficial in the prevention of functional decline, falls and related fractures in home-dwelling older adults.

# 3. PURPOSE OF THE STUDY

This doctoral thesis was intended to evaluate the effects of two exercise interventions and their combination on multiple risk factors for falls and fall-related fractures in home-dwelling older women. The exercise interventions included resistance training and balance-jumping training, alone or in combination. Furthermore, the feasibility of the exercise programs and maintenance of the training effects after cessation of the exercise intervention were evaluated.

The specific research questions were:

1. Which physiological factors are associated with dynamic balance and health-related quality of life in home-dwelling older Finnish women? (Study I)
2. Are high-to-moderate intensity resistance training and balance-jumping training feasible exercise modalities for relatively healthy older women? (Study II)
3. What are the effects of 12-month group-tailored resistance and balance-jumping training programs, alone or in combination, on physical performance, physical functioning, and bone mass and structure? (Study II)
4. Do the exercise effects persist one year after cessation of the exercise intervention? (Study III)
5. Have the exercise interventions effects on falls and fractures? (Studies II, III)
6. What are the effects of exercise on health-related quality of life and fear of falling? (Study IV)

# 4. MATERIAL AND METHODS

## 4.1 Study design

The thesis and related original publications are based on the KAAMU Study. The KAAMU Study was aimed to reduce risk factors for falls and fractures among older women, and was conducted at the UKK Institute for Health Promotion Research, Tampere, Finland 2002-2004.

The 12-month randomized controlled exercise trial (RCT) had four experimental groups:

1. A resistance training group (RES)
2. A balance-jumping training group (BAL)
3. A combination group doing resistance and balance-jumping training (COMB)
4. A non-training control group (CON)

Participants were relatively healthy, home-dwelling elderly women living in the city of Tampere, Finland. Participants are described in details below.

After the 12-month RCT study, a follow-up study was conducted to evaluate the maintenance of the exercise-induced benefits. During the 12-month follow-up study the participants were asked about their physical activity, health status, and falls and fractures on a monthly basis but no interventions were offered.

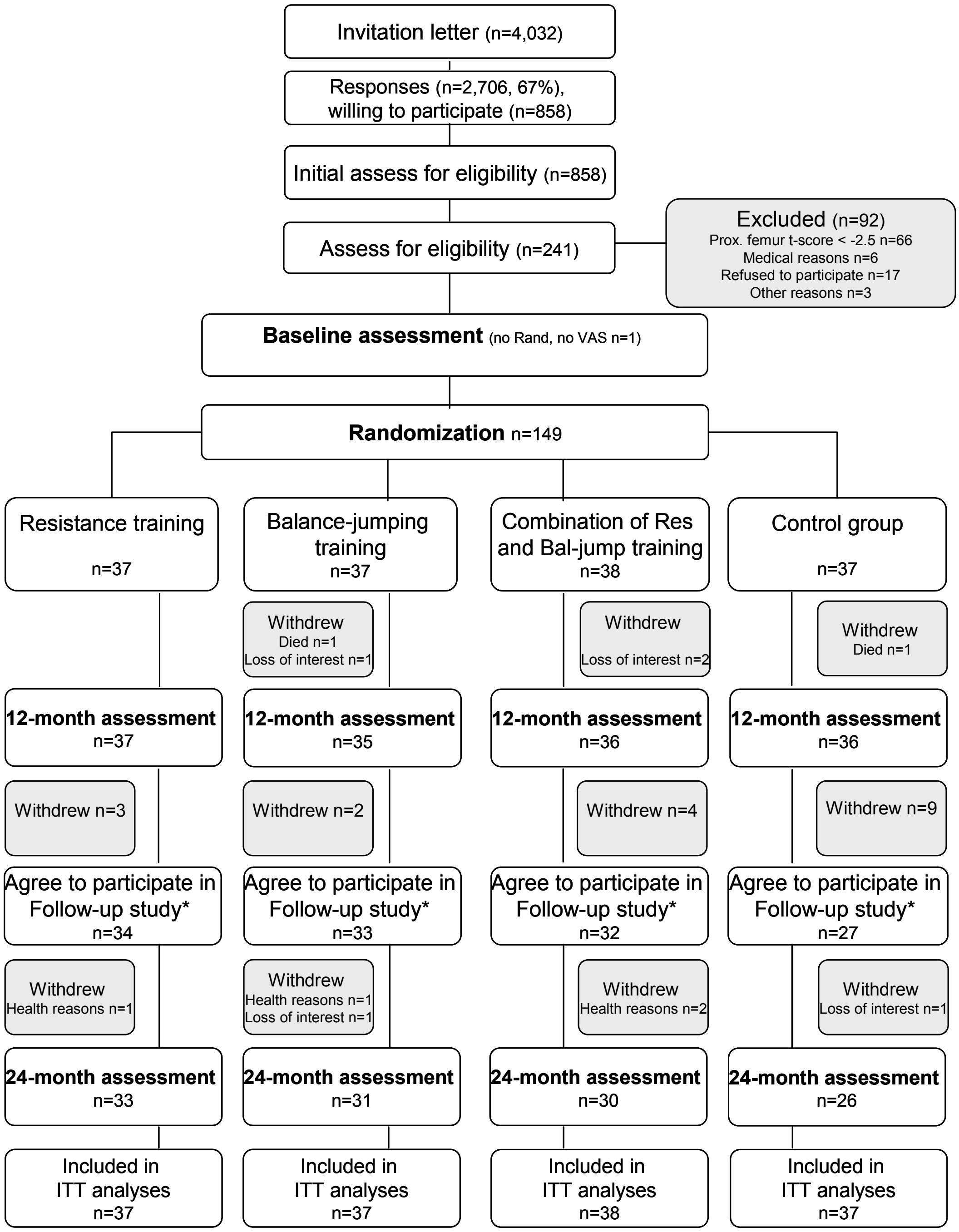
## 4.2 Recruitment of participants and progress of the study

### 4.2.1 Recruitment for the RCT study

Figure 7 shows a trial profile including withdrawal during the recruitment process.

A questionnaire was sent to a random population sample (n=4,032, half of the age group) of 70 to 79-year-old women living in the city of Tampere, Finland to inquire if they were interested in participating the KAAMU Study. A total of 2,706 women responded and 858 expressed initial interest. A physical therapist (SK) screened all the questionnaire responses of the women who were willing to participate (n=858) to ascertain an initial eligibility to the study. The inclusion criteria in this stage were: no reported history of any illness contraindicating exercise or limiting participation in the exercise program, no reported history of any illness affecting balance or bone, no reported uncorrected vision problems, and not reported taking medications known to affect balance or bone metabolism (within 12 months before the enrolment). The exclusion criterion was reported intensive exercise more than twice a week. Based on these criteria two hundred and forty-one eligible women were then invited to a screening examination including a medical examination, an interview and a measurement of femoral neck bone mineral density (BMD). Finally, 149 women met the inclusion criteria of the study.

The final inclusion criteria to the study then were: willingness to participate, age from 70 to 79 years, full understanding of the study procedures, no history of any illness contraindicating exercise or limiting participation in the exercise program, no history of any illness affecting balance or bone, no uncorrected vision problems, and not taking medications known to affect balance or bone metabolism (within 12 months before the enrolment). A subject was excluded if she was involved in intense exercise more than twice a week or her T-score for femoral neck BMD was lower than -2.5, which indicated osteoporosis and required medical attention.




*Participants were asked if they would be interested to continue the study including monthly questionnaire of physical activity, health and falls and participation of 24-month assessment.

Figure 7. Trial profile

## 4.2.2 Sample size, randomization and blinding

Sample size was based on pre-study power calculations by a statistician. Power calculations focusing on dynamic balance (figure-of-eight running test) as the outcome indicated that at an α level of 0.05 and common standard deviation of 10% for the balance change during the intervention, a sample size of 35 women in each group at the end of the study would give 80% power for the study to detect 5% treatment-effect in dynamic balance between the groups. This calculation was based on the assumption that in 2 x 2 factorial design the groups which had resistance training components (RES and COMB) and the groups which had balance-jumping training components (BAL and COMB) would be combined to form adequate groups (n=70) to determinate the effect of the training modality.

According to a computer generated randomization list participants (n=149) were randomly assigned to one of the four parallel groups (1:1:1:1 ratio) using a simple randomization method in two parts (part 1 n=68, part 2 n=81). Thus, 37 women were assigned to the RES group, 37 women to the BAL group, 38 women to the COMB group and 37 women to the CON group. A computer-generated randomization list was drawn up by the statistician, who was blinded to the study participants and their characteristics.

Since the intervention was exercise training and the control group had no training, blinding of study participants was impossible. The technician who did the bone measurements was blinded to the allocation. However, blinding of the other data collectors and outcome assessors could not be totally achieved. The physiologist who conducted the physical performance tests was also responsible for planning the balance-jumping training programs and therefore sometimes visited the training classes. In addition, the author of the dissertation had (as a PhD student) multiple roles in the study including participation in study and exercise program planning, data collection by surveys, guiding and assisting group supervisors, contacting the study participants, and analyzing and reporting the data.

### 4.2.3 Progress of the intervention study

Due to practical considerations, the study was conducted in two parts (Figure 8). After the responses to the invitation letters, assessment of eligibility, including medical examination and DXA measurement, and the baseline assessment were done separately in two phases. Randomization to intervention groups (RES, BAL, COMB and CON) was made separately in both Phases (I and II) (see details above).

Phase I (n=68) started the exercise intervention in the middle of June and Phase II (n=81) in the middle of October. Twelve-month assessment was done in Phase I and Phase II from May to June and October to November 2003, respectively. After the intervention period, all participants received personal feedback on their test results during the trial.

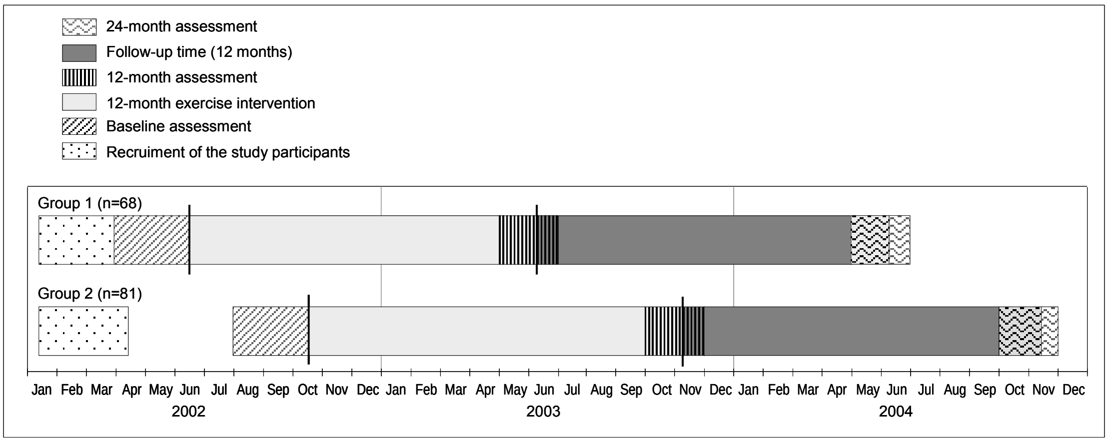



Figure 8. Progress of the KAAMU-study

### 4.2.4 Follow-up study

After the 12-month exercise intervention study the women who completed the intervention (n=144, 97%) were asked if they were interested in continuing another 12 months in a follow-up study. One hundred and twenty-six women (85% of the original study participants) were willing to participate in the follow-up study. In addition to 24-month assessment, the participants were sent monthly questionnaires concerning their physical activity, health, falls and fractures, but no exercise interventions were offered during the 12-month follow-up period. Six women withdrew before the follow-up measurements and therefore the 24-month measurements were made on 120 women (81% of the original study participants) (Figure 7 at page 52).

## 4.3 Training program

The exercise training classes were arranged 3 times a week for 12 months. Each class included a 7 to 10-minutes warm-up, 25-30 minutes of effective training part (see descriptions below) and an 8 to10-minutes period for cooling down. All classes were supervised by exercise leaders of the UKK Institute, who were trained to supervise these special training programs prior the trial. The exercise leaders kept a record for each attendance of the participants.

### 4.3.1 Resistance training

The RES group accustomed themselves to resistance training for six weeks. During the first two weeks the participants became familiar with the equipment. Then the instructors assessed the participants` training loads and taught them the individually-tailored resistance training program. The intensity of training stimulus was set at 50-60% of one repetition maximum (1RM) using 2 sets and 10-15 repetitions. Thereafter the intensity progressed to 75-80% of 1RM with work range of 3 sets and 8-10 repetitions. The intensity was assessed using rated perceived exertion (RPE) (Borg 1970). If the RPE dropped below 18 (max 20) the participants were asked to increase load (about 5%) or repetitions. A two-minute recovery was provided between the training sets and each set of repetitions. The program included large muscle group exercises, such as rising from a chair using a weight vest, squatting, and leg press, hip abduction, hip extension, calf raise and rowing using resistance training machines. To prevent the programs from being too monotonous, five different combinations of the abovementioned exercises in 10-week periods were used during the intervention (Appendix 1a).

### 4.3.2 Balance-jumping training

The primary training components in the BAL group were balance, agility and impact exercise. In detail, training classes included static and dynamic balance and agility training sessions, jumps and other impacts, and changes of direction exercises (such as acceleration and deceleration in back and forth, and sideways walking with stops and turns) with music. Jumps and other impacts were modified from previous high-impact programs developed at the UKK Institute and found to be safe and effective in pre- and postmenopausal women and in growing girls (Heinonen et al. 1996, Heinonen et al. 2000, Uusi-Rasi et al. 2003). Some of the exercises were done with a step-board. During the first six weeks, the trainees accustomed themselves to the balance and agility training. Thereafter, the degree of difficulty of movements, steps, impacts and jumps was gradually increased. The type of training was modified aerobics or step aerobics in two alternating weeks (two weeks "aerobics", two weeks "step aerobics") in 12-week periods. There were four different aerobics and step aerobics programs with different combination of the above noted balance-jumping movements during the intervention (Appendix 1b).

### 4.3.3 Combination of resistance and balance-jumping training

COMB training consisted of the resistance and balance-jumping training described above in alternating weeks. In addition to six-week familiarization period, two different resistance training and two different balance-jumping training programs were conducted during the entire intervention (Appendices 1a, 1b)

*Control Group.* The controls were asked to maintain their pre-study level of physical activity during the 12-month trial. In addition to the initial info meeting, the control group women were offered 2 meetings during the 12-month trial to maintain their interest to participate in the study. The first meeting was arranged near Christmas and the other prior to the 12-month assessments. The meetings were social in nature. After the follow-up period the controls were offered an opportunity to participate in two supervised exercise sessions consisting of exercises used in balance-jumping training.

## 4.4 Outcomes and data collection

The primary outcomes of the study were dynamic balance and agility, maximal isometric leg extensor strength and bone geometry and mass distribution of tibia and radius. As secondary outcomes, postural stability, dynamic lower limb muscle force, reaction time, bone mineral content (BMC) and bending strength of femoral neck, health-related quality of life (HRQoL), fear of falling (FoF), falls and fractures were assessed.

All the outcome measurements were done at baseline, immediately (12 months) and one year after the end of the exercise intervention (24 months). The technicians who made the physical performance and bone assessments were highly qualified for taking measurements and had several years' experience of these in the laboratory of the UKK Institute.

### 4.4.1 Background variables

General health and habitual physical activity were assessed by a questionnaire at baseline, primarily for recruitment purposes. The health questionnaire addressed medical conditions, current medications, years of menopausal estrogen therapy, history of fractures and current leisure time physical activity.

Dietary intake and possible use of vitamin and mineral supplements were assessed by a complete 3-day (two weekdays and a Sunday) food record at baseline and at 12 months, and calculated using Micro-Nutrica software (Social Insurance Institution, Helsinki, Finland) by a nutritionist.

### 4.4.2 Health, falls and fractures

During the intervention all participants reported their health status on monthly questionnaires. In addition to recent changes in health status or medication, occurrence of falls, fractures or other injuries, and hospitalization during the preceding month were elicited. Falls were elicited with the question: "Have you fallen since the last questionnaire? Yes/No" Reported falls and injuries were conformed and clarified from the participants by phone. A fall was defined as: "unintentionally coming to rest on the ground, floor, or other level. Coming to rest against furniture or a wall was not counted as a fall." (Buchner et al. 1993, Campbell et al. 1997) Falls occurring in the intervention exercise classes were counted and included in the analysis.

Type, frequency and duration of sports and other leisure physical activity were elicited monthly. Reported physical activity was converted to MET-hours/week (Ainsworth et al. 2000).

### 4.4.3 Physical performance tests

*Dynamic balance and agility.* Dynamic balance and agility was tested by a standardized figure-of-eight running test. The test was originally developed to evaluate the success of rehabilitation after an anterior cruciate ligament injury of the knee (Tegner et al. 1986), and has been modified for older adults by adding an extra lap (Heinonen et al. 1996, Carter et al. 2002, Uusi-Rasi et al. 2003). In the test, two poles were placed 10 m apart. The participant was asked to run or walk two laps as fast as possible. The running time was measured with a stop-watch. The best attempt of two trials was recorded.

*Isometric muscle force.* Maximal isometric lower limb extension force was measured with a leg press dynamometer (Tamtron, Tampere, Finland, leg press bench custom-made at the Pirkanmaa Vocational Institute, Tampere, Finland) at a knee angle of 90 degrees. The precision (coefficient of variation, CV) of the measurement is 5.4% in the UKK Institute laboratory (Heinonen et al. 1994). The best attempt of three trials was recorded and proportioned to body weight (N/kg). (If produced force increased in all three attempts, the maximum of two extra attempts was taken to discover the best result.)

*Postural stability.* Postural stability was tested with an unstable platform (The Biodex Stability System, Biodex Medical System, New York, USA) with two phases of increasing difficulty. In both phases test duration was one minute and during the test touches to the safety handrail were counted. As a result, stability indices for both phases were produced, and the stability index in phase 1 was used as an outcome (the higher the index, the poorer the balance).

*Dynamic muscle force.* Dynamic muscle force of lower the limbs was tested by measuring ground reaction forces (GRF) with a force platform (Kistler Quattro Jump, Kistler Instrumente AG, Winterhur, Switzerland) during common daily activities: a sit-to-stand and a step-on-a-stair. The GRF data were reported without the subject's body mass. The chair was 43 cm and the stair 18 cm in height. The best attempt of 3 trials was recorded and proportioned to body weight (N/kg).

*Reaction time.* Reaction time was assessed using a simple reaction time paradigm employing a random light or sound stimulus and a push-button for the finger as the response to any stimulus whatsoever (Digitest 1000, Digitest Ltd, Muurame, Finland). The seated subject placed the dominant hand on a table in front of the switch and light bulb. The equipment then recorded how quickly the switch was pressed after the stimulus release. A random stimulus was based on choice of the technician. Subjects had 10 practice trials and 10 experimental trials. Trials slower than 2000 ms or faster than 200 ms were removed and both the fastest time and a mean of the five fastest trials were recorded. (The fastest reaction time was used in the analysis in the first article. The main results of this thesis are based on a mean of the five fastest trials)

### 4.4.4 Bone measurements

Bone mineral density (BMD, g/cm$^2$) and content (BMC, g) of the right proximal femur were measured with dual-energy X-ray absorptiometry (DXA, Norland XR-26, Norland Inc., Fort Atkinson, WI, USA) according to UKK Institute standard procedures. The *in vivo* precision (CV) of BMD and BMC measurements in the UKK Institute laboratory is 0.8% and 0.9%, respectively (Sievanen et al. 1996). Femoral neck BMD was used for screening the study participants, while BMC of the femoral neck (divided by the height of the neck region) was used as the DXA outcome.

In addition, the gross structure of the narrowest femoral neck section was analyzed using the hip structure analysis (HSA) (Beck et al. 2000). In this study section modulus (Z, mm$^3$, as an index of bending strength), and periosteal diameter were used as outcomes. The *in vivo* precision (CV) of these measurements in the UKK Institute's laboratory is 4.8% and 2.5% respectively (Nikander et al. 2005).

Peripheral quantitative computed tomography (pQCT), (XCT 3000, Stratec Medizintechnik GmbH, Pforzheim, Germany) was performed at the distal sites (trabecular bone), and at midshaft (cortical bone) of the right radius and tibia according to UKK Institute standard procedures (Sievanen et al. 1998). For the distal sites, trabecular density (TrD, mg/cm$^3$), and density-weighted polar section modulus (BSI, mm$^3$, an index of torsion bending strength) were used, while the cortical area (CoA, mm$^2$), cortical density (CoD, mg/cm$^3$), and BSI were used for the shaft sites. The *in vivo* precision (CV) ranges from 0.7% (tibial shaft CoD) to 7.7% (distal radius BSI) in the UKK Institute laboratory (Sievanen et al. 1998).

### 4.4.5 Assessment of health-related quality of life and fear of falling

Health-related quality of life (HRQoL) was assessed by means of the standard Finnish version (Aalto et al. 1999) of the RAND-36 Health Survey (Hays et al. 1993) which is the parallel survey of the SF-36 (Hays et al. 1993, Hays and Morales 2001). These surveys are widely used in different settings including exercise interventions (de Vreede et al. 2007, Kelley et al. 2009, Martin et al. 2009, Teixeira et al. 2010). The psychometric properties of the surveys in late middle-aged and older adults have been found to be quite good compared to other generic HRQoL-instruments (Halvorsrud and Kalfoss 2007)

The RAND-36 Survey consists of eight scales, each comprising series of 2 – 10 questions. The scales represent separate but conceptually related aspects of HRQoL, while the overall level of subjective HRQoL is portrayed by the scale score profile. The items of Physical Functioning (PF) and Physical Role Functioning (RLP) scales reflect the respondent's self-rated capability in ADL activities and mobility. The other scales cover Emotional Well-being (EW), Energy and Vitality (E), Bodily Pain (P), General Health (GH) and limitations in role functions and interaction (Social Functioning SF, Emotional Role Functioning RLE). The item responses were scored and the scale values, 0–100 for each scale, were calculated according to standard procedure (Hays et al. 1993, Aalto et al. 1999). In addition, the sum of the 36-item score (total score) and the sum of the 8 scale scores (sum index score) were used in the study I.

PF scale of the RAND-36 Survey was also used separately to assess self-rated physical functioning in Studies II and III. The scale comprises of 10 questions on coping with daily activities, such as running, lifting heavy things, climbing stairs of several floors, and walking half a kilometer. Each item was scored according to standard procedure either as major restrictions (0 points), minor restrictions (50 points) or no restriction (100 points) (Aalto et al. 1999). An individual Physical Functioning Index score is the mean of scores all answered items.

Fear of falling (FoF) was assessed by a Visual Analogue Scale (VAS), that is, a horizontal 100 mm long line connecting the statements "No fear at all (0)" on the left and "Very great fear (100)" on the right. The participant was asked to indicate her overall fear of falling in daily life by drawing a mark on this line. The FoF score was the number of millimeters' between "no fear at all" and the subject's mark.

The participants completed the RAND-36 and VAS questionnaires at home and returned them when taking the physical performance tests. During this visit, participants were asked to verify the completeness of the answers.

## 4.5 Ethics

The study was approved by the Ethics Committee of the Pirkanmaa Hospital District (R02010). All participants gave their written informed consent prior to the 12-month intervention study, and again prior to the subsequent 12-month follow-up study.

## 4.6 Statistical analyses

In Study I, associations between the independent variables (age, weight, height, number of current diseases, education, years of education, years of estrogen use, leg extensor strength, sit-to-stand GRF step-on-a-stair GRF, postural stability and reaction time) and dependent variables (figure-of eight running time and quality of life) were determined by a Pearson product moment correlation coefficient. In addition, associations between some independent variables of interest (physical activity, walking per day) and the dependent variables were determined by a Spearman's rank order correlation coefficient. Thereafter, regression models were fitted to identify the best predictors of 1) figure-of-eight running time and 2) HRQoL score. Backward regression elimination procedure was used as a primary analysis. Stepwise selection procedure (forward stepping) was used to confirm that the selected models were consistent.

In Study II changes in weight, height and calcium intake were analyzed with a paired samples t-test. Analysis of covariance (ANCOVA) with 12-month measurements as dependent variables was used to assess the intervention-effect between the exercise and control groups. Baseline values, age and time interval between measurements were used as covariates. Post Hoc between-groups comparisons were done with Sidak´s adjustment for multiple comparisons. Due to skewed distributions in some outcome variables and to obtain the relative between-group differences, log-transformed variables of outcome were used in the ANCOVA. Geometric mean ratios and their 95% confidence intervals (CI) were calculated as antilogs of difference in group means at the end of the 12-month intervention. Pearson's Chi-square test and Poisson regression analysis were used to analyze between-group differences concerning fall variables. In addition, as an effect size Hedges' g was calculated for difference in change between the exercise (RES, BAL, COMB) and CON groups at 12 months using means of observed (unadjusted) values of the outcome variables and pooled standard deviation (S), (and multiplying by bias correction factor). Hedges' g:

$$g = \frac{\overline{X}_1 - \overline{X}_2}{S} \qquad S = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}}$$

$\overline{X}_1, \overline{X}_2$ = means in the groups, $n_1,n_2$ = number of subjects in the groups,
$s_1,s_2$ = standard deviations in the groups

In Study III only those variables which showed a statistically significant treatment effect after the 12-month exercise intervention were used as outcome variables. Linear mixed models with the restricted maximum likelihood estimation (REML) were used to assess the effects of exercise intervention at 12 months and the one-year follow-up. This type of analysis for repeated measures allows the incorporation of incomplete longitudinal data into the models. Post hoc between-group comparisons were performed using Sidak's adjustment for multiple comparisons. Due to the skewed distributions in some outcome variables and to obtain the relative between-groups differences, log-transformed variables of outcome were used in the linear mixed models. Proportional (%) differences and their 95 % confidence intervals (CI) were achieved by antilog of mean difference in changes between the groups.

In Study IV, psychometric properties of the RAND-36 scales were scrutinized at each measurement and compared to those of the Finnish standardization study (Aalto et al. 1999, Fayers and Machin 2007). The scale scores were compared to the population reference values and the values of the female age-equivalent samples of that study. Conceptual stability of the three measurements (McHorney 1996) was assessed by principal component analyses with orthogonal and oblique rotations (Nupponen and Karinkanta 2009). Based on the above described analyses, four RAND-36 variables (PF, EW, E and GH) were used as continuous variables in further analyses. The remaining four variables (RLP, SF, RLE, P) were considered dichotomous: ceiling effect (100) and no ceiling effect (<100). For the continuous variables linear mixed models with restricted maximum likelihood estimation (REML) were used to assess the effects of the exercise intervention at 12 months and 24 months. For the dichotomous variables, generalized estimating equations (GEE models) were used. These statistical models for repeated measures allow incorporation of incomplete longitudinal data into the analyses. Post hoc between-group comparisons were performed using Sidak's adjustment for multiple comparisons. Due to the skewed distribution of the FoF variable, original values were transformed for *logit* scores:

$$[\log\{(VAS)/(100-VAS)\}, 0=0.1, 100=99.9]$$

These logit scored variables were used in the linear mixed model analysis (Senn 1993, Fayers and Machin 2007). Analyses were age-adjusted.

Analyses in Study I were based on baseline data of all measured subjects (n=153). In Studies II and III, all comparisons were made between the four groups (3 training groups and the control group, n=149). However, in Study IV all comparisons were made between the pooled exercise intervention group (n=112) and the control group (n=37). Pooling was deemed to be justified as no between-group differences were indicated in the separate analyses of the three exercise groups.

In studies reporting the changes (II, III, IV), all results were based on the Intention-To-Treat analyses (ITT) of all available participants. In addition to the ITT analyses, efficacy analyses, that is, per protocol analyses of the exercise were conducted. The inclusion criterion for the active exercise group was the average training frequency at least twice a week during the 12-month trial. A significance level of 0.05 was maintained for all analyses in all studies.

# 5. RESULTS

## 5.1 Baseline data

Descriptive baseline characteristics of the study participants by groups are given in Table 3. There were no statistically significant differences between the groups at baseline. All the women lived independently at home and were retired. One third (32%) had a vocational education and 7% a university degree. About a third (36%) had no diagnosed chronic conditions, but 28% had at least two. The most common chronic diseases were high blood pressure (28%), high cholesterol (17%) and dysfunction of the thyroid gland (12%). In addition, 8% had diagnosed arthritis or reported joint pain. No one had any neurological disease or diabetes mellitus. Twenty-six percent of the women had used hormone replacement therapy (estrogen, HRT) at menopause. However, they had all stopped HRT use at least one year prior to the study.

One third (32%) of the participants reported taking brisk exercise or activity twice and 23% once a week. The most common brisk activities were walking, Nordic walking, cross-country skiing, swimming and aquatic exercises. Almost half (45%) of participants did not exercise regularly and were classified as sedentary.

*Table 3.* Descriptive data of the study participants by groups

| Variable | | RES[a] n=37 | BAL[b] n=37 | COMB[c] n=38 | CON[d] n=37 |
|---|---|---|---|---|---|
| Age, mean (SD) | | 73 (3) | 73 (2) | 73 (2) | 72 (2) |
| Height, cm, mean (SD) | | 161 (5) | 159 (6) | 159 (5) | 158 (6) |
| Weight, kg, mean (SD) | | 74 (11) | 71 (10) | 69 (11) | 74 (11) |
| BMI, kg/m$^2$, mean (SD) | | 29 (4) | 28 (3) | 28 (4) | 30 (4) |
| Calcium intake, mg/day, mean (SD) | | 940 (365) | 960 (331) | 916 (302) | 894 (264) |
| Years since menopause, mean (SD) | | 24 (6) | 22 (6) | 23 (5) | 23 (4) |
| Used HRT at menopause, n (%) | | 12 (32) | 7 (19) | 8 (21) | 11 (30) |
| Continuing medication by doctor, n (%) | | 19 (51) | 21 (57) | 20 (53) | 23 (62) |
| Self-rated general health, n (%) | | | | | |
| | very good | 1 (3) | 2 (5) | 1 (3) | 2 (5) |
| | good | 16 (43) | 13 (35) | 20 (53) | 13 (35) |
| | fair | 19 (51) | 21 (57) | 16 (42) | 21 (57) |
| | poor | 1 (3) | 0 (0) | 0 (0) | 1 (3) |
| | very poor | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Physical activity/week, n (%) | | | | | |
| | none or some | 19 (51) | 16 (43) | 15 (40) | 17 (46) |
| | brisk exercise 1x | 8 (22) | 8 (22) | 9 (24) | 9 (24) |
| | brisk exercise 2x | 10 (27) | 13 (35) | 14 (37) | 11 (30) |
| Walking/day, n (%) | | | | | |
| | less than 1 km | 2 (5) | 2 (5) | 2 (5) | 4 (11) |
| | 1 to 3 km | 23 (62) | 26 (70) | 23 (61) | 24 (65) |
| | 4 to 6 km | 10 (27) | 6 (16) | 10 (26) | 8 (22) |
| | over 6 km | 1 (3) | 3 (8) | 3 (8) | 1 (3) |

[a]Resistance training group, [b]Balance-jumping training group, [c]Combination of resistance and balance-jumping training group, [d]Control group, HRT=hormone replacement therapy (estrogen)

### 5.1.1 Factors associated with dynamic balance and health-related quality of life (HRQoL) (Study I)

Baseline data were collected from 153 women of whom 149 were randomized to the intervention study (one women refused to continue and three women were excluded from the intervention study due to medical reasons after the baseline measurements). The whole baseline data (n=153) was used to evaluate cross-sectional associations between physical performance, physical activity and health-related quality of life (HLQoL).

### 5.1.1.1 Dynamic balance and agility

As seen in Table 4, lower limb muscle strength, postural stability balance, brisk physical activity, number of diseases and age were statistically significantly associated with dynamic balance and agility measured by figure-of-eight running time. In particular, maximal isometric lower limb extension strength and the ground reaction forces (GRF) measured during the functional sit-to-stand and step-on-a-stair tests showed fair associations with figure-of-eight running time (r= -0.32 to -0.43; the better the strength, the better the balance and agility).

*Table 4.* Pearson product moment correlations between measures of dynamic balance (figure-of-eight running time) and health-related quality of life (HRQoL) scores and selective predictive variables.

| | | HRQoL scores | |
|---|---|---|---|
| **Predictor** | **Dynamic balance**[2] | RAND-36 total[3] | RAND-36 sum index[4] |
| Physical activity[1] | -.26** | .21* | .19* |
| Walk per day[1] | -.22** | .24** | .26** |
| Number of diseases | .11 | -.18* | -.20* |
| Weight | .20* | -.04 | -.02 |
| Age | .31*** | -.03 | .02 |
| Lower limb extension strength | -.32*** | .18* | .14 |
| Reaction time | .16 | -.03 | -.01 |
| Sit-to-stand GRF | -.35*** | .09 | .10 |
| Step-on-stair GRF | -.43*** | .20* | .18* |
| Postural stability | .27** | -.11 | -.06 |
| Figure-of-eight running | -- | -.31*** | -.24** |

GRF=Ground reaction forces, *p<0.05, **p<0.01, *** p<0.001
[1]Spearman's rank order correlation, [2]measured as figure-of-8 running time: lesser time indicates better dynamic balance [3]sum of 36 question scores (0-3600), [4]sum of 8 scale scores (0-800)
Pearson product moment correlation between RAND-36 total and sum index .98 (p<.001)

In the regression analysis with backward elimination, lower limb extension strength, step-on-stair and sit-to-stand GRFs, postural stability, age, brisk physical activity and number of diseases explained 42% of the variance of dynamic balance and agility (Table 5). The model was consist with the result of the stepwise selection method, and the step-on-stair GRF was the strongest predictor of the figure-of-eight running time, explaining 18% of variance.

*Table 5.* Dynamic balance (figure-of-eight running time) regression model summary

| Variable | Predictor | β | SE | p-value |
|---|---|---|---|---|
| Dynamic balance | Constant | 5.898 | | |
| | Step-on-stair GRF (N/kg) | -.370 | .096 | <.001 |
| | Age (yr) | .291 | .088 | .001 |
| | Lower limb extension strength (N/kg) | -1.176 | .639 | .068 |
| | Brisk exercise | | | |
| | ≥ 2 x week vs. none | -1.507 | .463 | .001 |
| | 1 x week vs. none | -.917 | .526 | .084 |
| | Number of diseases | .602 | .253 | .019 |
| | Sit to-stand GRF (N/kg) | -.450 | .187 | .017 |
| | Postural stability | .331 | .139 | .019 |
| $R^2$ = 0.42, SEE = 2.40, n = 149 | | | | |

GRF=Ground reaction forces

### *5.1.1.2 HRQoL*

Figure-of-eight running time was significantly correlated with HRQoL using Rand-36 scores (Table 4). Instead, predictors such as age and education were not associated with the Rand-36 scores. In the regression analysis with backward elimination, figure-of-eight running time, number of diseases and walking more than 3 km per day explained 14% of the variance of the Rand-36 total score. When using the Rand-36 sum index, only figure-of-eight running time and number of diseases remained in the final model and explained 9% of the variance. (Table 6) In the forward stepwise regression analysis, figure-of-eight running time was the strongest predictor, explaining 5 and 9% of the variance of the sum index and total Rand-36 scores respectively.

*Table 6.* Health-Related Quality of Life (RAND-36) regression models summaries

| Variable | Predictor | β | SE | p-value |
|---|---|---|---|---|
| RAND-36 total score[1] | Constant | 3506.82 | | |
| | Figure-of-8 running (s) | -35.80 | 10.77 | .001 |
| | Number of diseases | -75.45 | 41.22 | .069 |
| | Walk ≥ 3 km /day | 130.30 | 73.69 | .079 |
| $R^2$ = 0.14, SEE = 389, n = 150 | | | | |
| RAND-36 sum index score[2] | Constant | 815.77 | | |
| | Figure-of-8 running (s) | -7.57 | 2.74 | .007 |
| | Number of diseases | -23.46 | 10.70 | .030 |
| $R^2$ = 0.09, SEE = 102, n = 150 | | | | |

[1]sum of 36 question scores (0-3600), [2]sum of 8 scale scores (0-800)

## 5.2 Feasibility of the exercise intervention (Study II)

### 5.2.1 Adherence

The drop-out rate during the 12-month exercise intervention was low; only five persons (3.4%) withdrew from the study before the 12-month assessment. (The trial profile is shown in Figure 7 on page 52). There were four dropouts in the training groups and one in the control group: two women died (1 in the BAL and 1 in the CON) and three lost interest (1 in the BAL and 2 in the COMB).

Training compliance was good. Attendance (calculated as percentage of all training sessions offered) was 67% (individual range 0 to 100%), being highest in the RES group (74%), followed by the COMB group (67%) and the BAL group (59%). Moreover, 29 women (78%) in the RES, 25 (66%) in the COMB, and 22 (59%) in the BAL group trained on average at least twice a week. Two women in the COMB group did not start the training program and three women in the BAL group participated in fewer than 10 sessions.

### 5.2.2 Adverse events

Fourteen exercisers (13%) consulted the attending physician due to musculoskeletal symptoms or injuries during the 12-month intervention (Table 7). In addition, one woman was taken to the emergency unit due to acute low back pain during the class.

Twelve of these 15 women (80%) returned to training classes, and three women who did not return still participated in the 12-month assessment. Four exercisers (2 in the BAL and 2 in the COMB) fell during the supervised intervention exercise, but returned to the training classes within two weeks. There were no differences in the numbers of monthly reported health problems between exercisers and controls (p=.955) (Table 7).

*Table 7.* Reported symptoms and consultations of the study physician and accidents in exercise classes during the 12-month intervention by group.

| **Variable** | **RES**[a] (n=37) | **BAL**[b] (n=37) | **COMB**[c] (n=38) | **CON**[d] (n=37) |
|---|---|---|---|---|
| Reported some symptoms, n (%) | 19 (51) | 19 (51) | 17 (46) | 19 (51) |
| upper limb symptoms | 2 (5) | 1 (3) | 4 (11) | 2 (5) |
| knee pain | 9 (24) | 7 (19) | 5 (14) | 5 (14) |
| hip pain | 2 (5) | 2 (5) | 1 (3) | 3 (8) |
| ankle or heel pain/symptoms | 0 (0) | 2 (5) | 3 (8) | 4 (11) |
| low back pain | 4 (11) | 2 (5) | 6 (16) | 4 (11) |
| heart/respiration symptoms or stroke (TIA) | 2 (5) | 3 (8) | 0 (0) | 2 (5) |
| dizziness | 0 (0) | 2 (5) | 2 (5) | 3 (8) |
| muscle pain or disorder | 3 (8) | 5 (14) | 5 (14) | 2 (5) |
| other or general joint pain | 0 (0) | 1 (3) | 0 (0) | 1 (3) |
| Consulted the study physician, n (%) | 5 (14) | 5 (14) | 4 (11) | - |
| ligament injury of the knee | 1 (3) | 0 (0) | 0 (0) | - |
| minor knee injury | 1 (3) | 0 (0) | 1 (3) | - |
| partial rupture of the m. quadriceps femoris | 0 (0) | 1 (3) | 0 (0) | - |
| overuse symptoms | 3 (8) | 4 (11) | 3 (8) | - |
| Accidents at the exercise classes, n (%) | 1 (3) | 2 (5) | 3 (8) | - |
| were taken to the emergency unit | 0 (0) | 0 (0) | 1 (3) | - |
| fainted | 1 (3) | 0 (0) | 0 (0) | - |
| fell | 0 (0) | 2 (5) | 2 (5) | - |

[a] resistance training group, [b]balance-jumping training group, [c]combination of resistance and balance-jumping training group, [d]control group

There are no statistically significance differences between the groups.

## 5.3 Background variables

The 12-month assessment was done on 144 (97%) and the 24-month assessment on 120 (81%) women. There were no changes in height or calcium intake during the intervention. Mean weight decreased at least slightly in all groups, but statistically significantly only in the BAL (-0.76 kg, 95% CI: -1.46 to -0.07, p=0.033) and the COMB (-0.94 kg, 95% CI: -1.80 to -0.09).

The mean duration of moderate intensity (4.5 MET) non-intervention-related physical activity varied from 5 to 7 and 4 to 6 hours per week during the intervention and the follow-up, respectively. There were no statistically significant differences between the groups or time periods (intervention and follow-up). Six women in the RES group and eight in the COMB group continued resistance training at least at some level during the follow-up period. In addition, four women in the BAL group and one in the CON group started resistance training.

*Attendance at the post-training follow-up (24-mo) assessments*. There were more non-attendees (refused and withdrew) in the CON group than the training groups during the follow-up (10 vs. 4-6, see Figure 7 at page 52). The CON group non-attendees were slightly older and heavier, and more of them reported a decline in self-rated physical functioning during the intervention than the CON group attendees. The baseline bone values of the non-attendees did not differ from those of the attendees, except for slightly higher femoral neck Z among the attendees of the RES group. In addition, the attendees had slightly better baseline figure-of-eight – running time in the RES and COMB groups, and isometric lower limb extension force in the COMB group compared to respective non-attendees. In the training groups, the training compliance was somewhat better among the 24-month assessment attendees than non-attendees.

## 5.4 Effects of exercise intervention and maintenance of exercise-induced benefits (Studies II and III)

### 5.4.1 Physical functioning

The absolute values of the physical performance and self-rated physical functioning at baseline, 12 months and 24 months are given in Table 8.

*Table 8.* Observed values of the physical performance and self-rated physical functioning at baseline, 12 months and 24 months, and calculated effect size at 12 months.

| | Mean (SD) | | | |
|---|---|---|---|---|
| | **Baseline** n=149 | **12 months** n=144 | **24 months** n=120 | **Hedges' g*** **(95% CI)** |
| **Lower limb extension force (N/kg)** | | | | |
| RES | 16.2 (3.5) | 20.2 (4.6) | 18.9 (3.7) | .87 (.38, 1.37) |
| BAL | 16.5 (3.6) | 19.6 (4.3) | 19.1 (3.6) | .61 (.11, 1.11) |
| COMB | 16.6 (4.0) | 20.2 (4.4) | 19.1 (4.5) | .94 (.43, 1.44) |
| CON | 16.1 (2.5) | 17.6 (2.8) | 19.0 (2.7) | - |
| **Dynamic balance and agility (figure-of-8 running time, s)** | | | | |
| RES | 20.7 (3.2) | 20.0 (3.2) | 20.2 (3.8) | .48 (-.01, .96) |
| BAL | 20.6 (2.9) | 19.4 (3.0) | 19.4 (2.5) | .78 (.26, 1.30) |
| COMB | 21.0 (3.2) | 19.3 (2.2) | 20.0 (2.2) | .92 (.41, 1.40) |
| CON | 20.0 (2.6) | 20.0 (2.8) | 19.2 (1.4) | - |
| **Reaction time (ms)** | | | | |
| RES | 526 (100) | 517 (88) | 514 (96) | .28 (-.19, .75) |
| BAL | 539 (93) | 507 (91) | 541 (69) | .50 (.01, .99) |
| COMB | 546 (118) | 526 (101) | 532 (102) | .43 (-.05, .91) |
| CON | 509 (118) | 522 (98) | 537 (93) | - |
| **Postural stability (index)** | | | | |
| RES | 3.0 (1.2) | 2.5 (0.9) | 2.3 (0.8) | .25 (-.23, .73) |
| BAL | 2.4 (0.7) | 2.3 (0.7) | 2.2 (0.7) | -.22 (-.71, .27) |
| COMB | 2.9 (1.7) | 2.2 (1.0) | 2.2 (0.7) | .33 (-.16, .81) |
| CON | 2.7 (1.0) | 2.4 (0.9) | 2.1 (0.7) | - |
| **Self-rated physical functioning (index score 0-100)** | | | | |
| RES | 83.4 (11.7) | 84.8 (12.5) | 78.8 (20.0) | .24 (-.23, .70) |
| BAL | 84.6 (12.0) | 84.7 (11.5) | 85.5 (8.7) | .13 (-.34, .60) |
| COMB | 82.5 (14.9) | 86.0 (13.6) | 79.6 (19.9) | .37 (-.10, .84) |
| CON | 82.0 (12.4) | 80.3 (16.4) | 82.0 (14.2) | - |

*Effect size (Hedges' g) calculated for difference in change between the exercise (RES, BAL, COMB) and CON groups at 12 months. Effect sizes defined as small: g=.20, medium: g=.50 and large: g=.80
RES=Resistance training group, BAL=Balance-jumping training group, COMB=Combination of resistance and balance-jumping training group, CON=Control group

*Effects of exercise on physical performance.* Compared with the CON group, the mean gain in isometric lower limb extension force at 12 months was statistically significantly greater in the RES and COMB groups; treatment effect being 14% (95% CI: 4 to 25%) and 13% (95% CI: 2 to 25%) respectively. In addition, the figure-of-eight running time improved significantly more in the BAL (effect 6%; 95% CI: 1 to 11%) and in the COMB (8%; 3 to 12%) compared with the CON group. (Figure 9) Instead, there were no between-group differences in the secondary outcomes (reaction time (p=.308) and postural stability (p=.246)) after the intervention.

In the efficacy analysis, the above-noted between-group differences in lower limb extension force increased. Furthermore, the dynamic balance change was significantly higher in the BAL and COMB groups also compared with the RES group. (Figure 9)

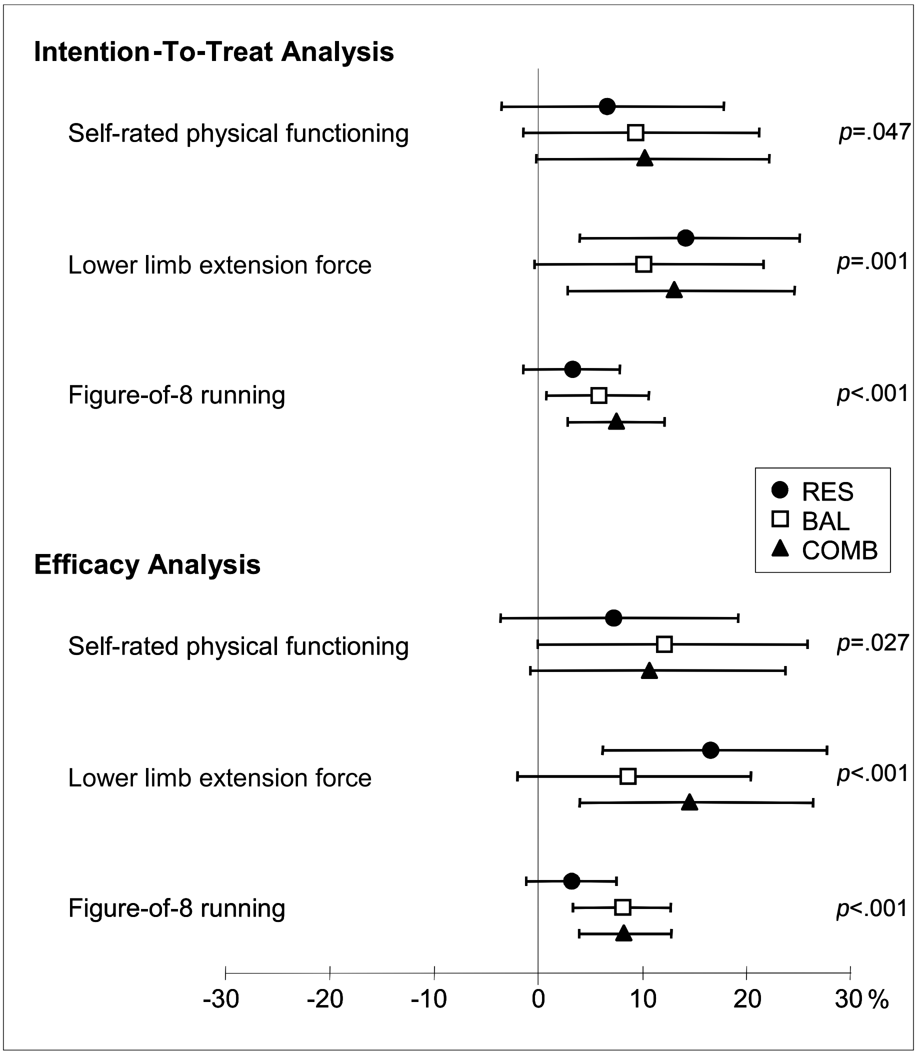



Figure 9. Adjusted percentage differences of the training participants compared with the controls (mean, 95% CI) after intervention in main physical functioning variables using Intention-to-Treat and Efficacy analysis. *RES* resistance training group, *BAL* balance-jumping training group, *COMB* combination training group. Baseline values, age, and time between measurements were used as covariates. *p v*alues are for between-group differences in the ANCOVA (F-test). The 95% CI are Sidak-adjusted. Adapted from the original publication (Karinkanta et al. 2007).

*Maintenance.* At 24 months, about a half of the exercise-induced gain in dynamic balance and agility (figure-of-eight running time) was still seen in the COMB group compared to CON group (4%, 95% CI 1 to 8%, Figure 10). Furthermore, in the efficacy analysis the residual exercise-effect increased in the COMB group (7%, 95% CI 3 to 10%) and was also seen in the BAL group (5%, 95% CI 1 to 9%).

Instead, about ten percent mean gain in isometric lower limb extension force in the RES and COMB groups at 12 months, was lost at 24 months (Figure 10).

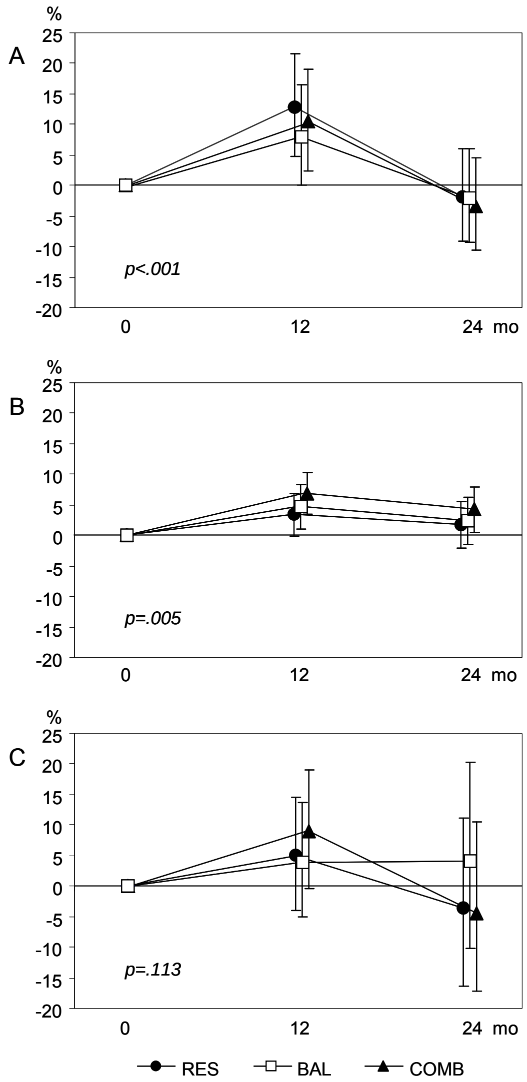



Figure 10. Trainees' age-adjusted percentage differences in change compared to controls (mean, 95% CI) after the intervention (12 months) and at the one-year follow-up (24 months) in physical functioning variables (Intention to treat –analysis). **A** lower limb extension force, **B** dynamic balance and agility **C** self-rated physical functioning. *RES* resistance training group, *BAL* balance-jumping training group, *COMB* combination training group. *p* values are for time*group interaction (3 time points, 4 groups), linear mixed model with age at baseline as covariate. Adapted from the original publication (Karinkanta et al. 2009).

*Self-rated physical functioning.* In all groups, the distribution of the Physical Functioning Index score (PF) clearly accumulated on the high values indicating good physical functioning. At baseline, 10% of the participants scored 100, maximum value of the Index. The mean baseline PF Index score for the total group (82.7, SD 13.0) was significantly higher (p<0.001) than the means observed in the standardized population samples aged 75-79 (45.1, SD 28.4) and 70-74 (54.1, SD 27.8) years (Aalto et al. 1999).

At 12 months, minor changes in the PF Index score means were observed in the COMB, RES, and CON groups (Table 8). A significant treatment effect was found between the COMB and CON groups (10%; 95% CI 0 to 22%) (Figure 9). The efficacy analyses indicated mean gain of 12% (95% CI 0 to 26%) in the BAL group and 11% (95% CI -1 to 24%) in the COMB group compared with the CON group (Figure 9 above). At 24 months, however, the within-group variance had increased and the between-group difference had disappeared (Figure 10).

### 5.4.2 Bone mass and structure

The absolute values of bone variables at baseline, 12 months and 24 are given in Table 9.

*Table 9.* Observed values of bone variables (mean and SD) at baseline, 12 months and 24 months, and calculated effect size at 12 months

| | Mean (SD) | | | |
|---|---|---|---|---|
| | **Baseline** n=149 | **12 months** n=144 | **24 months** n=120 | **Hedges' g* (95% CI)** |
| **Femoral neck** | | | | |
| BMC (g) | | | | |
| RES | 2.74 (0.35) | 2.71 (0.33) | 2.68 (0.37) | .14 (-.32, .60) |
| BAL | 2.77 (0.42) | 2.73 (0.40) | 2.69 (0.37) | .03 (-.44, .49) |
| COMB | 2.68 (0.28)) | 2.65 (0.29) | 2.63 (0.28) | .16 (-.30, .62) |
| CON | 2.71 (0.45) | 2.67 (0.44) | 2.59 (0.46) | - |
| Z ($mm^3$) | | | | |
| RES | 1,431 (238) | 1,430 (235) | 1,420 (244) | .38 (-.11, .87) |
| BAL | 1,389 (220) | 1,386 (239) | 1,395 (245) | .35 (-.16, .85) |
| COMB | 1,411 (164) | 1,353 (154) | 1,325 (216) | -.34 (-.85, .17) |
| CON | 1,395 (259) | 1,362 (247) | 1,326 (292) | - |
| **Distal tibia** | | | | |
| TrD ($mg/cm^3$) | | | | |
| RES | 220 (26) | 219 (26) | 221 (26) | .01 (-.45, .47) |
| BAL | 223 (34) | 224 (34) | 223 (35) | .41 (-.06, .88) |
| COMB | 215 (39) | 215 (39) | 213 (40) | .07 (-.39, .53) |
| CON | 227 (33) | 226 (33) | 222 (40) | - |
| **Distal tibia** | | | | |
| BSI ($mm^3$) | | | | |
| RES | 796 (313) | 781 (310) | 793 (311) | .18 (-.28, .64) |
| BAL | 867 (251) | 870 (247) | 842 (260) | .43 (-.04, .90) |
| COMB | 750 (325) | 741 (324) | 747 (338) | .30 (-.17, .76) |
| CON | 888 (306) | 862 (307) | 835 (321) | - |

Continued overleaf

Table 9 continued

| | Mean (SD) | | | |
|---|---|---|---|---|
| | **Baseline** n=149 | **12 months** n=144 | **24 months** n=120 | **Hedges' g*** **(95% CI)** |
| **Tibial shaft** | | | | |
| CoD (mg/cm$^3$) | | | | |
| RES | 1,130 (34) | 1,125 (35) | 1,127 (34) | -.52 (-.99, -.05) |
| BAL | 1,120 (31) | 1,121 (30) | 1,122 (31) | -.14 (-.61, .32) |
| COMB | 1,120 (34) | 1,118 (34) | 1,122 (36) | -.36 (-.37, .10) |
| CON | 1,125 (37) | 1,127 (40) | 1,117 (42) | - |
| CoA (mm$^2$) | | | | |
| RES | 245 (29) | 245 (29) | 241 (30) | .54 (.07, 1.00) |
| BAL | 248 (25) | 246 (25) | 247 (25) | .50 (.02, .97) |
| COMB | 238 (29) | 237 (30) | 236 (31) | .34 (-.13, .80) |
| CON | 245 (34) | 241 (33) | 242 (39) | - |
| BSI (mm$^3$) | | | | |
| RES | 1,334 (184) | 1,329 (197) | 1,324 (187) | .43 (-.04, .89) |
| BAL | 1,329 (197) | 1,323 (198) | 1,328 (197) | .40 (-.07, 87) |
| COMB | 1,303 (174) | 1,297 (177) | 1,293 (167) | .32 (-.14, .79) |
| CON | 1,273 (210) | 1,255 (211) | 1,239 (216) | - |
| **Distal Radius** | | | | |
| TrD (mg/cm$^3$) | | | | |
| RES | 189 (37) | 184 (42) | 185 (42) | - |
| BAL | 190 (45) | 189 (49) | 186 (48) | - |
| COMB | 180 (47) | 180 (47) | 179 (50) | - |
| CON | 186 (42) | 183 (44) | 177 (40) | - |
| BSI (mm$^3$) | | | | |
| RES | 232 (99) | 234 (83) | 224 (92) | - |
| BAL | 246 (70) | 248 (87) | 242 (88) | - |
| COMB | 217 (75) | 216 (81) | 219 (76) | - |
| CON | 256 (85) | 266 (79) | 254 (83) | - |
| **Radial shaft** | | | | |
| CoD (mg/cm$^3$) | | | | - |
| RES | 1,136 (45) | 1,135 (40) | 1,132 (43) | - |
| BAL | 1,136 (33) | 1,133 (34) | 1,131 (37) | - |
| COMB | 1,131 (40) | 1,126 (40) | 1,128 (40) | - |
| CON | 1,145 (39) | 1,143 (37) | 1,137 (42) | |
| CoA (mm$^2$) | | | | |
| RES | 68.3 (11.4) | 68.4 (10.7) | 68.2 (11.6) | - |
| BAL | 69.8 (9.9) | 69.7 (10.5) | 69.0 (9.0) | - |
| COMB | 66.6 (10.7) | 66.5 (11.1) | 67.2 (11.0) | - |
| CON | 68.8 (11.4 | 68.4 (11.5) | 66.7 (11.6) | - |
| BSI (mm$^3$) | | | | |
| RES | 212 (45) | 211 (40) | 213 (43) | - |
| BAL | 214 (43) | 214 (46) | 212 (37) | - |
| COMB | 204 (37) | 203 (39) | 207 (37) | - |
| CON | 201 (44) | 199 (43) | 192 (38) | - |

*Effect size (Hedges, g) calculated for difference in change between the exercise (RES, BAL, COMB) and CON groups at 12 months. Effect sizes defined as small: g=.20, medium: g=.50 and large: g=.80
RES=Resistance training group, BAL=Balance-jumping training group, COMB=Combination of resistance and balance-jumping training group, CON=Control group
BMC=bone mineral content, Z=section modulus at the femoral neck, TrD=trabecular density, BSI=bone strength index, CoA=cortical area, CoD=cortical density

*Effects of exercise on bone*. Concerning bone mass, the ITT analysis did not show any significant treatment effect at the femoral neck BMC (p=.820). Instead, concerning bone structural measures, a significant effect on the section modulus (Z) of the femoral neck between the RES and COMB groups was seen (effect: 5%; 95% CI 0 to 9%). However, this effect on Z did not reach statistical significance in the efficacy analysis. (Figure 11)

In the pQCT variables, there were no significant between-group differences in the ITT analysis of the distal or midshaft sites of the tibia or radius. In the efficacy analysis, however, tibial shaft bone strength index (BSI) decreased 2% (95% CI 0 to 4%) less in the COMB group than in the CON group (Figure 11). Moreover, a trend was seen suggesting that training could be beneficial for the tibial shaft cortical area and the distal tibia BSI, too (Figure 11).

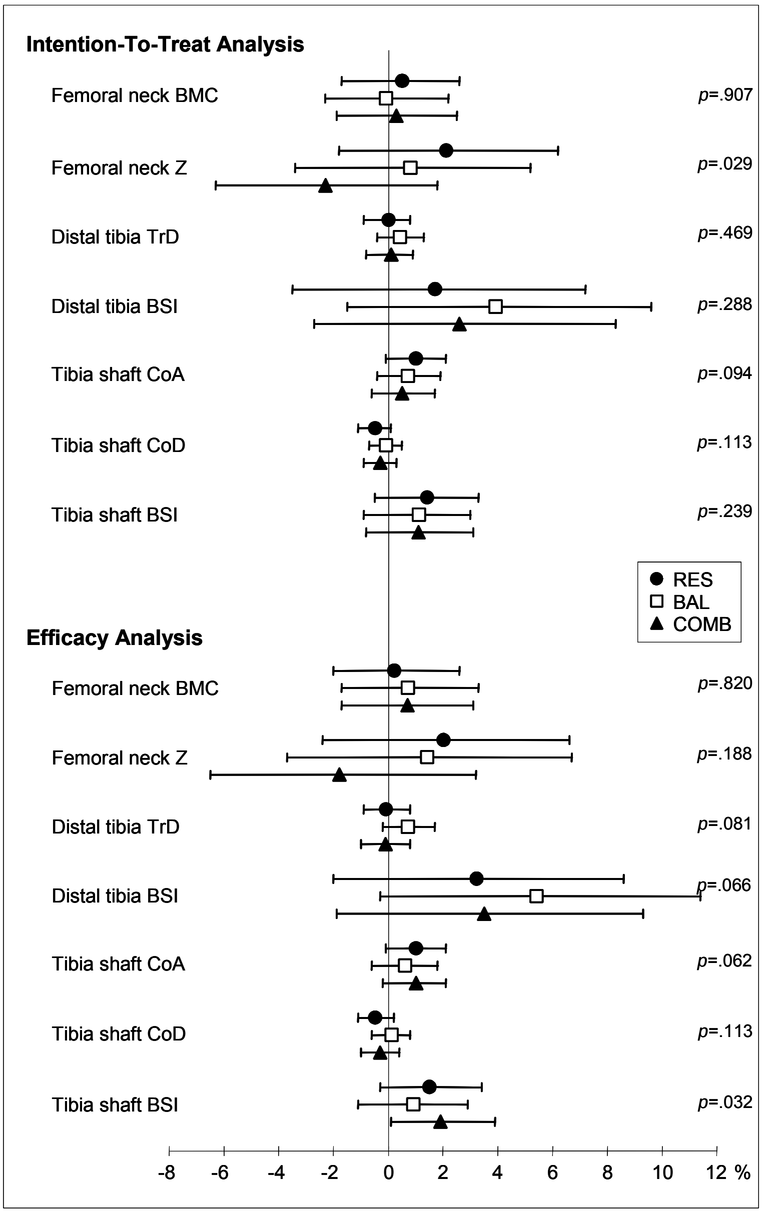



Figure 11. Adjusted percentage differences of the training participants compared with the controls (mean, 95% CI) after intervention in the lower limb bone variables using Intention-To-Treat and Efficacy analysis. *BMC* bone mineral content, *Z* section modulus at the femoral neck, *TrD* trabecular density, *BSI* bone strength index, *CoA* cortical area, *CoD* cortical density. *RES* resistance training group, *BAL* balance-jumping training group, *COMB* combination training group. Baseline values, age, and time between measurements were used as covariates. *p* values are for between-group differences in the ANCOVA (F-test). The 95% CIs are Sidak-adjusted. Adapted from the original publication (Karinkanta et al. 2007).

*Maintenance.* At 24 months, the between-group difference in the femoral neck Z between the RES and COMB groups had diminished, and did not reach statistical significance (Figure 12). By contrast, a borderline trend was seen in maintenance of exercise benefit in tibial shaft BSI among those COMB trainees who trained twice a week more during the intervention. Of 1.9% exercise effect achieved during the intervention, 1.3% was maintained at 24 months (95% -0.1 to 2.7%, p=.065) (Figure 12).

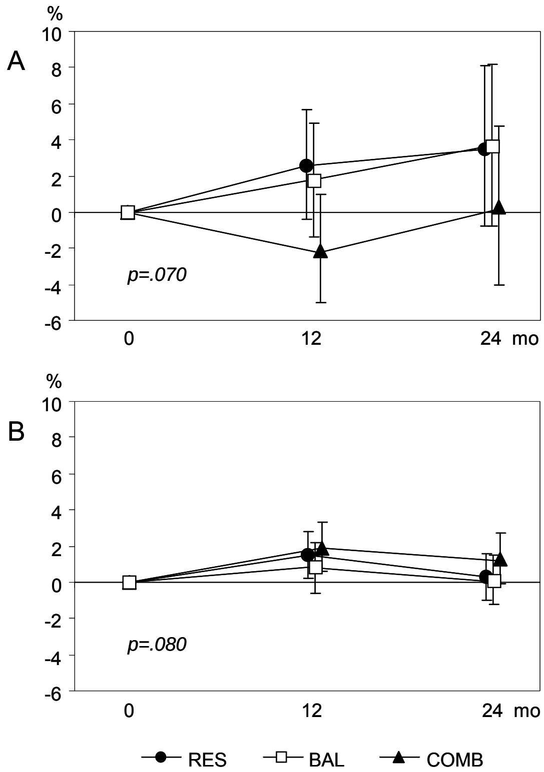



Figure 12. Trainees' age-adjusted percentage differences in change compared to controls (mean, 95% CI) after the intervention (12 months) and at one-year follow-up (24 months) in bone variables. **A** section modulus (Z) of the femoral neck (Intention to treat analysis), **B** tibial shaft bone strength index (BSI) (Efficacy analysis). *RES* resistance training group, *BAL* balance-jumping training group, *COMB* combination training group. *p* values are for time*group interaction (3 time points, 4 groups), linear mixed model with age at baseline as covariate. Adapted from the original publication (Karinkanta et al. 2009).

### 5.4.3 Falls and fractures

During the 12-month intervention period, there were altogether 58 falls, 38 fallers and 5 fractures (Table 10) with no statistically significant between-group differences. During the subsequent 12-month follow-up of 120 women, 49 falls and five fractures were reported. There were proportionally more fallers in the CON group (39% vs. 19-31%), but this difference did not reach the statistical significance (Table 10).

*Table 10.* Falls and fractures during the 12-month intervention and subsequent follow-up by group.

| Variable | RES[a] | BAL[b] | COMB[c] | CON[d] |
|---|---|---|---|---|
| **12-month intervention** | | | | |
| Falls, n | 8 | 18 | 19 | 13 |
| Falls/person years | 0.24 | 0.55 | 0.58 | 0.42 |
| Incidence Rate Ratio | 0.56 | 1.19 | 1.31 | 1 (ref.) |
| (95% CI) | (0.25-1.28) | (0.61-2.35) | (0.68-2.54) | |
| Fallers, n (%) | 7 (19) | 10 (27) | 13 (35) | 8 (22) |
| multiple fallers (≥ 2 falls) | 1 (3) | 6 (16) | 5 (14) | 4 (11) |
| Fractures, n | 2 | 0 | 0 | 2 |
| wrist (radius) | 2 | 0 | 0 | 1 |
| toe | 0 | 0 | 0 | 1 |
| **Subsequent 12-month follow-up*** | | | | |
| Falls, n | 11 | 11 | 13 | 13 |
| Falls/person years | 0.39 | 0.41 | 0.50 | 0.61 |
| Incidence Rate Ratio | 0.57 | 0.61 | 0.73 | 1 (ref.) |
| (95% CI) | (0.26-1.26) | (0.28-1.35) | (0.34-1.55) | |
| Fallers, n (%) | 9 (27) | 10 (31) | 6 (19) | 10 (39) |
| multiple fallers (≥ 2 falls) | 2 (6) | 1 (3) | 3 (9) | 2 (8) |
| Fractures | 2 | 1 | 1 | 1 |
| hip[#] | 1 | 0 | 1 | 0 |
| rib[#] | 1 | 0 | 0 | 0 |
| proximal humerus | 0 | 1 | 0 | 0 |
| patella | 0 | 0 | 0 | 1 |

[a]Resistance training group, [b]Balance-jumping training group, [c]Combination of resistance and balance-jumping training group, [d]Control group, ref.=reference group
*12-month period after the end of the exercise intervention (n=120), [#]High-energy fractures; caused by a bicycle accident and a fall from over 1 meter height.
There were no statistically significance differences between the groups.

## 5.5 Health-related quality of life (HRQoL) and fear of falling (Study IV)

### 5.5.1 Level of HRQoL and measurement properties of the scales

On all RAND-36 scales, the scores accumulated at the values indicating better health and well-being. Consequently, the score distributions were strongly skewed, except in the GH scale. Therefore the psychometric properties of the RAND-36 scales were somewhat impaired (Table 11). The Cronbach's alphas were around .80

and slightly lower than in the Finnish reference study (.80-.94) (Aalto et al. 1999). Ceiling effect in P, RLP, RLE and SF scales were larger than those in the Finnish population sample of 65-79 year-olds (Aalto et al. 1999).

*Table 11.* Descriptive data of HRQoL and FoF variables in total sample of participants at baseline, 12 months and 24 months

| Score | | n | Mean | SD | Range | Median | Ceiling effect[a] % | Complete responses % | Cronbach's Alpha |
|---|---|---|---|---|---|---|---|---|---|
| **RAND-36** | | | | | | | | | |
| Physical functioning (PF) | Baseline | 148 | 82.7 | 13.0 | 40–100 | 85 | 9.5 | 97.3 | .76 |
| | 12 mo | 142 | 84.0 | 13.6 | 25–100 | 85 | 14.1 | 99.3 | .80 |
| | 24 mo | 120 | 81.1 | 16.7 | 10–100 | 85 | 11.7 | 96.6 | .86 |
| Role functioning/ physical (RLP) | Baseline | 148 | 83.6 | 27.6 | 0-100 | 100 | 65.5 | 100.0 | .75 |
| | 12 mo | 142 | 80.8 | 31.2 | 0-100 | 100 | 64.1 | 100.0 | .81 |
| | 24 mo | 120 | 74.4 | 34.5 | 0-100 | 100 | 55.0 | 99.2 | .81 |
| Role functioning /emotional (RLE) | Baseline | 148 | 76.8 | 33.4 | 0-100 | 100 | 60.1 | 100.0 | .71 |
| | 12 mo | 142 | 83.1 | 28.8 | 0-100 | 100 | 67.6 | 100.0 | .66 |
| | 24 mo | 120 | 75.6 | 34.5 | 0-100 | 100 | 52.5 | 99.2 | .54 |
| Energy/ fatigue (E) | Baseline | 148 | 73.5 | 17.0 | 30–100 | 75 | 6.8 | 100.0 | .79 |
| | 12 mo | 142 | 73.6 | 17.3 | 25–100 | 75 | 6.3 | 100.0 | .83 |
| | 24 mo | 120 | 70.4 | 18.5 | 15–100 | 75 | 4.2 | 99.2 | .79 |
| Emotional well-being (EW) | Baseline | 148 | 83.1 | 14.5 | 40–100 | 88 | 10.1 | 100.0 | .82 |
| | 12 mo | 142 | 83.3 | 13.7 | 36–100 | 88 | 11.3 | 100.0 | .79 |
| | 24 mo | 120 | 80.8 | 16.4 | 32–100 | 84 | 10.8 | 98.3 | .81 |
| Social functioning (SF) | Baseline | 148 | 92.7 | 13.5 | 50–100 | 100 | 72.3 | 100.0 | .74 |
| | 12 mo | 141[b] | 93.2 | 14.0 | 12.5–100 | 100 | 73.8 | 99.3 | .70 |
| | 24 mo | 120 | 88.8 | 18.7 | 12.5–100 | 100 | 65.0 | 100.0 | .91 |
| Pain (P) | Baseline | 148 | 80.9 | 17.6 | 10–100 | 80 | 27.0 | 100.0 | .77 |
| | 12 mo | 142 | 80.3 | 19.9 | 22.5–100 | 90 | 31.7 | 100.0 | .84 |
| | 24 mo | 120 | 78.9 | 20.5 | 10–100 | 80 | 30.0 | 100.0 | .85 |
| General health (GH) | Baseline | 148 | 65.3 | 14.4 | 25–95 | 65 | 0.0 | 100.0 | .60 |
| | 12 mo | 142 | 67.4 | 14.9 | 25–100 | 70 | 1.4 | 100.0 | .64 |
| | 24 mo | 120 | 65.5 | 15.4 | 25–100 | 65 | 1.7 | 99.2 | .67 |
| **FoF** | Baseline | 148 | 24.0 | 19.3 | 0-87 | 23 | 9.5 | . | . |
| | 12 mo | 140 | 13.0 | 17.7 | 0-88 | 5 | 36.4 | . | . |
| | 24 mo | 120 | 16.5 | 20.4 | 0-92 | 9 | 41.7 | . | . |

[a] In the FoF score floor effect (0, no fear at all) also meaning "best possible"
[b] One participant had a missing item on this 2-item scale and therefore the score could not be calculated

Principal component analyses revealed two uncorrelated components (Peaceful Mind and Vitality, Physical Capability) with almost equal proportions of explained variance and nearly identical item loadings and communalities at the three measurements. Total percents explained were 36-40%. (Nupponen and Karinkanta 2009, Nupponen and Karinkanta 2011) (Appendix 2).

The psychometric properties, especially the high ceiling effect of some RAND-36 scales, were taken into account in the analyses of exercise effect on HRQoL. PF, EW, E and GH scales were used as continuous variables, and the remaining four variables (RLP, SF, RLE, P scales) were considered dichotomous: ceiling effect (100) and no ceiling effect (<100).

### 5.5.2 Effects of exercise intervention on HRQoL

During the intervention, statistically significant between-group differences were found in one of the eight HRQoL variables: GH improved slightly in the pooled exercise group (EX), but decreased in the CON group, the mean difference in change being 6 scores (95% CI 1 to 11, p=.019) (Figure 13, Table 12). However, this minor benefit in GH was lost at 24-month assessment. By contrast, no statistically significant between-group difference was found in Energy score (E) at 12 months, but it decreased in the EX group and increased in the CON group at 24 months (Figure 13). The efficacy analyses of subjects who trained at least twice a week showed larger effect in GH and a significant between-group difference in E at 12 months, favoring the EX group (Figure 13).

*Table 12.* Proportion (%) of ceiling effects in four RAND-36 scales by groups (CON and EX) at baseline, 12-month and 24-month.

| | | **Ceiling effect %** | | | |
|---|---|---|---|---|---|
| **Scale** | **Group** | **Baseline (n=148)** | **12-month (n=142)** | **24-month (n=120)** | **p-value[a]** |
| Role functioning/ physical (RLP) | CON | 76 | 57 | 56 | |
| | EX | 62 | 66 | 55 | .14 |
| Role functioning/ emotional (RLE) | CON | 57 | 63 | 56 | |
| | EX | 61 | 69 | 52 | .74 |
| Social functioning[b] (SF) | CON | 76 | 71 | 72 | |
| | EX | 71 | 75 | 63 | .52 |
| Pain (P) | CON | 38 | 34 | 28 | |
| | EX | 23 | 31 | 31 | .21 |

[a]p-value for time*group interaction (3 time points, 2 groups), GEE model of binary responses (ceiling effect and no ceiling effect) with age at baseline as covariate, [b]n=141 at 12-month, CON=Control group, EX=Pooled exercise group

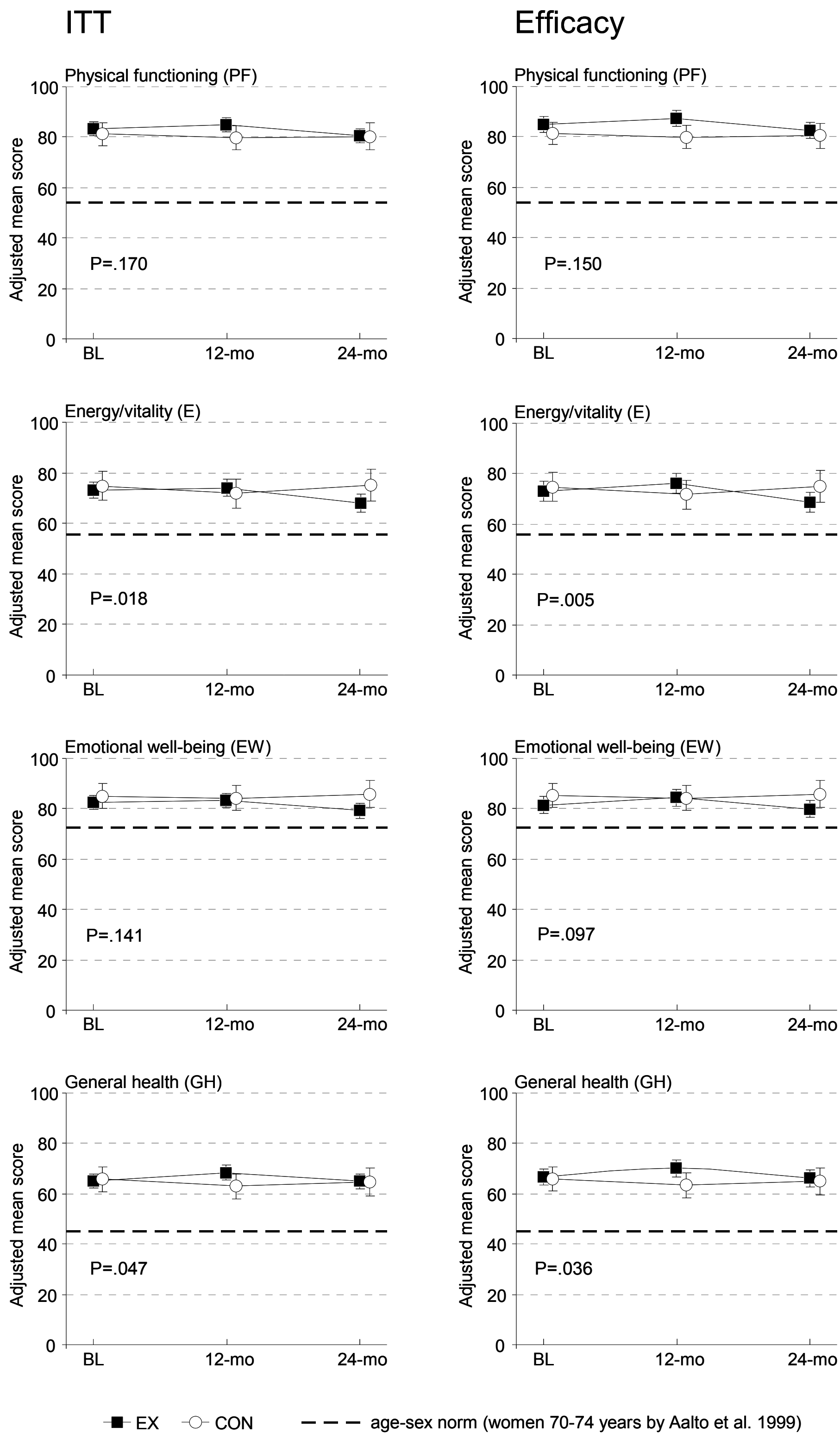



Figure 13. Age-adjusted mean score and 95% CI in four main RAND-variables at baseline, 12 months and 24 months by group. *EX* pooled exercise group, *CON* control group. *ITT* Intention to treat analysis, *Efficacy* efficacy analysis (≥2 x week trained participants). *p* values are for time*group interaction (3 time points, 2 groups), linear mixed model with age at baseline as covariate.

### 5.5.3 Fear of falling

The descriptive data on fear of falling (FoF) by group are given in Table 13. FoF was already rather low at baseline: VAS responses accumulated near zero and the median was 23. Only 6% reported unambiguous (>50) FoF during daily activities and 10% reported no fear at all (0, floor effect).

During the intervention FoF decreased further, but the linear mixed model revealed no between-group difference in change at 12 and 24 months (p=.824).

*Table 13.* Descriptive data of fear of falling using VAS by group (EX, CON) at baseline, 12 months and 24 months.

| | | | | | | Proportion, % | |
|---|---|---|---|---|---|---|---|
| **Assessment** | **Group** | **n** | **Mean (SD)** | **Range, 0-100** | **Median** | **0 mm[a]** | **>50 mm[b]** |
| Baseline | CON | 37 | 24.9 (19.0) | 0-87 | 23 | 5 | 11 |
| | EX | 111 | 22.4 (18.3) | 0-70 | 22 | 11 | 6 |
| 12-month | CON | 34 | 16.9 (21.2) | 0-65 | 7 | 41 | 6 |
| | EX | 106 | 10.7 (15.7) | 0-80 | 3 | 35 | 2 |
| 24-month | CON | 26 | 22.2 (24.7) | 0-92 | 16 | 39 | 12 |
| | EX | 94 | 15.1 (19.1) | 0-85 | 6 | 43 | 6 |

[a] indicating no fear of falling, [b] indicating unambiguous fear of falling, CON=Control group, EX=Pooled exercise group

# 6. DISCUSSION

This thesis was intended to evaluate the effects of two exercise interventions and their combination on multiple risk factors for falls and fall-related fractures in home-dwelling older women. The supervised exercise interventions included resistance training and balance-jumping training, alone or in combination, three times a week for 12 months. Feasibility of the exercise programs and maintenance of the training effects after cessation of the exercise intervention were moreover evaluated.

It was found that resistance and balance-jumping training were safe and feasible training modalities, and, especially in combination, prevented functional decline by improving muscle and dynamic balance performance as well as self-rated physical functioning in home-dwelling older women. In addition, the positive exercise effect seen in the structure of the loaded tibia suggested that training was able to prevent bone fragility. About half of the exercise-induced benefits were still apparent in dynamic balance and agility and in structure of the loaded tibia one year after cessation of the exercise intervention. However, the benefits in lower limb muscle force and self-rated physical functioning were lost indicating the necessity of continued exercise.

## 6.1 Feasibility of the exercise programs

Adherence to the training protocol is an important factor that affects the assessed outcomes. High withdrawal and low adherence rates and protocol violation especially may radically influence the observed intervention effect, and thus flaw the conclusions (Moher et al. 2010, Logghe et al. 2011). Poor adherence may also indicate that the exercise program used is unsuitable for the target group. Therefore, adherence and adverse events of the exercise intervention are important when considering the feasibility of the program. (Liu and Latham 2010, Moher et al. 2010, Logghe et al. 2011)

In our study withdrawal during the intervention was very low (3%) and training compliance was very good: attendance was 67% of all sessions offered. Attendance was highest in the RES group (74%) and lowest in the BAL group (59%). This variation between the three training groups may indicate differences in the convenience of the programs. Perhaps the resistance training was more pleasant than the more physically demanding jumping parts in the balance-jumping training. However, the COMB group also underwent jumping training with good compliance. Thus, one reason for these compliance differences may be the size of the training classes. Due to practical arrangements, both the RES and COMB group trainees trained in smaller training classes (8 to 11 participants) than the BAL group trainees (17 to 21). Smaller classes may have enhanced the grouping process by helping participants to get to know each other better, and this may have created a positive pressure for the group members to attend the training sessions in the RES and COMB groups (Carron et al. 2005). Especially in recent years, the evidence concerning both feasibility and effectiveness of group-delivered exercise training has increased (Sherrington et al. 2004, Howe et al. 2007, Gillespie et al. 2009, Liu and Latham 2009).

Adverse effects were carefully recorded in our study by monthly questionnaires, especially since the jumping training protocol had not been implemented in adults over 70 years before at the time when the study protocol was planned. Moreover, Liu and Latham (2010) recently emphasized the importance of reported adverse events concerning exercise intervention studies. In their systematic review of progressive resistance training (PRT) studies only about a half of 121 RCTs commented this important safety issue. The most typical adverse events in PRT studies were musculoskeletal problems, such as muscle strain or joint pain. This was also the case among our trainees. In addition, six accidents happened during the training classes in one year’s training; four participants fell, one fainted and one was taken to the emergency unit due to back pain. However, no differences in the health problems or adverse events were seen between the groups. One important factor for the rather low adverse events may have been that, although the training target was moderate-to-high intensity training, we started at a low level and extra attention was paid, and extra time offered to the trainees so that they became familiar with both the training apparatus and performance safety. To further limit adverse events, it might be useful to provide more individually-tailored exercises in small groups (less than ten participants), especially for those with several health problems.

Good training compliance with low rate of adverse events indicates that supervised and progressively advanced balance-jumping and resistance training, alone and in combination, are safe and feasible exercise modalities for high-functioning older women. The small size of the training groups, however, should be considered to support commitment to training and to ensure safety in moderate-to-high intensity training.

## 6.2 Effects of exercise on fall and fracture risk

Our exercise interventions did not have a statistically significant effect on falls and fractures, which were secondary outcomes of the study. Nor was any effect found on fear of falling. Instead, positive intervention effects were seen in multiple risk factors for falls and related fractures including physical functioning and bone rigidity.

### 6.2.1 Falls, fall-related fractures and fear of falling

Twenty-six percent of the all study participants fell at least once during the intervention year and 29% during the subsequent one year follow-up. This is somewhat less than reported earlier in samples of 65 years and older (Blake et al. 1988, Tinetti et al. 1988). However, our study subjects were fairly healthy and high-functioning and thus not at highest risk for falling.

Regarding falls per person years, 0.45 in the first and 0.48 in the second year, Korpelainen et al. (2006b) found a fairly similar falls proportion in their study among older Finnish women (mean age 73 y.) with low bone mass (0.47, calculated from the given data). Nevertheless, the incidence of fall-related fractures was somewhat higher in their study, and in contrast to our results, the between-group difference was statistically significant favoring the exercise (Korpelainen et al. 2006b). Due to challenge of the outcome (e.g. a rather rare event) the study by

Korpelainen is the only RCT study so far to show a clear positive exercise effect on fracture occurrence among older adults (6 fractures in the exercise group vs. 16 in the controls over 30 months) (Korpelainen et al. 2006b). In the other studies the between-group difference has remained non-significant (McMurdo et al. 1997, Ashburn et al. 2007, Kemmler et al. 2010). Interestingly, the extended 4-year follow-up of the study by Korpelainen et al. (2010) showed no hip fractures in the exercise group, but five hip fractures in the control group.

Exercise intervention did not affect fear of falling (FoF) in our high-functioning women. For both groups (the pooled exercise group and the control group), the FoF scores indicated less fear at 12 months and at 24 months than at baseline, but no statistically significant between-group differences were seen. However, the level of fear was low – an average 24 on a scale of 0 to 100 at baseline. For example, in the study by Lin et al. (2007) Taiwanese older adults with a recent fall had an average starting level of 70. Experience of a recent fall probably mainly explains this major difference to our study.

The observed floor effect in FoF suggests that either the women in our study did not have FoF or visual analogue scale (VAS) was not a sufficiently sensitive indicator of fear in high-functioning women. When the KAAMU study was planned, no validated instruments for measuring FoF had been adapted for use in Finland. Thus a simple global measure of FoF, the VAS, was chosen. Afterwards, several FoF instruments have been questioned since they lack sensitivity to detect different levels of fear, and in addition, they do not assess fear during different activities (Jorstad et al. 2005, Yardley et al. 2005). Further, wording has been criticized. Fear is strong expression, and thus “concern” has been suggested to be a better term, since it is closely related to fear but less intense and emotional. Therefore, “concern about falling” may also be a more socially acceptable expression than “fear of falling” among older adults. (Yardley et al. 2005) In response to criticism, promising new instruments have been developed (Yardley et al. 2005, Kempen et al. 2007, Kempen et al. 2008, Talley et al. 2008). However, their responsiveness to change, especially in high-functioning older adults, needs to be tested (Jorstad et al. 2005, Talley et al. 2008).

### 6.2.2 Physical functioning

The 12-month training improved physical performance and self-rated physical functioning in older women. Exercise effects were found in all primary outcomes of physical functioning including isometric lower limb extension force, dynamic balance and agility, and self-rated physical functioning. Only secondary outcomes, postural stability and reaction time, did not reach statistically significant between-group differences.

Although our baseline data analysis suggested that good lower limb muscle force is crucial for proper body balance, the exercise effects seen after the intervention were task-specific. Resistance training increased muscle force and balance-jumping training improved dynamic balance and agility, but no clear overlapping was seen. Thus, resistance training did not improve balance and balance-jumping training did not increase muscle force.

This finding of task-specificity is consistent with the study by Wolfson et al. (1996), who likewise observed no clear overlapping effect of balance and strength training after three months intensive training among healthy home-dwelling older Americans (mean age 79 yrs.). Our result is also supported by the systematic review of 29 RCT studies (n=2,174), which found limited evidence that PRT in isolation can improve balance in older adults mean age 60 years or more (Orr et al. 2008). Only about a fifth of all balance tests showed improvement. The review included older adults with the whole range of functional ability: from healthy to frail and mobility-limited persons with chronic comorbidities. Nevertheless, most participants were healthy and community-dwelling (n=1,090), and a subanalysis did not reveal a significant cohort effect. Single resistance training studies, however, have been also shown to be beneficial for dynamic balance (Nelson et al. 1994, Barrett and Smerdely 2002, Sousa and Sampaio 2005). Variation in age of the participants, length and intensity of the exercise intervention, and methods used for assessing balance may at least partly explain the inconsistent results between the studies. Furthermore, Orr et al. (2008) note the possible role of hip abductor and adductor strength gain in achieving beneficial functional outcomes. However, in our study hip abduction or adduction exercises were included in each resistance training program without clear positive effects on balance in the RES group.

More importantly, however, combined training of resistance and balance-jumping exercises was able to improve *both* muscle force and dynamic balance. The gains were similar to those achieved in single training groups. In addition to improved physical performance *per se*, a positive exercise effect was seen in self-rated physical functioning. The participants in the COMB group practiced resistance and balance-jumping training in alternate weeks using the same frequency (3 times a week) as the other two groups. Thus, the dose of single exercise component (resistance training or balance-jumping training) was half less than in the single training RES and BAL groups. The observed multiple effects in the COMB group confirms the importance of use of multiple training components in older adults' exercise.

Multi-component training models, including at least balance and strength exercises, have been shown to reduce the progression of functional decline and tendency to fall, especially in physically frail older people living at home (Gill et al. 2002, Lord et al. 2003, Nelson et al. 2004, Daniels et al. 2008). Our study suggests, in turn, that a progressive moderate-to-high intensity group program including balance, jumping and lower limb strength exercises could maintain or even improve the initially good physical functioning of healthy older women. A previous non-randomized exercise intervention study showed that one-year strength, balance and flexibility training improved both muscle function and functional ability in healthy community-dwelling women aged 75 years and older (Capodaglio et al. 2005). Also, functional task exercises were found to be more effective than resistance training to improve healthy older Dutch women's ability to carry on daily tasks (de Vreede et al. 2005).

However, only the study by Korpelainen et al. (2006a) used jumping exercises in the training program in addition to balance and strength training. They did not assess self-rated physical functioning, but improvements in different physical performance tests (e.g. lower limb strength, walking speed and timed up and go (TUG) test) indicated the program to be effective. Thus, the results of Korpelainen et al. (2006a) can be considered to be in line with our findings concerning improved physical performance and self-rated physical functioning after balance, jumping and lower limb strength exercises.

Secondary physical performance outcomes, i.e., postural stability and simple reaction time, did not improve in the training group compared to the controls. Direct balance measure, such as postural sway measure via force platforms, has been suggested to be less sensitive to interventions than indirect dynamic balance tests, partly due to variation in the quantities used and in interpretation of the data (Howe et al. 2007). In this study only one quantity, overall stability index during the first phase, was used as an outcome. Thus, more varied use of the quantities (e.g. anterior-posterior and medial-lateral stability indices) might have added the information concerning postural stability (Arnold and Schmitz 1998, Chaudhry et al. 2011). On the other hand, our balance training focused more on dynamic balance and agility than static balance exercises, and thus improvements seen in dynamic balance and agility instead of postural stability measured by postural sway can be considered fairly logical. Furthermore, the power calculation of the study was based on dynamic balance and agility (figure-of-eight running time). Therefore the possibility that the study was underpowered to assess changes in postural stability cannot be totally excluded.

The same concerns reaction time. Simple dominant hand reaction time slightly improved in the training groups and deteriorated slightly in the control group (effect size from .28 to .50) after the intervention, but the differences remained statistically non-significant indicating no exercise effect. The between-group differences were practically unchanged when the mean of five best attempts or the best attempt were used in the analysis. Lack of exercise effect may be due to insufficient statistical power, inappropriate assessment method, or ineffectiveness of the exercise program. In previous exercise RCT studies both positive and negative results have been achieved (see Table 1 on pages 27-28 in the Review of the Literature Section). Positive effects have been seen in studies using rather similar study protocols with KAAMU, that is, long-term supervised exercise intervention with multiple exercises (balance, strength and aerobic) (Rikli and Edwards 1991, Lord et al. 1995, Williams and Lord 1997, Lord et al. 2003). On the other hand, our study participants were probably more high-functioning than older adults in earlier studies, and thus not so susceptible to major changes in reaction time. In addition, given the nature of our training programs, assessment of foot reaction time or some more functional responses might have been useful.

### 6.2.3 Bone fragility

In the present study, exercise in any form, did not increase bone mineral content (BMC) at the femoral neck in older women. This concurs with studies by Liu-Amborose et al. (2004b) and McCartney et al. (1995) which found no exercise effect on total hip, femoral neck or trochanteric bone mineral density (BMD), or whole body BMC after 6-10 month resistance or agility training in older adults aged 70 years or more.

On the other hand, some positive responses in femoral neck BMD were recently seen after multi-component training in German (Kemmler et al. 2010) and Portuguese (Marques et al. 2011) women (mean age 69-69.9 years). However, the results concerning multi-component training cannot be considered consistent since multi-component training was not shown to be effective in older Australian or Italian women (Lord et al. 1996b, Villareal et al. 2004), and showed inconsistent response in older Finnish women with low bone mass (Korpelainen et al. 2006b). In addition, a Swedish study among community living older women showed a fairly high (8%) increase in Ward's triangle BMD after combined weight-bearing exercises, but no effect was seen in femoral neck or trochanter BMD (Englund et al. 2005). Previously, Kerr et al. (1996) and Kohrt et al. (1997) have also shown exercise effect on the Ward's triangle region without a response in femoral neck BMD in younger postmenopausal women. In our study, however, interpretation concerning bone mineral mass response to exercise was limited to femoral neck BMC, and effects on trochanter or Ward's triangle were not analyzed.

Instead, we used the hip structure analysis by Beck et al. (2000) to analyze effects of exercise on estimated bone structural strength, especially since hip section modulus has been reported to be more closely related to physical activity than BMD in older women (Kaptoge et al. 2003). A significant group difference in femoral neck section modulus was observed between the RES and COMB groups, indicating that resistance training might have redistributed bone mineral within the femoral neck and thus strengthened the structure. However, efficacy analysis could not confirm the results, probably due to reduced sample size, although the trend was found to be similar.

At the tibia, where loading-induced stresses in all likelihood were highest, we saw a positive exercise effect on bone structure among those COMB group trainees who trained at least twice a week. This finding of structural response is consistent with earlier exercise studies using pQCT measures among post-menopausal women (Hamilton et al. 2010). In the study by Uusi-Rasi et al. (2003) post-menopausal women's (mean age 54 years) bone strength index (BSI) and ratio of cortical bone to total bone area at the distal tibia increased about 3.5% after 12-month weight-bearing and jumping exercise. In women of the same age, about 1% exercise effects at distal tibial (diaphysis) cortical density and ultradistal tibial trabecular density were also found as a result of 12-month tai-chi training (Chan et al. 2004). Even more interestingly, Liu-Ambrose et al. (2004b) were able to show about 1% exercise effect on cortical bone at the tibial shaft in older women with low bone mass (mean age 79 years) after 6 months of agility training, but not after resistance training. In our study, about 2% exercise effect was seen in BSI at the tibial shaft. In addition, a non-significant trend suggested possible gain in other important measures of tibial structure, including tibial shaft cortical area and distal tibia BSI. Future studies, however, are needed to confirm our findings.

We also included radius measures by pQCT to our study to assess site-specificity of the training. Earlier, Adami et al. (1999) suggest that bone structural and geometrical changes are site-specific, since they found positive effects in the ultradistal cross-sectional area, but not in the radial shaft, hip or lumbar spine after strength training designed to maximize the stress on the wrist in postmenopausal women. Our findings concerning exercise effect at the tibial shaft but the absence of effects on radial shaft or distal radius after resistance and balance-jumping training targeted at the lower limbs supports the notion of the site-specificity of the training effects. Our study thus somewhat contradicts the study by Liu-Ambrose et al. (2004b), which observed increased cortical density at the radial shaft after progressive resistance training among older women with low bone mass. However, the exercise program in that study was focused in increasing strength in both upper and lower extremities.

## 6.3 Exercise and health-related quality of life

Our study did not indicate unambiguously that exercise had positive effects on health-related quality of life (HRQoL) measured by RAND-36 in relatively healthy older women. Of the eight measured scale scores, only General Health (GH) score increased slightly in the pooled exercise group and decreased in the CON group. The absolute between-group difference (6 score units) was small and of hardly any clinical relevance given the rather poor psychometric properties of the GH scale in this study. The difference, however, is in line with other studies reporting exercise effect on this subscale (Okamoto et al. 2007, Grahn Kronhed et al. 2009, Martin et al. 2009). On the other hand, Teixeira et al. (2010) and Eyigor et al. (2009) have quite recently reported much larger and clinically significant HRQoL improvements in this subscale as well as other scales in Brazilian osteoporotic postmenopausal women and Turkish healthy older women respectively. Our results, however, are congruent with the recent meta-analysis by Kelley et al. (2009), which indicated a rather weak role of exercise interventions for older community-dwelling adults' HRQoL (as measured by SF-36, a parallel survey of RAND-36).

Our observations with those of other RCTs showing minimal or no effect of exercise on health-related quality of life (Cress et al. 1999, Greendale et al. 2000, Stiggelbout et al. 2004, de Vreede et al. 2007, Okamoto et al. 2007) raise questions concerning measuring HRQoL in exercise interventions. First, have the measured changes in the physical performance and capacity been large enough to be recognized by the participants? More importantly, do these changes make any difference in their everyday lives? Currently it is not known which particular time point during the training would be optimal for the perception of changes (Rejeski and Mihalko 2001, McAuley et al. 2005). One year might have been too long a period for assessing. Furthermore, the relevance of the Physical Functioning items cannot be guaranteed among high-functioning individuals.

Second, it is possible that the participants adapt to successive minor changes due to training, which eventually modifies their internal standards for HRQoL. This interpretation is supported by our notion that most RAND-36 scores decreased in the pooled exercise group after the follow-up period with no supervised exercise, but the same effect was not seen in the CON group. In the Energy score this divergent trend between the groups was actually statistically significant. De Vreede et al. (2007) have reported corresponding observations after a 6-month follow-up period in community-dwelling older Dutch women.

The effect of exercise training on HRQoL among older people with normal or good physical functioning has been questioned (Rejeski and Mihalko 2001). In our study, the assessment tool, the RAND-36 survey, showed good technical quality and sufficient conceptual stability (McHorney 1996, Aalto et al. 1999, Nupponen and Karinkanta 2009, Nupponen and Karinkanta 2011). However, the level of scores was much higher and ceiling effects larger than in the age-equivalent reference group (Aalto et al. 1999). The similar accumulation has also been reported in the other exercise intervention studies using SF-36 scores, especially when older participants have been high-functioning (Cress et al. 1999, Greendale et al. 2000, Oken et al. 2006, de Vreede et al. 2007).

The strong ceiling effect and diminished variation impair the psychometric properties of the scales, rule out any substantial raise in scores and may conceal differential changes in a bunch of outcome variables. Insufficient responsiveness of the scales may thus mask the effects of an exercise intervention, and may be one important factor why no clear evidence exists to show that exercise interventions are beneficial for HRQoL in community-dwelling older adults (Kelley et al. 2009). In addition, HRQoL has typically been studied as a secondary outcome, as also here. Thus most exercise intervention studies among older adults, including the present study, have been unpowered (Cress et al. 1999, Greendale et al. 2000, Oken et al. 2006, de Vreede et al. 2007). Only the recent study by Martin et al. (2009), which showed that higher doses of aerobic exercise were associated with greater improvements in mental and physical aspects of HRQoL in sedentary, overweight or obese postmenopausal women, appears to be adequately powered to assess this challenging outcome.

## 6.4 Maintenance of exercise-induced benefits

Maintenance of exercise-induced benefits was evaluated one year after the end of the intervention. Some benefits were still apparent in dynamic balance and agility and rigidity of the tibia, but the training effect in muscle force and self-rated physical functioning had disappeared. The results are of great value since only few studies have assessed the long-term maintenance of achieved exercise effects among older adults.

Wolfson et al. (1996) showed that gains in balance achieved by intensive balance training can be maintained to some extent by low-intensity Tai Chi training once a week in community-dwelling older people. Nevertheless, when the exercise has been completely stopped among middle aged and older adults, the exercise-induced benefits in dynamic balance and agility have typically been lost (Helbostad et al. 2004, Uusi-Rasi et al. 2004, Toraman and Ayceman 2005, Toulotte et al. 2006). In our study, however, about half of the training benefits in dynamic balance and agility were still to be seen in the COMB group as well as among the active BAL group trainees one year after cessation of supervised training. These contradictory results may at least partly be due to differences in training and follow-up periods, in methods assessing balance and agility (Helbostad et al. 2004, Toraman and Ayceman 2005, Toulotte et al. 2006), as well as younger (Uusi-Rasi et al. 2004) or frailer (Helbostad et al. 2004) participants compared to those in our study.

In contrast to positive maintenance effect in dynamic balance and agility, the exercise-induced benefits in lower limb extension force had vanished during the one-year detraining period. The force was still above the baseline level, but achieved gain compared to the controls was totally lost – partly due to increased muscle force among the controls.

It is well known that cessation of strength training causes decreases in muscle force and power. Studies among older adults suggest that muscle force gains can be maintained to some extent at least one to six month (Lexell et al. 1995, Sforzo et al. 1995, Taaffe and Marcus 1997). In addition, Henwood and Taaffe (2008) showed that a 3-month retraining period was able to restore the losses seen in strength and power after 6-month detraining (subsequent to 6-month muscle strength or muscle power training).

However, 12 months appears to be too long a period to maintain major force gains unless the strength training is continued at some intensity (Lexell et al. 1995, Porter et al. 2002, Trappe et al. 2002). Furthermore, according to a recent study by Bickel et al. (2010), older adults may require a higher dose of weekly loading than younger adults to maintain the achieved gains e.g. in muscle size.

One year also seemed too long a period to maintain about 10% gain in self-rated physical functioning. In our study, within-group variability increased at 24 months, suggesting that an additional year increases older person's risk to falling ill and thus may impair or even stop functional ability. Somewhat different from our finding, the study by de Vreede et al. (2005) showed that six months after the end of functional training among healthy older Dutch women, the physical functional performance of the trainees was still higher than that in controls. Shorter follow-up time and a different method of assessing functional ability may explain the disparity. Concerning our study, it has also to be remembered that those women in the CON group who participated in the follow-up study were slightly younger and fewer of them had negative changes in the self-rated physical functioning during the intervention than the non-attending control persons. Since this was not the case in training groups, this fact may partly explain the reduced functionality differences between the training groups and control group at follow-up.

Previously bone has been suggested to need continued exercise – according to the "use it or lose it" principle. However, this notion arises mainly from the assessment of bone mass rather its structure or geometry (Dalsky et al. 1988, Iwamoto et al. 2001, Karlsson 2003). Using only DXA scans it is impossible to adequately assess cortical and trabecular density or other structural particulars which are pertinent to bone rigidity and may also change without changes in BMD or BMC (Jarvinen et al. 1998, Adami et al. 1999, Sievanen 2000, Currey 2001, Warden et al. 2007).

In our study, about 2% exercise effect was seen in the loaded tibia among active COMB trainees. Interestingly, about a half of this gain was still seen one year after cessation of the exercise intervention. This may indicate that bone-enhancing exercise, including jumping and resistance training exercises also has long-term benefits in older women. The finding was based, however, on a statistical borderline trend only, and thus needs to be confirmed in future studies.

To the best of our knowledge, no prior studies exist assessing the maintenance of exercise-induced benefits in bone structural properties among older adults. Bone quantity based studies indicate that decreased training may partially maintain exercise-induced benefits in young adults (Heinonen et al. 1999, Kontulainen et al. 1999, Kontulainen et al. 2001), while in the long term, exercise-induced bone benefits seem to disappear if training is considerably reduced or the sports career or exercise intervention ceases (Gustavsson et al. 2003, Nordstrom et al. 2005, Valdimarsson et al. 2005, Englund et al. 2009) (Gustavsson et al. 2003, Nordstrom et al. 2005, Valdimarsson et al. 2005, Englund et al. 2009). Interestingly, former athletes' fracture risk in older age may be lower than that of non-athletic controls (Nordstrom et al. 2005). Animal experimental studies using pQCT measures or mechanical tests suggest that the structural benefits achieved by exercise during the growth period and adulthood may last quite long, but there is disagreement as to where these benefits are eventually lost at older age (Jarvinen et al. 2003, Pajamaki et al. 2003, Warden et al. 2007, Honda et al. 2008, Umemura et al. 2008).

There are several possible explanations for the positive results seen in dynamic balance and agility, and rigidity of the tibia after cessation of the exercise intervention. First, the most effective training program, COMB, was high-intensity in nature combining many effective training components, such as versatile balance and agility exercises, jumping exercises and progressive resistance training. Second, the participants did intensive training, on average twice a week, for 12 months enabling them to achieve greater and probably more permanent effects, perhaps not only on balance and agility, but also on mobility functions overall. Last, our study participants did not entirely stop exercising after the exercise intervention. It was almost impossible to continue balance-jumping training as the form of intervention since no groups were available. Resistance training was more feasible via commercial and non-commercial providers but only fourteen women continued it at some level. However, other physical activity, such as walking, was quite well maintained among participants. Average moderate physical activity during follow-up varied from 4 to 6 hours per week between the groups, being highest in the COMB group. Therefore, habitual physical activity may also have a role in the partial maintenance of the gains achieved. As shown earlier, continued exercise, even at a lower level, can maintain exercise-induced benefits to some extent (Wolfson et al. 1996, Heinonen et al. 1999, Bird et al. 2011). On the other hand, in our study lower volume resistance training and general physical activity were only weakly associated with the observed changes.

## 6.5 Methodological considerations

The KAAMU Study has several strengths. Firstly, the study design was a randomized, controlled study with three different exercise groups and a non-exercising control group, which made it possible to compare exercise programs with each other. Secondly, the intervention period was fairly long (12 months) compared to most earlier studies (McCartney et al. 1995, Liu-Ambrose et al. 2004a, Liu-Ambrose et al. 2004b, Villareal et al. 2004, Howe et al. 2007, Liu and Latham 2009, Marques et al. 2011), and subsequent one year follow-up was also included to assess the maintenance of the possible exercise-induced benefits.

Thirdly, exercise effects were evaluated broadly using various methods. For example, concerning bone, both measures for mass (DXA) and structure (pQCT, HSA-analysis) were used. In most other studies only DXA scans were used (McCartney et al. 1995, Lord et al. 1996b, Villareal et al. 2004, Englund et al. 2005, Korpelainen et al. 2006b, Kemmler et al. 2010, Marques et al. 2011).

Fourthly, the main statistical analyses were, according to the Consort statement (Moher et al. 2001, Moher et al. 2010), based on the intention-to-treat principle. Per protocol analyses were used as a secondary analysis to assess the efficacy of the exercise programs. Fifthly, only few dropouts (~3%) occurred during the intervention. This is unusual in long-lasting RCT studies. For example, of ten good quality studies referred to in this thesis, only four have drop-out rates under 10% (6-8%) (Lord et al. 2003, Uusi-Rasi et al. 2003, Liu-Ambrose et al. 2004a, Liu-Ambrose et al. 2004b, Kemmler et al. 2010). In the other six studies, the drop-out rates vary from 13 to 24 % (Lord et al. 1995, McCartney et al. 1995, Lord et al. 1996b, Liu-Ambrose et al. 2004b, Englund et al. 2005, Korpelainen et al. 2006b, 2006a, Marques et al. 2011). Lastly, feasibility of the exercise programs was carefully evaluated and shown to be good.

The study also has some limitations. Initially enquiries about participation were sent to a random population sample of 70 to 79-year-old women living in Tampere in 2002, which actually covered half of this population. However, mainly based on rather strict exclusion and inclusion criteria, the study participants were fairly healthy and high-functioning, and therefore also capable of vigorous exercise. For example, the mean self-rated physical functioning score for the study participants at baseline was much higher than observed in the standardized age-matched population samples (82.7 vs. 45.1-54.1) (Aalto et al. 1999). Thus, the results cannot be generalized to all older women. To include in exercise interventions more people with mobility and functional limitations or prior falls and related fractures, the process of recruitment need to be more flexible than ours and exploit health and social systems, such as home help service, as well as unofficial, e.g. patients' organizations, to reach this target group. In addition, individual motivation of sedentary people to participate should be paid more attention. Transportation arrangements and applied exercise groups are probably needed to increase the participation of older people with impaired physical or cognitive functions.

Due to the nature of the exercise intervention it was impossible to blind participants to the treatment provided. Instead, concerning data collection and outcome adjudication, blinding was used in bone measurements. However, mainly due to the multiple role of the PhD student, blinding was not achieved in the other outcome measures. Therefore potential bias by reason of partial non-blinding cannot be totally excluded (Moher et al. 2010).

The preliminary power calculations of the required sample size were based on dynamic balance and agility (figure-of-eight running test). Thus, the data was clearly underpowered for assessing the exercise effects in some secondary outcomes, such as number of falls and fractures and HRQoL. The same may also concern postural stability and reaction time. Moreover, sophisticated measurements would have been needed to precisely evaluate exercise effects on postural stability and reaction time.

In HRQoL all comparisons of change were made between the pooled exercise group and the control group. Pooling was deemed justified as no between-group differences were indicated in the separate analyses of the three exercise groups. Pooling made group size unequal, which, however, has less harmful effects on statistical power than if the exercise groups had been kept apart.

For practical reasons, the RES and COMB group trained in smaller training classes than the BAL group. As discussed earlier, this may have had some effect on adherence to training sessions, favoring the smaller size groups (the RES and the COMB).

During the intervention, only few drop-outs occurred, as stated earlier. However, not all participants who completed the intervention study continued to the subsequent one-year follow-up study, even though the participation rate was still quite high (81%). In addition, there were more dropouts in the control group than in the other groups. The attending controls were slightly younger and maintained their self-rated physical functioning better during the intervention than their non-attendee counterparts. Since this was not the case in the exercise groups, it may have led to underestimation of actual maintenance of exercise-induced benefits. Missing data, however, was taken into consideration in the statistical method chosen (linear mixed model with restricted likelihood) which allowed incorporation of incomplete longitudinal data into the model.

Finally, assessment of multiple outcomes gave a definitely larger perspective on potential exercise effects. On the other hand, it made it impossible to go very deep into every single outcome. For example, additional measures for assessing different balance and muscle function related properties may have provided more information, but would also have overcharged the measurement protocol. In addition, the assessment properties of some measurement tools (RAND-36 and FoF-VAS) were found to be quite unsuitable for the target group, as discussed earlier.

## 6.6 Implications for future studies

This study indicated that relatively healthy older women with initially good physical functioning seem to have a good capacity to prevent age-related functional decline by participating in group-based moderate-to-high intensity multi-component training. Positive effects were also found in the structure of the loaded tibia indicating that exercise may also play a role in preventing bone fragility. In the future, however, this latter finding especially needs to be studied in different sub-groups of aged people (based e.g. on physical functioning or bone status). In addition, in future studies more attention should be paid to using bone-enhancing exercise programs, such as jumping and resistance training, in parallel with exercise programs found to be useful in fall prevention.

In our study, successful completion of the training programs with a low rate of adverse effects suggested that the training programs were feasible for previously untrained older women. In future studies, the feasibility needs to be confirmed in other sub-groups of older adults.

Exercise-induced benefits in dynamic balance and agility may partly be maintained one year after cessation of the exercise intervention. The same may concern the rigidity of the loaded tibia. In future studies, the long-term effects of periodical training (in which habitual physical exercise is applied between the high-intensity training periods) could be assessed.

The main challenge of future studies, however, is to ascertain the potential exercise effects among older adults in a broader perspective. For example, the awareness that exercise is a potential method to prevent cognitive decline has increased greatly (Angevaren et al. 2008, Snowden et al. 2011). Thus it is important to test fall and fracture prevention exercise programs in this respect. People cannot simply follow several exercise programs simultaneously. We need to understand what kinds of exercise modalities are best overall.

# 7. CONCLUSIONS

Referring to the main findings of the study, the conclusions can be summarized as follows:

1. High-to-moderate intensity resistance and balance-jumping training are safe and feasible exercise modalities for relatively healthy and high-functioning older women.
2. Group-based resistance and balance-jumping training, especially when used in combination, prevent functional decline and may prevent bone fragility in home-dwelling older women.
3. Some of the exercise-induced benefits in dynamic balance and agility and in the structure of the loaded tibia can be maintained one year after the cessation of intensive exercise in home-dwelling older women. However, to maintain lower limb muscle force and self-rated physical functioning continued training seems necessary for older adults.
4. In spite of reducing multiple risk factors for falls and related fractures, intensive exercise training does not seem to reduce falls and fractures in high-functioning older women.
5. The exercise training has somewhat limited effects on health-related quality of life and fear of falling in high-functioning older women. However, this result may be partly due to insufficient responsiveness of the assessment instruments used.

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# APPENDICES

*Appendix 1a*. Exercise program of resistance training

| | Gym Familiarizing | Gym 1 | Gym 2 | Gym 3 | Gym 4 | Gym 5 |
|---|---|---|---|---|---|---|
| **Warm-up 7-10 min** | e.g. marching, marching with upper limb and shoulder movements, skiing movements, slight squatting, abdominal and back muscle training | | | | | |
| **Active session 25-30 min** | 2 x 20<br>• Leg press<br>• Sit to stand<br>• Rowing<br>• Chest press<br>• Hip abduction<br>• Hip adduction<br>• Heel rise | 3 x 8-10<br>• Leg press<br>• Sit to stand<br>• Chest press<br>• Hip abduction<br>• Heel rise | 3 x 8-10<br>• Leg press<br>• Sit to stand /squatting with weight rod<br>• Rowing<br>• Hip adduction<br>• Heel rise | 3 x 8-10<br>• Leg press<br>• Sit to stand/ squatting with weight rod<br>• Chest press<br>• Hip abduction<br>• Hip extension | 3 x 8-10<br>• Leg press<br>• Squatting with weight rod /sit to stand<br>• Upper body rotation<br>• Hip abduction<br>• Heel rise | 3 x 8-10<br>• Leg press<br>• Squatting with weight rod / sit to stand<br>• Rowing<br>• Hip extension<br>• Heel rise |
| **Cool-down 8-10 min** | Stretching of major muscle groups on a floor and in sitting position | | | | | |

Leg press, rowing, chest press, hip abduction/adduction, upper body rotation and heel rise were done in sitting position and hip extension and squatting in upright position. In squatting, both safety bars and ensuring by a supervisor were used.
Abdominals and back muscle training were done during warm-up.

*Appendix 1b.* Exercise programs of balance-jumping training

| | Familiarizing period | Program I | | Program II | | Program III | | Program IV | |
|---|---|---|---|---|---|---|---|---|---|
| | | Aerobic | Step aerobic | Aerobic | Step aerobic | Aerobic | Step aerobic | Aerobic | Step aerobic |
| **Warm-up 7-10 min** | e.g. marching, marching with upper limb and shoulder movements, side-touching, heel touches, sideward steps, slight squatting, mambo-steps, V-steps, basic steps on a step board | | | | | | | | |
| **Active session 25-30 min** | side-touching by feet marching forwards and backwards rhythmic clapping touching forward and backward by toes when weight is on other leg 2 steps forward, curtsying and 2 steps backward 8 steps sideward, 4 raises to toes, 8 steps back (sideward) “jenkka” (3 steps and knee raise, 4 knee raises) by moving in the room | raising bended knee with rotating upper body and touching opposite hand for a knee a step backward when straightening upper limbs forward, back to start position heel-touch forward tandem-walking forward and backward trying a horizontal position rapid toe raises and heel drops | heel-touch to a step-board (powerful) V-step to a board with slow and high tempo step on a board and slow raise of bended leg with and without staying in a one-leg position powerful knee-up on a board with or without a jump a step backward with slow and high tempo marching on a step-board dropping leg (with bending knee) from | raising bended knee with or without toe-raising sideward-step, slight squat and raise of bended knee standing on one leg when other leg is drawing figure of 8 V-step V-step with changing direction of the movement (forward, right, backward, left) spurt forward and backward by stamping skipping in place (without skip rope) side-touching by feet | sideward steps slight squat step on a board and straightening – bending a knee, step off a board step over a step board powerful knee-up on a board with and without a slight jump powerful sidewalk step on a board in series going forward, marching backward on a floor powerful sidewalk step on a board in series going | mambo step with changing direction of the movement sideward-step, slight squat and raise of bended knee with slow and high tempo tandem-walking forward (x3)and backward (x3), and raising bended leg (fourth step) three marching steps forward and toe touches with or without a jump same but turning round sideward jump right and left step backward | step on a board, standing with one leg (right, left), step off a board 4 toe touches to a board, step on a board, dropping off a board powerful step on a board with bended knee with and without a jump (forward, obliquely forward) slight squats step on a board, sideward steps, step off a board with slow and high tempo | sideward cross steps x3, and standing one leg standing one leg, other leg bent, rotating of upper body “jenkka” at place without and with a jump “jenkka” by moving in the room with a jump twisting down x4, going forward by four skips, spurt backward (slow and high tempo) “letkis” (2 touches right, 2 touches left, jump forward, jump backward | a one leg curtsy from a board and pushing back with a) bended knee b) straighten leg for sideward (abduction) c) straighten leg for backward (extension) on a board: one leg curtsy, tandem walking forward, one leg standing, when other leg is moving forward and backward, backward tandem walking walking forward on a board, dropping down (a board between the legs) and steps back on a board x3, |

Continued overleaf

Appendix 1b continued

| Familiarizing period | Program I | | Program II | | Program III | | Program IV | |
|---|---|---|---|---|---|---|---|---|
| | Aerobic | Step aerobic | Aerobic | Step aerobic | Aerobic | Step aerobic | Aerobic | Step aerobic |
| | (with impact) stamping on the spot and when turning round (360°)<br>skipping in place (without skip rope)<br>raising bended/ straightened leg with or without slight jump<br>side-touching by feet, curtsying and V-steps between the movement series | a step—board and pushing back on a board<br>curtsying on a board<br>marching and touching toes to a step-board between the movements series | crossing mambo-step with transferring body weight for the front leg slightly and powerfully (by dropping)<br>turning steps with and without a jump | forward and backward stepping OR dropping from a board to floor, step back on a board<br>marching, sideward steps and touching toes to a step-board between the movements series | stamping with slight jump to right and left<br>skipping in place (without skip rope)<br>marching with rhythmic clapping<br>heel drops with slow and high tempo<br>marching, sideward steps and heel touching between the movements series | marching on a step board<br>dropping leg (with bending knee) from a step—board and pushing back on a board<br>giant step<br>stepping on a board between the movement series | 3 forward jumps) at place and moving in line in the room<br>marching, side- and backward touching by feet, heel touches between the movement series | dropping down (forward), walking backwards<br>moving forward by (sideward) skips<br>pushing up on board and upward jump<br>step over a step board<br>a step backward<br>ski jump on a board<br>V-step<br>sideward step on a board, dropping off a board<br>standing on one leg on a board and other leg pawing |
| **Cool down 8-10 min** | Stretching of major muscle groups and short relaxation on a floor | | | | | | | |

*Appendix 2.* Principal component analysis of the RAND-36 data in the total group participants at baseline, 12 months and 24 months. Complete item responses included in the analysis, the two first Varimax-rotated components presented. Decimal dots deleted, item loadings ≥ .40 printed in bold. Item 2 of the survey is not included in scales.

| Scale Item | Item content | Baseline n=144 | | | 12 months n=140 | | | 24 months n=113 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | I[3] | II[4] | $h^2$ | I[4] | II[3] | $h^2$ | I[4] | II[3] | $h^2$ |
| PF | *Health limits* | | | | | | | | | |
| 3 | vigorous activities | 14 | **47** | 24 | **55** | 27 | 37 | **58** | 22 | 38 |
| 4 | moderate activities | 35 | **46** | 33 | **60** | 20 | 41 | **63** | 17 | 43 |
| 5 | lifting or carrying groceries | 29 | **55** | 39 | **51** | 38 | 40 | **69** | 18 | 50 |
| 6 | climbing several flights of stairs | 15 | **50** | 27 | **61** | -01 | 37 | **63** | 17 | 43 |
| 7 | climbing one flight of stairs | -12 | **52** | 28 | **68** | -12 | 47 | **75** | -01 | 56 |
| 8 | bending, kneeling, or stooping | 27 | **58** | 41 | **50** | 11 | 27 | **63** | 00 | 39 |
| 9 | walking more than 2 km | -00 | **74** | 55 | **73** | 01 | 53 | **74** | 01 | 54 |
| 10 | walking several blocks | -23 | **57** | 38 | **57** | 01 | 33 | **72** | -08 | 52 |
| 11 | walking one block | -24 | **53** | 33 | **43** | 01 | 19 | **66** | -30 | 52 |
| 12 | bathing or dressing | -06 | **50** | 26 | **42** | -10 | 19 | 27 | **40** | 23 |
| RLP | *Problems due to physical health* | | | | | | | | | |
| 13 | cut down the amount of time spent on work or other activities | **66** | -01 | 23 | **60** | 29 | 44 | 38 | 33 | 25 |
| 14 | accomplished less than would like | **70** | -10 | 25 | **64** | 25 | 48 | 34 | **56** | 43 |
| 15 | were limited in the kind of work or other activities | **44** | **49** | 43 | **71** | 11 | 51 | **57** | **43** | 51 |
| 16 | had difficulty performing the work or other activities | **43** | **49** | 43 | **48** | 16 | 26 | **48** | **46** | 45 |
| RLE | *Problems due to emotional problems* | | | | | | | | | |
| 17 | cut down the amount of time spent on work or other activities | **66** | -01 | 43 | 33 | **44** | 30 | 08 | **46** | 22 |
| 18 | accomplished less than would like | **70** | -10 | 49 | 26 | **55** | 37 | 10 | **58** | 34 |
| 19 | didn't do work or other activities as carefully as usual | **48** | -07 | 23 | 15 | 12 | 04 | 08 | 04 | 01 |
| E | *Has been feeling during 4 past weeks* | | | | | | | | | |
| 23 | full of pep | **-64** | -21 | 45 | -30 | **-71** | 60 | -30 | **-66** | 52 |
| 27 | have a lot of energy | **-70** | -25 | 55 | -27 | **-70** | 56 | -19 | **-73** | 57 |
| 29[1] | worn out | **-54** | 12 | 30 | -24 | **-64** | 46 | 12 | **-58** | 35 |

Continued overleaf

Appendix 2 continued

| Scale | | Baseline n=144 | | | 12 months n=140 | | | 24 months n=113 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Item** | **Item content** | **I[3]** | **II[4]** | **$h^2$** | **I[4]** | **II[3]** | **$h^2$** | **I[4]** | **II[3]** | **$h^2$** |
| 31[1] | tired | **-65** | 25 | 49 | -35 | **-62** | 50 | -25 | **-60** | 42 |
| EW | *During 4 past weeks has been feeling* | | | | | | | | | |
| 24 | very agitated | **52** | 04 | 27 | -07 | **67** | 45 | 16 | **56** | 34 |
| 25 | down in the dumps | **72** | -04 | 53 | -09 | **75** | 57 | -01 | **72** | 52 |
| 26[1] | calm and peaceful | **69** | -06 | 47 | -06 | **66** | 43 | 08 | **69** | 48 |
| 28 | downhearted and blue | **81** | -04 | 66 | -01 | **84** | 71 | 19 | **69** | 51 |
| 30[1] | happy | **69** | -04 | 48 | -08 | **70** | 50 | -06 | **71** | 50 |
| SF | *Health or emotional problems have interfered with social activities* | | | | | | | | | |
| 20 | to what extent | **-64** | -11 | 42 | -11 | **-60** | 37 | **-58** | **-44** | 53 |
| 32 | how much of the time | **-66** | 12 | 45 | -18 | **-51** | 29 | **53** | **55** | 58 |
| P | *Bodily pain* | | | | | | | | | |
| 21 | how much | **-41** | **-55** | 47 | **-69** | -23 | 53 | **-68** | -22 | 51 |
| 22 | how much pain interfered with work | **-50** | **-46** | 47 | **-71** | -22 | 55 | **-75** | -25 | 62 |
| GH | *Self-rated health* | | | | | | | | | |
| 1 | in general | -37 | -30 | 23 | **-51** | -35 | 38 | -34 | -36 | 24 |
| 33[1] | gets sick more easily than other people | -39 | 17 | 18 | -12 | **-45** | 22 | 01 | **-43** | 18 |
| 34 | as healthy as anybody else | -21 | -16 | 07 | -22 | -19 | 08 | -15 | -14 | 04 |
| 35[1] | expects health to get worse | -18 | 20 | 07 | -08 | -31 | 10 | 07 | -32 | 10 |
| 36 | health is excellent | -33 | -33 | 21 | -36 | **-42** | 31 | -22 | **-46** | 26 |
| | **Eigenvalue** | 8,11 | 4,60 | | 6,77 | 6,74 | | 7,05 | 6,94 | |
| | **Variance accounted, %** | 23,18 | 13,13 | | 19,34 | 19,25 | | 20,14 | 19,84 | |

[1] Scoring reversed.[2]Communality ($h^2$) [3]The component *Peaceful mind and vitality* [4]The component *Physical capability*

PF=Physical Functioning, RLP=Role Limitations/Physical, RLE=Role Limitations/Emotional, E=Energy, EW=Emotional Well-being, SF=Social Functioning, GH=General Health

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# Factors Predicting Dynamic Balance and Quality of Life in Home-Dwelling Elderly Women

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**Key Words**

Fall prevention · Balance · Muscle strength · Elderly women

**Abstract**

***Background:*** Proper balance seems to be a critical factor in terms of fall prevention among the elderly. ***Objective:*** The purpose of this cross-sectional study was to examine factors that are associated with dynamic balance and health-related quality of life in home-dwelling elderly women. ***Methods:*** One hundred and fifty-three healthy postmenopausal women (mean age: 72 years, height: 159 cm, weight: 72 kg) were examined. General health and physical activity were assessed by a questionnaire. Quality of life was measured using a health-related quality of life questionnaire (Rand 36-Item Health Survey 1.0). Dynamic balance (agility) was tested by a figure-of-eight running test. Static balance (postural sway) was tested on an unstable platform. Maximal isometric strength of the leg extensors was measured with a leg press dynamometer. Dynamic muscle strength of lower limbs was tested by measuring ground reaction forces with a force platform during common daily activities (sit-to-stand and step-on-a-stair tests). ***Results:*** Concerning physical activity, 33% of the subjects reported brisk exercise (walking, Nordic walking, cross-country skiing, swimming and aquatic exercises) at least twice a week, and 22% some kind of brisk activity once a week in addition to lighter physical exercise. The remaining 45% did not exercise regularly and were classified as sedentary. The correlations of step-on-a-stair and sit-to-stand ground reaction forces, and leg extensor strength to dynamic balance were from –0.32 to –0.43 (the better the strength, the better the balance). In the regression analysis with backward elimination, step-on-a-stair and sit-to-stand ground reaction forces, and leg extensor strength, age, brisk physical activity, number of diseases and dynamic postural stability explained 42% of the variance in the dynamic balance. Similarly, dynamic balance (figure-of-eight running time), number of diseases and walking more than 3 km per day explained 14% of the variance in the quality of life score. Of these, figure-of-eight running time was the strongest predictor of the quality of life score, explaining 9% of its variance. ***Conclusion:*** This study emphasizes the concept that in home-dwelling elderly women good muscle strength in lower limbs is crucial for proper body balance and that dynamic balance is an independent predictor of a standardized quality of life estimate. The results provide important and useful information when planning meaningful contents for studies related to fall prevention and quality of life and interventions in elderly women.



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## Introduction

The absolute numbers and age-specific incidence rates of osteoporotic fractures have clearly increased all over the world during recent decades, and without population level interventions, the increasing trend is likely to continue, thus creating a true public health problem for our societies [1]. For example, the number of hip fractures in Finnish people aged 50 or over increased more than three times between 1970 and 1997 [1]. Over 90% of hip fractures are caused by falls [2, 3]. One third of 65-year-old or older persons fall at least once a year, [4] and half of the fallers fall repeatedly [5].

Many disabilities and impairments, such as compromised static and dynamic balance, gait, lower limb strength, vestibular function, sensation, vision and cognition, predispose to falling [6]. Previously, it has been noticed that exercise, including intensive strength and endurance training [7] or functional balance training [8], and especially the combination of balance and strength training [9], can reduce the fall risk in elderly subjects. Also, a meta-analysis of 7 FICSIT trials showed that particularly those interventions that included balance training reduced the risk of falls [10], thus suggesting that proper balance training can be a critical factor in terms of fall prevention among elderly people. Consequently, it is important to identify factors that predict body balance. The purpose of this cross-sectional study was, therefore, to examine factors that are associated with dynamic balance and health-related quality of life in home-dwelling elderly women.

## Methods

*Subjects*

A questionnaire was sent to a random population sample of 4,032 women from a cohort of 70- to 78-year-old women living in the city of Tampere, asking if they were interested in participating in a randomized, controlled exercise intervention study of elderly women. Eight hundred and fifty-eight women expressed their initial interest. Two hundred and forty-one potentially eligible women were invited to a screening examination and baseline measurements. Besides willingness to participate, the inclusion criteria were: understanding of study procedures, intense exercise no more than twice a week, no history of any illness for which exercise is contraindicated or that would limit their participation in an exercise program, no history of any illness that would affect balance or bone, no uncorrected vision problems, no intake of medications known to affect balance or bone (within 12 months of enrolment) and t score for bone mineral density at femoral neck more than –2.5 (i.e. no osteoporosis).

Of the above noted 241 women, 153 met the inclusion criteria, and their baseline measurements formed the basis of the analysis of the current study. The study was approved by the Ethics Committee of The Pirkanmaa Hospital District, and all participants gave their informed consent.

*Questionnaire and Quality of Life*

General health, physical activity and quality of life were assessed by questionnaires. The health questionnaire included questions on medical conditions, current medications, years of menopausal estrogen therapy, history of fractures and current physical activity. Quality of life was measured using a standardized health-related quality of life questionnaire (Rand 36-Item Health Survey 1.0). The Rand-36 has been developed to measure health-related quality of life by 8 separate scales: general health, physical functioning, mental health, social functioning, vitality, bodily pain, role of physical functioning and role of emotional functioning. It has been validated in the Finnish general population [11].

*Physical Performance*

Dynamic balance (agility) was tested by a figure-of-eight running test around two poles placed 10 m apart [12]. The subject was asked to run or walk 2 laps of the course as fast as possible. The running time was measured using a stopwatch. The best attempt of 2 trials was recorded. The test has been performed in premenopausal [13], postmenopausal [14] and elderly [15] women. Static balance (postural sway) was tested with an unstable platform (The Biodex Stability System, Biodex Medical System, New York, N.Y., USA); the higher the index, the poorer the balance.

The maximal isometric strength of the leg extensors was measured with a leg press dynamometer (Tamtron, Tampere, Finland) with a knee angle of 90° [16]. Dynamic muscle strength of lower limbs was tested by measuring ground reaction forces (GRF) with a force platform (Kistler Quattro Jump, Kistler Instrumente AG, Winterhur, Switzerland) during common daily activities: a sit-to-stand and a step-on-a-stair. In the GRF data analysis, the subjects' weight was omitted from the sit-to-stand and step-on-a-stair GRF values. The chair was 43 cm and the stair 18 cm in height.

Reaction time was assessed using a simple reaction time paradigm, employing a random light or sound stimulus and a finger pushbutton as the response to the stimulus. The seated subject placed the dominant hand on a table in front of the switch and light bulb. The equipment then recorded how quickly the switch was pressed after the stimulus release. Subjects had 10 practice trials and 10 experimental trials. The best attempt of the 10 trials was recorded.

*Statistical Analysis*

Descriptive data (means, SD and range) were reported for variables of interest. Associations between the independent variables or predictors (age, weight, height, number of current diseases, education, years of education, years of estrogen use, leg extensor strength, sit-to-stand GRF, step-on-a-stair GRF, static balance and reaction time) and the dependent variables or outcomes (figure-of-eight running time and quality of life) were determined by a Pearson product moment correlation. In addition, associations between some independent variables of interest (physical activity, walking per day) and the dependent variables were determined by a Spearman's rank order correlation. Thereafter, regression models were developed to identify the best predictors of (1) figure-of-eight running time and (2) quality of life score. We primarily used the backward regression elimination procedure. A stepwise selection procedure (forward stepping) was used to confirm that the selected models were consistent.

## Results

*Descriptive Characteristics*

Characteristics for the 153 women are given in table 1. One third (31%) of the participants had a vocational education and 7% had a university degree. Thirty-seven percent of the subjects had no diagnosed chronic diseases, but 27% had at least two. The most common diseases were high blood pressure (28%), high cholesterol (16%), dysfunction of thyroid gland (12%) and arthritis/joint pain (8%). No participants had any neurological disease or diabetes mellitus. At the menopause, 26% of women had used hormone therapy; however, all of them had stopped the hormone therapy more than a year before study entry. One third (33%) of the subjects reported taking brisk exercise such as walking, Nordic walking (i.e. walking with poles), cross-country skiing, swimming and aquatic exercises at least twice a week. Twenty-two percent were involved in some kind of brisk activity once a week, in addition to lighter physical exercise. Almost half of the subjects (45%) did not exercise regularly and were classified as sedentary. Twenty-eight percent of the subjects reported more than 3 km of walking per day.

**Table 1.** Descriptive characteristics (n = 153)

| Variable | Mean (SD) | Range |
|---|---|---|
| Age, years | 72.7 (2.3) | 70–78 |
| Height, cm | 159.4 (5.5) | 147.7–173.0 |
| Weight, kg | 72.4 (10.8) | 52.5–105.2 |
| BMI, kg/m$^2$ | 28.5 (3.9) | 18.8–38.0 |
| Femoral neck BMD, g/cm$^2$ | 0.785 (0.106) | 0.646–1.150 |
| Leg extensor strength, N/kg | 16.2 (3.4) | 8.6–27.3 |
| Sit-to-stand GRF, N/kg[a] | 4.2 (1.2) | 1.3–7.9 |
| Step-on-a-stair GRF, N/kg[a] | 8.5 (2.2) | 3.1–14.4 |
| Figure-of-eight time, s | 20.7 (3.1) | 15.0–31.5 |
| Postural sway | 2.87 (1.50) | 1.10–12.90 |
| Reaction time, s | 0.443 (0.108) | 0.175–0.716 |
| Quality of life score (Rand-36) | 2,732 (416) | 1,570–3,355 |

BMD = Bone mineral density.
[a] The body weight has been omitted from the GRF values.

*Dynamic Balance*

Table 2 shows statistically significant correlations between the figure-of-eight running time and selected predictor variables. The correlations to dynamic balance were highest for step-on-a-stair GRF (r = –0.43), sit-to-stand GRF (r = –0.35) and leg extensor strength (r = –0.32) (the better the strength, the better the balance). In the regression analysis with backward elimination, step-on-a-stair GRF, age, leg extensor strength, brisk physical activity, number of diseases, sit-to-stand GRF and static balance explained 42% of the variance of dynamic balance (table 3). In the stepwise selection method, the model was consistent with the backward method noted above, and the step-on-a-stair GRF was the strongest predictor of the figure-of-eight running time, explaining 18% of the variance.

**Table 2.** Pearson product moment and Spearman's rank order correlations between measures of dynamic balance (figure-of-eight running time) and quality of life scores (Rand-36) and selected predictive variables

| Predictor | Dynamic balance | Quality of life scores |
|---|---|---|
| Physical activity[1] | –0.26** | –0.21* |
| Walk per day[1] | –0.22** | 0.24** |
| Number of diseases | 0.11 | 0.18* |
| Weight | 0.20* | – |
| Age | 0.31*** | –0.03 |
| Leg extensor strength | –0.32*** | 0.18* |
| Reaction time | 0.16 | – |
| Sit-to-stand GRF | –0.35*** | 0.09 |
| Step-on-a-stair GRF | –0.43*** | 0.20* |
| Postural sway | 0.27** | –0.11 |
| Figure-of-eight running | – | –0.31*** |

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.
[1] Spearman's rank order correlation.

*Quality of Life*

There was a significant correlation (r = –0.31; $p < 0.001$) between the figure-of-eight running time and the quality of life score (table 2), i.e. the faster the figure-of-eight running time, the better the quality of life. Predictors such as age and education were not associated with the quality of life score. In the backward regression analysis, the figure-of-eight running time, number of diseases and walking more than 3 km per day explained 14% of the variance of the quality of life score (table 4). In the forward stepwise regression analysis, figure-of-eight running time and number of diseases were taken into the final model. Figure-of-eight running time was the strongest predictor of the variance of the quality of life score, explaining 9% of the variance.

**Table 3.** Dynamic balance (figure-of-eight running time) regression model summaries

| Variable | Predictor | $\beta$ | SE | p value |
|---|---|---|---|---|
| Dynamic balance | Step-on-a-stair GRF, N/kg | –0.370 | 0.096 | <0.001 |
| | Age, years | 0.291 | 0.088 | 0.001 |
| | Leg extensor strength, N/kg | –1.176 | 0.639 | 0.068 |
| | Brisk exercise | | | |
| | ≥2 × week | –1.507 | 0.463 | 0.001 |
| | ≤1 × week | –0.917 | 0.526 | 0.084 |
| | Number of diseases | 0.602 | 0.253 | 0.019 |
| | Sit-to-stand GRF, N/kg | –0.450 | 0.187 | 0.017 |
| | Postural sway | 0.331 | 0.139 | 0.019 |

$R^2$ = 0.42, SEE = 2.40, n = 149.

**Table 4.** Quality of life (Rand-36) regression model summaries

| Variable | Predictor | $\beta$ | SE | p value |
|---|---|---|---|---|
| Quality of life | Figure-of-eight running, s | –35.80 | 10.77 | 0.001 |
| | Number of diseases | –75.45 | 41.22 | 0.069 |
| | Walk ≥3 km/day | 130.30 | 73.69 | 0.079 |

$R^2$ = 0.14, SEE = 389, n = 150.

## Discussion

In this study, lower limb muscle strength, brisk physical activity, number of diseases, age and static balance were related to dynamic balance in elderly women. Especially, the isometric leg extensor strength and the GRF measured in the functional sit-to-stand and step-on-a-stair tests showed strong associations with balance. These observations are in line with previous studies that have also found a beneficial connection between knee extensor strength and dynamic balance in elderly women [17, 18]. In addition, there is evidence that good muscle strength predicts improved mobility, such as walking speed [19]. Randomized controlled studies have, in turn, showed that strength training improves balance in elderly people [20, 21].

Sit-to-stand and step-on-a-stair tests are commonly used functional tests in elderly people [22]. Lord et al. [23] reported that the sit-to-stand test is affected by the lower limbs strength, sensation, speed, balance and other related physiological processes. In the present study, we measured the GRF (instead of just measuring the test-related performance time) in order to get additional information on the lower limbs' muscle strength during these functional tests. The step-on-a-stair test is probably a more demanding task in terms of physiological and psychological processes than the sit-to-stand test. However, both these tests are likely to describe well the strength required in activities of daily living of elderly persons.

Previously, it has been shown that elderly women who are continuing with moderate exercise programs over many years have better muscle strength, balance, gait and health ratings and sustain fewer fractures than women in general [24]. In a large prospective study of postmenopausal women, hip fracture risk was reduced by 6% for each brisk walking hour per week [25]. Our results agree with these findings by showing that physical activity was positively, and a number of diseases negatively, associated with dynamic balance.

In the present study, the test of static balance was associated with dynamic balance, the latter measured by the figure-of-eight running test. This is in line with the study of Carter et al. [17], which showed a strong association between postural stability (measured by computerized posturography) and the figure-of-eight running test, thus indicating that a field test of agility and mobility can have good potential as a screening test for people with impaired balance. Furthermore, the inexpensive figure-of-eight running test may be a better overall measure of functional balance than any static test, as it bears closer resemblance to ambulation, gait and functional tasks [17].

Reaction time can be considered a relevant component in balance and postural stability. Previously, a significant relationship has been found between reaction time and postural stability [26] and mobility [27]. However, in the present study, there was no statistically significant correlation between reaction time and dynamic balance, and in the regression analysis, reaction time was not included in the final model. The weak association between dynamic balance and reaction time in our study can be explained, at least partly, by using an upper limb test for the latter. In fact, since lower limb performance is more essential for body balance than that in the upper limb, it would probably have been reasonable to measure the reaction time of the lower limbs, too.

The elderly women of the present study had a higher quality of life scores than those in the population level study of Finnish older adults [11]. This was not a surprise, since our subjects were selected by good functional capacity and health and no contraindication for exercise. Despite this selection (and thus compressing the range of the quality of life scores), dynamic balance was positively associated with health-related quality of life in Finnish home-dwelling elderly women. Together with a low number of diseases and walking distance more than 3 km a day, it explained 14% of the variance of the quality of life score. This is likely to mean that better mobility is able to increase a more independent and socially active life style. On the other hand, 86% of the variance in the quality of life scores could not be explained by the predictors noted above, thus indicating that there are a large number of additional genetic and environmental factors, such as social and psychological determinants, that are important in terms of quality of life. Dynamic balance seems, however, to be one of the most important determinants to protect independency later in life.

In conclusion, this study emphasizes the concept that in home-dwelling elderly women good muscle strength of lower limbs is crucial for proper body balance, and that dynamic balance is an independent predictor of a standardized quality of life estimate. The results provide important and useful information when planning meaningful contents for studies related to fall prevention and quality of life  and interventions in elderly women. Further studies, using a randomized, controlled design, should assess whether a systematic training of muscle performance and dynamic balance could improve living independency and quality of life in elderly women. If large and long enough, the studies could also determine whether such exercises would help decreasing the number of falls and fractures among these people.

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ORIGINAL ARTICLE

# A multi-component exercise regimen to prevent functional decline and bone fragility in home-dwelling elderly women: randomized, controlled trial

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**Abstract**
*Summary* This study showed that combination of strength, balance, agility and jumping training prevented functional decline and bone fragility in home-dwelling elderly women. The finding supports the idea that it is possible to maintain good physical functioning by multi-component exercise program and thus postpone the age-related functional problems.
*Introduction* This 1-year randomized, controlled exercise intervention trial assessed the effects of two different training programs and their combination on physical functioning and bone in home-dwelling elderly women.
*Methods* One hundred and forty-nine healthy women aged 70–78 years were randomly assigned into: group 1—resistance training (RES), group 2—balance-jumping training (BAL), group 3—combination of resistance and balance-jumping training (COMB), and group 4—controls (CON). Self-rated physical functioning, leg extensor force, dynamic balance, and bone mass and structure were measured.
*Results* Self-rated physical functioning improved in the COMB group, but was reduced in the CON group; the mean inter-group difference was 10% (95% CI: 0–22%). Mean increase in the leg extensor force was higher in the RES (14%; 4–25%) and COMB (13%; 3–25%) compared with the CON groups. Dynamic balance improved in the BAL (6%; 1–11%) and in the COMB (8%; 3–12%) groups. There were no inter-group differences in BMC at the proximal femur. In those COMB women who trained at least twice a week, the tibial shaft structure weakened 2% (0–4%) less than those in the CON group.
*Conclusions* Strength, balance, agility, and jumping training (especially in combination) prevented functional decline in home-dwelling elderly women. In addition, positive effects seen in the structure of the loaded tibia indicated that exercise may also play a role in preventing bone fragility.

**Keywords** Balance training · Bone fragility · Bone strength · Functional decline · Osteoporosis · Strength training

These data were presented in part at the American Society for Bone and Mineral Research meeting held in Seattle, Washington on 1–5 October 2004 and at the 18th Congress of the International Association of Gerontology held in Rio de Janeiro, Brazil on 26–30 June 2005.

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## Introduction

Proper physical functioning and ambulation are essential determinants of quality of life among home-dwelling elderly people. Functional decline predisposes to the need for home services and hospitalization [1, 2] and impaired mobility is an independent predictor of falls and fall-induced injuries (fractures) in older adults [3–5]. In addition, in conjunction with risk factors for falling, decreased bone strength attributable to osteopenia or osteoporosis is associated with their low-energy fractures [6]. Thus, there is a need to develop and test efficient, safe, and feasible ways to prevent functional decline and bone loss among elderly persons.

Exercise has been shown to be an effective method of preventing falls in elderly individuals [7, 8], especially when balance and strength training are combined [8]. There is also evidence that aerobics, weight-bearing, and resistance exercises have positive effects on bone mineral density (BMD) of the spine, as does walking on the hip BMD among postmenopausal 45- to 70-year-old women [9], but data are sparse in women over 70 years of age, especially those concerned with bone structure. It seems quite evident that exercise that focuses primarily on improving underlying impairments in balance, muscle strength, and mobility can prevent functional decline [10–12]. However, the study participants have typically been frail, with reduced physical function, low bone mass, and previous falls and fractures. Therefore, it is also important to study whether exercise can prevent functional decline and bone loss in healthy, home-dwelling elderly people—perhaps the most profitable target population in terms of primary prevention. In other words, the key research questions are whether it is possible to maintain good physical functioning and bone health among these people by physical training, and thus postpone the age-related functional decline, and, if so, is it then crucial to train balance, or muscle strength of lower limbs, or both?

The purpose of this 1-year randomized, controlled exercise intervention trial was to evaluate separately the specific effects of resistance training, balance-jumping training, and their combination on physical functioning and bone strength in home-dwelling 70- to 79-year-old women.

## Materials and methods

### Design

The study was a randomized controlled trial with four experimental groups:

1. A resistance training group (RES)
2. A balance-jumping training group (BAL)
3. A combination group doing resistance training and balance-jumping training (COMB)
4. A non-training control group (CON)

The assigned training frequency was three times a week for 12 months. All measurements were done at baseline (before the intervention) and at the end of the 12-month intervention.

### Participants

The trial profile is presented in Fig. 1. First, a questionnaire was sent to a random population sample ($n$=40,32) of 70- to 79-year-old women living in the city of Tampere, Finland, inquiring whether they were interested in participating this randomized, controlled exercise intervention study of elderly women. A total of 2,706 women responded and 858 expressed their initial interest. Two hundred and forty-one eligible women were then invited to a screening examination, and 149 of them met the inclusion criteria (see below). According to a computer-generated randomization list, 37 women were assigned to the RES group, 37 women to the BAL group, 38 women to the COMB group, and 37 women to the CON group. A computer-generated randomization list was drawn up by the statistician (MP), who was blinded to the study participants and their characteristics, and randomly allocated participants into four groups (simple randomization).

The inclusion criteria were: willingness to participate, age between 70 and 79 years, a full understanding of the study procedures, no history of any illness contraindicating exercise or limiting participation in the exercise program, no history of any illness affecting balance or bones, no uncorrected vision problems, and not taking medications known to affect balance or bone metabolism (for 12 months before the enrolment). A participant was excluded if she was involved in intense exercise more than twice a week or the T-score for femoral neck bone mineral density (BMD) was lower than −2.5 (i.e., indicating osteoporosis and subsequent medical attention).

The baseline characteristics of the participants are given in Table 1. The study was approved by the Ethics Committee of the Pirkanmaa Hospital District. All participants gave their written informed consent prior to the study.

### Training programs

The exercise training classes were arranged 3 times a week for 12 months. Each class included a warm-up of 7–10 min, 25–30 min of effective training (see descriptions below) and an 8- to 10-min period for cooling down. All classes were supervised by exercise leaders of the UKK Institute, who had been trained to supervise these special training programs before the trial began. They also kept an attendance record for each of the participants.

#### *Resistance training*

The RES group accustomed themselves to resistance training for 6 weeks. During the first weeks the participants became familiar with the equipment. Then the instructors assessed the participants' training loads

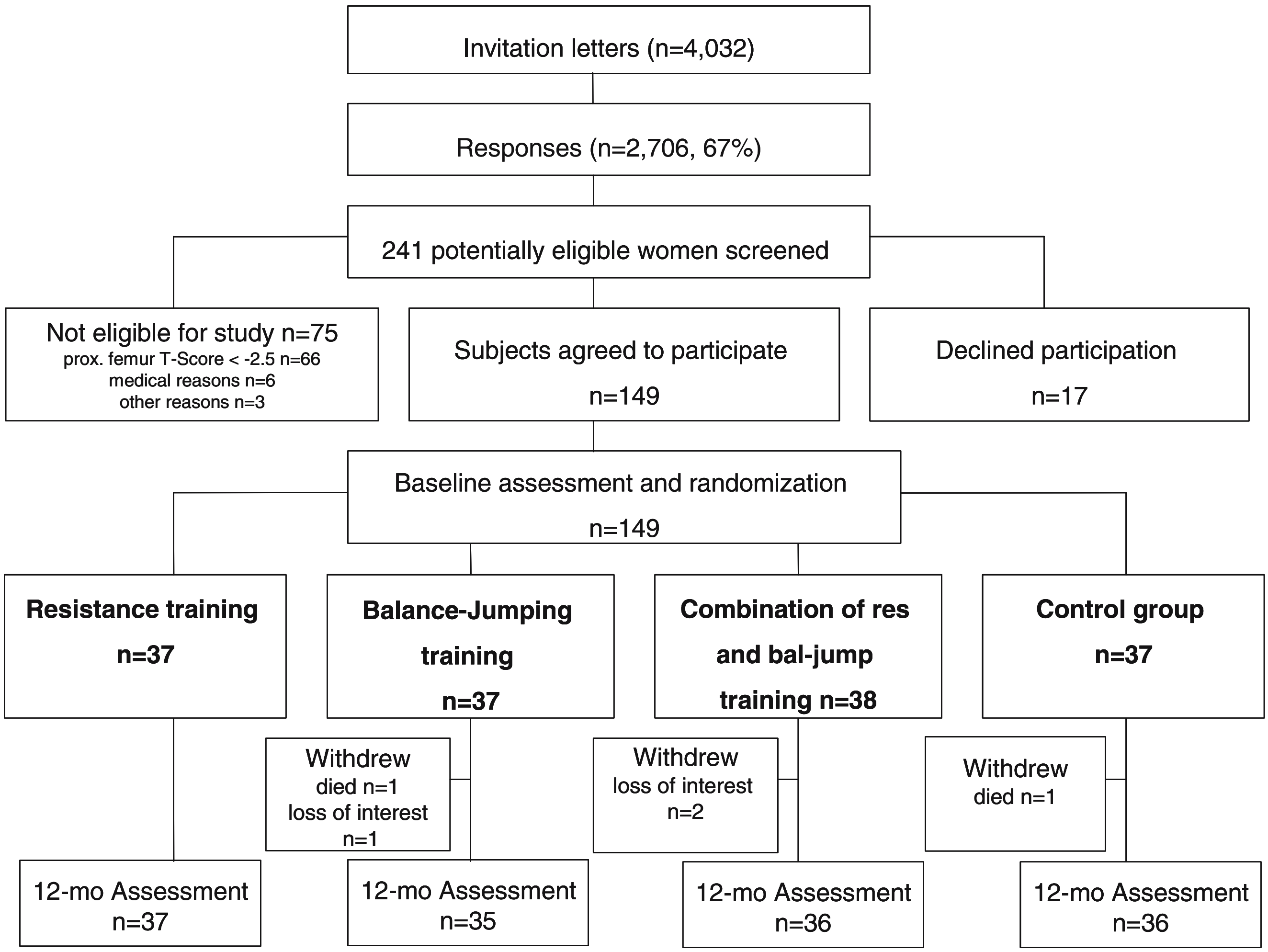


**Fig. 1** Trial profile

and taught them the individually tailored resistance training program. The intensity of training stimulus was set at 50–60% of one repetition maximum (1RM) using 2 sets and 10–15 repetitions. Thereafter, the intensity progressed to 75–80% of 1RM with work range of 3 sets and 8–10 repetitions. The intensity was assessed using rated perceived exertion (RPE). If the RPE dropped below 18 (maximum 20) the participants were asked to increase load (about 5%) or repetitions. A two-min recovery was provided between the training sets and each set of repetitions. The program included large muscle group exercises, such as raising from a chair using a weight vest, squatting, leg presses, hip abduction, hip extension, calf rise, and rowing using resistance training machines. To prevent the programs being too monotonous, five different combinations of the above-mentioned exercises in 10-week periods were used during the intervention.

*Balance-jumping training*

The primary training components in the BAL group were balance, agility, and impact exercise. In detail, training classes included static and dynamic balance and agility training sessions, jumps and other impacts, and changes of direction exercises (such as acceleration and deceleration back and forth, and sideways walking with stops and turns) with music. Some of the exercises were done with a step-board. During the first 6 weeks, the trainees accustomed themselves to the balance and agility training. Thereafter, the degree of difficulty of movements, steps, impacts, and jumps was gradually increased. The type of training was modified aerobics or step aerobics alternating every 2 weeks (2 weeks' aerobics, 2 weeks' step aerobics) in 12-week periods. There were four different aerobics and step aerobics programs with different combinations of the above noted balance-jumping movements during the intervention.

**Table 1** Group characteristics at baseline

| Variable | RES[a] $n$=37 | BAL[b] $n$=37 | COMB[c] $n$=38 | CON[d] $n$=37 |
|---|---|---|---|---|
| Age, mean (SD) | 72.7 (2.5) | 72.9 (2.3) | 72.9 (2.2) | 72.0 (2.1) |
| Height, cm, mean (SD) | 160.5 (4.8) | 159.0 (6.1) | 159.1 (5.3) | 158.4 (5.8) |
| Weight, kg, mean (SD) | 74.3 (11.0) | 70.9 (9.6) | 69.4 (10.6) | 74.3 (10.8) |
| BMI, kg/m$^2$, mean (SD) | 28.8 (4.0) | 28.0 (3.2) | 27.5 (4.2) | 29.6 (3.7) |
| Calcium intake, mg/day, mean (SD) | 940 (365) | 960 (331) | 916 (302) | 894 (264) |
| Physical activity/week, $n$ (%) | | | | |
| None or some | 19 (51.4) | 16 (43.2) | 15 (39.5) | 17 (45.9) |
| Brisk exercise 1× | 8 (21.6) | 8 (21.6) | 9 (23.7) | 9 (24.3) |
| Brisk exercise 2× | 10 (27.0) | 13 (35.1) | 14 (36.8) | 11 (29.7) |
| Chronic diseases and symptoms, $n$ (%) | | | | |
| Hypertension | 6 (16.2) | 12 (32.4) | 10 (26.3) | 13 (35.1) |
| Hyperlipidemia | 3 (8.1) | 8 (21.6) | 5 (13.2) | 9 (24.3) |
| Hypo-/hyperthyroidism | 5 (13.5) | 2 (5.4) | 2 (5.3) | 9 (24.3) |
| Arthritis/joint pain | 3 (8.1) | 4 (10.8) | 2 (5.3) | 3 (8.1) |

[a] Resistance training group
[b] Balance-jumping training group
[c] Combination of resistance and balance-jumping training group
[d] Control group

*Combination of resistance and balance-jumping training*

The COMB training consisted of the above described resistance and balance-jumping training on alternate weeks. In addition to the 6-week familiarizing periods, two different resistance training and two different balance-jumping training programs were performed during the entire intervention.

*Control group*

The controls were asked to maintain their pre-study level of physical activity during the 12-month trial.

Questionnaires

General health and habitual physical activity were assessed by a questionnaire at baseline. A health questionnaire addressed medical conditions, current medications, years of menopausal estrogen therapy, history of fractures, and current physical activity in leisure time.

All participants reported their health status and physical activity (type, frequency, and duration) monthly during the intervention. Reported weekly physical activity was converted to MET (metabolic equivalent) hours/week [13].

Dietary intake and possible use of vitamin and mineral supplements were assessed by a complete 3-day (2 weekdays and a Sunday) food record at baseline and at the end, and calculated by Micro-Nutrica software (Social Insurance Institution, Helsinki, Finland).

Physical functioning

*Physical performance tests*

Dynamic balance and agility was tested by a standardized figure-of-8 running test around two poles placed 10 m apart [14, 15]. The participant was asked to run or walk two laps of the course as fast as possible. The running time was measured using a stop-watch. The best attempt of two trials was recorded. The maximal isometric leg extension force was measured with a leg press dynamometer (Tamtron, Tampere, Finland) at a knee angle of 90° with precision of about 5% [16].

*Self-rated physical functioning*

Self-rated physical functioning was assessed with the standardized Finnish Physical Functioning Scale of the Rand 36-Item Health Survey [17, 18]. The participants filled in the questionnaire at home and it was checked together with the participant during her visit for the physical performance tests. The Scale comprises 10 questions on coping with daily activities, such as running, lifting heavy things, climbing stairs of several floors, and walking half a kilometer. Each item is scored either to major restricts (0 points), minor restricts (50 points) or no restrict (100 points). An individual Physical Functioning Index score is the mean of scores of all answered items. In the case of no reply to more than 5 items, no Index score was calculated. In a Finnish population sample for standardization aged 18–79 years the homogeneity, i.e., the mean of the item intercorrelations of the Scale, was 0.63 and Cronbach alpha 0.94 [18].

Bone measurements

Bone mineral density and content (BMD and BMC) of the right proximal femur were measured with dual-energy X-ray absorptiometry (DXA, Norland XR-26; Norland, Fort Atkinson, WI, USA) according to our standard procedures with in vivo precision of about 1% [19]. Femoral neck BMD was used for the screening of the study participants, while BMC of the femoral neck (divided by the height of the neck region) was used as the primary outcome.

In addition to BMC assessment, the gross structure of the narrowest femoral neck section was analyzed using the hip structure analysis (HSA) [20]. In this study, section modulus (Z; as an index of bending strength) and periosteal diameter were used. The in vivo precision of these measurements was 4.8% and 2.5% respectively [21].

The peripheral quantitative computed tomography (pQCT; XCT 3000; Stratec Medizintechnik, Pforzheim, Germany) were performed at the distal sites (trabecular bone), and at midshaft (cortical bone) of the right radius and tibia according to our standard procedures [22]. For the distal sites, trabecular density (TrD), and density-weighted polar section modulus (BSI, an index of torsion bending strength) were used, while the cortical area (CoA), cortical density (CoD), and BSI were used for the shaft sites. In our laboratory, the in vivo precision ranges from 0.7% (tibial shaft CoD) to 7.7% (distal radius BSI) [22].

### Statistical analyses

Means and standard deviations (SD) were used as descriptive statistics. Primary outcome variables were self-rated physical functioning, physical performance (balance and lower limbs muscle force), and bone mass and structure.

All results were based on the Intention-To-Treat analyses (ITT) of all available participants. In addition to the ITT analyses, efficacy or per protocol analyses of the exercise were carried out for the self-rated physical functioning, physical performance, and bone variables. The inclusion criterion for this active exercise group was the average training frequency at least twice a week during the trial.

Changes in weight, height, and calcium intake were analyzed with a paired sample $t$ test. Analysis of covariance (ANCOVA) with 12-month measurements as dependent variables was used to assess the treatment effect between the exercise and control groups. Baseline values, age, and time interval between measurements were used as covariates. Post hoc between-groups comparisons were performed using Sidak's adjustment for multiple comparisons. Due to the skewed distributions in some outcome variables and to obtain the relative between-group differences, log-transformed variables of outcome were used in the ANCOVA. Geometric mean ratios and their 95% confidence intervals (CI) were calculated as antilog of difference in group means at end of the 12-month intervention. All data were analyzed using SPSS 11.5 statistical software.

Preliminary power calculations focusing on dynamic balance (figure-of-8 running test) as the outcome variable indicated that at $\alpha$ level of 0.05 and common standard deviation of 10% for the change during the intervention, a sample size of 70 women in each group would give 80% power for the study to detect a 5% treatment effect in dynamic balance between the groups. The actual number of participants in each group was 37 (in 3 groups) and 38 (in 1 group) at the onset of the study. If necessary, for the sake of statistical power, it was decided that groups that had resistance training components (RES and COMB, $n$=75) and groups that had balance-jumping training components (BAL and COMB, $n$=75) could be combined to provide adequate groups for determining the effect of resistance training or balance-jumping training by comparing them with the pooled group of the remaining participants.

## Results

### Descriptive characteristics

Baseline clinical characteristics for the study groups are given in Table 1. There were no differences among the groups. The participants in all the groups had a similar history of hormone replacement therapy [23]. There were no changes in height or calcium intake during the intervention. Weight (mean, 95% CI) decreased at least slightly in all groups, but significantly in the BAL group (−0.76 kg, −1.46 to −0.07, $p$=0.033) and in the COMB group (−0.94 kg, −1.80 to −0.09, $p$=0.031). The mean duration of moderate non-intervention physical activity (4.5 MET) during the intervention was 5 (SD 3) h per week in the RES and BAL groups and 7 (SD 4) h per week in the COMB and CON groups. During the intervention period there were 8 falls in the RES, 18 falls in the BAL, 19 falls in the COMB, and 13 falls in the CON groups. Two members of the RES group and one of the CON group suffered a radius fracture. Also, one of the controls suffered a fracture of a toe. There were no statistically significant differences among the groups.

### Program feasibility

The drop-out rate was 3.4%. There were four drop-outs in the training groups and one in the control group. Figure 1 shows the reasons for withdrawal. Mean training compliance, measured as attendance at all offered training sessions, was 67% (range 0 to 100%), being highest in the RES group (74%), followed by the COMB group (67%), and the BAL group (59%). Twenty-nine women (78%) in the RES, 25 (66%) in the COMB, and 22 (59%) in the BAL group trained an average of at least twice a week (and were included in the efficacy analysis).

During the intervention, 14 participants from the training groups consulted the attending physician due to musculoskeletal injuries or symptoms (1 ligament injury of the knee, 2 minor knee injuries, 1 partial rupture of the quadriceps femoris muscle, and 10 participants had overuse symptoms). In addition, 1 participant was taken to the emergency unit due to acute low back pain. Three of them did not return to the training classes, but they participated in the 12-month measurements and were included in the analyses according to the ITT principle. Four exercisers (two in the BAL and two in the COMB groups) fell during supervised intervention exercise, but returned to the training classes within 2 weeks. Altogether, there were no differences in the numbers of monthly reported health problems between exercisers and controls ($p$=0.955).

Physical functioning

*Physical performance*

The absolute values of the physical performance at baseline and after 12 months are shown in Table 2. After the 12-month trial, the mean gain in isometric leg extension force was statistically significantly greater in the RES group (effect: 14%, 95% CI: 4–25%) and in the COMB group (13%; 2–25%) compared with the CON group. In addition, the figure-of-8 running time improved significantly more in the BAL group (6%; 1–11%) and in the COMB group (8%; 3–12%) compared with the CON group (Fig. 2).

In the efficacy analysis, the above-noted significant between-group differences in leg extension force were enhanced (Fig. 2). In addition, the dynamic balance change was significantly higher in the BAL group (5%; 1–10%) and in the COMB group (5%; 0–10%) compared with the RES group.

*Self-rated physical functioning*

The Index score could be calculated for 99% of the total group ($n$=148) at baseline and for 95% of those who participated in the assessments at 12 months ($n$=142). Cronbach alpha was 0.76 and the mean inter-item correlation 0.25 at baseline. After 12 months, the corresponding values were 0.80 and 0.30. In all groups, the distributions of the item scores and the Index score clearly accumulated to the high values, thus indicating good physical functioning. At baseline, 10% ($n$=14) of the participants scored 100, the maximum value of the Index. The mean baseline Index score for the total group (82.7, SD 13.0) was significantly higher ($p$<0.001) than the means observed in the standardized population samples aged 75–79 years (mean 45.1, SD 28.4) and 70–74 years (mean 54.1, SD 27.8) [16].

After 12 months, minor changes in the Index score means were observed in the COMB (+3.5), RES (+1.4), and CON (−1.7) groups (Table 2). A significant treatment effect was found between the COMB and CON groups (effect: 10%; 95% CI: 0–22%; Fig. 2). The efficacy analyses indicated the mean benefit of 12% (0–26%) in the BAL group and 11% (−1–+24%) in the COMB group compared with the CON group (Fig. 2).

Bone measurements

The observed bone values at baseline and after 12 months are shown in Table 2. The ITT analysis did not show any significant treatment effect at the femoral neck BMC, while there was a significant effect on the section modulus (Z) of the femoral neck between RES and COMB (effect: 5%; 95% CI: 0–9%; due to technical limitations this analysis could be performed in 124 of the 144 measured participants; Fig. 3). However, this effect on Z did not reach statistical significance in the efficacy analysis.

In the pQCT variables, there were no significant between-group differences in the ITT analysis of the distal or midshaft sites of the tibia or radius. In the efficacy analysis, in turn, tibial shaft bone strength index (BSI) decreased 2% (0–4%) less in the COMB group than in the CON group (Fig. 3). In addition, there was a trend suggesting that training could be beneficial for the tibial shaft cortical area and the distal tibia BSI.

## Discussion

This 12-month randomized, controlled intervention study showed a significant increase in self-rated physical functioning, dynamic balance, and isometric muscle force of the lower limbs among 70- to 78-year-old healthy women as a response to the combined resistance and balance-jumping training. As could be expected, resistance training improved muscle force and balance-jumping training improved dynamic balance. Further, positive effects of combined training were seen at the structure of the loaded tibia. Although exercise did not increase femoral neck bone mass, a treatment effect in the femoral neck structure was observed between the training groups, as judged from the DXA-derived section modulus data.

In our study, the effects of exercise were task-specific in terms of muscle force and balance. Consequently, the resistance training increased muscle force, but did not alter dynamic balance, while balance-jumping training improved balance without any statistically significant improvement in lower limb force, and importantly, the combined training improved both muscle force *and* balance characteristics. These results are consistent with Wolfson et al. [24], who did not find a clear overlapping effect of balance and strength training among healthy elderly individuals. In contrast to our findings, Nelson et al. [25] found that high-intensity strength training twice a week could also improve balance, estimated by backward tandem walking, among

**Table 2** Observed baseline and 12-month values of physical functioning and bone variables (mean and SD)

| Variable | | RES | BAL | COMB | CON |
|---|---|---|---|---|---|
| Self-rated physical functioning | | | | | |
| (0–100) | Baseline | 83.4 (11.7) | 84.6 (12.0) | 82.5 (14.9) | 82.0 (12.4) |
| | 12 months | 84.8 (12.5) | 84.7 (11.5) | 86.0 (13.6) | 80.3 (16.4) |
| Physical performance | | | | | |
| Leg press, N/kg | Baseline | 16.2 (3.5) | 16.5 (3.6) | 16.6 (4.0) | 16.1 (2.5) |
| | 12 months | 20.2 (4.6) | 19.6 (4.3) | 20.2 (4.4) | 17.6 (2.8) |
| Figure-of-8 running time, s | Baseline | 20.7 (3.2) | 20.6 (2.9) | 21.0 (3.2) | 20.0 (2.6) |
| | 12 months | 20.0 (3.2) | 19.4 (3.0) | 19.3 (2.2) | 20.0 (2.8) |
| Bone health | | | | | |
| Femoral neck | | | | | |
| BMC, g | Baseline | 2.74 (0.35) | 2.77 (0.42) | 2.68 (0.28) | 2.72 (0.45) |
| | 12 months | 2.71 (0.33) | 2.73 (0.40) | 2.65 (0.29) | 2.67 (0.44) |
| Z, $mm^3$ | Baseline | 1,431 (238) | 1,389 (220) | 1,411 (164) | 1,395 (259) |
| | 12 months | 1,430 (235) | 1,386 (239) | 1,353 (154) | 1,362 (247) |
| Width, mm | Baseline | 32.0 (2.2) | 31.7 (2.2) | 32.2 (2.2) | 31.4 (2.0) |
| | 12 months | 32.0 (2.2) | 31.6 (2.4) | 32.2 (2.1) | 31.4 (2.0) |
| Distal tibia | | | | | |
| TrD, $mg/cm^3$ | Baseline | 220 (26) | 223 (34) | 215 (39) | 227 (33) |
| | 12 months | 219 (26) | 224 (34) | 215 (39) | 226 (33) |
| BSI, $mm^3$ | Baseline | 796 (313) | 867 (251) | 750 (325) | 888 (306) |
| | 12 mo | 781 (310) | 870 (247) | 741 (324) | 862 (307) |
| Tibial shaft | | | | | |
| CoD, $mg/cm^3$ | Baseline | 1,130 (34) | 1,120 (31) | 1,120 (34) | 1,125 (37) |
| | 12 months | 1,125 (35) | 1,121 (31) | 1,118 (34) | 1,127 (40) |
| CoA, $mm^2$ | Baseline | 245 (29) | 248 (25) | 238 (29) | 245 (34) |
| | 12 months | 245 (29) | 246 (25) | 237 (30) | 241 (33) |
| BSI, $mm^3$ | Baseline | 1,334 (184) | 1,329 (197) | 1,303 (174) | 1,273 (210) |
| | 12 months | 1,331 (187) | 1,323 (198) | 1,297 (177) | 1,255 (211) |
| Distal radius | | | | | |
| TrD, $mg/cm^3$ | Baseline | 189 (37) | 190 (45) | 180 (47) | 186 (42) |
| | 12 months | 184 (42) | 189 (49) | 180 (48) | 183 (44) |
| BSI, $mm^3$ | Baseline | 232 (99) | 246 (70) | 217 (75) | 256 (85) |
| | 12 months | 234 (83) | 248 (87) | 216 (81) | 266 (79) |
| Radial shaft | | | | | |
| CoD, $mg/cm^3$ | Baseline | 1,136 (45) | 1,136 (33) | 1,131 (40) | 1,145 (39) |
| | 12 months | 1,135 (40) | 1,133 (34) | 1,126 (40) | 1,143 (37) |
| CoA, $mm^2$ | Baseline | 68.3 (11.4) | 69.8 (9.9) | 66.6 (10.7) | 68.8 (11.4) |
| | 12 months | 68.4 (10.7) | 69.7 (10.5) | 66.5 (11.1) | 68.4 (11.5) |
| BSI, $mm^3$ | Baseline | 212 (45) | 214 (43) | 204 (37) | 201 (44) |
| | 12 months | 211 (40) | 214 (46) | 203 (39) | 199 (43) |

*BMC* bone mineral content, *Z* section modulus, *TrD* trabecular density, *BSI* bone strength index, *CoD* cortical density, *CoA* cortical area

50- to 70-year-old women. The younger age compared with our participants and different methods of assessing dynamic balance may at least partly explain the inconsistent results.

In addition to improved physical performance per se, the combined resistance and balance-jumping training had a positive effect on self-rated physical functioning. It has been previously shown that a home-based training program including balance and strength exercises can reduce the progression of functional decline among physically frail elderly people living at home [26], especially when underlying impairments in physical abilities are targeted [10]. In contrast to these studies, our participants were healthy. Nevertheless, our regular progressive group-exercise program could maintain, or even improve their initially good physical functioning during the 12 months. This effect was partially attributable to the small age-related decline among controls.

Our results are consistent with a recent nonrandomized exercise study, in which 1-year strength training accompanied by flexibility and body balance exercises, significantly improved not only muscle function, but also functional ability among healthy community-dwelling women aged 75 or over [27]. On the contrary, a recent meta-analysis of progressive resistance training in elderly people did not show any effect on physical disability despite a large positive effect on strength and a modest effect on gait speed

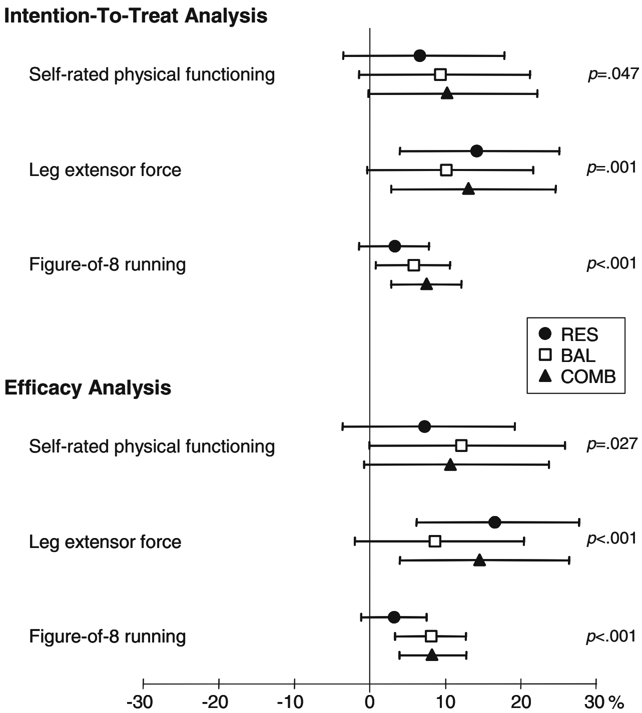


**Fig. 2** The adjusted percentage differences of the training participants compared with the controls (mean, 95% CI) after intervention in physical functioning variables using Intention-To-Treat and Efficacy analysis. *RES* resistance training group, *BAL* balance-jumping training group, *COMB* combination training group. Baseline values, age, and time between measurements were used as covariates. *p* Values are for the between-group differences in the ANCOVA (F-test). The 95% CI are Sidak-adjusted

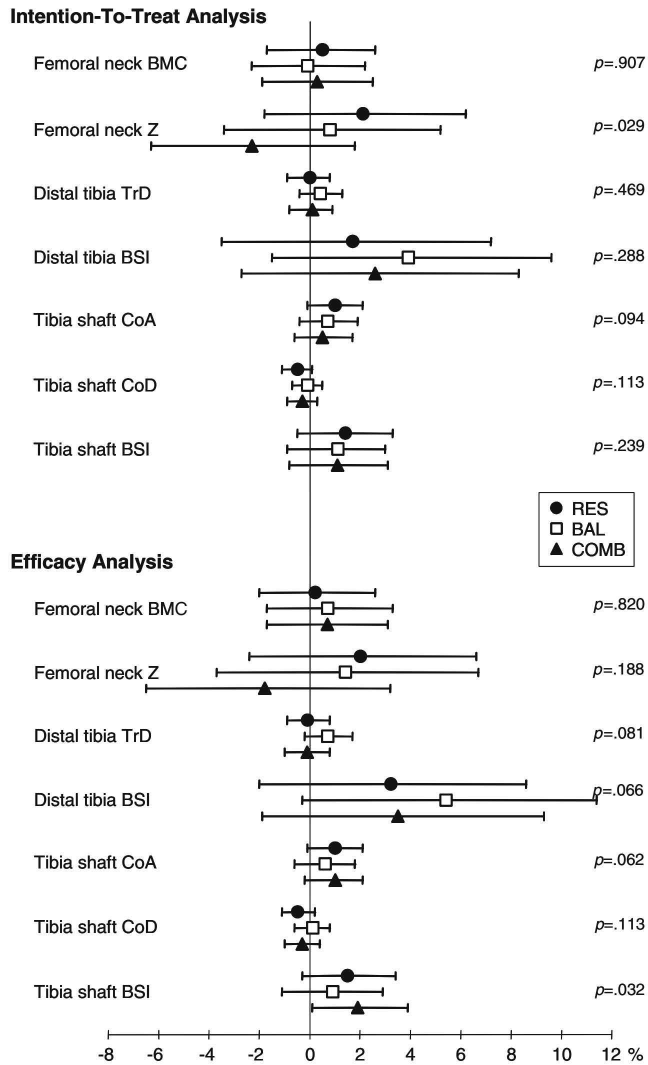


**Fig. 3** The adjusted percentage differences of the training participants compared with the controls (mean, 95% CI) after intervention in the lower limb bone structure variables using Intention-To-Treat and Efficacy analysis. *BMC* bone mineral content, *Z* section modulus at the femoral neck, *TrD* trabecular density, *BSI* bone strength index, *CoA* cortical area, *CoD* cortical density. Baseline values, age, and time between measurements were used as covariates. *p* Values are for the between-group differences in ANCOVA (F-test). The 95% CI are Sidak-adjusted

[28]. Moreover, de Vreede and co-workers [29] recently concluded that functional task exercises were more effective than resistance training in improving healthy elderly women's ability to carry on daily tasks. In our study the combined resistance and balance-jumping training was most effective in improving self-rated physical functioning. Simultaneously, significant improvements in body balance and muscle strength of lower limbs were observed in this group. Presumably, the improved body balance and better force of the lower limbs had a positive influence on self-rated physical functioning. Our results thus support the idea that it is possible to maintain or even improve the good baseline physical functioning of elderly women with balance, jumping, and lower limb strength exercises.

Previously, it has been suggested that group-delivered exercise would be less effective than individually prescribed home exercise, especially in fall prevention [8]. However, some group exercise interventions have successfully maintained physical functioning and prevented falls [30, 31]. Our results support the latter, showing that group-based resistance and balance-jumping training can be effective in preventing functional decline in healthy home-dwelling elderly women. In addition, Day et al. [32] have reported that a weekly group-based combined training program, including strength, balance, and flexibility training (supported by small amounts of home exercise) improved body balance and reduced falls in healthy home-dwelling elderly people within 15 weeks.

We did not find any exercise effect on bone mineral mass of the femoral neck in contrast to some studies showing a positive response to exercise at the femoral neck among elderly women [25, 33, 34]. However, some other findings are more consistent with our results, indicating no such exercise effect [15, 35, 36]. Recently, Villareal et al. [37] did not find relatively vigorous multi-component exercise training to increase BMD compared with low intensity exercise in frail elderly persons.

Concerning the findings above and bone strength in general, we should recall, however, that it is more important to see an exercise effect on bone structural strength than on BMD or BMC. Previously, Kaptoge et al. [38] reported that among elderly women hip section modulus was more strongly related to physical activity than BMD. In our study a significant difference in femoral neck section modulus (Z) was observed between the RES and COMB groups, indicating that resistance training might have redistributed bone mineral within the femoral neck and thus strengthened the structure. Probably due to reduced sample size, this effect could not be confirmed by the efficacy analysis, although the trend was similar.

At the tibia, where loading-induced stresses are apparently highest, we observed a strengthening effect of combined training on bone structure among those participants who trained at least twice a week. This finding is consistent with our previous study [15]. Recently, Liu-Ambrose et al. [39] also found that agility training may have positive effects on cortical bone at the tibial shaft of elderly osteoporotic women.

This study has several strengths. First, it was a randomized controlled exercise intervention trial with three different training groups and a control group, and with only very few drop-outs. Second, the training participants did not report more health problems or training-induced injuries compared with the controls during the intervention. Third, the general training compliance was good (67%), although there was variability among the training groups (the highest compliance was in the RES and the lowest in the BAL groups). Perhaps the resistance training was more convenient to participants than the more physically demanding (balance-)jumping training. However, the COMB group also underwent (balance-)jumping training with good compliance. One reason for differences in compliance may be the group size at the training classes: the RES and COMB groups trained in smaller groups (8 to 11 participants) compared with the BAL group (17 to 21). This fact, solely due to practical arrangements, might have enhanced the grouping process, helping participants to get to know each other better, thus creating a positive "pressure" for the group members to attend the training sessions. Despite the strengths of the study, the results cannot be generalized to all elderly women since the participants were clinically healthy and had fairly good self-rated physical functioning, and were therefore capable of exercising vigorously.

## Conclusion

Healthy elderly women with initially good physical functioning seem to have a good capacity to prevent age-related functional decline by participating in a progressive group exercise regimen of balance, agility, jumping, and strength training. Positive effects found in the structure of the loaded tibia indicated that exercise may also play a role in preventing bone fragility. In addition, successful completion of the training with a low rate of adverse effects suggested that the training program was feasible for these previously untrained women. These findings may be of great importance regarding prevention of many unwanted long-term consequences of aging and functional decline, such as falls, fall-induced injuries, and premature institutionalization.

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ORIGINAL ARTICLE

# Maintenance of exercise-induced benefits in physical functioning and bone among elderly women

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**Abstract**
*Summary* This study showed that about a half of the exercise-induced gain in dynamic balance and bone strength was maintained one year after cessation of the supervised high-intensity training of home-dwelling elderly women. However, to maintain exercise-induced gains in lower limb muscle force and physical functioning, continued training seems necessary.
*Introduction* Maintenance of exercise-induced benefits in physical functioning and bone structure was assessed one year after cessation of 12-month randomized controlled exercise intervention.
*Methods* Originally 149 healthy women 70–78 years of age participated in the 12-month exercise RCT and 120 (81%) of them completed the follow-up study. Self-rated physical functioning, dynamic balance, leg extensor force, and bone structure were assessed.
*Results* During the intervention, exercise increased dynamic balance by 7% in the combination resistance and balance-jumping training group (COMB). At the follow-up, a 4% (95% CI: 1–8%) gain compared with the controls was still seen, while the exercise-induced isometric leg extension force and self-rated physical functioning benefits had disappeared. During the intervention, at least twice a week trained COMB subjects obtained a significant 2% benefit in tibial shaft bone strength index compared to the controls. A half of this benefit seemed to be maintained at the follow-up.
*Conclusions* Exercise-induced benefits in dynamic balance and rigidity in the tibial shaft may partly be maintained one year after cessation of a supervised 12-month multi-component training in initially healthy elderly women. However, to maintain the achieved gains in muscle force and physical functioning, continued training seems necessary.

**Keywords** Balance training · Bone strength · Maintenance · Physical functioning · Osteoporosis · Strength training

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## Introduction

Falls and related fractures are a major and a worldwide healthcare problem causing functional decline and impaired quality of life in elderly people. On the other hand, physical limitations, such as impaired balance and mobility and decreased muscle strength of lower limbs predispose older adults to falls [1, 2]. Moreover, in conjunction with risk factors for falling, increased bone fragility attributable to osteopenia or osteoporosis is associated with low-energy fractures [3, 4].

Several randomized, controlled trials have found that exercise has beneficial effects on the risk factors of falls and fragility fractures of elderly people [5–10]. The participants in these studies have quite often been frail, with reduced physical function, low bone mass, and previous falls and fractures. However, in primary prevention it is important to start preventing functional impairments, bone loss and falls already among relatively healthy elderly individuals, since during the next few years many of these people will also be at risk for functional decline and fracture.

Intensity of effective exercise interventions, especially among the relatively healthy elderly persons, has often been rather high, requiring a lot of time, energy and motivation from participants. Thus, it is not very likely that many older people are able or willing to continue vigorous training on their own after cessation of supervised exercise intervention; therefore, it is important to understand the influence of reduced training on their functional ability and skeleton.

The effects of detraining on neuromuscular function and bone has been somewhat studied among different age groups including, older adults [11–15]. However, these results cannot be directly generalized to all elderly people due to large heterogeneity in the health status and functional ability in this age group. Thus, we cannot say, for example, if the residual bone benefits seen in exercised premenopausal middle-aged women could be seen among older women as well [13]. It is also unclear whether relatively healthy elderly women could partly maintain the exercise-induced benefits in risk factors for falls, as was seen in a study of at least mildly frail elderly women with low bone mass [15]. Additionally, the type and intensity of the exercise, as well as the length of training and detraining periods, are important. For instance, in the majority of the high-intensity training studies of healthy elderly adults, the training and detraining periods have lasted no more than a few months. Therefore, more studies are needed to describe the consequences of cessation of exercise interventions among older people with varying health and functioning status.

In our recent 12-month randomized exercise trial we showed that especially a combination of strength, balance, agility and jumping training prevented functional decline and bone fragility in relatively healthy home-dwelling elderly women [16]. The purpose of this study was to evaluate whether the observed exercise-induced benefits persisted one year after cessation of the exercise intervention.

## Materials and methods

### Design

This study is a one-year follow-up of a four-arm 12-month randomized, controlled exercise intervention trial comprising two different types of training programs, their combination, or controls. Thus, in this article the term “intervention” is used to mean the period of 12-month randomized, controlled exercise intervention. The results of the intervention have been reported previously [16]. A “follow-up” denotes the one-year period after the end of the intervention, and is the focus of this study.

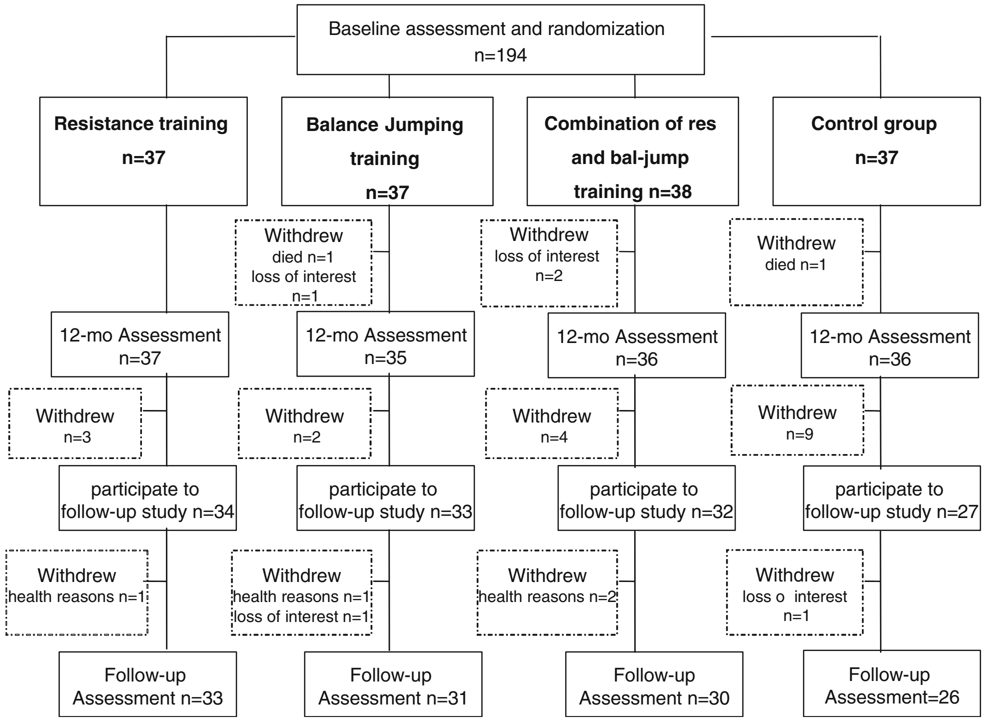
All measurements were done at baseline, after intervention, and at follow-up. Of note, this follow-up study assesses only those physical performance or bone traits which showed a treatment-effect during the intervention [16], and the methods are described accordingly. In particular, after the intervention the treatment-effects were observed in dynamic balance, maximal isometric leg extension force, self-rated physical functioning, and bending strength of the tibial shaft and femoral neck.

### Participants

Originally, a questionnaire was sent to a random sample ($n$=4,032) of 70-year-old to 79-year-old home-dwelling women in the city of Tampere, Finland, inquiring whether they were interested in participating randomized, controlled exercise intervention. Of 858 women who expressed their initial interest, 241 eligible women were invited to a screening examination. Of these women, 149 met the inclusion criteria (see below), and were randomly assigned to four groups: 1) a resistance training group (RES), 2) a balance-jumping training group (BAL), 3) a combination group doing resistance training and balance-jumping training (COMB), and 4) a non-training control group (CON). One hundred and forty-four women (97%) completed the intervention [16]. Of the 126 women who were willing to participate in the follow-up study, six withdrew before the follow-up measurements (Fig. 1).

In addition to age and willingness to participate, the inclusion criteria to the intervention study were the following: a full understanding of the study protocol, no history of any illness contraindicating exercise or limiting participation in the exercise program, no history of any illness affecting balance or bones, no uncorrected vision problems, and not taking medication known to affect balance or bone metabolism (for 12 months before the enrolment). A participant was excluded if she was involved in intense exercise more than twice a week or the T-score for femoral neck bone mineral density (BMD) was lower than −2.5.

**Fig. 1** Trial profile




Each participant provided her written informed consent before the study, and the study protocol was approved by the Ethics Committee of the Tampere University Hospital, Tampere, Finland.

## Training programs (exercise intervention)

The supervised training programs during the intervention have been described in the original intervention report [16]. Briefly, exercise training classes were arranged 3 times a week for 12 months and were supervised by exercise leaders, who were trained to supervise these special training programs. All programs advanced progressively. The RES group training consisted of progressive resistance training (PRT) exercises for large muscle group exercises and the intensity increased from 50–60% of 1RM to 75–80% of 1RM (RM = repeated maximum). The BAL group training comprised modified aerobics and step aerobics, including a variety of balance, agility, and impact exercises. The degree of difficulty of movements, steps, impacts and jumps was gradually increased. The COMB training consisted of the above mentioned resistance and balance-jumping training in alternate weeks. The controls were asked to maintain their pre-study level of physical activity during the 12-month trial.

## Questionnaires

In addition to baseline questionnaire of general health and habitual physical activity, all participants reported their health status and level of physical activity (type, frequency and duration) monthly during the intervention and follow-up. Reported weekly physical activity was converted to MET-hours/week [17].

Dietary intake and possible use of vitamin and mineral supplements were assessed by a complete 3-day (two weekdays and a Sunday) food record at baseline, after the intervention and at follow-up, and calculated by Micro-Nutrica software (Social Insurance Institution, Helsinki, Finland).

## Physical functioning

### *Physical performance tests*

Dynamic balance and agility was tested by a standardized figure-of-eight running test around two poles placed 10 m apart [18, 19]. The participant was asked to run or walk two laps of the course as fast as possible. The running time was measured using a stop-watch. The best attempt of two trials was recorded. The maximal isometric leg extension force was measured with a leg press dynamometer (Tamtron, Tampere, Finland) at a knee angle of 90 degrees with precision of about 5% [20].

### *Self-rated physical functioning*

Self-rated physical functioning was assessed with the standardized Finnish Physical Functioning Scale of Rand 36-Item Health Survey [21, 22]. The participants filled in the questionnaire at home and it was checked together with the participant during her visit for the physical performance tests. The scale comprises ten questions on coping with daily activities, such as running, lifting heavy things, climbing stairs of several floors, and walking half a kilometer. Each item is scored as either a major restriction (0 points), minor restriction (50 points) or no restriction (100 points). An individual physical functioning index score is the mean of scores all answered items.

### Bone measurements

The right proximal femur was measured with dual-energy X-ray absorptiometry (DXA, Norland XR-26, Norland Inc., Fort Atkinson, WI, USA), according to our standard procedures [23]. Then, the gross structure of the narrowest section of femoral neck was analyzed using the hip structure analysis (HSA) [24]. In this study, section modulus (Z) (as an index of bending strength) was used. The in vivo precision of Z is about 5% [25].

The peripheral quantitative computed tomography (pQCT), (XCT 3000, Stratec Medizintechnik GmbH, Pforzheim, Germany) was performed at midshaft (cortical bone) of the tibia, according to our standard procedures [26]. The density-weighted polar section modulus (BSI, an index of torsion bending strength) was used. In our laboratory, the in vivo precision of this measurement is 2.5% [26].

### Statistical analyses

All results were based on the intention-to-treat analyses (ITT) of all available participants. In addition to the ITT analyses, efficacy analyses for the exercise were done. The inclusion criterion for the efficacy analysis was that the average training frequency of an individual was twice a week or more during the trial. It is recalled, that only those variables which showed a significant treatment-effect after the intervention were used as outcome variables in this study.

Linear mixed models with the restricted maximum likelihood estimation (REML) were used to assess the effects of exercise intervention at 12 months and the one-year follow-up. This type of analysis for repeated measures allows incorporation of incomplete longitudinal data into the models. Post hoc between-group comparisons were performed using Sidak's adjustment for multiple comparisons. Due to the skewed distributions in some outcome variables and obtain the relative between-group differences, log-transformed variables of outcome were used in the linear mixed model. Proportional (%) differences and their 95% confidence intervals (CI) were achieved by antilog of mean difference in changes between the groups.

## Results

### Attendance at the follow-up study

The follow-up assessment was done to 120 (81%) women. There were ten non-attendants (refused and withdrew) in the CON group and from four to six in the training groups. (Fig. 1). The CON group non-attendants were slightly older and heavier, and more of them reported a decline in the self-rated physical functioning during the intervention as compared to the attendants. The baseline bone values of the non-attendants did not differ from the attendants, except slightly higher femoral neck section modulus (Z) among the attendants of the RES group. Also, the attendants had slightly better baseline dynamic balance and agility in the RES and CON groups, and isometric leg extension force in the COMB group compared to the respective non-attendants. In the training groups, the training compliance was somewhat better among the follow-up attendants than non-attendants.

### Descriptive characteristics

Descriptive baseline characteristics of the study groups are given in Table 1. At baseline there were no between-group differences. The mean duration of moderate physical activity (4.5 MET) between the groups varied from 4 to 6 hours per week during the follow-up, and did not significantly differ from non-intervention-related physical activity during the intervention period. Six women in the RES group and eight in the COMB group continued resistance training at least at some level during the follow-up. Additionally, four women in the BAL group and one of the controls started resistance training during the follow-up.

During the one year follow-up period, participants reported 11 falls in the RES and BAL groups each, 13 falls in the COMB group and 14 falls in the CON group. In detail, nine women (27%) in the RES group, 10 (32%) in the BAL group, six (20%) in the COMB group, and ten (39%) in the CON group fell at least once during the follow-up period. One woman in the COMB group suffered a hip fracture due to a bicycle accident, and another woman in the RES group suffered a hip fracture along with a rib fracture as consequence of a fall from over 1 meter height. Also, one woman in the BAL group had a shoulder fracture and one woman in the control group had a patella fracture, both caused by a fall.

### Physical functioning

#### *Physical performance*

The absolute values at baseline and exercise effect on physical performance variables after the intervention and at the follow-up are given in Table 2.

**Table 1** Group characteristics, mean (SD)

| Variable | RES[a] $n$=37 | BAL[b] $n$=37 | COMB[c] $n$=38 | CON[d] $n$=37 |
|---|---|---|---|---|
| Age at baseline, years | 72.7 (2.5) | 72.9 (2.3) | 72.9 (2.2) | 72.0 (2.1) |
| Height at baseline, cm | 160.5 (4.8) | 159.0 (6.1) | 159.1 (5.3) | 158.4 (5.8) |
| Weight at baseline, kg | 74.3 (11.0) | 70.9 (9.6) | 69.4 (10.6) | 74.3 (10.8) |
| Calcium intake at baseline, mg | 940 (365) | 960 (331) | 916 (302) | 894 (264) |
| Training compliance of intervention, per cent | 74.4 (23.1) | 59.2 (29.3) | 67.0 (24.8) | – |
| Length of intervention, months | 13.2 (0.8) | 12.9 (0.6) | 13.1 (0.7) | 13.1 (1.1) |
| Length of follow-up, months[e] | 12.1 (0.7) | 12.4 (0.6) | 11.9 (0.8) | 12.0 (0.4) |

[a] Resistance training group
[b] Balance-jumping training group
[c] Combination of resistance and balance-jumping training group
[d] Control group
[e] Among those who participated the follow-up assessment ($n$=120)

After the intervention, mean gain in leg extension isometric force was statistically significantly greater in the RES group (12%; 95% CI: 4 to 20) and in the COMB group (9%; 1 to 17) compared to the controls. However, at the follow-up, no between-group differences were seen (Fig. 2).

Twenty-three subjects (19%) were unable to perform the figure-of-eight running test in the follow-up measurements with no between-group differences. Exercise intervention significantly improved the figure-of-eight running time in the COMB (7%; 3% to 10%) and BAL (5%; 1% to 8%) groups, respectively, compared to the CON group. At the follow-up, a 4% training effect (1% to 8%) was still observed in the COMB group compared with the CON group (Fig. 2). Furthermore, in the efficacy-analysis the exercise-effect seen at the follow-up enhanced and was also seen in the BAL group (trained at least twice a week during the intervention) (Table 2).

### *Self-rated physical functioning*

Borderline statistical difference was seen in the self-rated physical functioning between the COMB and CON groups (9%; 0 to 19%) after the intervention, favoring the combination training. At the follow-up, the within-group variance had increased and the between-group difference had disappeared (Fig. 2).

### Bone rigidity

Exercise effects on bone traits after 12-month intervention and one-year follow-up are given in Table 2. After the intervention, there was a significant between-group difference in the section modulus (Z) at the femoral neck between the RES and COMB groups (4%; 0% to 7%) favoring the resistance training. However, the difference was diminished at the follow-up, and did not reach statistical significance (Fig. 3).

In contrast, there was a borderline trend that the 1.9% exercise benefit in the tibial shaft bone strength index in those COMB trainees who trained at least twice a week, was still partly maintained at the follow-up (1.3%; −0.1 to 2.7%, $p$=0.065) (Fig. 3).

## Discussion

In this one-year follow-up of the 12-month randomized, controlled exercise trial among healthy elderly women, some exercise-induced benefits in the dynamic balance and rigidity of the tibia were still seen one year after cessation of the supervised training. However, the training effect in muscle force and self-rated physical functioning had disappeared.

Previously it has been shown that gains in balance achieved by intensive balance training can be maintained to some extent by one weekly low-intensity Tai Chi training among community-dwelling elderly people [27]. However, in studies where supervised training has been completely stopped, exercise-induced benefits in balance and agility have been lost [14, 28–30]. In contrast to these latter findings, we found that about half of the training benefits in dynamic balance and agility were still seen in the COMB group at the follow-up, one year after the end of the supervised training. In addition, training effect was partly maintained among the active BAL trainees. Shorter training and follow-up periods, different designs (non-RCT) and methods to assess balance and agility [28–30], as well as younger [14] or frailer participants [28] may at least partly explain why the previous studies have obtained different results than we did.

In contrast to the partial maintenance of dynamic balance and agility, the training effect on the lower limb muscle force and physical functioning disappeared during the one-year follow-up time. It is well known that after cessation of

**Table 2** Mean (SD) values at the baseline in all study groups and mean (95% CI) percent difference in change between the training groups and controls at the end of the intervention and at the follow-up (the exercise effect)

| | Baseline | Exercise effect (%) end of intervention[a] | *p*-value | Exercise effect (%) follow-up[a] | *p*-value |
|---|---|---|---|---|---|
| Leg extensor force (N/kg) | | | | | |
| RES | 16.2 (3.5) | 12.8 (4.7 to 21.5) | 0.002 | −1.9 (−9.1 to 6.0) | 0.560 |
| BAL | 16.5 (3.4) | 7.9 (0.0 to 16.4) | 0.049 | −2.0 (−9.3 to 6.0) | 0.419 |
| COMB | 16.3 (3.9) | 10.4 (2.5 to 19.0) | 0.009 | −3.3 (−10.6 to 4.5) | 0.228 |
| CON | 15.8 (2.7) | ref. | | ref. | |
| *p*-value for between-group differences <0.001 | | | | | |
| Dynamic balance and agility (figure-of-eight running time, s)[b] | | | | | |
| RES | 21.0 (3.5) | −3.4 (−6.8 to 0.2) | 0.063 | −1.8 (−5.5 to 2.1) | 0.356 |
| BAL | 20.4 (2.8) | −4.8 (−8.3 to −1.2) | 0.009 | −2.4 (−6.2 to 1.5) | 0.227 |
| COMB | 20.9 (3.1) | −6.9 (−10.2 to −3.4) | <0.001 | −4.3 (−8.0 to −0.5) | 0.029 |
| CON | 20.2 (2.6) | ref. | | ref. | |
| *p*-value for between-group differences 0.005 | | | | | |
| Dynamic balance and agility (figure-of-eight running time, s)[b] among those who trained at least twice a week (*n*=113) | | | | | |
| RES | 20.3 (2.9) | −3.0 (−6.4 to 0.5) | 0.092 | −1.3 (−4.7 to 2.3) | 0.476 |
| BAL | 19.9 (2.7) | −7.0 (−10.5 to −3.4) | <0.001 | −4.9 (−8.5 to −1.2) | 0.01 |
| COMB | 20.9 (3.5) | −8.7 (−12.0 to −5.2) | <0.001 | −6.7 (−10.3 to −3.0) | 0.001 |
| CON | 20.2 (2.6) | ref. | | ref. | |
| *p*-value for between-group differences <0.001 | | | | | |
| Self-rated physical functioning (0–100) | | | | | |
| RES | 83.4 (11.7) | 4.9 (−3.9 to 14.5) | 0.282 | −3.6 (−16.4 to 11.2) | 0.609 |
| BAL | 84.3 (11.6) | 3.9 (−5.0 to 13.6) | 0.399 | 4.0 (−10.1 to 20.3) | 0.595 |
| COMB | 81.5 (15.9) | 8.9 (−0.3 to 19.0) | 0.057 | −4.4 (−17.3 to 10.6) | 0.544 |
| CON | 81.6 (12.7) | ref. | | ref. | |
| *p*-value for between-group differences 0.113 | | | | | |
| Femoral neck Z ($mm^3$) | | | | | |
| RES | 1,405 (258) | 2.6 (−0.4 to 5.7) [c] | 0.094 | 3.5 (−0.8 to 8.1) | 0.113 |
| BAL | 1,449 (327) | 1.7 (−1.4 to 4.9) | 0.285 | 3.6 (−0.8 to 8.2) | 0.111 |
| COMB | 1,385 (183) | −2.1 (−5.0 to 1.0) | 0.178 | 0.3 (−4.0 to 4.8) | 0.890 |
| CON | 1,388 (265) | ref. | | ref. | |
| *p*-value for between-group differences 0.070 | | | | | |
| Tibial shaft BSI ($mm^3$) | | | | | |
| RES | 1,334 (184) | 1.3 (−0.1 to 2.7) | 0.064 | 0.3 (−1.0 to 1.6) | 0.666 |
| BAL | 1,343 (209) | 1.0 (−0.4 to 2.4) | 0.145 | 0.2 (−1.1 to 1.6) | 0.722 |
| COMB | 1,301 (171) | 1.1 (−0.3 to 2.5) | 0.127 | 0.6 (−0.7 to 1.9) | 0.374 |
| CON | 1,275 (207) | ref. | | ref. | |
| *p*-value for between-group differences 0.598 | | | | | |
| Tibial shaft BSI ($mm^3$) among those who trained at least twice a week *(n=113)* | | | | | |
| RES | 1,333 (191) | 1.5 (0.2 to 2.8) | 0.020 | 0.3 (−1.0 to 1.6) | 0.655 |
| BAL | 1,355 (196) | 0.8 (−0.6 to 2.2) | 0.242 | 0.1 (−1.2 to 1.5) | 0.848 |
| COMB | 1,341 (187) | 1.9 (0.6 to 3.3) | 0.006 | 1.3 (−0.1 to 2.7) | 0.065 |
| CON | 1,275 (207) | ref. | | ref. | |
| *p*-value for between-group differences 0.080 | | | | | |

RES = resistance training group, BAL = balance-jumping training group, COMB = combination of resistance and balance-jumping training group, CON = control group

[a] Difference in change (95% CI) between the training groups and controls (ref. = reference group) are based on analysis of linear mixed models (age-adjusted) and the 95% CI are Sidak-adjusted

[b] Negative change (decreased time) indicates beneficial outcome (improved dynamic balance and agility)

[c] Notice: statistical significant difference was seen between RES and COMB, this comparison is made with CON

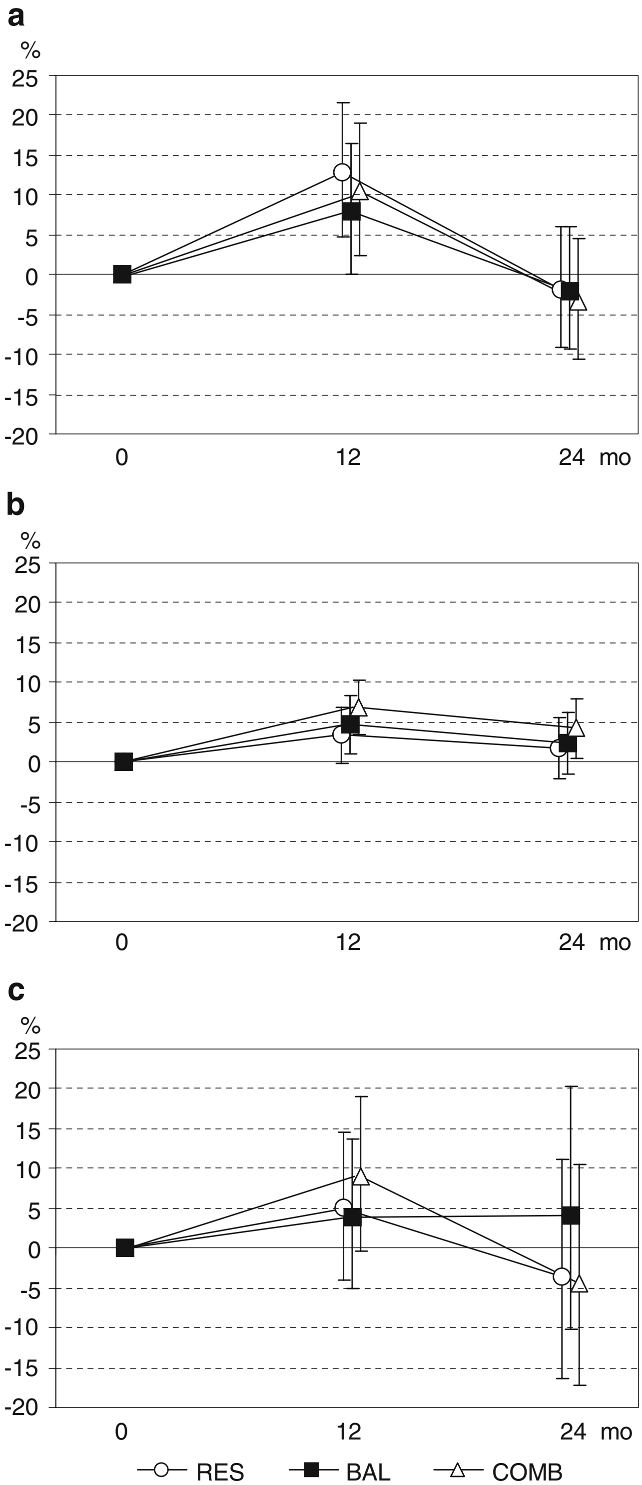



**Fig. 2** Physical functioning variables: The trainees' age-adjusted percentage differences in change compared to controls (mean, 95% CI) after the intervention (12 months) and at the one-year follow-up (24 months) (ITT analysis). **A** = leg extensor force**, B** = dynamic balance and agility**, C** = self-rated physical functioning RES, resistance training group; BAL, balance-jumping training group; COMB, combination training group

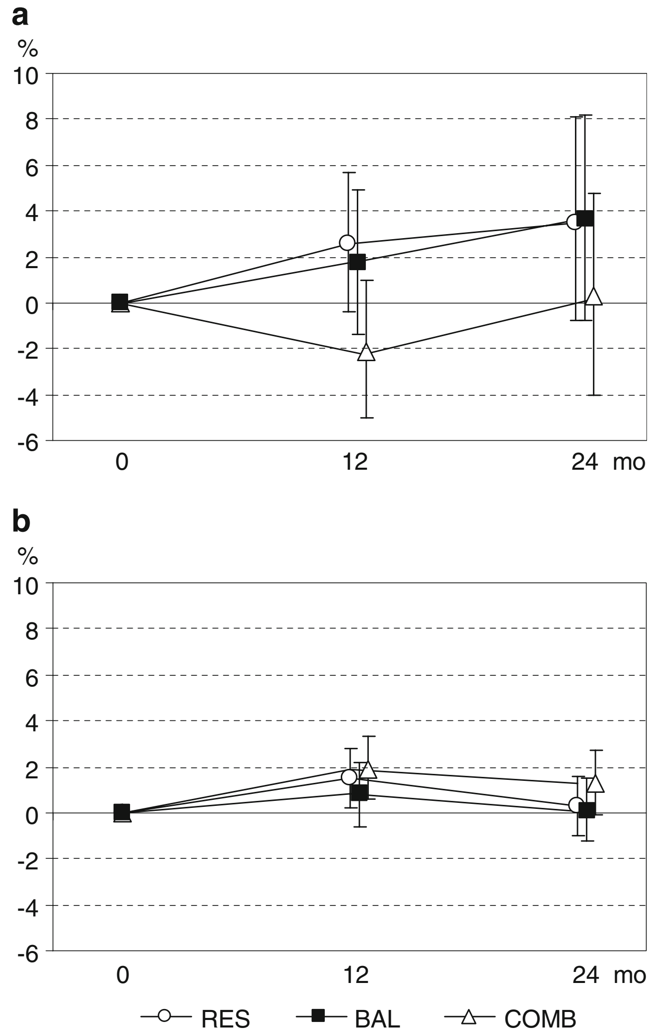



**Fig. 3** Bone variables: The trainees' age-adjusted percentage differences in change compared to controls (mean, 95% CI) after the intervention (12 months) and at the one-year follow-up (24 months). **A** = section modulus (Z) of the femoral neck (ITT analysis), **B** = tibial shaft bone strength index (BSI) (efficacy analysis*) RES, resistance training group; BAL, balance-jumping training group; COMB, combination training group. * Trainees who trained an average a twice a week or more

strength training the training-induced muscle force begins to decrease, although muscle force gains among older adults achieved by strength training can be maintained to some extent from 5 to 27 weeks [31–33]. However, one year appears to be too long a period to maintain major gains in lower limb muscle force [34] unless the strength training is continued at least at some level [31, 34, 35].

An additional year increases older person's risk to become ill and thus may well decline or even collapse her or his functional ability. This was also seen in this follow-up study. The ~10% beneficial treatment effect seen in self-rated physical functioning of the COMB group women had vanished—partly due to large within-group variability at the follow-up. In this context, it is recalled that those women in the control group who participated in the follow-up study were slightly younger and fewer of them had negative changes in the self-rated physical functioning during the intervention than the non-attending control persons. This was not the case in the training groups, and thus this fact may partly explain the reduced functionality differences between the training groups and control group at the follow-up.

The "use it or lose it" principle applies also to maintenance of improved bone rigidity after cessation of (vigorous) exercise. However, this notion arises largely from assessment of bone mass rather than structure or geometry [36–38]. It is well known that DXA in itself is not an adequate tool to assess cortical and trabecular density or other structural particulars [39]. However, these structural traits are pertinent to bone rigidity [40]. Moreover, they may change without changes in BMD or BMC [41–43]. Recently Sornay-Rendu and co-workers [4] found that fragility fractures among elderly women were associated with architectural alterations of trabecular and cortical bone which were partly independent of low BMD. In our study, apparently the weight-bearing tibia was particularly loaded during our exercises, and ~2% training effect was seen in the bone strength index at the tibial shaft among active COMB trainees after the intervention. More than a half of this effect in bone rigidity appeared to be maintained one year after cessation of the training program. However, this finding was based on a statistical borderline trend, and need therefore to be confirmed in future studies.

As far as we know, this is the first study to demonstrate possible maintenance of dynamic balance and agility one year after cessation of supervised high-intensity training in relatively healthy elderly women. Furthermore, a positive sign was seen that some benefits in bone strength might still be present. There are many possible explanations for these observations. Firstly, the most effective training program (COMB) was high-intensity in nature combining many effective training components, such as versatile balance and agility exercises, jumping exercises and progressive resistance training. Secondly, the participants performed intensive training (twice a week on average) for 12 months enabling one to achieve larger and probably more permanent effects, perhaps not only on balance and agility per se, but also on overall mobility functions. Thirdly, the participants of our study did not stop exercise entirely after the training intervention. Average moderate physical activity varied from 4 to 6 hours per week between groups during the follow-up period, being highest in the COMB group. Thus, habitual physical activity may also play a role in maintenance of the achieved benefits. As shown earlier, the benefits can, at least partly, be maintained if exercise is continued, even at lower level [11, 27]. However, in our study a lower volume resistance training and general physical activity were only weakly associated with the changes seen at the follow-up.

There are several strengths in this study. First, this follow-up study evaluated the maintenance of the treatment-effects of a randomized controlled exercise intervention trial of a well-defined group of elderly women. Second, bone structure, instead of conventional BMC or BMD, was assessed, and third, two different training programs, and their combination, were compared.

Our study had also some limitations. All participants did not continue to the follow-up study, although the participation rate was yet quite high (81%) at the follow-up. In addition, as noted above, the attending controls were slightly younger and maintained their self-rated physical functioning better during the intervention than their non-attendants counterparts, a fact that may have led to underestimation of actual maintenance of exercise-induced benefits. Finally, we had some missing data at the follow-up. This was taken into consideration in the used statistical method allowing incorporation of incomplete longitudinal data into the model.

In summary, exercise-induced benefits in dynamic balance and agility of initially healthy elderly women may be partly maintained at least for one year after cessation of 12-month high-intensity resistance and balance-jumping training. The same might concern the rigidity of the loaded tibia. However, in order to maintain the achieved training effects in the other relevant factors related to independent living and prevention of falls and fracture, such as muscle force or physical functioning, moderate-to-vigorous exercise probably should be continued at some level.

In terms of clinical importance, the present findings may help to devise training programs for prevention of falls and fragility fractures of healthy elderly people. Since it is unlikely that elderly people are able or willing to continue high-intensity training for years, the supervised intensive training should, perhaps, be delivered periodically, an approach in which habitual physical exercise is applied between the high-intensity training periods. However, future long-term studies are needed to test the usefulness and effectiveness of periodical training.

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**Conflicts of interest** None.

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ORIGINAL RESEARCH

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# Effects of Exercise on Health-Related Quality of Life and Fear of Falling among Home-Dwelling Older Women: a 12-month RCT and a One Year Follow-up

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## Abstract

This randomised, controlled trial evaluated the effects of exercise on health-related quality of life (HRQoL) and fear of falling (FoF) among 149 home-dwelling older women. The 12-month exercise programme was intended to reduce risk for falls and fractures. HRQoL was assessed by RAND-36 Survey, and FoF by Visual Analogue Scale, at baseline, 12- and 24-month. On all RAND-36 scales, the scores accumulated at the values indicating better health and wellbeing. The exercise had hardly any effect on HRQoL; only General Health –score improved slightly compared with controls at 12-month ($p$=.019), but this gain was lost at 24-month. FoF decreased in both groups during the intervention with no between-group difference at 12- or 24-month. In conclusion, despite beneficial physiological changes, the exercise intervention showed rather limited effects on HRQoL and FoF among relatively high-functioning older women. This modest result may be partly due to insufficient responsiveness of the assessment instruments used.

**Key words:** HRQoL, aged, exercise intervention, falling, well-being

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A number of observational studies have reported beneficial associations between exercise and well-being in both younger and older adults: compared to their sedentary age-mates, more active older persons feel better (e.g. Netz, Wu, Becker, & Tenenbaum, 2005; Wolin, Glynn, Colditz, Lee, & Kawachi, 2007). Regular exercise seems to be associated with enhanced global satisfaction, improved mood and bodily or emotional well-being among late middle-aged and older adults; interestingly, objectively measured improvement in fitness is not necessitated (Netz et al., 2005; Rejeski & Mihalko, 2001). Several studies also suggest that a perceived improvement in functioning or well-being may reinforce the adoption of regular exercise and serve as a personal incentive to continued activity (McAuley, Elavsky, Jerome, Konopack, & Marquez, 2005; Rejeski & Mihalko, 2001).

Fall-related injuries are, in turn, a growing global problem among older people as they often result in pain, functional limitations, impaired quality of life, extra health care costs and excess mortality (Kannus, Sievanen, Palvanen, Jarvinen, & Parkkari, 2005). In the broad field of fall prevention interventions, regular exercise seems promising since, in addition to preventing falls, it maintains physical functioning, mobility and health (Chodzko-Zajko et al., 2009; Gillespie et al., 2009; Karinkanta, Piirtola, Sievänen, Uusi-Rasi, & Kannus, 2010; Liu & Latham, 2009). It is also expected that exercise is conducive to older adults' independence, social activity and mood (Chodzko-Zajko et al., 2009).

In exercise intervention studies, assessment of the spectrum of subjective experience rather than the level of global life-satisfaction is warranted. One commonly used approach has been to assess health-related quality of life (HRQoL). Self-rated HRQoL encompasses subjective experience of one's body and emotions as well as perception of functioning. The core of the concept is not the objective level of functioning or health status but the individual's perception and appraisal of these. (Fayers & Machin, 2007; Halvorsrud & Kalfoss, 2007; Hays & Morales, 2001)

A favourable HRQoL response to exercise interventions has been observed in many clinical and healthy adult samples (Gillison, Skevington, Sato, Standage, & Evangelidou, 2009). However, evidence among older adults is inconsistent. In single randomised controlled trials (RCT) both positive response and no response have been found among healthy or medically stable older adults (Cress et al., 1999; de Vreede et al., 2007; Martin, Church, Thompson, Earnest, & Blair, 2009; Okamoto, Nakatani, Morita, Saeki, & Kurumatani, 2007) and clinical older samples (Grahn Kronhed, Hallberg, Ödkvist, & Möller, 2009; Liu-Ambrose et al., 2005; Teixeira et al., 2010). Two meta-analyses of RCTs with physical activity interventions also indicate the heterogeneity in the HRQoL outcomes. Li, Chen, Yang and Tsauo (2009) found improvements in scores for pain, energy, physical function and role limitations due to physical problems in four RCTs of older women with osteoporosis and osteopenia. However, Kelley, Kelley, Hootman and Jones (2009) observed only a modest increment in physical functioning score in a meta-analysis of 11 RCTs among community-dwelling older subjects.

Several exercise programmes and HRQoL instruments have been applied in exercise intervention studies. The importance of physical functioning is self-evident for purposes of falls-prevention, but aspects of well-being such as positive mood or freedom from pain should also be considered. Increased fear of falling (FoF) has been associated with decreased HRQoL (Scheffer, Schuurmans, van Dijk, van der Hooft, & de Rooij, 2008; Chang, Chi, Yang & Chou, 2010). Further, FoF may propel an older person into a vicious circle of loss of confidence, restricted activity, impaired mood, impaired physical functioning, falls and loss of independence. Exercise seems to be a promising intervention to reduce FoF and break the circle since it may directly prevent the decline in physical functioning and mobility. However, only few studies have assessed the effects of exercise on FoF; some beneficial results of Tai Chi training have been obtained. (Zijlstra et al., 2007.)

We recently completed a one-year exercise RCT among relatively healthy, home-dwelling older women. The intervention reduced risk factors of falling and related fractures by preventing functional decline and bone fragility (Karinkanta et al., 2009; Karinkanta et al., 2007). In the present study we evaluated effects of the intervention on HRQoL and FoF.

# Methods

## Design and Participants

The study was a 12-month exercise RCT followed by a subsequent one-year follow-up. The exercise intervention was intended to affect risk factors of falls and related fractures. The primary outcomes have been reported earlier (Karinkanta et al, 2009; Karinkanta et al., 2007). In this study, the secondary outcomes, HRQoL and FoF, are reported.

All assessments were done at baseline, after the intervention (12 months), and at follow-up (24 months) at the UKK-institute (Tampere, Finland) between 2002 and 2004.

The trial profile is presented in Figure 1. An invitation letter and a pre-screening questionnaire were mailed to a random population sample (n=4032) of 70 to 79-year-old women living in the city of Tampere, Finland. Of the 858 women who expressed initial interest, 241 were eligible and invited to attend a screening examination; 149 of them met the inclusion criteria.

Besides age, the inclusion criteria were: willingness to participate, full understanding of the study procedures, no history of any illness contraindicating exercise or limiting participation in the exercise programme or of illness affecting balance or bone, no uncorrected vision problems, and no medications known to affect balance or bone metabolism (within 12 months before the enrolment). A subject was excluded if she did high intensity exercises more than twice a week or if her femoral neck T-score was lower than -2.5 (i.e., indicating osteoporosis and subsequent medical attention).

The baseline characteristics of the participants have been reported earlier (Karinkanta et al., 2007) and are also given in Table 1. Briefly, participants were relatively healthy, medically stable older women, living independently at home. Mean (SD) age was 72.7 (2.3) years. About half of women reported no or some exercise weekly, the other half reported brisk exercise once or twice a week.

Participants were randomly assigned to three exercise training groups (a resistance training group, a balance-jumping group, a combination group doing resistance and balance-jumping training) and a non-training control group (CON, n=37) (computer-generated randomisation list, simple randomisation with random allocation sequence to ensure equal group sizes) (Karinkanta et al., 2007). For the present analysis the exercise groups were pooled (EX, n=112) to increase the statistical power. It is known from the literature that the exercise dose rather than its type influences HRQoL and well-being (Gillison et al., 2009; Martin et al., 2009; Netz et al., 2005).

The study was approved by the Ethics Committee of the Pirkanmaa Hospital District. All participants gave their written informed consent prior to the study.

**Table 1 Baseline characteristics of the participants**

| Characteristics | | Exercise group (n=112) | Control group (n=37) |
|---|---|---|---|
| Age, years, mean (SD) | | 72.8 (2.3) | 72.0 (2.2) |
| BMI, kg/m$^2$, mean (SD) | | 28.1 (3.8) | 29.6 (3.7) |
| Physical activity/week, n (%) | | | |
| | None or some | 50 (45) | 17 (46) |
| | Brisk exercise 1x | 25 (22) | 9 (24) |
| | Brisk exercise 2x | 37 (33) | 11 (30) |
| Walking/day[a], n (%) | | | |
| | less than 1 km | 6 (5) | 4 (11) |
| | 1 to 3 km | 72 (65) | 24 (65) |
| | 4 to 6 km | 26 (23) | 8 (22) |
| | over 6 km | 7 (6) | 1 (3) |
| Self-rated general health[b], n (%) | | | |
| | very good | 4 (4) | 2 (5) |
| | good | 49 (45) | 13 (35) |
| | fair | 56 (51) | 21 (57) |
| | poor | 1 (1) | 1 (3) |
| | very poor | 0 | 0 |
| Continuing medication by doctor n, (%) | | 60 (54) | 23 (62) |

[a] n=148, [b] n=147

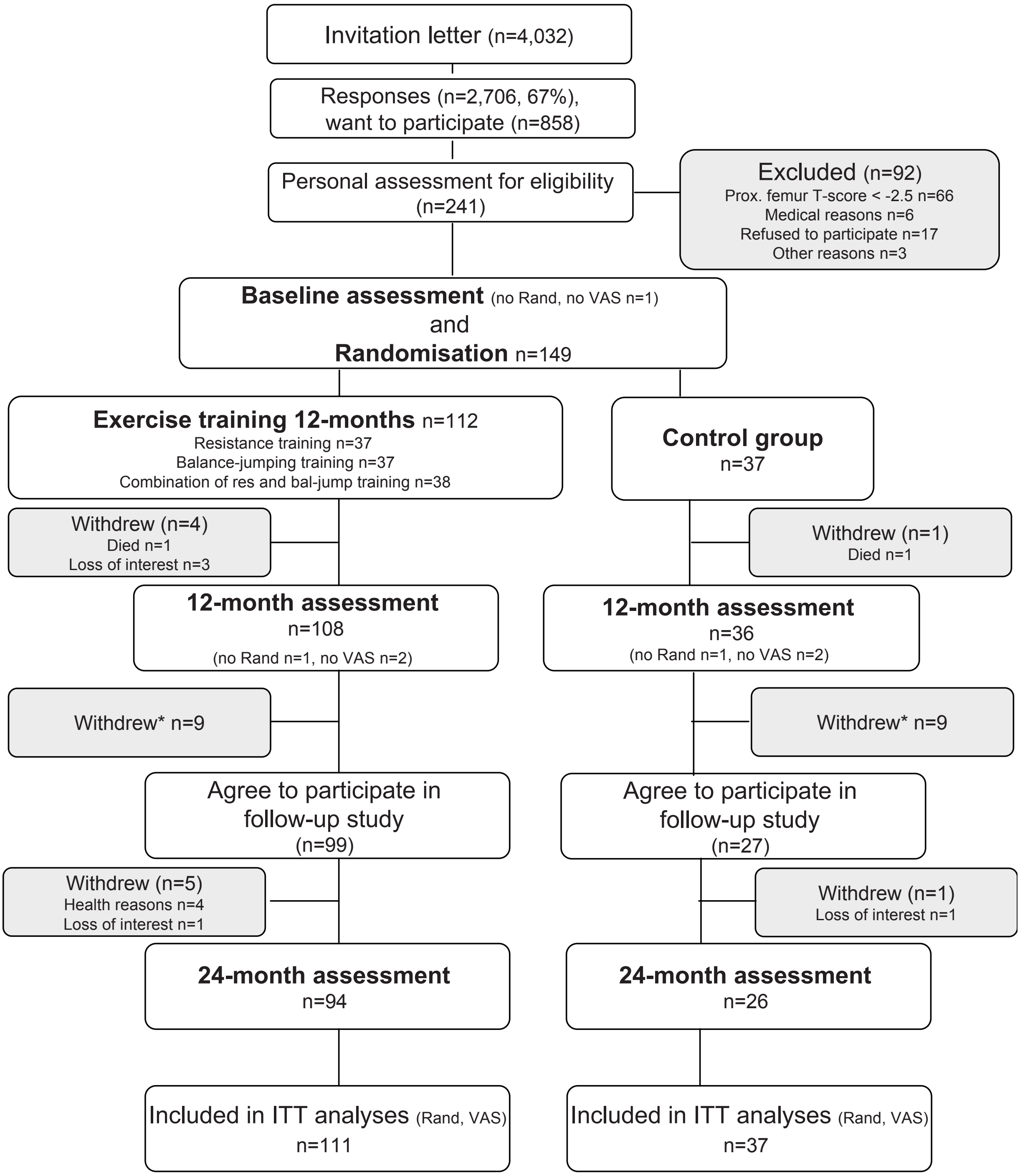


**Figure 1** Trial profile

*Participants were asked if they would be interested to continue the study including monthly questionnaire of physical activity, health and falls and participation of 24-month assessment.

## Training Programmes

The supervised training programmes have been described elsewhere (Karinkanta et al., 2007). Briefly, training intensity was moderate to high and the assigned training frequency was three weekly sessions of 45 minutes for 12 months. All programmes were progressive. The resistance training consisted of exercises for large muscle groups with increased intensity from 50-60% of 1RM to 75-80% of 1RM (RM=repetition maximum). The balance-jumping training comprised modified aerobics and step aerobics including a variety of balance, agility and impact exercises. The degree of difficulty of movements, steps, impacts and jumps was gradually increased. The combination training programme consisted of resistance and balance-jumping training in alternate weeks. All classes took place in a downtown fitness centre with easy access by public transportation. The control group was asked to maintain their pre-study level of physical activity during the 12-month trial.

## Instruments and Assessments

HRQoL was assessed by means of the standard Finnish version (Aalto, Aro, & Teperi, 1999) of the RAND-36 Health Survey which is the parallel survey of the SF-36 (Hays & Morales, 2001; Hays, Sherbourne, & Mazel, 1993). These surveys are widely used in different settings including exercise interventions (de Vreede et al., 2007; Kelley et al., 2009; Martin et al., 2009; Teixeira et al., 2010). The psychometric properties of these surveys in late middle-aged and older adults have been found to be quite good compared to other generic HRQoL-instruments (Halvorsrud & Kalfoss, 2007)

The RAND-36 consists of eight scales, each comprising series of 2 – 10 questions. The scales represent separate but conceptually related aspects of HRQoL, while the overall level of subjective HRQoL is portrayed by the scale score profile. The items of Physical Functioning (PF) and Physical Role Functioning (RLP) scales reflect the respondent’s self-rated capability in ADL activities and mobility. The other scales cover Emotional Well-being (EW), Energy and Vitality (E), Bodily Pain (P), General Health (GH) and limitations in role functions and interaction (Social Functioning SF, Emotional Role Functioning RLE). The item responses were scored and the scale values, 0–100 for each scale, were calculated according to standard procedure (Aalto et al., 1999).

To assure adequacy of RAND-36 scores, we scrutinised the psychometric properties of the scales at each measurement and compared them to those of the Finnish standardisation study (Aalto et al., 1999; Fayers & Machin, 2007). The scale scores were compared with the population reference values and the values of the female age-equivalent samples of that study. Conceptual stability of the three measurements (McHorney, 1996) was assessed by principal component analyses with orthogonal and oblique rotations (Nupponen & Karinkanta, 2009).

FoF was assessed by a Visual Analogue Scale (VAS), that is, a horizontal 100 mm long line connecting the statements “No fear at all (0)” on the left and “Very great fear (100)” on the right.

The participant was asked to indicate her overall fear of falling during daily life by drawing a mark on this line. The FoF score was the number of millimetres between “no fear at all” and the subject’s mark.

The participant filled in the RAND-36 and VAS questionnaires at home and returned them when taking the physical performance tests. During this visit she was asked to verify the completeness of the answers.

## Statistical Analyses

The results were based on the intention-to-treat analyses (ITT) of all available participants. In addition, efficacy analyses for the exercise were done by including only those participants whose average training frequency was twice a week or more during the intervention.

Based on the preliminary analyses concerning psychometric properties of the RAND-36, four variables (PF, EW, E and GH) were used as continuous variables. The remaining four variables with limited dispersion and accumulation to the high end of the scale (RLP, RLE, SF, P) were considered dichotomous: ceiling effect (score=100) and no ceiling effect (score<100). For the continuous variables linear mixed models with restricted maximum likelihood estimation (REML) were used to assess the effects of the exercise intervention at 12 months and 24 months. For the dichotomous variables, generalised estimating equations (GEE models) were used. These statistical models for repeated measures allow incorporation of incomplete longitudinal data into the analyses. Post hoc between-group comparisons were performed using Sidak’s adjustment for multiple comparisons. Due to the skewed distribution of the FoF variable, original values were transformed for logit scores: [log{(VAS)/(100-VAS)}, 0=0.1, 100=99.9], which were used in the linear mixed model analysis (Fayers & Machin, 2007; Senn, 1993). All analyses were age-adjusted.

All comparisons of change were made between the pooled exercise intervention group (n=112) and the control group (n=37). Pooling was deemed to be justified as no between-group differences were indicated in the separate analyses of the three exercise groups (data not shown). Pre-study power analysis for estimating the required sample size was based on the primary outcomes of the study (Karinkanta et al., 2007). SPSS 17.0 version was used and a significance level of 0.05 was maintained for all analyses.

# Results

## Adherence

The feasibility and safety of the exercise programme has been reported elsewhere (Karinkanta et al., 2007). Briefly, mean training compliance, measured as attendance at all training sessions provided, was 67% (range 0 to 100%), and 76 women (68%) trained on average twice a week a more. The rate of drop-outs and missing data was low during the intervention (12 months) and acceptable during the follow-up (24 months) (Figure 1). There were no differences in the numbers of monthly reported health problems between the exercisers and controls (p=.955) (Karinkanta et al., 2007).

There were proportionally more dropouts in the CON group than in the EX group at 24 months (28% vs. 13%) (Figure 1). Those controls who failed to complete the 24-month assessment were slightly older and heavier, and compared to the attendees, many of them showed a decline in self-rated physical functioning during the first year. No corresponding selection was seen in the EX group. However, training compliance was somewhat better among the trainees who attended the follow-up than among those who did not. (Karinkanta et al., 2009)

## Level of HRQoL and Measurement Properties of the Scales

The rates of complete responses were high for all RAND-36 scales (Table 2). The RAND-36 item distributions accumulated at the favourable end of the response scale indicating healthier or more satisfactory values. Consequently, the score distributions were strongly skewed; GH scores were the only exception. Compared to the age-matched female reference data (Aalto et al., 1999), mean values were higher and variances smaller in the present study. The means, medians, and standard deviations of the scale scores are given in Table 2.

Homogeneity, convergence and discriminatory power of the scales were somewhat impaired due to the heavy accumulation of the responses. In this study, the alphas were around .80 (Table 2) and slightly lower than in the Finnish reference study (.80–.94). The proportion of the highest scores (ceiling effect) for P, RLP, RLE and SF (Table 2) were larger than those in the population sample of 65–79 year-olds (Aalto et al., 1999). Principal component analyses revealed two uncorrelated components (Peaceful mind and vitality, Physical capability) with almost equal proportions of explained variance and nearly identical item loadings and communalities at the three measurements; total percents explained were 36-40% (Nupponen & Karinkanta, 2009).

**Table 2 Descriptive data of HRQoL and FoF variables in total sample of participants at baseline, 12 months and 24 months.**

| Score | | n | Mean | SD | Range | Median | Ceiling effect[a] % | Complete responses % | Cronbach's Alpha |
|---|---|---|---|---|---|---|---|---|---|
| **RAND-36** | | | | | | | | | |
| Physical functioning (PF) | Baseline | 148 | 82.7 | 13.0 | 40–100 | 85 | 9.5 | 97.3 | .76 |
| | 12 mo | 142 | 84.0 | 13.6 | 25–100 | 85 | 14.1 | 99.3 | .80 |
| | 24 mo | 120 | 81.1 | 16.7 | 10–100 | 85 | 11.7 | 96.6 | .86 |
| Role functioning/ physical (RLP) | Baseline | 148 | 83.6 | 27.6 | 0-100 | 100 | 65.5 | 100.0 | .75 |
| | 12 mo | 142 | 80.8 | 31.2 | 0-100 | 100 | 64.1 | 100.0 | .81 |
| | 24 mo | 120 | 74.4 | 34.5 | 0-100 | 100 | 55.0 | 99.2 | .81 |
| Role functioning/ emotional (RLE) | Baseline | 148 | 76.8 | 33.4 | 0-100 | 100 | 60.1 | 100.0 | .71 |
| | 12 mo | 142 | 83.1 | 28.8 | 0-100 | 100 | 67.6 | 100.0 | .66 |
| | 24 mo | 120 | 75.6 | 34.5 | 0-100 | 100 | 52.5 | 99.2 | .54 |
| Energy/ vitality (E) | Baseline | 148 | 73.5 | 17.0 | 30–100 | 75 | 6.8 | 100.0 | .79 |
| | 12 mo | 142 | 73.6 | 17.3 | 25–100 | 75 | 6.3 | 100.0 | .83 |
| | 24 mo | 120 | 70.4 | 18.5 | 15–100 | 75 | 4.2 | 99.2 | .79 |
| Emotional well-being (EW) | Baseline | 148 | 83.1 | 14.5 | 40–100 | 88 | 10.1 | 100.0 | .82 |
| | 12 mo | 142 | 83.3 | 13.7 | 36–100 | 88 | 11.3 | 100.0 | .79 |
| | 24 mo | 120 | 80.8 | 16.4 | 32–100 | 84 | 10.8 | 98.3 | .81 |
| Social functioning (SF) | Baseline | 148 | 92.7 | 13.5 | 50–100 | 100 | 72.3 | 100.0 | .74 |
| | 12 mo | 141[b] | 93.2 | 14.0 | 12.5–100 | 100 | 73.8 | 99.3 | .70 |
| | 24 mo | 120 | 88.8 | 18.7 | 12.5–100 | 100 | 65.0 | 100.0 | .91 |
| Pain (P) | Baseline | 148 | 80.9 | 17.6 | 10–100 | 80 | 27.0 | 100.0 | .77 |
| | 12 mo | 142 | 80.3 | 19.9 | 22.5–100 | 90 | 31.7 | 100.0 | .84 |
| | 24 mo | 120 | 78.9 | 20.5 | 10–100 | 80 | 30.0 | 100.0 | .85 |
| General health (GH) | Baseline | 148 | 65.3 | 14.4 | 25–95 | 65 | 0.0 | 100.0 | .60 |
| | 12 mo | 142 | 67.4 | 14.9 | 25–100 | 70 | 1.4 | 100.0 | .64 |
| | 24 mo | 120 | 65.5 | 15.4 | 25–100 | 65 | 1.7 | 99.2 | .67 |
| **FoF** | Baseline | 148 | 24.0 | 19.3 | 0-87 | 23 | 9.5 | . | . |
| | 12 mo | 140 | 13.0 | 17.7 | 0-88 | 5 | 36.4 | . | . |
| | 24 mo | 120 | 16.5 | 20.4 | 0-92 | 9 | 41.7 | . | . |

[a] In the FoF score floor effect (0, no fear at all) also means "best possible"

[b] One participant had a missing item on this 2-item scale and therefore the score could not be calculated

## Effects of the Intervention on HRQoL

Statistically significant between-group differences in change were found in only two of the eight HRQoL variables (Figure 2, Table 3). During the intervention GH score slightly improved in the EX group, but decreased in the CON group. Mean difference in change was 6 score units (95% CI 1 to 11, $t_{259.9}$=2.369, p=.019). However, this minor benefit in change in GH at 12 months was lost at 24 months. (Figure 2.) By contrast, no statistically significant between-group difference was found in E-score at 12 months, but it was decreased in the EX group and increased in the CON group at 24 months (mean difference in change 9 score units, 95% CI 3 to 16, $t_{261.0}$= -2.846, p=.005). (Figure 2.)

In the efficacy analyses of subjects who trained at least twice a week, the between-group difference in change in GH score was statistically significant and larger than in the ITT (Figure 2). In addition, there was a significant between-group difference in E score at 12 months, favouring the EX group (Figure 2).

## Fear of Falling

The FoF responses accumulated near zero at baseline; the median was 23. Only 6% of the participants expressed unambiguous (>50) FoF during daily activities at baseline and 10% reported no fear at all (0, floor effect). (Table 2.) Decreased values were found at 12 months and 24 months: in the total sample the FoF median was 5 and 9 respectively. (Table 2.) However, the linear mixed model revealed no between-group difference in change at either measurement ($F_{2, 268.7}$=0.194, p= .824). The descriptive data of FoF by group at baseline, 12 months and 24 months are given in Table 4.

**Table 3 Ceiling effects in four RAND-36 scales by group (EX, CON) at baseline, 12 months and 24 months. The between-group differences were analysed by General Estimation Equations (GEE model) of binary responses [ceiling effect (score=100) and no ceiling effects (Score<100)].**

| Scale | Group | Ceiling effect % | | | Wald $\chi^2_2$ | p-value[a] |
|---|---|---|---|---|---|---|
| | | Baseline (n=148) | 12-month (n=142) | 24-month (n=120) | | |
| Role functioning / physical (RLP) | CON | 76 | 57 | 56 | | |
| | EX | 62 | 66 | 55 | 3.965 | .14 |
| Role functioning / emotional (RLE) | CON | 57 | 63 | 56 | | |
| | EX | 61 | 69 | 52 | 0.611 | .74 |
| Social functioning[b] (SF) | CON | 76 | 71 | 72 | | |
| | EX | 71 | 75 | 63 | 1.321 | .52 |
| Pain (P) | CON | 38 | 34 | 28 | | |
| | EX | 23 | 31 | 31 | 3.122 | .21 |

[a] p-value for time*group interaction (3 time points, 2 groups), GEE model with age at baseline as covariate, [b] n=141 at 12 months , CON=Control group, EX=Pooled exercise group

**Table 4 Descriptive data of fear of falling using VAS by group (EX, CON) at baseline, 12 months and 24 months.**

| Assessment | Group | n | Mean (SD) | Range, 0-100 | Median | 0 mm[a], proportion, % | >50 mm[b], proportion, % |
|---|---|---|---|---|---|---|---|
| Baseline | CON | 37 | 24.9 (19.0) | 0-87 | 23 | 5 | 11 |
| | EX | 111 | 22.4 (18.3) | 0-70 | 22 | 11 | 6 |
| 12-month | CON | 34 | 16.9 (21.2) | 0-65 | 7 | 41 | 6 |
| | EX | 106 | 10.7 (15.7) | 0-80 | 3 | 35 | 2 |
| 24-month | CON | 26 | 22.2 (24.7) | 0-92 | 16 | 39 | 12 |
| | EX | 94 | 15.1 (19.1) | 0-85 | 6 | 43 | 6 |

[a] indicating no fear of falling, [b] indicating unambiguous fear of falling, CON=Control group, EX=Pooled exercise group

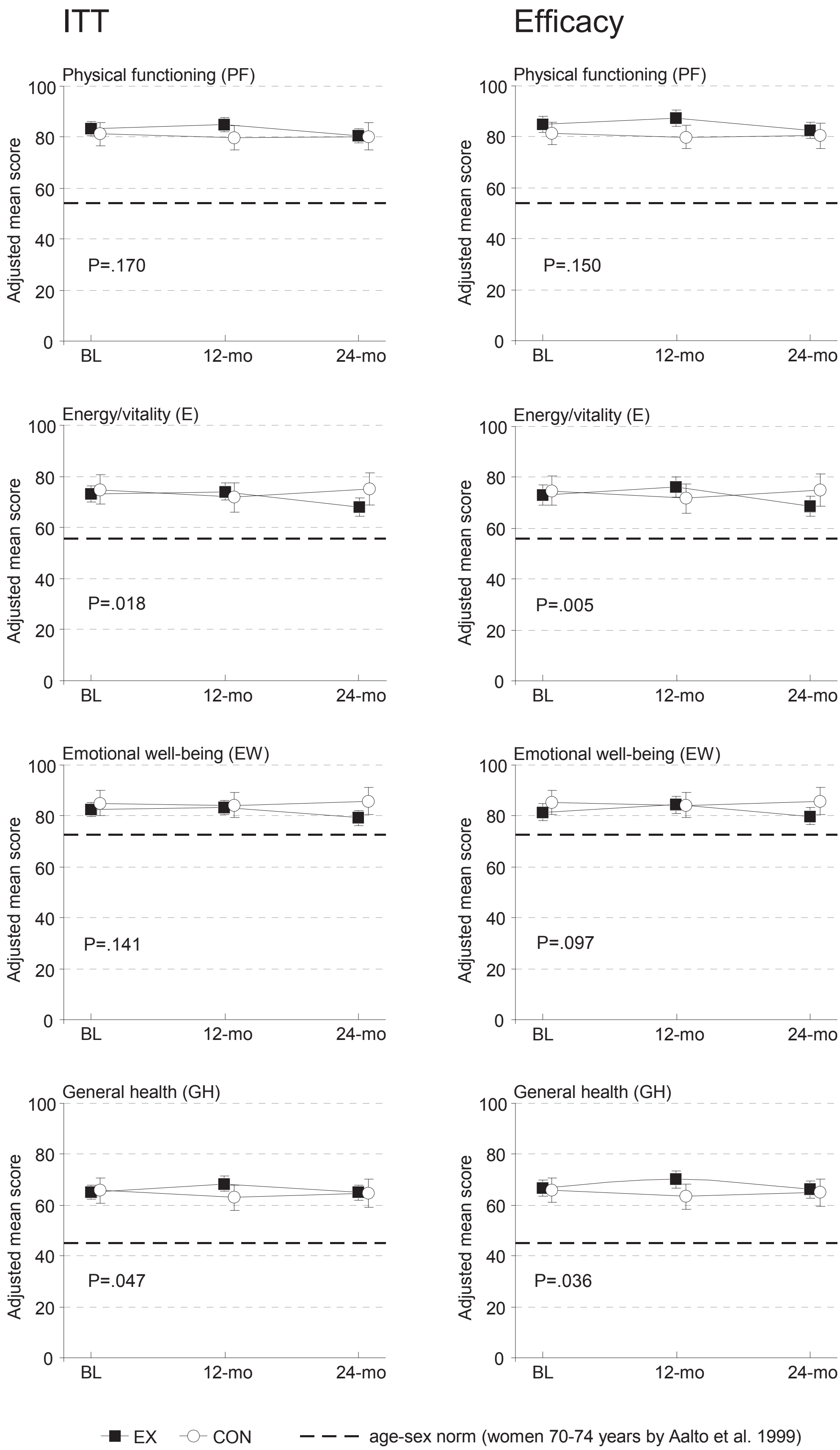


**Figure 2** Age-adjusted mean score and 95% CI in four main RAND-variables at baseline, 12 months and 24 months by group (EX=Exercise group, CON=Control group).
ITT=Intension to treat –analysis, Efficacy=Efficacy analysis (≥2 x week trained participants)
P-values are for time*group interaction (3 time points, 2 groups), linear mixed model analysis with age at baseline as covariate

# Discussion

Our study evaluated the effects of a moderate-to-high intensity exercise intervention on health-related quality of life and fear of falling among relatively healthy home-dwelling older women. This study was explorative; no hypotheses were set concerning the effects of the exercise programme on RAND-36 variables or FoF response. Although positive effects were observed in muscle strength, dynamic balance and bone structure (Karinkanta et al., 2009; Karinkanta et al., 2007), we found hardly any impact of training on HRQoL and FoF.

In RAND-36 variables we found only one statistically significant exercise effect after the intervention: General Health score slightly increased in the EX and decreased in the CON group. The absolute between-group difference (6 score units) was small and trivial considering the rather poor psychometric properties of the GH scale in this study. However, this difference is in line with other studies reporting exercise effect on this subscale (Grahn Kronhed et al., 2009; Martin et al., 2009; Okamoto et al., 2007). On the other hand, Teixeira et al. (2010) and Eyigor, Karapolat, Durmaz, Ibisoglu and Cakir (2009) recently reported much larger and clinically significant HRQoL improvements in this subscale as well as other scales among Brazilian osteoporotic postmenopausal women and Turkish healthy older women respectively. Our results, however, are congruent with the recent meta-analysis by Kelley et al. (2009), which indicated rather a weak role of exercise interventions for HRQoL.

Our observations together with those of other RCTs with minimal or no effect (e.g. Cress et al., 1999; de Vreede et al., 2007; Okamoto et al., 2007) raise the question whether the measured changes in the physical capacity variables are large enough to be recognised by the participant, and more importantly, whether this change makes any difference in her everyday life. It is not known which particular point during training period would be optimal for the perception of changes (McAuley et al., 2005; Rejeski & Mihalko, 2001). In addition, the relevance of the PF items is not guaranteed in high-functioning individuals. It is also possible that the participant adapts to successive minor changes due to exercise training, which eventually modifies her internal standard for HRQoL. This latter interpretation is supported by the notion that in our study most RAND-36 scores decreased after the follow-up period (with no supervised exercise) in the EX group, but not in the CON group. In E score this divergent trend between the groups was statistically significant. Corresponding observations have been reported by de Vreede et al. (2007) after a 6-month follow-up period in community-dwelling older Dutch women.

In light of the recurrent observations, Rejeski and Mihalko (2001) have questioned the effect of exercise training on HRQL in older persons with normal or good physical functioning. In our high-functioning participants, RAND-36 data showed good technical quality and sufficient conceptual stability (Aalto et al., 1999; McHorney, 1996; Nupponen & Karinkanta, 2009). However, the level of scores was higher and ceiling effects larger than in the age-equivalent reference groups. High level and substantial ceiling effect of SF-36 scores have been reported in several other exercise interventions with high-functioning older participants (e.g. Cress et al., 1999; de Vreede et al., 2007). Lesser but still notable accumulation of scores has been observed in large population samples (e.g. Wolin et al., 2007) and among community-dwelling aged respondents (e.g. McHorney, 1996) but less consistently in exercise interventions among non-clinical frail older adults (e.g. Helbostad, Sletvold, & Moe-Nilssen, 2004).

The strong ceiling effect and diminished variation impair the psychometric properties of the scales, rule out any substantial raise in scores and conceal differential changes in a bunch of outcome variables. Insufficient responsiveness of the scales may thus mask the effects of an exercise intervention. So far no studies have been published on the sensitivity to change of the Finnish RAND-36 in healthy samples. Further, HRQoL has typically been studied as a secondary outcome and most exercise intervention studies among older adults, including our study, have been unpowered (e.g. Cress et al., 1999; de Vreede et al., 2007); only the recent study by Martin et al. (2009) appears to be adequately powered.

Fear of falling is conceptually linked with the level of physical functioning (Zijlstra et al., 2007). In this study, the univariate correlations with the PF-scores were -.20 (baseline) to -.40 (24 months). No significant difference in change was found between the exercise and control groups. For both groups, the FoF scores indicated less fear at 12 months and at 24 months than at baseline. However, the level of fear was low compared to observations by Lin, Wolf, Hwang, Gong and Chen (2007), probably because the participants in that study had experienced a recent fall.

The observed floor effect suggests that FoF assessed by VAS was not a sufficiently sensitive indicator of fear in our high-functioning women. When we designed this study no validated instruments for measuring FoF had been adapted for use in Finland. Thus simple global measure of FoF, VAS, was chosen even if good validation studies of this instrument were not available. Later, several FoF instruments have been questioned since they lack sensitivity to detect different levels of fear and they do not assess fear during different activities (Yardley et al., 2005). The other criticism concerns the wording. The term “concern about falling” is closely related to fear, but is less intense and emotional and may thus be a more socially acceptable expression than “fear” among older people (Yardley et al., 2005). Promising new instruments have recently been developed, but their responsiveness to change, especially in high-functioning older adults, needs to be tested (Delbaere et al., 2010; Yardley et al., 2005).

## Conclusions

The 12-month exercise intervention showed rather limited effects on health-related quality of life and fear of falling among relatively healthy high-functioning older Finnish women. However, this may have been due to deficient responsiveness of the assessment instruments used.

High ceiling effects and insufficient sensitivity have recurrently been reported in assessments of change by SF-36 and the parallel survey RAND-36. Therefore, the utility of this commonly used generic multi-component HRQoL instrument can be questioned, especially among high-functioning older adults. Another concern is the dynamic nature of HRQoL, which is susceptible to changes in internal standards. To assess fear of falling, more activity-specific surveys have recently been developed, but they need to be studied further in various older populations.

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## Conflicts of interest

None declared.

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